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NEWSLETTER

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"No Patient Shall Be Harmed By Opioid-Induced Respiratory Depression"

[Proceedings of "Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period" Conference]

Matthew B. Weinger, MD, and Lorri A. Lee, MD, for the Anesthesia Patient Safety Foundation

The APSF believes that clinically significant, drug-induced respiratory depression in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality since it was first addressed by the APSF in 2006.[1] The APSF envisions that *"no patient shall be harmed by opioid-induced respiratory depression in the postoperative period,"* and convened the second multidisciplinary conference on this serious patient safety issue in June of this year in Phoenix, AZ, with 136 stakeholders in attendance. The conference addressed "Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period."

Attendees included clinicians and researchers from nursing, anesthesia, and surgery (more than half of conference attendees), with representation from the Veterans Health Administration, the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, American Academy of Anesthesiologists Assistants, American Hospital Association, American College of Surgeons, American Society of PeriAnesthesia Nurses, the Joint Commission, Association for the Advancement of Medical Instrumentation, American Society of Healthcare Risk Management, Institute for Safe Medication Practices, and other societies and non-profit agencies. Additionally, malpractice insurers and family members of patients who have died from this complication provided input on the scope and impact of the problem, and representatives from the monitoring technology industry (about one-fourth of attendees) discussed the potential for improved monitoring of patients' respiratory status in the postoperative period.

Drs. Robert K. Stoelting, APSF president, and Frank J. Overdyk, adjunct professor of Anesthesiology at the Medical University of South Carolina, co-moderated the conference consisting of 24 brief presentations, 6 small breakout groups, and a discussion session. Two questions were posted to all speakers and audience members:

1) *Should electronic monitoring be utilized to facilitate detection of drug-induced postoperative respiratory depression?*
2) *If "Yes" to electronic monitoring, who should be monitored (inclusively or selectively) and what monitors/technology should be utilized?*

Dr. Stoelting opened the conference by asserting that continuous electronic monitoring of oxygenation and/or ventilation may allow for more rapid diagnosis and prevention of drug-induced, postoperative respiratory depression. He commented that we cannot wait for the perfect technology before we intervene, and that "maintaining the status quo in hopes that a different result will occur is unrealistic." He noted that the goal of the conference was to utilize the available evidence to discern the best monitoring strategies for providing effective early warning of postoperative respiratory depression.

Dr. Overdyk followed and noted that this complication occurs more frequently and is much easier to detect than awareness under general anesthesia where significant resources have been invested in research and monitoring. He believes that this initiative should become a "national patient safety priority." Dr. Overdyk discussed research that demonstrated that approximately one-third of code blue arrests in hospitals are from respiratory depression,[2] and that naloxone is administered in about 0.2-0.7% of patients receiving postoperative opioids.[3,4]

Following these introductory remarks, family members of patients who died from drug-induced respiratory depression recounted their loved ones' medical tragedies. They all noted the lack of monitoring for their loved ones during their last days in the hospital after undergoing elective routine surgery. They implored the group to enact changes immediately that would prevent such future tragedies.

Dr. Matthew B. Weinger, professor of Anesthesiology at Vanderbilt University, showed multiple studies that provide evidence for frequent use of naloxone for postoperative opioid-induced respiratory depression. He stated that the literature suggests that in the U.S. about 0.3% of postoperative patients receive naloxone rescue accounting for up to 20,000 patients annually. He further estimated that one-tenth of these patients suffer significant sequelae. Dr. Weinger also provided evidence demonstrating that all types of parenteral opioids and routes are involved in these events. He then discussed the reliability, sensitivity, specificity, and response time for the various types of monitors for oxygenation and ventilation to detect respiratory depression. For patients who are not intubated, pulse oximetry was the best monitor when supplemental oxygen was not being utilized. In the presence of supplemental oxygen, capnography fared best (see Table 1).[1]

After this presentation, Dr. Nikolaus Gravenstein, a professor at the University of Florida, highlighted the remarkable observation that patients having vital signs checked every 4 hours are left unmonitored 96% of the time. He noted, as did many speakers, that supplemental oxygen may mask hypoventilation, and that under these circumstances pulse oximetry is a very late detector of respiratory depression. Lethal hypercarbia is possible despite normal oxygen

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New Scientific Evaluation Committee Members

Annually, the APSF Scientific Evaluation Committee (SEC) considers the addition of new members to participate in the review of clinical and educational patient safety grants. Applicants for SEC membership should be experienced patient safety researchers with a track record of funding and peer-reviewed publication. The SEC is particularly interested in applicants with safety related expertise in informatics, simulation, or the responsible conduct of research. Interested applicants should submit their curriculum vitae and a cover letter explaining interest and qualifications to Dr. Sorin Brull at brull@apsf.org.

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NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

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A Tribute to Ellison C. (Jeep) Pierce, Jr., MD, the Beloved Founding Leader of the APSF

by John H. Eichhorn, MD, and Jeffrey B. Cooper, PhD

Ellison C. Pierce, Jr., MD, affectionately known to so many as "Jeep," was the cornerstone of the conception and evolution of anesthesia patient safety. His passing on April 3, 2011, at age 82 was a tremendous loss to everyone involved with anesthesia in particular and heath care in general. Patients as well as providers perpetually owe Dr. Pierce a great debt of gratitude, for Jeep Pierce was *the* pioneering patient safety leader. He made a huge difference in the safety of health care for everyone. A true visionary, he saw what needed to be seen and said what needed to be said. He was on a perpetual mission to prevent patients from being injured or killed by anesthesia care. When he embarked on that mission, he did not know that the impact would extend far beyond the specialty to which he devoted his life.

While he had experienced close calls in the OR like all anesthesiologists, Dr. Pierce did not describe being directly involved in a serious anesthesia accident. However, we have an interesting revelation on one source of Dr. Pierce's passion for safety from a recollection of Robert H. Bode, MD. Dr. Bode, a longtime, close associate of Dr. Pierce and former vice chairman to Dr. Pierce at the New England Deaconess Hospital in Boston (and currently affiliated with New England Baptist Hospital and associate professor of Anesthesia at Boston University School of Medicine) spoke at the memorial service held at the historic Trinity Church in downtown Boston. He told of how, during the times covered by Dr. Pierce's early and middle career, the most grievous anesthesia errors causing catastrophic outcomes included unrecognized esophageal intubations and disconnections from the breathing apparatus. Dr. Pierce witnessed the impact of such an occurrence first hand. It involved the 18-year old daughter of one of his friends. She arrested and died during anesthesia for dental surgery after an accidental esophageal intubation, which was not recognized until it was too late. From the way Jeep told that story on a few occasions, it surely was one of several stimuli that provoked him to work toward preventing all such tragic anesthetic accidents. And because he was so dedicated to anesthesiology, he pursued this quest with all of his vigor and dogged persistence because he knew it was the most important thing that he could do for our specialty. Fortunately for all of us, he also had the wisdom and significant political savvy to achieve great progress.

Early "Primitive" Days

Raised in North Carolina, educated at the University of Virginia and Duke University School of Medicine, Dr. Pierce retained part of a southern accent in spite of his decades in Boston. This was clearly audible as Dr. Pierce elegantly outlined his personal history in his memorable 1995 Rovenstine Lecture at the

American Society of Anesthesiologists Annual Meeting.[1] He recounted how he first gave anesthesia as a resident in July 1954, when the equipment and practices were primitive by today's standards. Cyclopropane was often used with an IV started only after induction, although thiopental was common and sometimes also used as a maintenance infusion. Tonsillectomy was done with open drop ether and no endotracheal tube. Rectal drug administration was employed and, also, spinals were very common—including for upper abdominal procedures. Intubation was relatively uncommon, and mask anesthesia was even used for thyroidectomy. Controversy raged about the newly introduced class of drugs, muscle relaxants, and prolonged blocks requiring postoperative hand ventilation in the newly created entity called the "recovery room" were not uncommon. Intraoperative monitoring was a blood pressure cuff and perhaps a precordial stethoscope. An ECG monitor was rarely available. There were no blood gas measurements. Introduction of the brand new copper kettle vaporizer led to an epidemic of ether overdoses. Intraoperative cardiac arrests from a variety of causes were not unusual. When a patient died on the table, the family was simply told that the patient just could not tolerate the anesthesia—"too bad." Estimates of mortality caused solely by anesthesia care ranged from 1 to 12 per 10,000 cases. It was this environment that first inspired Dr. Pierce's awareness that anesthesia care could actually be more threatening to patients than their underlying surgical pathology. He noted that he agreed with his longtime friend, Dr. William K. Hamilton of UC San Francisco, that "anesthetic deaths" were most likely 90% due to human error.

Dr. Pierce recounted in the Rovenstine lecture[1] his early interest in anesthesia accidents: "In 1962, I became interested in anesthesia patient safety. I had joined Leroy Vandam at the Peter Bent Brigham Hospital as de facto vice chairman. In his inimitable way, one day he assigned me the subject, 'anesthesia accidents,' to be given as a resident's lecture. I still have notes in my files from that talk, which began as a collection of anesthesia mishaps that I knew about personally." He often repeated his sad disbelief regarding how many patients he heard about from all over the country who were injured or killed by unrecognized esophageal intubations. In the 1970s, when he was chair of Anesthesia at the New England Deaconess Hospital, Dr. Pierce's interest in safety deepened further when his department was 1 of 4 recruited for the initial landmark studies by Jeffrey B. Cooper, PhD, of the Massachusetts General Hospital and Harvard on the analysis of anesthesia "critical incidents." Thus, the stage was set for a key coincidence that helped start Dr. Pierce

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Dr. Pierce Proclaims "Protect Patients First"

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on a path which ultimately birthed a movement permanently changing anesthesia practice and, in fact, all of health care.

