

# **NEWSLETTER**

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### Fall 2007

## Safety Topics Abound at 2007 ASA

by Lorri A. Lee, MD

### **APSF to Co-Sponsor Workshop on Teamwork**

The 2007 Annual Meeting of the American Society of Anesthesiologists (ASA) will be held from Saturday, October 13, through Wednesday, October 17, at the Moscone Center in San Francisco, CA. Patient safety will again be the focus of numerous refresher courses, special lectures, scientific presentations, panels, and workshops, which are highlighted below. This year the APSF is proud to co-sponsor a workshop on *Teamwork and Team Training in the Operating Room* (#817) to be led by Drs. David Gaba and Robert McQuillan on Monday, October 15, from 2:00-5:00 pm in the Moscone Center West (Rm 2001). This workshop will demonstrate how patient safety can be optimized when everyone in the OR works as a team (see page 53 for details). Other workshops that focus on patient safety include *Healthcare Team Training in a Virtual Environment* (#822A and B, Tuesday, October 16, from 8:00-9:30 am and 9:30-11:00 am, Rm 2001, Moscone Center West); *Applying Human Factor Methods to Anesthesia Care* (#824, Wednesday, October 17, from 8:00-11:00 am Rm 2001, Moscone Center West); and fiberoptic workshops throughout Saturday and Sunday, October 13 and 14 (Rm 130 and 132, Moscone Center North).

### Refresher Course Lectures Encompass Variety of Patient Safety Topics

Saturday. October 13, 2007: The 58th Annual Refresher Course Lecture Program kicks off Saturday morning with Dr. Jan Ehrenwerth discussing pitfalls of *A Fire in the Operating Room! It Could Happen to You* (#136, 8:30-9:20 am, Rm #3022). Following this presentation, medico-legal lectures include Dr. Christopher Spevak providing a *Health Law Update for Anesthesiologists* (# 126, 9:40-10:30 am, Rm 3014) and Dr. Fred Berry outlining *What to Do After an Adverse Outcome* (#134, 2:50-3:40pm, Rm 3018). Helpful guidelines and updates to improve patient safety and outcomes will be provided on the topics of *CVP and PAC Monitoring* by Dr. Jonathan Mark (#102, 9:4010:30 am, Rm 2014), concurrent with Dr. Ronald Miller's *Update on Transfusion Medicine* (#108, Rm 2018). These lectures will be followed by *Controversies in Perioperative Pacemaker and Defibrillator Management* by Dr. Mark Rozner (#110, 1:40-2:30 pm, Rm 2018), and in the same room, *The ASA Obstructive Sleep Apnea Guidelines* by Dr. John Benumof (#111, 2:50-3:40 pm). Dr. Jessica Alexander's lecture on *The Potential Hazards of Perioperative Herb and Dietary Supplement Use* will provide useful information regarding our growing patient population who ascribe to complementary and alternative medicine (#118, 4:00-4:50 pm, Rm 2022).

<u>Sunday, October 14, 2007</u>: Sunday morning starts with a broad overview of *Evidence Based Medicine in Perioperative Care—Does It Help Us Improve Care*? by

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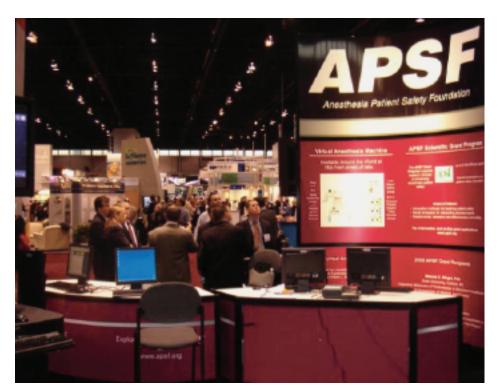
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Dr. Brenda Fahy (#213, 8:30-9:20 am, Rm 2022), concurrent with The ASA Closed Claims Project and its Registries moderated by Dr. Karen Domino (#236, Rm 3022). Later in the day, a directed approach to Anesthesia and Patient Safety: It's Not Only About Getting Out of the OR Alive! will be provided by Dr. Elizabeth Martinez (#210, 1:40-2:30 pm, Rm 2018). Management of common perioperative problems will be discussed by Dr. Christian Apfel in PONV: Current Thinking and New Directions (#215, 10:50-11:40 am, Rm 2022), followed in the same room by Dr. Jerrold Levy on Anaphylaxis and Adverse Drug Reactions (#216, 1:40-2:30 pm). How to protect yourself and your patient from infection will be presented by Dr. Jeanine Wiener-Kronish in her lecture Infection and the Anesthesiologists (#223, 2:50-3:40 pm, Rm 3010). Dr. James Rathmell will elucidate potential Complications in Pain Medicine and their prevention (#226, 9:40-10:30am, Rm 3014), followed by a similar presentation by Dr. Steven Roth entitled Complications in Neuroanesthesia (#221, 10:50-11:40 am, Rm 3010).