"Reality" TV Hits Home

The ABC television program *20/20* aired on April 22, 1982, a segment called "The Deep Sleep: 6,000 Will Die or Suffer Brain Damage." The announcer opened with "If you are going to go into anesthesia, you are going on a long trip and you should not do it, if you can avoid it in any way. General anesthesia is safe most of the time, but there are dangers from human error, carelessness, and a critical shortage of anesthesiologists. This year, 6,000 patients will die or suffer brain damage." After scenes of patients who had experienced anesthesia mishaps, the program stated, "The people you have just seen are tragic victims of a danger they never knew existed—mistakes in administering anesthesia." They showed a patient who was left in a coma after the anesthesiologist mistakenly turned off the oxygen rather than the nitrous oxide at the end of an anesthetic. Later, one of the hosts was told that, "There is a hospital in New York City where there are 2 anesthesia people covering 5 operating rooms." He appeared incredulous and asked, "How do they do it?" The reply: "Well, they run quickly and pray a lot." Public attention and reaction were significant, just compounding the already extant "malpractice crisis" in anesthesia practice. Dr. Pierce thought about protecting patients first, doctors second. That was a potentially risky political move but he didn't hesitate. He just did the right thing.

Dr. Pierce related, "The *20/20* program was a watershed for anesthesia patient safety endeavors. At the time, I was first vice president of the American Society of Anesthesiologists (ASA) and decided to establish a new ASA committee, the Committee on Patient Safety and Risk Management . . . . never before had the concept of patient safety been so specifically addressed by our specialty society." [1] This appears to have been the first use in this context of the now ubiquitous term "patient safety."

ISPAMM and APSF

Soon after, Dr. Pierce helped organize and host an unprecedented and important gathering—the International Symposium on Preventable Anesthesia Mortality and Morbidity in Boston. Strongly stimulated by that energetic assemblage, Dr. Pierce conceived of the idea of the Anesthesia Patient Safety Foundation (APSF). Through his charisma, political know-how, patience, and persistence, he created and was the first president of the organization that has been the beacon for patient safety in anesthesia and far beyond.

Through APSF and his many connections in the world of medicine, Dr. Pierce's vision was moved forward to become what is now a global movement to prevent needless injuries and deaths from errors both human and system-induced. He was an attractor, someone we all wanted to help to accomplish his goals. When he assembled the nimble independent team that would build the APSF, he was inclusive and strategic. Beyond anesthesiologists, the original Board of Directors included lawyers, pharmaceutical and device manufacturers, a biomedical engineer, risk managers, nurse anesthetists, malpractice insurers, and representatives from the Food and Drug Administration, the Joint Commission, the American College of Surgeons, and the American Medical Association. As Dr. Pierce noted, such diversity of stakeholders certainly was not possible in the structured environment of the ASA at that time. He knew just how far he could go, just what kinds of people together were needed to do the job.

Dr. Pierce wasn't the one with all the detailed ideas. Yet, he instantly could spot a good one. And, he made the person who had it feel like a genius. He was generous and sincere with his praise; yet he wasn't looking for it himself (but he received a lot of it, including many recognitions of his pioneering efforts). He was happy and satisfied in himself to see the good work being done—the *APSF Newsletter* informing and educating the entire community of anesthesia professionals, the research grants program supporting patient safety research for the first time ever and yielding some truly groundbreaking insight and innovation, the catalysis of new technologies, the development of high-fidelity mannequin-based simulation and teamwork training (focused both on human error analysis and crisis resource management), and the innumerable special projects that came from APSF during these past 26 years—all the result of an organization that was built from Dr. Pierce's astute sense of people, diplomacy, and timing. Further, as immediate past president of the ASA in 1985, Dr. Pierce participated in the creation of the ASA Closed Claims Project that persuaded several malpractice insurance companies to open their files for analysis of what caused anesthesia accidents. In subsequent years, that project yielded several important studies contributing directly to safety improvements.

Visionary Success

While the exact statistics can be (and are) debated, there is widespread recognition that anesthesia care, particularly in the USA but also throughout the developed world, has become much safer for the patient over the last 26 years. Contributing to this dramatic improvement have been many factors, including especially the practice standards and protocols started at Harvard and expanded by the ASA that Dr. Pierce supported so strongly, but all of the factors together relate back to the original drive by Dr. Pierce to implement the simple idea that is the APSF's vision: "that no patient shall be harmed by anesthesia."

In his Rovenstine lecture,[1] Dr. Pierce emphasized how extremely proud he was of the fact that at the 1995 ASA meeting, there were 139 scientific papers presented in the section featuring patient safety, and that a mere 10 years previously, the topic existed nowhere on the program. Building to a conclusion, he characteristically exhorted, "Patient safety is not a fad. It is not a preoccupation of the past. It is not an objective that has been fulfilled or a reflection of a problem that has been solved. Patient safety is an ongoing necessity. It must be sustained by research, training, and daily application in the workplace." He was very concerned that production pressures and cost concerns "could easily undo many of the gains that we cherish so highly," but he concluded his epic and riveting presentation with, "Patient safety is truly the framework of modern anesthetic practice, and we must redouble efforts to keep it strong and growing."

Well-Deserved Recognition

Among the numerous honors Dr. Pierce received, perhaps the most meaningful was his induction as an American into the prestigious Royal College of Anaesthetists in the UK. Also, he received a special citation from the Food and Drug Administration for his work, and received awards from the Royal Society of Medicine (UK), the American Medical Association, and the Russian Society of Anesthesiology. Dr. Pierce spoke on the topic of anesthesia safety across the US, as well as in Japan, Russia, and also various cities in Europe, South America, and Australia. He is known to anesthesia practitioners the world over for his appearances in safety and training films (many of which he helped produce) sponsored by the FDA, the ASA, and the APSF.

Dr. Robert K. Stoelting, MD, current president of the APSF, at Dr. Pierce's memorial service, summarized several tributes he had received honoring Dr. Pierce, including one from E.S. "Rick" Siker, MD, the first APSF secretary and then executive director who commented, "I am comforted by the knowledge that he made an indelible mark on American medicine and that his contributions will never be forgotten." Also, Mr. Michael Scott, the long-time ASA legal counsel added, "It was a privilege to work with Dr. Pierce on the formation of the APSF. As ASA counsel for many years I worked closely with a succession of dedicated, able leaders of the specialty, but none displayed the intense sense of singular mission at all hours of the day and night than did Dr. Pierce with respect to improving patient safety. He was truly an uncommon man."

James F. English, MD, who succeeded Dr. Pierce as president of Anesthesia Associates of Massachusetts in 1998, spoke of his close friend and mentor at the memorial service. He lauded Dr. Pierce's remarkable successes and continued, "Jeep didn't accomplish all this by being a shrinking violet. He had a very strong and distinct personality. He

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Pierce Labeled Transcendent Visionary

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knew how to get what he wanted, and one of his main tools was his skill in communicating. Jeep was very erudite and articulate and he reveled in being descriptive. For example, one of his pet peeves was false piety. When he encountered it, he relished using the word *sanctimonious*. . . . it would roll off his tongue, often preceded by an interesting adjective and always followed by a colorful noun." Dr. English recounted one of his favorite stories of Jeep: " A young doctor joined us who had all kinds of ideas about how Jeep's beloved group and hospital could be improved. Jeep disagreed with every suggestion, at first politely but with increasing vehemence as this doctor persisted. A few times he even had to resort to his patented rebuke: 'YOU CAIN'T DO THAYAT!'"

Dr. Pierce was also eulogized by Dr. Bob Bode, who shared illuminating personal insights: "Briefly, I would like to describe the Jeep Pierce I grew to love and respect. Jeep was impeccably honest, had a great sense of humor, and was a wonderful mentor to me and to many others. He treated everyone with dignity and respect, whether you were a senior physician, nurse anesthetist, anesthesia technician, orderly, or receptionist at the Prudential Towers. Jeep was also an iconoclast, a rebel of sorts, who basically did not care how others felt about him as long as he knew in his heart that he was doing the right thing.... Jeep was a great leader whose style was always deliberate and he often raised his voice for effect. He was a highly respected man, but many nurses at the Deaconess thought that he could be intimidating at times. Jeep would deny this."

Dimensional Diversity

Despite his intensity about patient safety, Dr. Pierce was far from unidimensional. He had other loves as well—surely the most for his late wife, Elizabeth, and his children Chip and Wendy, and his 3 grandchildren. Also, in a social moment, he'd reveal his passion for large pipe organs and their magical music, including the one at Boston's Trinity Church where his memorial service was held. He traveled the world to see the special ones. Functionally a "renaissance man," he loved opera and architecture, too, but especially history. Winston Churchill was his hero; he read all he could about the great leader and statesman (and displayed a Churchill bust in the vestibule of his apartment, a gift from the APSF on his retirement as president). Dr. Pierce always had a delightful sense of humor and contagious laughter, and he was quick to help others, even when he himself might have been in need.

Passionate, persistent, patient, jovial, charming, and dedicated completely to a cause he believed in, he was an inspiration to all of us. Dr. English rightfully labeled him "transcendent" ("surpassing; extending or lying beyond the limits of normal experience"). Ellison C. Pierce, Jr., MD, was truly a "great man." He has left anesthesia practice an order of magnitude safer and the world generally a better place. We do and will miss him enormously.

Dr. John Eichhorn, Professor of Anesthesiology at the University of Kentucky, was the founding editor of the APSF Newsletter *and remains on the Editorial Board and serves as a senior consultant to the APSF Executive Committee. Dr. Jeffrey B Cooper, Director, Center for Medical Simulation and Professor of Anaesthesia, Harvard Medical School, Boston, MA, is Executive Vice President of the APSF and one of the founding members of the Executive Committee.*

Reference

1. Pierce, EC. The 34th Rovenstine Lecture: 40 Years behind the Mask: Safety Revisited. *Anesthesiology* 1996;84:965-975.

Letters to the Editor

Reader Questions Conclusions on Remote Locations

To the Editor:

I am writing in response to the recent article "Risks of Anesthesia Care in Remote Locations" in the spring-summer 2011 issue. I feel the authors draw the wrong conclusions from the described tragedy. The patient was given 3 drugs that are respiratory depressants. The dose was adjusted until the patient was asleep, felt no discomfort, and tolerated a foreign body in his throat. That state was formerly described as anesthetized, but the term MAC now seems to have replaced it. It now seems that *general anesthesia* is a term only used if a volatile agent is also used.

One could argue that the semantics are not important, but the whole issue of sedation versus anesthesia needs to be further examined.

With a general anesthetic it is customary to guarantee an airway, not to assume that it is probably OK. It is customary to use a capnogram, not just when it is probably needed, but in all cases. It is also customary not to take chances and hope that the outcome will be good. Putting an unconscious patient face down in the dark would be a triumph of optimism over prudence. To do it without a Plan B for instant access to the airway is hard to understand.

All of this has nothing to do with "Remote Locations." What is remote is the observance of traditional anesthesia practices.

The authors describe the difficulties of providing safe care and describe dark rooms, inadequate anesthesia support, variability of monitoring, and so forth. To quote Nancy Reagan, "Just say no." If one feels that the environment is not safe, then one must refuse to participate.

I think many anesthetists worry that they will be regarded as troublesome and uncooperative if they hold out for safety issues, but in fact, the opposite is true. Most surgeons, endoscopists, and the like have little training or knowledge of airway management. They want us to take charge of the safety issues, set the guidelines, organize the equipment, and make it safe. I believe they respect our expertise; the last thing they want is an anesthetic crisis, especially when preventable.

Kenneth Green, MB, BS, FFARCS
Waterville, ME

In Reply:

We thank Dr. Green for his interest in our newsletter article and we agree that anesthesia leadership in patient safety for out-of-operating room sedation is important. The intent of the anesthesia provider in the case presented was to administer moderate sedation. This case illustrates that with the continuum of sedation, moderate sedation may quickly progress to general anesthesia and be unrecognized, particularly when multiple drugs are administered during a short period and respiratory monitoring is inadequate. The transition from moderate sedation to general anesthesia also varies from patient-patient, as well as with changing degrees of procedural stimulation and pain.

Based upon the cases we analyzed, we hoped to deliver a clear message: vigilance and respiratory monitoring should be similar for sedation as for general anesthesia, independent of the place where anesthesia care is provided. As pointed out in your letter, continuous monitoring of exhaled CO_2 constitutes the key preventative measure to respiratory mishaps in patients undergoing procedural sedation. The American Society of Anesthesiologists (ASA) Standards of Monitoring now requires capnography for monitoring ventilation during monitored anesthesia care, unless precluded or invalidated by the nature of the patient, procedure, or equipment (effective July 1, 2011).

Sincerely,

Julia Metzner, MD

Karen B. Domino, MD, MPH

Leaders and Experts Share Perspectives

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saturation. He also predicted that the increased emphasis on postoperative pain management by centers that govern reimbursement will undoubtedly result in a higher incidence of opioid-induced respiratory depression.

There was not uniform agreement initially regarding selective versus universal monitoring, or risk stratification, for patients receiving postoperative opioids. Several speakers discussed coexisting conditions and diseases associated with postoperative drug-induced respiratory depression including obesity, sleep apnea syndromes, advanced age, organ system dysfunction, concurrent CNS depressant use, and preoperative chronic opioid tolerance. Many of these risk factors (especially obesity) have been increasing in the general population. Yet, some of these conditions that predispose to opioid-induced respiratory depression may be undiagnosed in the surgical patient. In particular, Dr. Frances E. Chung, professor of Anesthesiology at the University of Toronto presented data showing that over three-quarters of men and women with moderate to severe sleep apnea are undiagnosed, with a 7-22% prevalence.[5] Therefore, risk stratification for increased postoperative electronic monitoring would potentially miss a large population of patients that is at increased risk for opioid-induced respiratory depression.

Ray R. Maddox, PharmD, from St. Joseph's/Candler Health System in Savannah, GA, shared his experience during the general audience discussion session. His hospital instituted capnography with or without pulse oximetry monitoring over 5 years ago for all patients receiving parenteral or neuraxial opioids postoperatively after some high-severity adverse events involving opioids. They found early in their beta testing that it was not possible to reliably predict opioid responsiveness based on risk stratification and elected to monitor all patients receiving postoperative opioids. To date, they have not had any respiratory arrests related to the administration of postoperative opioids since they instituted the increased monitoring.[6]

Further data from Dr. Chung demonstrated that monitoring patients postoperatively for respiratory depression may entail more than one or two nights after surgery. Her data showed that the apnea-hypopnea index (AHI) in sleep apnea patients is highest on the third night after surgery and remains above the preoperative baseline out to the seventh postoperative night.[7] Further research is needed to determine if the type and duration of surgery and anesthesia impact these findings. It remains unclear how to best monitor severe sleep apnea patients after procedures that would be considered outpatient surgery.

Dr. Scott F. Gallagher, associate professor of Surgery from the University of Florida in Tampa, FL provided data showing that bariatric sleep apnea patients will have severe prolonged hypoxemia even with their continuous positive airway pressure (CPAP) in place.[8] Consequently, monitoring of oxygenation and ventilation is still needed in these patients postoperatively, even when they are using CPAP.

Dr. J. Paul Curry, clinical professor of Anesthesiology at the University of California in Los Angeles David Geffen School of Medicine, and staff anesthesiologist at Hoag Memorial Hospital Presbyterian in Newport Beach, CA, and Dr. Larry A. Lynn, a pulmonary intensivist and the executive director of the Sleep and Breathing Research Institute in Columbus, OH, presented unique data describing 3 different patterns of unexpected hospital deaths. These patterns included progressive metabolic acidosis (e.g., sepsis), opioid-induced carbon dioxide narcosis, and drug-induced arousal failure with sleep apnea (see article on page 32). They showed different trends in pulse oximetry values, minute ventilation, respiratory rate, and arterial carbon dioxide levels associated with each of these 3 patterns of death.[9] They noted that health care providers are not well educated about these patterns and may miss early warning signs. Further, they believe that monitors with threshold alarms (i.e., alarm upon reaching a specific value) are not useful because of their inability to distinguish meaningful from nuisance alarms, depending on the death mechanism. They also discussed that early detection of deteriorating patient conditions will be poor when threshold alarms such as pulse oximetry are set to lower values to reduce the incidence of "false" alarms. Drs. Curry and Lynn encouraged industry to develop smart technologies that could detect the specific patterns of vital signs preceding these types of death and alert care providers.

In agreement with the use of smart technologies for pattern recognition, Dr. Richard E. Moon, Professor of Anesthesiology and Medicine at Duke University, suggested that multimodal monitoring was necessary to detect postoperative, drug-induced respiratory depression. He believed we could incorporate the technology used with automated implantable cardioverter-defibrillators (AICD) that utilize complex time-dependent pattern recognition algorithms based on reference waveforms. Dr. Mark R. Montoney, MD, MBA, Executive VP and CMO, Vanguard Health Systems, Nashville, TN, concurred that smart technologies must be developed that can reliably detect early progression of clinical instability and trigger prompt caregiver responses. Dr. Elizabeth A. Hunt, a pediatric intensivist from John Hopkins University School of Medicine also observed that progressive types of multimodal monitoring for vital signs that could be incorporated to identify patterns and percent deviation from baseline vital signs would

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Table 1. Comparison of Available Monitoring Modalities for Detection of Opioid-Induced Respiratory Depression in the Postoperative Period

Monitoring Modality	Sensitivity *	Specificity	Reliability	Response Time
$P_{et}CO_2$ (intubated)	High	High	High	Fast
S_pO_2 (no O_2 supplement)	High	Moderate-High	High	Fast
$P_{et}CO_2$ (unintubated)	High	Moderate-High§	Moderate	Fast
P_aCO_2	High	High	High	Slow
P_vCO_2	High	Moderate	High	Slow
$P_{tc}CO_2$	Moderate	High	Low-Moderate‡	Medium
S_pO_2 (with O_2 supplement)	Moderate	Moderate	High	Slow
Clinical assessment (skilled clinician)	Moderate	Moderate-High	Moderate	Slow
Respiratory rate (newer technology)	Moderate	Moderate†	Moderate	Medium
Tidal volume (unintubated)	Moderate	Moderate	Low	Medium
Chest wall impedance (for respir. rate)	Low-Moderate	Low†	Low	Medium
Clinical assessment (less skilled clinician)	Low-Moderate	Low-Moderate	Low-Moderate	Slow

* Definitions: Sensitivity = positive in the presence of respiratory depression (low false negative rate); Specificity = negative in the absence of respiratory depression (low false positive rate); Reliability = accuracy and availability (likelihood of an available and accurate reading at the time of respiratory depression); Response time = average time from the onset of respiratory depression until the variable reads abnormally if it is going to do so.

§ If $P_{et}CO_2$ is high, this is highly specific for respiratory depression. However, if is low, because of unknown dead space, it can only be used as a measure of respiratory rate.

‡ New $P_{tc}CO_2$ technologies may be more reliable.

† In some patients, respiratory rate alone may not be a good measure of opioid-induced respiratory depression.

Small Groups Agree on Electronic Monitoring

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be useful to provide early detection of deterioration in the pediatric setting.

David A. Scott, MB, BS, PhD, Associate Professor of Anaesthesia at St. Vincent's Hospital in Melbourne, Australia, presented data showing the importance of the assessment of sedation level in preventing ventilatory impairment from opioids. He noted that opioids affect consciousness (sedation), airway tone, and central respiratory drive and that monitoring strategies should address all of these parameters. He again espoused the importance of assessing trends. Consistent with Dr. Scott's presentation, Chris Pasero, RN-BC, a pain specialist from El Dorado Hills, CA, also commented on the importance of nurses being able to assess and document sedation levels as part of a multimodal monitoring strategy to detect drug-induced respiratory depression. Some audience members suggested that sedation should be the sixth vital sign. Ms. Pasero also advocated for individualized pain treatment strategies with an emphasis on multimodal analgesia.