<u>Monday, October 15, 2007</u>: Monday morning refresher courses start with Dr. Steve Hall discussing *The Child With a Difficult Airway: Recognition and Management* (#326, 8:30-9:20 am, Rm 3022), concurrent with Dr. Robert Sladen's presentation of *Perioperative Care of the Patient With Renal Dysfunction* (#301, Rm 2014). Dr. Lee Fleisher shares his expertise on *Preop Assessment of the Patient with Cardiac Disease* (#308,

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### In Memorium

We note with sadness the passing of Dr. Arthur Keats, whose accomplishments in anesthesia very many and varied. He played an important role in the early years of APSF by being the first chair of our Scientific Evaluation Committee. He used his extensive research acumen to organize the system for soliciting and reviewing grants, based on his experience on NIH study sections. The rigor he brought to that process has remained essentially the same. His incisive thinking and quick wit made for serious, yet enjoyable discussions.



Arthur Keats, MD





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## Safety Papers to Be Presented Over 5 Days

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1:40-2:30 pm, Rm 2018), logically followed by Dr. John Ellis's lecture on Myocardial Ischemia and Postoperative Monitoring (#314, 2:50-3:40 pm, Rm 2022). Dr. Girish Joshi will try to clarify the hot controversy of managing The Patient with Sleep Apnea Syndrome For Ambulatory Surgery (#309, 2:50-3:40 pm, Rm 2018), concurrent with another debated topic of Depth of Anesthesia: Clinical Applications, Awareness and Beyond presented by Drs. Daniel Cole and Karen Domino (#324, Rm 3018). Dr. David Chestnut will share his vast experience and expertise to help us manage Problems in Obstetric Anesthesia: Blood Pressure, Blood Loss and Blood Patch (#315, 4:00-4:50 pm, Rm 2022). Lastly, as operating room capacity expands in many centers, and technology grows, Dr. Keith Ruskin will provide insight on Perioperative Communication Devices: Impact on Patient Safety (#325, 4:00-4:50 pm, Rm 3018).

Tuesday, October 16, 2007: Dr. Lucinda Everett starts off Tuesday's Refresher Course lectures with a discussion of Quality and Safety Initiatives: Implications for Ambulatory Anesthesia (#401, 8:30-9:20 am, Rm 2014). Dr. Therese Horlocker will provide her expert assessment of the safety of Anticoagulation and Regional Anesthesia (#411, 8:30-9:20 am, Rm 2022), followed in the same room by Dr. Ton Gan's knowledgeable guidance with Management of Postoperative Nausea and Vomiting (#412, 9:40-10:30 am). As Hurricane Katrina provided us with a shocking glimpse of medical emergencies during disasters, Dr. Joseph McIsaac will provide some insight into considerations for Hospital Preparation for Disasters (#413, 1:40-2:30 pm, Rm 2022). With the rapidly expanding waistlines in America, Dr. Thomas Ebert will discuss the Perioperative Considerations for the Morbidly Obese (#404, 2:50-3:40 pm, Rm 2014). Concurrent with this talk, Dr. Cliff Deutschman will review The Biologic Response to Surgery and Injury-Clinically Relevant Basic Science (#409, Rm #2018).