Other speakers provided evidence that all patients could benefit from increased postoperative monitoring, and that the increased costs of monitoring would be offset financially by improved outcomes. With continuous monitoring, patients had fewer transfers to the intensive care unit and better survival if in-hospital arrests occurred, compared to patients with traditional monitoring every 2-4 hours. Supportive of this supposition, experts in the implementation of rapid response teams including Dr. Michael A. DeVita, an intensivist from St. Vincent's Hospital in Bridgeport, CT, provided evidence that while increased monitoring improved survival for in-hospital arrests, the patients' associated medical conditions only predicted about 50% of arrest or near-arrest events.[10] In other words, risk stratification of patients using a specific set of predictors could miss up to half of those who will have serious inpatient events. Dr. George T. Blike, a professor of Anesthesia at Dartmouth University, observed that one of the essential differences separating the best and worst quality hospitals was not their number of complications, but their management of complications once they occur. He summarized his research in which patients who were under continuous postoperative pulse oximetry surveillance with alarms that alerted nurses of abnormal vital signs had significantly fewer rescues and unanticipated transfers to the intensive care unit.[11]

Steven R. Sanford, JD, president and COO of Preferred Physicians Medical, discussed that one-third of their 96 malpractice insurance claims involving postoperative respiratory arrests focused on allegations of drug-induced respiratory arrest resulting in death or brain damage. Another third of this subset of claims involved patients with obstructive sleep apnea with inadequate monitoring alleged by expert witnesses or reviewers.

Dr. Robert A. Wise from the Joint Commission (JC) discussed the rigorous process for translating a patient safety issue into a National Patient Safety Goal or Standard. The JC focuses on one to two safety issues each year so that the importance of each issue is highlighted. He noted that educational publications by accrediting or standards-making bodies can be accomplished more quickly.

Timothy W. Vanderveen, PharmD, MS, from CareFusion, Roger S. Mecca MD, from Covidien, Catherine W. Parham, MD, MBA, from GE Healthcare, Michael O'Reilly, MD, MS, from Masimo (and a professor of Anesthesiology and Perioperative Care, University of California, Irvine), David Lain, PhD, JD, FCCP, RRT from Oridion Capnography, and Andreas Bindszus from Philips Healthcare all provided their thoughts on continuous electronic monitoring to prevent drug-induced respiratory depression in the postoperative period. These industry leaders updated the audience on the currently available monitors of oxygenation and ventilation. Pulse oximetry monitors wired to a central location with alarms, nasal capnography monitors that alert providers, pulse oximetry and/or capnography monitors integrated into PCA pumps that can alarm and halt the delivery of further opioid, and acoustic monitors of respiratory rate coupled with pulse oximetry that alert providers of abnormal situations were all discussed.

One of the recurring concerns noted by multiple speakers was the issue of "alarm fatigue" in nurses due to frequent false positive alarms, often caused by displaced monitoring sensors or artifact, but also from threshold alarms set at levels to minimize false negative outcomes (i.e., no or late alarm in a deteriorating patient). Frequently unreliable monitors can result in delayed or no response from rescuers (e.g., nurses) when real events occur. Many speakers and audience members implored industry to develop multimodal monitors that would be able to detect patterns from multiple vital signs, and theoretically, prove more reliable.

Following the formal lectures, audience members were assigned to breakout groups to reach consensus on the two questions posed at the opening of the conference. Summaries of their group sessions were provided by the group leaders to the reassembled participants. There was excellent agreement across all groups that electronic monitoring should be utilized to facilitate detection of drug-induced postoperative respiratory depression. Similarly, most groups believed all patients receiving postoperative opioids should be monitored continuously, but that this process may need to be implemented in a graded fashion because of resource limitations. The duration of monitoring recommended, particularly in light of Dr. Chung's presentation, was not clear. Additionally, management of outpatients postoperatively was not adequately addressed at this meeting.

There was very good agreement between groups that pulse oximetry should be utilized for monitoring as many patients as possible because of its existing wide availability, ease of use, and provider familiarity. However, if supplemental oxygen was being used for patients, then most groups believed capnography should also be applied to patients to detect hypoventilation. Some groups believed that an electronic central observation area for the monitors and alarms would be useful. Improved education and assessment of sedation level by nursing was also noted by many groups as desirable.

A few audience members believed that taking action on this patient safety issue was premature because there was sparse evidence-based medicine demonstrating that increased monitoring improved outcomes. They believed that more research was needed to devise more reliable monitors with outcomes studies before recommending these costly interventions. Most conference participants acknowledged the legitimacy of this concern, but believed the continued loss of lives from this preventable complication warranted immediate intervention with the best available monitors until superior monitors were developed.

See "Monitoring," Next Page

Letter to the Editor

UVA Launches Difficult Intubation Label

To the Editor:

I would like to share a practice recently adopted by the University of Virginia to assist health care providers to identify intubated patients who experienced a difficult intubation. When a difficult intubation is encountered, a bright orange sticker labeled "difficult intubation" is placed circumferentially around the endotracheal tube, below the connector—a literal "red flag." This alerts the caregivers involved in extubation of the patient that reintubation, if necessary, would possibly require special equipment in order to be successful. This avoids any miscommunication among health care providers regarding the airway management history.

Geraldine Syverud, CRNA
Charlottesville, VA

Consensus Supports Continual Monitoring

From "Monitoring," Preceding Page

During the question and answer session, Dr. Steven F. Shafer, editor-in-chief of *Anesthesia & Analgesia*, urged everyone to study the outcomes of any new monitoring initiatives. Dr. Mark A. Warner, ASA President, offered to facilitate implementation of these recommendations by having ASA work with key nursing and surgical groups.

In summary, the consensus of conference attendees was that continual electronic monitoring should be utilized for inpatients receiving postoperative opioids. When supplemental oxygen is not being used, pulse oximetry was thought to be the most reliable and practical monitor currently available. If supplemental oxygen is added, then monitors of ventilation (e.g., capnography) were thought to be necessary to detect hypoventilation. Improved education of all care providers on the dangers of postoperative opioids, and better assessment of sedation level were thought to be critical steps in the prevention of postoperative drug-induced respiratory depression. It was acknowledged that limited resources may result in a staged implementation of continual monitoring strategies with the highest risk groups being monitored first, but with the goal of monitoring all inpatients receiving postoperative opioids. Risk stratification was shown to be insufficient to eradicate postoperative opioid-induced respiratory depression.

Preventable deaths and anoxic brain injury from unrecognized opioid related sedation and respiratory depression remain a serious and growing patient safety concern. The issues identified and the actions recommended by this group should mitigate these risks with the goal to eventually eradicate this cause of preventable patient harm.

A summary of the conclusions and recommendations from this conference can be found at the APSF website at http://apsf.org/announcements.php?id=7 or by clicking on the link under Announcements at www.apsf.org, and a brief Meeting Report of the proceedings of the conference will be published in *Anesthesia and Analgesia* (in press).

Dr. Weinger is the Norman Ty Smith Chair in Patient Safety and Medical Simulation, and Professor of Anesthesiology, Biomedical Informatics, and Medical Education at Vanderbilt University School of Medicine and a Senior Staff Physician Scientist in the Geriatric Research Education and Clinical Center (GRECC) in the VA Tennessee Valley Healthcare System. Dr. Lee is an Associate Professor in the Department of Anesthesiology and Pain Medicine at the University of Washington and Co-editor of the APSF Newsletter.

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Methadone References Supplied by Request

In the last issue of this *Newsletter* (Volume 26, No. 1), Dr. Joan Christie authored an important article addressing the risks of methadone and means to mitigate such risk. Both Dr. Christie and the editors have received correspondence requesting references for this article. These references were omitted from the original article due to space limitations as an editorial decision. In light of the recent requests, we are providing these general pertinent references as follows:

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Letter to the Editor

Plastic Covering of Stylet Can Shear Off During Intubation

To the Editor:

A 2-hour-old, 1400 gm neonate was brought to the OR for gastrochisis repair. After an uneventful, intravenous induction with propofol and rocuronium and easy mask ventilation, we intubated the neonate with a 3.0 uncuffed endotracheal tube styleted with a 6 F Rusch Flexi-Slip™ stylet (Teleflex Medical, Research Triangle Park, NC, USA) without any difficulties. While the resident held on to the endotracheal tube, the stylet was removed with some difficulty. At a glance upon removal, the stylet looked intact. The endotracheal tube placement was confirmed by end-tidal CO_2 and auscultation of bilateral breath sounds. While taping the endotracheal tube in place, we noticed a foreign object in the tube. We removed the tube and returned to mask ventilating the patient. The foreign object was found to be the distal end of the plastic covering of the stylet. The neonate was reintubated without a stylet and the vital signs remained stable throughout. After securing the second endotracheal tube, we reinspected the stylet and noticed that the plastic covering had retracted exposing the metal internal rod. The anesthetic proceeded uneventfully.

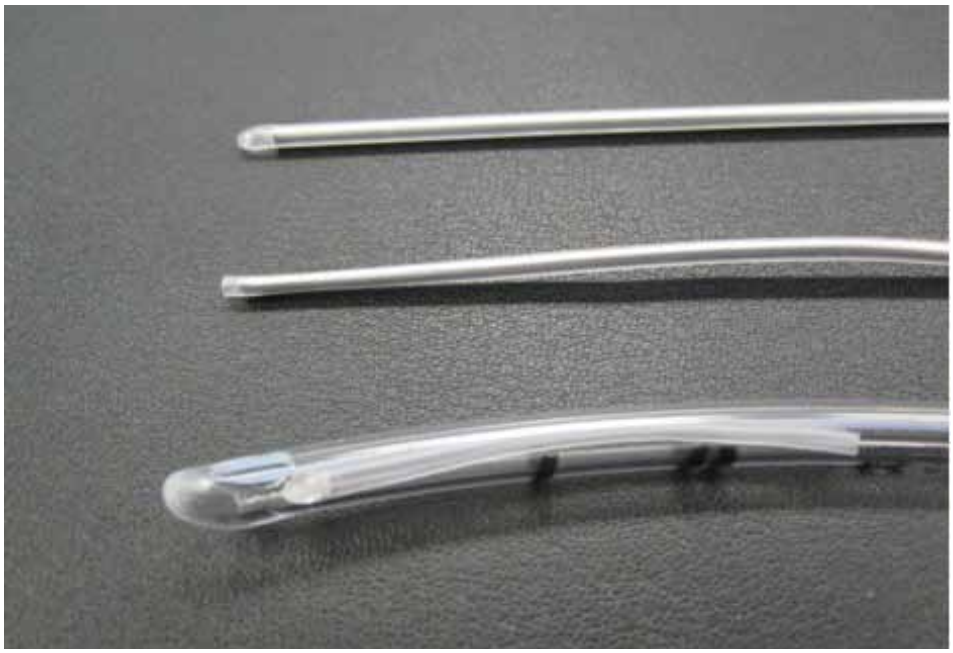

Figure 1: From top to bottom: Intact stylet; stylet immediately after distal end sheared off; sheared off tip in endotracheal tube.

The following day, we were able to reproduce the shearing-off of the distal end of the plastic covering of the 6 F Flexi- Slip™ stylet by again using a 3.0 endotracheal tube and holding on tightly to the tube during removal of the stylet.

In discussing this event with colleagues, some of them mentioned that they routinely lubricate the stylet before inserting it in such a small endotracheal tube. Others, though, never use a lubricant because of concerns of residual dried lubricant in an already small endotracheal tube lumen. I did try to reproduce the shearing off of the plastic covering with a lubricated stylet and was not able to do so.

I have intubated a good number of newborns with styleted endotracheal tubes without lubrication and have never experienced any shearing-off of plastic prior to this event. The stylet slides into the 3.0 endotracheal tube easily and only if the tube is held tightly is it difficult to remove. A smaller tube size may increase the chance of difficulties in removing the stylet. This stylet is recommended for use in endotracheal tube sizes of 2.0-3.5.

We have reported this event to the distributor and sent the stylet and sheared off tip to them for an investigation. Additionally, we did inform the FDA/ MedWatch Alerts and sent out a safety alert to all pediatric anesthesiologist working at our institution.

The shearing-off of the plastic covering within an endotracheal tube can potentially lead to a serious adverse event. In our case it was recognized early and negative consequences were avoided. Nevertheless, we should all be aware of this potential complication.

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Christina D. Diaz, MD
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Figure 2: Stylet after plastic covering retracted.

Dear SIRS

Reusable Anesthesia Breathing Circuits Considered

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

Dear SIRS refers to the Safety Information Response System. The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. This process was developed by Dr. Michael Olympio, former chair of the Committee on Technology, and Dr. Robert Morell, co-editor of this newsletter. **Dear SIRS** made its debut in the Spring 2004 issue. Dr. A William Paulsen, current chair of the Committee on Technology, is overseeing the column and coordinating the readers' inquiries and the responses from industry.

Dear SIRS:

I am being asked to consider reusable anesthesia breathing circuits with Pall filters. Searching the *APSF Newsletter,* I found several questions regarding this topic in the Spring 09 issue. Some of those questions were printed under the "On the Horizon" title. I haven't found any follow-up since. What is the status of this debate?

R. Mauricio Gonzalez MD
Clinical Assistant Professor of Anesthesiology
Boston University School of Medicine
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Response

Dear Dr. Gonzalez:

It has become increasingly common to use anesthesia breathing circuit filters in an effort to decrease infectious risk from diseases such as HIV, hepatitis C, tuberculosis, SARS, vCJD, and H1N1 influenza.[1] This trend may also be fueled, in part, by liability concerns regarding the possibility of transmitting such dangerous infections in health care.[1] When the SARS pandemic hit in Canada, 50% of the deaths were health care workers, including 3 anesthesiologists.[2] Once it was better understood how the infection was being spread, the Ontario Ministry of Health mandated the use of pleated hydrophobic submicron filters.[2]

There are several reports in the literature of contamination potentially spreading through anesthesia machines. In 2 instances, a seemingly unlikely pathogen, HCV, (Hepatitis C Virus) spread from patient to patient via the anesthesia breathing circle system.[3] Studies have shown that anesthesia machines can become contaminated, and ventilators have been shown to spread infections from patient to patient.[4,5] If an anesthesia machine is used in caring for a patient who is recognized as being colonized or infected, it should be decontaminated. Too often, however, decontamination consists of merely wiping the machine with a disinfectant. This does little or nothing to protect subsequent patients from organisms that may be residing in the machine or soda lime canister.

The anesthesia environment presents a difficult challenge for a filter or a heat and moisture exchange filter (HMEF). High levels of moisture may negatively affect filtration efficiency. Filters that test well in a dry environment may be less effective in the relatively moist environment found in the anesthesia setting.[6] Vulnerable patients may be suffering from preexisting infections, may be immunocompromised, intubated, and placed in an environment that is warm and moist, resulting in considerable risk for infection.

There are 2 basic types of filters, mechanical (pleated hydrophobic) and electrostatic. Electrostatic filters have an applied charge on the media. This applied charge will attract aerosolized particles of the opposite charge, and hold them on the media. Mechanical filters have no applied charge. Instead, they filter primarily by having smaller interstices in the media, and they are often pleated to increase the surface area in order to keep resistance to a minimum.[7]

Electrostatic filters may perform well in the dry environment during testing, but not as well in the more humid environment associated with anesthesia delivery.[8] It is important to keep patient respiratory secretions from entering the media, which may facilitate infectious contamination. Several studies have shown that many filters are penetrated by fluid even when low pressures are applied.[6,9,10] The pressure needed to drive the fluid through the filter media is often below those pressures commonly used to deliver anesthetic gases to patients. It has been shown that pleated hydrophobic HMEF require substantially higher pressures to force fluid into the media.[11] The entry of fluid into filter media is particularly problematic for electrostatic filters that may lose much of their efficacy when they become wet.[10] Should the HMEFs or filters be breached, the anesthesia circuit may become contaminated.[12]

The International Organization for Standardization (ISO) has addressed breathing system filters for anesthetic and respiratory use and promulgated a standard, ISO 23328-1.[13] A key point is that this international standard requires filter validation by means of a standardized test using a 0.3 micron particle challenge. It also mandates specific tidal volumes and flow rates to be used to insure consistency and accuracy of testing. This type of standardization provides a more consistent and scientifically objective method for judging the effectiveness of a filter and should be used along with studies that evaluate filtration performance in a moist environment.

We have known for a long time that anesthesia machines and circuits may become contaminated.[14,15] The discussion of filtration use has, however, gradually moved from answering the question: "Can filters contribute to decreasing machine and circuit contamination?" to "Are filters a safe alternative to the individual replacement of breathing circuits and can we extend circuit life?"[16]

From the standpoint of infection control and circuit reuse it is important to think of the circuits as a part of the machine, rather than a separate entity. The entire circle system may become contaminated, including the soda lime, and the machine.[17,18] Bernards et al. found infectious contamination by *Acinetobacter baumannii* in critical care unit ventilators. Critical care ventilators are similar enough to anesthesia machines to raise concern that the latter may serve as vehicles for infection as well.[19]

See "Dear SIRS," Next Page

Products Should Be Chosen That Support Multiple Patient Use

Pall Ultipor™ 25 Filter and Multiple-Patient-Use Breathing Circuits.

"Dear SIRS," From Preceding Page

In the United States it is becoming more common for circuits to be reused between patients, when an HMEF is being used at the patient wye. This practice is much more widespread in Europe, where anesthesia caregivers are especially aware of the issues associated with disposable plastics and the environment. The Association of Anaesthetists of Great Britain and Ireland supports circuit reuse for multiple patients when using an effective HMEF.[20] A recent German Anesthesia and Infection Control Associations **(DGKH/DGAI)** statement allows for anesthesia circuits to be reused for multiple patients according to the circuit labeling, when employing an HMEF with an efficiency of >99% measured according to ISO 23328-1, with an important caveat relating to liquid penetration values.[21]

An earlier **Dear SIRS** column posed a question about a company (Pall Corporation) that has had a 510(k) for circuit reuse since 2002.[22] This company's HMEF (Pall Ultipor™ 25 filter) uses a pleated ceramic, hydrophobic sub-micron media, which has performed at the highest levels, irrespective of testing methodology. These filters work equally well in a dry or moist environment and have been shown to prevent contamination of the circuit in clinical use for 24 hours.[23,24] This particular HMEF has also been used, *in vivo*, on a standard anesthesia breathing circuit over a 72-hour period with a new filter being utilized for each patient. No patient contamination of the circuit occurred.[25]

If a hospital chooses to reuse its circuits for multiple patients, in the interests of cost savings and the environment, it is extremely important to be certain that the HMEFs have been properly validated against organisms, resistance, and fluid penetration and that the circuit is labeled specifically to permit reuse for multiple patients. If a hospital chooses to go "off label," using a circuit that is labeled "Single Patient Use," effective filtration may not be assured and risks of cross contamination and infection may exist. Therefore, it is important that products be selected which are intended for and support multiple patient use.