Wednesday, October 17, 2007: The ASA Refresher Courses conclude on Wednesday with Dr. Kathryn McGoldrick informing us about the largest growing segment of our population in The Graying of America: Anesthetic Implications for Geriatric Outpatients (#501, 8:30-9:20 am, Rm 2014), concurrent with Dr. James Eisenkraft's presentation of the Hazards of the Anesthesia Workstation (#511, Rm 2022), addressing how to prevent and manage critical incidents associated with anesthesia gas delivery systems. As perioperative glucose control has become a national patient safety initiative, Dr. Daniel Brown will describe best practice for Perioperative Management of the Diabetic Patient (#513, 10:50-11:40 am, Rm 2022). Lastly, Dr. Carin Hagberg will update us on Current Concepts in the Management of the Difficult Airway (#510, 1:50-2:40 pm, Rm 2018).

### Scientific Papers Highlight Patient Safety

The Scientific Papers sessions at the 2007 ASA Annual Meeting include 4 poster discussion sessions and 4 poster sessions with a focus on patient safety with 1 or more sessions each day of the meeting. Topics in these sessions include efficiency in operating room scheduling, outcomes after initiation of national patient safety initiatives, outcomes with bariatric surgery, numerous sleep apnea patient studies, the effect of mild hypothermia on intraoperative blood loss, and many others.

On Saturday, October 13, 2007, from 9:00-11:00 am (Hall D, Area G, Moscone Center North), begins the first poster presentation on the topic of Predicting Risk and Outcome from Patient Registries and Quality Databases, which includes posters on prospective perioperative adverse event databases in 2 different European hospitals (A178, Piacevolli and Barach from A.C.O. San Felippo Neri, Rome, Italy, and A179, Lehman et al. from University Hospital, Basel, Switzerland), a meta-analysis of large trials with > 5000 patients describing a reduction in perioperative mortality over time (A189, Bainbridge et al., University of Western Ontario), a presentation by Vichova and colleagues from Hospital Louis Pradel in Lyon Bron, France, on Patients with Coronary Stents and Non-Cardiac Surgery: Preliminary Results of POS-TENT Study (A193), and A Meta-Analysis of the Effects of Mild Perioperative Hypothermia on Transfusion Requirement (A201) by Rajagopalan et al. from the Cleveland Clinic. In the afternoon from 1:30-3:00 pm (Rm 301 Moscone Center South), the first poster discussion session on the Public Health Impact of Anesthesiology Practice will include studies on Do Chronic Oral Opioids Impair Driving Skills? A Randomized Controlled Trial (A278, Buvanendran et al., Rush Medical College), Smoking-Induced Burn Injury While on Chronic O2 Therapy (A282, Somers-Dehaney et al., University of South Florida), and Increases in Methadone Drug Related Emergency Room Visits and Poisoning Deaths (A284, Moric et al., Rush University Medical Center).

Scientific paper sessions for Sunday, October 14, 2007 include a morning poster discussion session (9:00-10:30 am, Rm 123, Moscone Center North) on *Opportunities for Patient Safety from Practice-Based Learning* with studies on *Delirium in the Recovery Room Is Associated with Preoperative Fasting* (A501, Radtke et al., Charité-Universitätsmedizin Berlin) and *Validity of Preoperative Stress Testing in Vascular Surgery and Its Association with Gender* (A502, Sun et al., Beth Israel Deaconess Medical Center). The Sunday afternoon session (2:00-4:00 pm, Hall D, Area O, Moscone Center North) will highlight *Airway & Respiratory Risk; Obstructive Sleep Apnea* and consists of multiple studies on screening tools for obstructive sleep apnea (OSA) syndrome as well as management of the airway for OSA/morbidly obese patients and perioperative complications in this patient group.

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On Monday, October 15, 2007, one scientific paper session will take place entitled *Patient Risk & Genetic Predisposition; Metabolic Interventions; Substance Abuse* (9:00-10:30 am, Rm 125, Moscone Center North). The poster discussions in this session include genetic studies on 5 HT3 Antagonists and Cardiac Repolarization Time in Patients Genetically Prone to QTc Prolongation (A1029, Quraishi et al., Pennsylvania State University College of Medicine) and Novel Causative RYR1 Mutations in Malignant Hyperthermia (A1030, Girard et al., University Hospital of Basel, Switzerland), and substance abuse studies on detection of drug diversion in an operating room (A1035, Epstein et al., Jefferson Medical College).

On Tuesday, October 16, 2007, 2 patient safetyoriented scientific paper sessions are slated, starting with Drug and Device Safety, Medical Errors & Prevention (9:00-11:00 am, Hall D, Area G, Moscone Center North). This session has 3 papers dealing with MRI-related adverse events (A1596, A1599, and A1607), 2 papers on perioperative temperature control (A1611, A1612), and 3 papers on the implications of differing water content in 3 different sevoflurane formulations (A1591, A1593, and A1597). See sevoflurane article on page 48 for more on this topic. The afternoon poster session on National Patient Safety Goals, Life Safety, Patient Education and Safety Culture (2:00-4:00 pm, Hall D, Area O, Moscone Center North) includes original research on patient handoffs by Joseph and co-authors (A1782, Transfer of Anesthesia Care: Are We Compromising Patient Safety?) and by Mayer et al. (A1785, Facilitating Patient Safety through an Anesthesia Resident Hand-Off of Care Training Module). Three papers deal with handwashing to prevent transmission of pathogens to patients and staff (A1786-88). Richard Cook and colleagues provide data on a novel approach to investigating medical adverse events similar to the National Transportation Safety Board investigations (A1789) so that defects in the process of care can be identified and corrected. Barach and coworkers present 2 papers on wrong-site anesthesia events (A1783) and risk factors for retained instruments and sponges after surgery (A1791).

Wednesday, October 17, 2007, marks the last patient safety scientific paper session with a poster discussion on *Can We Train More and Use Information Systems to Enhance Patient Safety and Outcome*? (1:30-3:00 pm, Rm 123, Moscone Center North). These 8 posters include 3 papers on increasing education about physician handwashing (A2139-41), 2 papers on using automated reminders for

### Medication Administration in Anesthesia Time for a Paradigm Shift

by Mike Stabile, Craig S. Webster, and Alan F. Merry

**In 1999 the Institute of Medicine called for a halving of error in health care within 5 years.** Numerous other authoritative calls for improved safety have been made since, including legislative moves by Congress and the Food and Drug Administration. Despite this, the vast majority of drugs used in health care continue to be administered by traditional error-prone means, and drug error remains a hazard to patients everywhere. The problem is of particular concern in anesthesia, where large numbers of potent drugs are given, often in rapid sequence. Historically, system redesign in anesthesia has been successful in eliminating error, for example in the elimination of problems with the delivery of oxygen to patients. However, we believe that much of the low hanging fruit of the benefit of simple engineering solutions has now been plucked. Thus, rather than an entirely blameless culture of safety focused solely on systems, we propose a "just culture," where accidents can be identified as blameless errors, or culpable violations. We all make errors, even when doing our best to avoid them—they are unintentional, blame is usually unhelpful, and they are the appropriate target of system redesign. We believe what is now required to further reduce error in drug administration is a more sophisticated approach, involving a better understanding of the nature of human error itself, and better compliance in the adoption of safety procedures and systems.

Congress has recently passed legislation that includes steps to prevent hospital medication errors. In part this was in response to the tragic deaths of 3 premature infants in Indianapolis in September 2006, after they were accidentally administered adult doses of heparin. The Institute of Medicine (IOM) has estimated that each year medication errors injure at least 1.5 million Americans and cost the health system more than \$3.5 billion.1 Drug errors feature prominently in every large-scale study of iatrogenic injury conducted.<sup>2</sup> In 1999 the IOM called for a halving of errors (including medication errors) in health care over the next 5 years. In 2004 the Food and Drug Administration (FDA) mandated the use of barcodes at unit-dose level on all medications;3 these are being phased in over 5 years. However, little else seems to have changed, and the IOM's goal of a 50% error reduction certainly has not been achieved in relation to medication administration. In 2007, the vast majority of drugs used in health care are still administered by traditional means, and drug error remains a significant hazard to the health of patients everywhere.