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Threshold Monitoring, Alarm Fatigue, and the Patterns of Unexpected Hospital Death

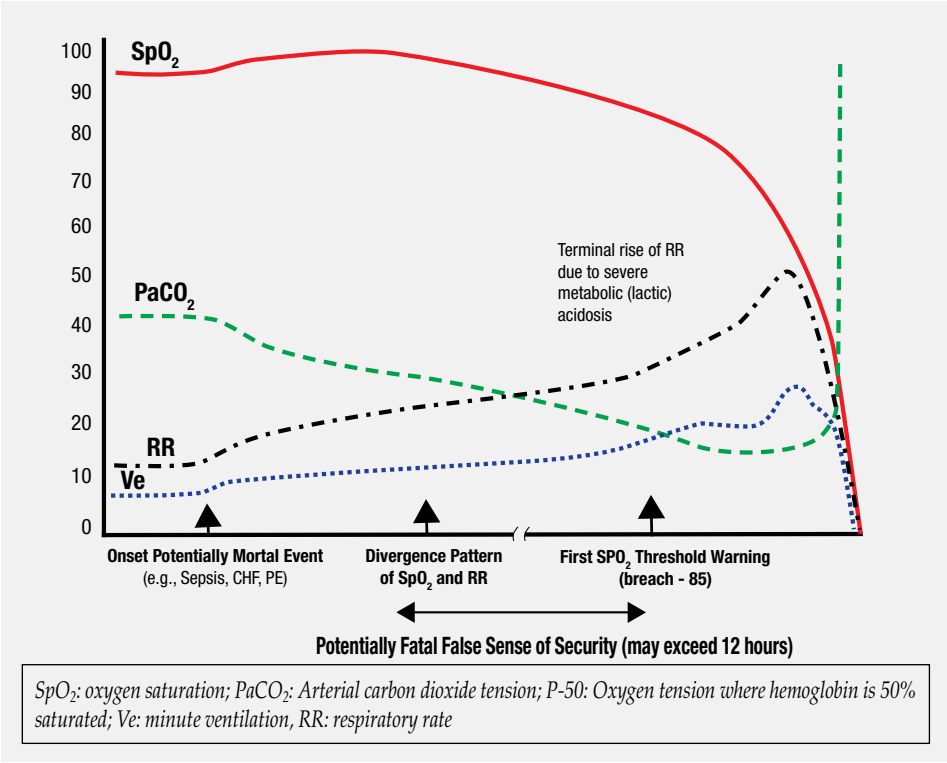
J. Paul Curry, MD, and Lawrence A. Lynn, DO

Introduction

Following the great fire of London in 1666, the first automated detector and threshold fire alarm was invented. This alarm was comprised of a string that stretched through each room of a house, and then extended to the basement where it was connected to a weight suspended over a gong. In theory, a fire in this "threshold monitored" home would burn through the string and trigger the alarm, resulting in a "better late than never" arousal of its occupants. Today, hospital care-givers and their patients still rely on this simple threshold alarm model, substituting threshold values of SPO_2, RR, heart rate, and $etCO_2$ as clinical surrogates for the string. Unfortunately, clinical trials[1,2] and a recent comprehensive research review[3] suggest that these threshold monitors, like the string, are not as effective as their designers first believed.

With our evolving recognition of the weakness single thresholds provide, variations on the threshold alarm method, such as the modified early warning score (MEWS), have been introduced. The MEWS system generates numeric scores from a range of threshold breaches and then adds these scores to produce a super "fusion" threshold. While MEWS may be an improvement, as we will see, it suffers from significant risk inducing anomalies inevitable whenever simple addition is used to quantify complex pathophysiologic processes.

One reason threshold monitors and MEWS may not be as effective as expected on hospital general care floors is that patients often die unexpectedly by progression through a range of 3 common, but distinctly different dynamic patterns of instability. We call these "Patterns of Unexpected Hospital Death" (PUHD) (Table 1). While these death patterns are not overly complex, they cannot be detected early by any single or multi-parameter threshold breach.



SpO_2: oxygen saturation; $PaCO_2$: Arterial carbon dioxide tension; P-50: Oxygen tension where hemoglobin is 50% saturated; Ve: minute ventilation, RR: respiratory rate

Figure 1. Type I Pattern of Unexpected Hospital Death (e.g., Sepsis, CHF).

The Common Patterns of Unexpected Hospital Death (PUHD)

Type I Pattern of Unexpected Hospital Death (e.g., Sepsis, CHF, PE)

This pattern reflects a clinically evolving process associated with microcirculatory failure induced by such common conditions as CHF, sepsis, and pulmonary embolism. The pattern generally begins with subtle hyperventilation and a persistent respiratory alkalosis (RA) despite subsequent progressive increases in anion gap and lactic acid levels. This stage occurs well before the development of dominate metabolic acidosis (MA), which is usually associated with its late and terminal stages. These progressive pattern phases (initial isolated RA followed by mixed RA and MA, followed by dominate MA) comprise the typical progression of Type I PUHD, and are shown in Figure 1.

Unfortunately, the very high respiratory rate thresholds (above 30/min) commonly used to trigger rapid response team activations,[5,6] occur most often in non-survivors[7] with no evidence showing they are breached early in sepsis or other conditions producing the Type I PUHD. Very high respiratory rates (above 30/min), like high lactate levels,[8] are likely to assist detection when severe metabolic acidosis, a late Type I PUHD manifestation, enters the picture. These are best considered markers of severity and diagnostic delay[9] rather than useful warnings for early disease.

Eventually microcirculatory failure in the lungs causes a fall in PaO_2,[10] but hyperventilation can perpetuate SPO_2 values well above 90% regardless of a

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Table 1—The 3 Clinical Pattern Types of Unexpected Hospital Death (PUHD)

TYPE I	**Hyperventilation Compensated Respiratory Distress (e.g., Sepsis, PE, CHF)** Stable SPO_2 with progressively falling $PaCO_2$ eventually yields to slow SPO_2 decline (mitigated by respiratory alkalosis), which is followed by precipitous SPO_2 decline when metabolic acidosis dominates.
TYPE II	**Progressive Unidirectional Hypoventilation (CO_2 Narcosis)** Progressive rise in $PaCO_2$ (and $etCO_2$) and fall in SPO_2 over 15 minutes to many hours. (Often due to overdosing of narcotics or sedatives)
TYPE III	**Sentinel Rapid Airflow/SPO_2 Reductions Followed by Precipitous SPO_2 Fall** A state of "arousal dependent survival" that occurs only during sleep. Arousal failure allows precipitous hypoxemia during apnea causing terminal arousal arrest.

Three Patterns are Associated With Unexpected Arrest

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falling PaO_2 because of respiratory alkalosis.[11] It's precisely these early, compensatory physiologic changes, and the oximetry patterns from Type I PUHD, which can fool clinicians into mistakenly believing these patients aren't in trouble.

The failure of single thresholds has led to the development of reliance on multiple perturbed parameters combined to generate a Modified Early Warning Score (MEWS). However, reliance on the sum of threshold perturbations of multiple parameters presents unique problems. In just one example, a heart patient receiving a beta blocker may require a higher respiratory rate to achieve a threshold MEWS score than a patient without heart disease. These types of anomalies illustrate the weakness of oversimplified and arbitrary scoring like MEWS.

To summarize, this unique Type I process starts with a rising minute ventilation and a falling $PaCO_2$, then a late slow fall in SPO_2 and a more rapid rise in minute ventilation (and at this point a severe rise in respiratory rate and marked additional fall in $PaCO_2$), followed then by a rapid drop in SPO_2 (often only now passing through the SPO_2 alarm threshold). If supplemental oxygen is provided, the SPO_2 can remain stable even closer to the death point, prolonging the false sense of security. Threshold breaches of RR, SPO_2, or the MEWS are generally late and unpredictable markers of the Type I pattern.

Type II Pattern of Unexpected Hospital Death (CO_2 Narcosis)

Since the 1950s,[12] nurses and physicians in training have learned that narcotics produce death through a singular path involving progressive hypoventilation. Perceived as a deteriorating, self-propagating process, both the narcotics and a rising $PaCO_2$ contribute to the central depression of ventilatory drive, ultimately leading to "CO_2 Narcosis" severe enough to bring on respiratory arrest. As hypoventilation progresses, supplemental low flow oxygen can hide it entirely from the pulse oximeter until very late,[13-15] just as it does with Type I PUHD.

Classic cases of this are seen in accidental narcotic overdose, and those patients with hypoventilation syndromes, such as adult patients with congenital central hypoventilation syndrome, e.g., PHO2XB mutations.[16]

In summary, (as illustrated in Figure 2) the Type II PUHD comprises first a progressive fall in minute ventilation due to declines in tidal volume and/or respiratory rate, both unpredictably variable. This induces a progressive rise in $PaCO_2$ with the patient exhibiting progressively higher sedation scores to the point of stupor and death. Patients provided with supplemental oxygen can maintain SPO_2 values in the 90-100% range until very late.

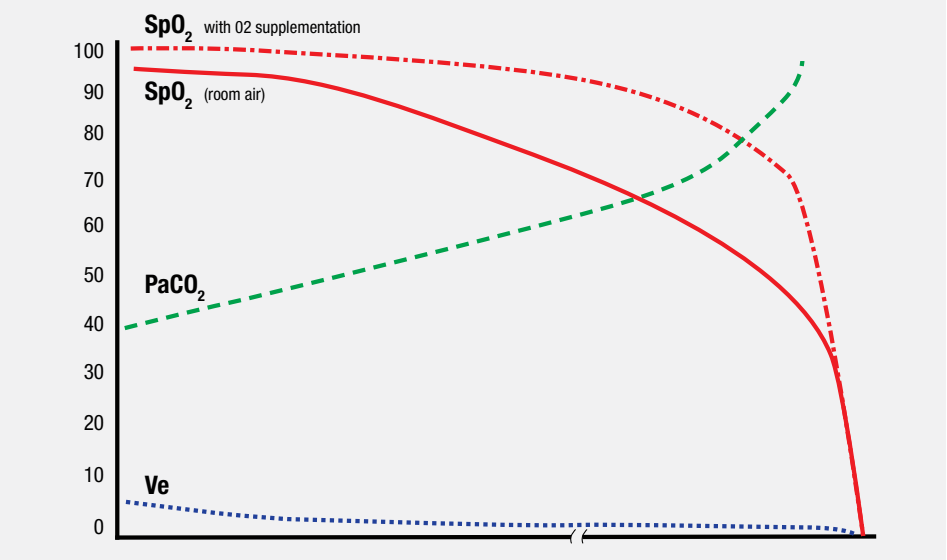

Figure 2. Type II Pattern of Unexpected Hospital Death (CO_2 Narcosis).