### The Extent of the Problem

There is no aspect of anesthesia that occupies a more important place in the safe management of our patients than the accurate administration of medications. It is therefore surprising how little has been published dealing with reducing medication error in anesthesia. A recent systematic review of the literature from 1978 to 2002 identified only 98 references on this subject, and only 1 involved a randomized trial (conducted with a human-patient simulator), only 2 could be considered experimental or quasi-experimental, and only 11 contained observational data.4 The landmark 1978 paper by Cooper et al., the starting point for the analysis in the above study, identified 359 incidents.5 The first, second, and fourth most frequent incident categories were breathing circuit disconnection, inadvertent gas flow change, and gas supply problems. The third most frequent was syringe swap. In 1984 a further critical-incident analysis published by Cooper's team, showed a similar pattern of problems.6 The most frequently cited critical incident category was breathing circuit disconnection. The next 8 categories included both syringe swap and ampule swap. Drug overdose (via syringe and vaporizer) was also listed. Cooper's group concluded that human error was the dominant issue in anesthesia safety and encouraged the specialty to direct patient safety efforts toward monitoring instrumentation and improvement in equipment using human-factors techniques. Today history has vindicated this vision. Engineering innovations have virtually eliminated problems with the delivery of oxygen to patients. A recent review of 4,000 incidents and over 1,200 medico-legal notifications reported by anesthetists in Australia revealed no cases of hypoxic brain damage or death from inadequate ventilation or misplaced tubes since the introduction of oximetry and capnography.7 However, no such systematic innovations have yet been widely adopted to reduce medication error.

We don't know what the rate of medication error was in 1978, but recent data have shown that the magnitude of the problem today is more serious than previously thought. Using facilitated incident monitoring (which provides a denominator) and prospectively collecting data from over 10,000 anesthetics in New Zealand, approximately 1 error was shown to occur for every 130 anesthetics.<sup>8</sup> A very similar rate was found in Seattle, using the same study method.<sup>9</sup> Other studies from various countries and types of institution suggest that these estimates are of the correct order of magnitude<sup>10-13</sup> (Table 1, page 47) and reflect the situation in anesthesia as it is widely practiced today, rather than any local aberrations in standard of care.

Orser's group took a different approach. They sent an anonymous survey to all 2,266 members of the Canadian Anesthesiologists' Society in 1995.<sup>14</sup> Thirty percent of the members responded to the survey and 1,038 drug-related events were examined in detail. Most anesthesiologists had experienced >1 drug error. Syringe swap was the most common category of error. Fifteen of the errors (1.4%) resulted in major morbidity (including 4 deaths). In a similar survey in New Zealand, 89% of respondents admitted having made at least 1 drug error.<sup>15</sup> The Canadian study provides valuable insights into the root causes of drug error. For example, although 86% of respondents were aware of the Canadian Standards Association labeling standards, and 86.9% agreed or strongly agreed that these labels reduced the incidence of drug errors, only 72% actually used them. Furthermore, fewer than half the respondents "always" read the label. These findings are not edifying for a specialty group with a claim to being leaders in safety, and there is no reason to believe that the practices described, and the attitudes that drive them, are confined to Canada. One of us administered a questionnaire to 210 delegates at a New Zealand anesthesiology conference, asking 12 questions concerning perceptions about the drug error problem.16 Respondents answered questions in relation to their own practice and anesthesia practice in general (hence their colleagues). The majority of anesthesiologists felt that drug error in anesthesia was a significant problem, and one the public was becoming increasingly intolerant of; however, few were concerned over the chance of harming an individual patient in this way themselves, and most felt that error was more of a problem with other anesthesiologists' practices than with their own. Similarly, in Australia, anesthesiologists estimated the risk of awareness in their personal practices as half as likely than in that of their colleagues.<sup>17</sup> These are classic examples of optimist bias, a common psychological phenomenon in which individuals, on average, view

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their own abilities as better than average (a statistical impossibility).

### Lessons from Intensive Care

Disguised-observer studies in the ICU literature offer lessons for the anesthesia professional in the operating room. The disguised-observer technique is known to accurately identify rates of error in hospital environments, and there are many similarities between the ways drugs are given in the ICU and in the operating room during anesthesia.

At 2 Dutch hospitals van dem Bemt et al. used the disguised-observer technique.<sup>18</sup> The researchers observed 233 drug administrations to 24 patients over the 5-day study period. The error rate was 44.6% (104/233) when wrong-time errors were included and 33% (77/233) when wrong-time errors were excluded. A wrong-time error was defined as the administration of a drug >60 minutes earlier or later than prescribed.

If these data are even partially indicative of the problem in anesthesia, then it is considerably worse than that suggested by the studies summarized in Table 1. This possibility is reinforced by recent (as yet unpublished) work in New Zealand using direct observation in human-patient simulation involving complex anesthetic cases.

### Why Medication Error in Anesthesia Continues to Occur

It is not difficult to inject 1 drug safely, but the challenge the anesthesia professional faces is to participate in the administration of perhaps half a million drugs during a professional lifetime. Doing this 100% accurately is very difficult. Many of our patients have diminished physiologic reserve to tolerate drug error. As they are sedated or anesthetized they cannot correct or detect drug errors themselves. They depend on us to do this, and this is a responsibility we should not take lightly.

### **Errors, Outcome, and Blame**

The outcome of an error is largely determined by chance. You back out of your driveway and run over an unseen squirrel that dashes under your car. Or, you back out of your driveway and run over an unseen child that does the same thing. The error mechanism is identical in each case, but both you and society will judge yourself differently. The same can be said of drug errors. There is no moral difference between a drug error that causes no harm and one that results in death.

Recently one of us was asked to debrief a trainee who inadvertently administered 200 mg of dopamine as a bolus, using an unlabeled syringe (this was a look-alike problem, set up by a recent change in the formulations of 2 drugs). With help from his supervisor, he was able to respond to the sudden catastrophic rise in blood pressure, the patient's life was saved, and in the end no harm ensued. In 1990, another anesthesiologist gave the identical drug in error (having also been set up, this time by having the ampule of dopamine placed in the compartment in the drug drawer labeled "Dopram").<sup>19</sup> The patient lost her life and the anesthesiologist was convicted of manslaughter.

The importance of an adverse event should be judged by its potential outcome rather than its actual outcome. The enormity of the potential outcome from a drug error does not justify recourse to the criminal law, but surely it does justify taking the problem seriously, reporting the incident, and (as a minimum) labeling one's syringes and reading one's ampules. This concept is encapsulated in a World Health Organization motto, which states, "To err is human; to cover up is unforgivable; to fail to learn is inexcusable."

### **Changing Culture**

It is impossible to address drug error effectively without addressing the organizational culture of anesthesia. In Human Error James Reason advocated a blame free culture as necessary for effectively reducing error. In the end, few people are really comfortable with the notion that blame should be set aside completely. Today most authorities (including Reason) would probably advocate a "Just Culture."20 This implies early triage of incidents into those in which blame may be appropriate, and those in which it is not. By definition, errors fall into the latter category. In fact, if the aim is to promote patient safety, the former category should be reserved for clearly egregious behaviors, such as leaving an anesthetized patient unattended, or working under the influence of alcohol or drugs.

Aviation, for most anesthesiologists and nurse anesthetists, is the obvious model for safety. There are lessons to be learned from aviation, as there are from high-reliability organizations in other fields such as the nuclear power industry.<sup>21</sup> However, the metaphor of the anesthesia professional as a pilot, and the notion that "take-offs" and "landings" are like induction and emergence is limited. For a start, the system formed by the patient, the anesthesiologist and/or the CRNA, and the surrounding environment of the operating room (including personnel and equipment) is more complex than that which characterizes commercial aviation.<sup>2</sup> It does seem that aviation has embraced a safety culture for decades, whereas some anesthesia providers seem to harbor an attitudinal barrier to safety.16,22 In a safety culture, accidents are interpreted as evidence of faulty system design. Both accidents and incidents are viewed as opportunities to redesign the work environment and improve safety. Such cultures, therefore, embrace a healthy incident reporting system. Individual errors may not be foreseeable, but the contributing factors can be anticipated and addressed.23 By contrast, a person-centered approach to error involves blaming individuals for their carelessness, forgetfulness, or other character weakness when things go wrong. Such an approach has been called the culture of denial and effort: denial, because it denies the psychological reality that error is a statistically inevitable consequence of human action; and effort, because it implies that with sheer effort alone all error can be avoided.<sup>24</sup> It directs attention away from faulty work systems, leaving them untouched and able to predispose to further errors and failures in the future. The culture of denial and effort is the antithesis of the culture of safety and is clearly unhelpful and unsound. Despite this, the person-centered approach persists in health care (including anesthesia), and often hinders the adoption of safety systems and procedures.