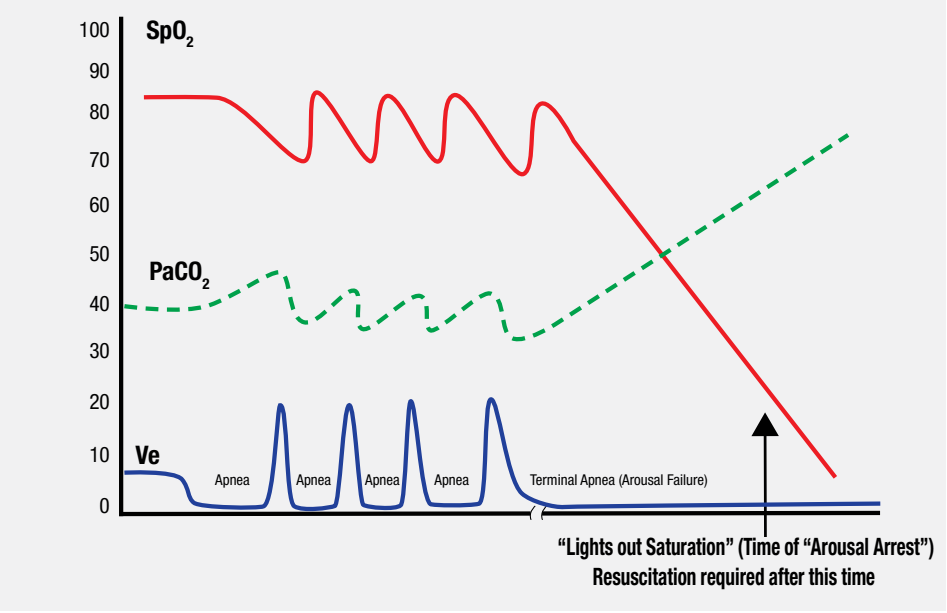

Figure 3. Type III Pattern of Unexpected Hospital Death (Sleep Apnea with Arousal Failure).

Type III Pattern of Unexpected Hospital Death (Sleep Apnea)

Having just discussed the prevailing belief held for decades (and still being taught in Medical Schools) on the cause of respiratory failure and death induced by narcotics and sedatives, we're now ready to unsettle any certainty and comfort this simplistic belief might provide. A "stand alone" Type II concept has fomented the widely held perception that sedation scores combined with threshold alarms from pulse oximeters and/or capnometry can reliably provide early detection.

Back in 2002, Lofsky[17] described a cluster of unexpected hospital deaths involving patients with risk factors for obstructive sleep apnea. These patients died in bed in spite of acceptable dosing of narcotics. Surprisingly, they all shared a unique clinical course that started with being alert, then sleeping, and then dying within brief timelines. We now know that sleep apnea with arousal failure produces a distinct pattern during sleep, which we've named the Type III PUHD. It differs from our classic Type II CO_2 narcosis process, in that it occurs only during sleep and may not be associated with prior elevated sedation scores. When awake, patients with profound Type III arousal failure may exhibit no pathognomonic symptoms or signs, or show evidence of any "awake" sedation. In other words, patients with arousal failure are orphaned,

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Major Focus and Clinical Trials Are Needed

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remaining completely concealed within our typical pre and postoperative populations. As shown in Figure 3, the sentinel instability component of Type III PUHD is induced by sleep apnea in the presence of arousal failure.

This Type III pattern architecture is comprised of repetitive reductions in airflow and SPO_2 from sleep related cycling collapses of the upper airway.[18,19] This cycling shown in Figure 4, with initial collapsing and then reopening of the upper airway, produces a typical and very distinctive pattern of signal clusters that is reliably acquired through high resolution pulse oximetry.

Obstructive sleep apnea can be best understood as a condition where during sleep, one's upper airway collapses and is held closed by vigorous but ineffective respiratory effort (much like trying to suck on a collapsed cellophane straw). Each apnea in a repetitive sequence of cyclic apneas is generally terminated by a micro-arousal. The arousal then causes brief "overshoot" hyperventilation that drives the $PaCO_2$ below normal. This drop in $PaCO_2$ triggers a fall in central ventilation drive and upper airway tone. Since the upper airway is already unstable it collapses again, causing the cycle to reenter and self-propagate, producing its sentinel pattern of repetitive reductions in airflow and SPO_2.[18] Narcotics,[20-22] spinal anesthesia,[23] sedatives,[24] and cycling hypoxemia[25] can increase the arousal threshold (cause arousal delay), and then respiratory arrest can occur from complete arousal failure (arousal arrest).[26,27] Once this occurs, if no intervention is provided immediately, a Type III death will follow suddenly during sleep without warning due to precipitous hypoxemia, and most often without much progressive $PaCO_2$ elevation because of insufficient time for hypercarbia to develop.

It has been postulated that chronic arousal failure may develop as a function of neural plasticity in response to repetitive exposures to rapid declines in oxygen saturation over many years. As the central arousal system adjusts its response, the arousal itself can become progressively more delayed (much as it would to intermittent loud sounds after years of sleep exposure to the passing of nearby trains). By the time the patient, exposed to many years of repetitive desaturations every night, arrives for surgery, the arousal failure may have unknowingly progressed to profoundly low pre-op levels.

One reason arousal delay becomes so critical is that SPO_2 is able to fall at very rapid rates during apnea. Many physicians accustomed to witnessing preoxygenated apnea lack a full appreciation for the extremely early and very steep desaturation slopes seen in recumbent, obese patients with apnea. In fact, since postoperative functional residual capacity does not have definable lower limits, oxygen desaturation rates may in some cases exceed 1.5% per second with SPO_2 falling to critical values with no time for contemporaneous hypercarbia to develop.[28] Occasionally a patient's arterial oxygen saturation falls to a point where the brain no longer receives sufficient oxygen for central arousal to occur.[21,26,27] This is called the "Lights Out Saturation" (LOS) and happens because the human brain is incapable of generating sufficient anaerobic metabolism and depends on a continuous supply of oxygen to support arousal. If arterial oxygen saturations fall below this critical value where the hemoglobin molecule simply cannot release sufficient oxygen to the brain, EEG slowing occurs promptly and arousal becomes totally suppressed: the "lights go out."

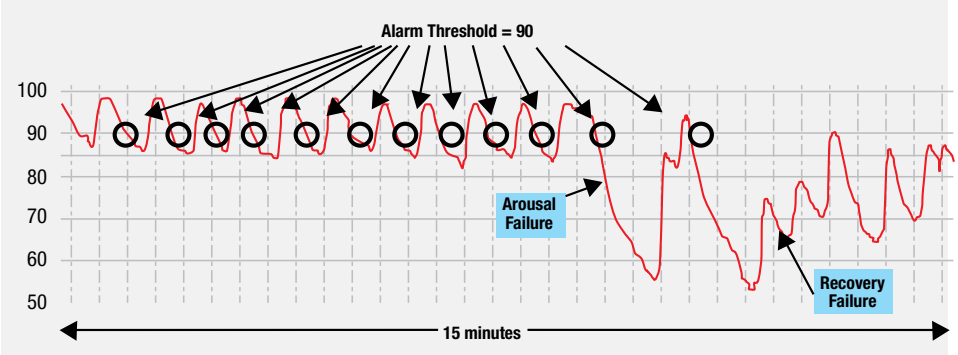

Figure 4. Type III Pattern: Note the Potential for Alarm Fatigue Preceding Arousal Failure.

Once the LOS is breached, airway reopening without resuscitation isn't to be expected. The body remains alive and continues to burn glucose and fat, and the heart pumps ever mounting CO_2 stores through an anoxic body. If the patient is discovered now and resuscitation initiated, the immediately drawn blood gas will show the $PaCO_2$ to be quite high, disguising this incident as a Type II event.

In summary, if unrecognized sleep apnea with its unique state of arousal dependent survival exists, the cycling SPO_2 signals can provide sentinel markers for both cyclical apnea and arousal failure. Unknowing administration of narcotics and/or sedatives to patients with preexisting arousal failure can delay an already failing arousal to the point of arousal arrest.

Discussion

Like the London string, the primary limitations of threshold monitors are due to their oversimplified design. If there was only one pattern of a house fire, or one pattern of unexpected respiratory instability, it might be possible to find a "best" string position in the house, and a best clinical threshold in the hospital. However, there are 3 common patterns of unexpected hospital death, all at counter purpose to one another regarding their detection, effects on physiology, and potential for alarm fatigue. Optimize a threshold to reduce alarm fatigue for one pattern and you inadvertently place patients suffering from the other patterns at risk for greater delays. Thresholds which appear effective in one population with a high grouping of one pattern may fail in another population with a different distribution. For this reason, alarm research studies must identify the distribution of patterns rendering the alarms before any conclusions can be drawn. Finally, "beeps" and/or MEWS that do not tell the health care worker which death pattern is evolving, and how far advanced the death pattern is, are easy to ignore and provide too little information for action.

However old, threshold devices still do have benefits, and these are the only devices presently available to protect our patients. Change to more advanced alarm processing technology will take time. One immediate solution is to expedite the development of a training course (analogous to the advance cardiac life support course) to certify all health care workers using patient monitors. This training would include modules designed to teach the PUHDs, the technical and pathophysiologic causes of alarm fatigue, and the benefits/limitations of monitoring and sedation scoring in relation to each distinct death pattern.

Formal training would also help prevent delay and death due to threshold based "technical trivialities" such as a patient's MEWS changing too late from a score of 3 to 4, or the generation of alarm fatigue by a death pattern which produces many early "threshold breaches" before an actual death event occurs, or a failure to alarm at all from the threshold monitoring of an unappreciated, compensated parameter.

An understanding of the relational and conformational complexity of the PUHDs also argues strongly for computational transparency of all alarm processors, which simply means that the original clinical data set, the processed data set, and the basis for outputs as a function of the processing are exposed (or readily exposable) in real time at the bedside by the clinical care-givers managing patients. Physicians should take charge of this process.

Finally, a major focus on improving patient monitors and clinical trials is required. Patients are dying in hospitals with smart phones in their pockets that can identify a song just by "listening" to it, while the monitors they are connected to are not smart enough to identify even one pattern of unexpected death.

Conclusion

There are 3 common fundamental pathophysiologic patterns of unexpected hospital death. These patterns are too complex for early detection by any unifying numeric threshold or summation score. Furthermore, alarms responsive to simple fragments

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Patterns and Training Are Important

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of patterns (e.g., thresholds or trends) rather than the patterns themselves have the potential to induce alarm inflation. Those using or designing patient monitors should receive formal training relevant to the patterns of unexpected hospital death. Clinical trials on alarms should identify the distribution of the patterns that generated them. In addition, new methods and technologies which detect, identify, quantify and track the actual patterns of unexpected hospital death should be investigated. It's time to cut the string.

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Dr. Lynn is a pulmonary and critical care physician and serves as executive director of the Sleep and Breathing Research Institute in Columbus Ohio. He also serves on the FDA standards committee for pulse oximetry monitoring.

Disclosure: Dr. Curry has nothing to disclose. Dr. Lynn holds patents and receives royalties relating to inventions in the field of patient monitoring and pattern detection.

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In Memoriam

In memory of William J. Beightler, MD (Texas Society of Anesthesiologists)
In memory of E. H. Boyle, MD (Philip F. Boyle, MD)
In memory of Jose M. Brito-Suarez, MD (Texas Society of Anesthesiologists)
In memory of Hank Davis, MD (Sharon Rose Johnson, MD)
In memory of Steve Edstrom, MD (Larry D. Shirley, MD)
In memory of Margie Frola, CRNA (Sharon Rose Johnson, MD)
In memory of Andrew Glickman, MD (Sharon Rose Johnson, MD)
In memor y of Roy C. Kang, MD (Texas Society of Anesthesiologists)
In memory of Stevon S. Kebabjian, DO (Texas Society of Anesthesiologists)
In memory of Max K. Mendenhall, MD (Texas Society of Anesthesiologists)
In memory of Ellison C. Pierce, Jr., MD (founding president of APSF) (multiple donors)
In memory of Robert Romero, MD (Texas Society of Anesthesiologists)
In memory of Sylvan E. Stool, MD (Lawrence M. Borland, MD)
In memory of Leroy D. Vandam, MD (Dr. and Mrs. George Carter Bell)

Note: Donations are always welcome. Donate online (www.apsf.org) or send to APSF, 520 N. Northwest Highway, Park Ridge, IL 60068-2573. (Donor list current through September 1, 2011.)

Dr. John Walsh Receives MGH Annual Cooper Patient Safety Award

At its graduation ceremony on June 16, the Department of Anesthesia, Critical Care and Pain Medicine (DACCPM) of the Massachusetts General Hospital awarded its third annual Jeffrey B. Cooper Patient Safety Award, which is named in honor of the APSF executive vice president. This year the award was given to Dr. John Walsh for his many enhancements and applications of the department's anesthesia information system, which he has spearheaded since its inception over 10 years ago, and for his dedication to the teaching of safe medication administration practices within the department. The entire department votes on this award each year, based on the following solicitation email:

"This award honors the dedication and contributions of Dr. Jeffrey B. Cooper to patient safety. Dr. Cooper is a Professor of Anaesthesia, Harvard Medical School, and the Executive Director of the Center for Medical Simulation. The intent is to annually recognize the exemplary contributions of an individual member of the department to the provision of safe patient care. Another goal of the award is to foster a culture of safety among the members of the department: **What can you do to promote safe patient care?**"

Eligible persons included members of the DACCPM attending staff, clinical fellows, residents, nurse anesthetists, critical care/monitoring nurses, anesthesia technicians, and biomedical engineers. Candidates were nominated based upon how their practice exemplifies Dr. Cooper's ideals for patient safety, their recognition of a significant patient safety problem, their proposal and/or implementation of a solution to a patient safety issue, and other contributions to patient safety.

Dr. Robert Peterfreund (right), Department Quality Assurance Committee chair, presents the award to Dr. John Walsh.

Congratulations to Dr. Walsh for the honor of receiving this award for his contributions to anesthesia patient safety.

Editor's note:

If your department or organization recognizes patient safety efforts with an award of any kind, please let the APSF Newsletter *know.*

Letter to the Editor

All That's White Isn't Necessarily Propofol

To The Editor:

I'm writing to inform you of a near miss at our institution, a large community hospital. During my morning room set-up, I noticed a medication vial containing a white substance found on my anesthesia Pyxis® machine table top. This substance could have easily been mistaken for propofol as it was identical to our current propofol supply in vial shape, size, cap color, label color, solution color, and consistency, as evidenced in Figure 1. The substance was a product called Rotaglide® lubricant. It is used as a medical lubricant for guidewires.

As with any near miss or drug error, there were a series of unusual circumstances that led to this product being placed on an anesthesia table top. Following our institution's investigation, it is known that we carry this product in a very limited quantity in our catheter lab and interventional radiology suites. The product is not stocked by our hospital pharmacy but through a separate supplier. It was brought to our operating room suites to show a surgeon who was looking for a new medical lubricant. The vial was left in the room for the surgeon to look at after he completed his case. During or after the case it remained in the OR and was evidently mistaken for an anesthesia medication, as evidenced by its placement on our anesthesia Pyxis® machine. Our hospital has since taken steps to make sure Rotaglide® lubricant remains secured until we find a suitable replacement that is not identical to propofol.

It was not all that long ago that we didn't label syringes of propofol because it was the only "white stuff." I hope this letter serves as a reminder to always read medication labels prior to drawing it up, as things are not always as they seem.

Susan Duerr-Trebilcock, CRNA, MS

Figure 1. Top panel is the front view of a vial of propofol (left) next to a vial of Rotaglide (right). Bottom panel is the back side of these vials.

Monitor Displays: Non-Moving Waveforms May Be Superior to Moving Waveforms

by Jonathan V. Roth, MD

Optimizing At-A-Glance Monitoring

Ford et al. reported that anesthesiologists frequently look at monitors for very short periods of times and have called for designs that take this behavior into consideration.[1] In this spirit, monitors that display traces that do not move (i.e., the static waveforms that are over-written with each new sweep), as opposed to waveforms that move across the screen, may have advantages that should be considered in future designs.

As an example, the Datascope "Expert" (Datascope Corporation, Paramus, NJ) has waveforms that do not move across the screen; the static waveforms get replaced as each new sweep comes by. It takes about 6 seconds for each sweep across the screen of the ECG, pulse oximeter, and pressure waveforms. It takes about 15 seconds for the sweep of the capnograph. If one quickly counts the ECG, pressure, or pulse oximeter displayed waveforms and multiplies that number by 10, or multiplies the number of capnograph waveforms by 4, one can closely estimate the rate per minute. Sometimes there are artifacts that cause the numerical display to be incorrect. Knowledge of these monitor specific relationships allows one to quickly determine the actual state of affairs.

As examples, the ECG and pulse oximeter rates displayed may either be unobtainable or in error as a result of a double count or artifact. If this is not recognized, it has the potential to lead to wrong treatment. This author has witnessed a situation where the actual heart rate was 55 beats per minute, both the pulse ox and ECG were double counting and displaying a rate of 110, and a beta blocker was administered. With moving waveforms, it would seem that it would more difficult for practitioners to learn that a given distance between moving complexes equates to a given rate over a range of rates. The respiratory rate displayed on the ventilator system may be falsely elevated if the ventilatory system is recognizing cardiac oscillations as breaths. This author has witnessed a patient with an actual respiratory rate of 12 breaths per minute, the ventilator displaying a rate of 34 because it was counting cardiac oscillations, and an opioid narcotic was administered.

Another advantage is that if one needs a display to be static in order to closely examine some feature of a waveform, it may be easier and faster to look at a non-moving display than one that is moving. Monitors with a moving display require at least one extra step in order to freeze the moving display. Whether or not a practitioner is more likely to recognize an abnormality on a static display than on a moving waveform is a question that will require further study.

In summary, it seems possible or likely that it is easier and faster with a static waveform system to recognize an abnormal waveform, or that the numerical display is incorrect, and obtain a more accurate rate. As with the Expert system, sweep speeds should be set so that a minute rate can be obtained by a whole number multiple of the number of waveforms displayed. Future studies will be required to support the above opinion.

Reference

1. Ford S, Birmingham E, King A, Lim J, Anesermino M. At-a-glance monitoring: covert observations of anesthesiologists in the operating room. Anesth Analg 2010;111:653-8.

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Letter to the Editor

Disposing of Meds

To the Editor:

I read Dr. Terman's article "Opioid Prescribing: REMS Sleep, Need Reawakening" from the spring/summer issue with keen interest. I am a non-medical person married to an anesthesiologist who is active in the ASA. With the support of our state medical society, our alliance of physician's spouses started a Safe Disposal of Medicine project over a year ago. We have been providing informational material to our physicians and their patients about how, where, and why to safely dispose of unneeded medication. We are also stressing the importance of secure storage of medicine and never giving someone medicine not prescribed for them. We have found that a large portion of drug abuse can be attributed to teenagers taking medicine they find in their homes and selling it or sharing it with their friends. I applaud your efforts to work on this important safety issue. Please let me know if our organization can be of any help with your efforts.

Michele Kalish
Immediate Past President, Alliance to MedChi
The Maryland State Medical Society
Safe Disposal of Medicine Project, Chair

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"No Patient Shall Be Harmed By Opioid-Induced Respiratory Depression"

Also:

Tribute to Jeep Pierce

Dear SIRS: Reusable Anesthesia Breathing Circuits Considered

Threshold Monitoring, Alarm Fatigue, and the Patterns of Hospital Death