In the end, perhaps the biggest single difference between anesthesia and aviation relates to the perception that expenditure on safety is justified. The numbers involved in a single airline accident grab public attention and demand a response. Individual anesthesiologists or CRNAs harm harm patients 1 at a time. Collectively and over time the harm mounts up, but because it is sporadic it is largely invisible. Imagine the public's response to 5,000 plus cases of intraoperative awareness if they all occurred in 1 hospital in the first 2 weeks of January, instead of being spread out over the calendar year and the entire country.<sup>25</sup>

In anesthesia, and health care generally, the predominant cultural focus is on productivity. The current common demand on the part of hospital administrators for a "business case" or a "return on investment" (ROI) to justify expenditure on safety is misguided if it doesn't factor in the wider picture which includes the very real cost of iatrogenic harm.<sup>24</sup> It is reminiscent of the saga of the Ford Pinto.<sup>26</sup> This car was designed in such a way that the fuel tank would rupture and explode in certain rearend collisions, burning or killing its occupants. Ford knew about these risks. However, the business case was taken that it would be cheaper for Ford to continue to sell Pintos, let its customers burn, and to pay out the lawsuits on these somewhat infrequent cases, than to recall all Pintos and fix the problem. In the end it turned out cheaper than expected to fix the problem, so even the business case seems to have been flawed. In addition, the public outcry that followed the exposure of Ford's commercial cynicism did enormous damage to the company's reputation and sales. Ford earned the dubious distinction of being the first corporation to be charged with the criminal offence of reckless homicide. A similar situation often occurs in health care. Safety should be funded because it is the right thing to do, not because of any ROI directives. However, in health care, doing the right thing, first time to the right patient, usually turns out to be the best from a business perspective as well. Harming patients during their treatment, and then having to treat them for such harm, is extraordinarily inefficient and expensive. The savings from even one avoided case of significant iatrogenic

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harm would pay for a great deal of safety. Furthermore, the cost to the health care organization in terms of lost reputation can be many times larger than the cost of treating the harmed patient. Iatrogenic harm simply doesn't pay.

### How Should We Administer Drugs?

Administering drugs is fundamental to anesthesia, and its importance should be elevated in programs of continuing professional development, in priorities for research, and in self-directed reading. For example, in a recent survey of anesthesiologists, only 19% reported having received specific training on how to administer drugs safely.<sup>16</sup>

A systematic literature review has brought together received wisdom on how best to reduce the risk of drug administration error during anesthesia.<sup>4</sup> Five strong recommendations survived testing against actual incident reports (Table 2, page 47). These would seem to be a good starting point for action.

Furthermore, involvement of pharmacists in the operating room has been recognized as a core principle for improving drug safety in anesthesia.<sup>27</sup> The preparation and labeling of drugs in a central pharmacy should decrease the incidence of error. In the pharmacy 2 people check each other's work, multiple syringes are prepared for 1 drug at a time, and the environment is one in which distractions are few, order reigns, and time is available to check and recheck (and record the checking on a form). In addition, dispensing accuracy generally improves administration accuracy.

One thing is clear—we will not make progress while we continue to embrace idiosyncratic approaches to this problem. Health care organizations must establish sound techniques for drug administration, teach them to their residents, and provide role models of their use. There is an increasing range of solutions available for the problem of drug administration error in anesthesia (Table 3, page 47).<sup>27,31</sup> Incident data, prospectively collected over a period of 5 years, have shown that the use of a system incorporating a number of these safety principles has been associated with a significantly lower rate of drug error per bolus administered.<sup>32</sup>

### The Need for a New Paradigm

A few years ago a senior colleague made a drug error while anesthetizing a human-patient simulator. He admitted it and said, "I must try harder in the future." Here is the heart of the problem. This is the person-centered view that impedes progress and is doomed to fail. The truth is that he was trying as hard as he could—he was under the direct observation of several of his peers, and was very motivated to perform as well as possible. That is the defining point about errors; we make them, unintentionally, even when we are trying not to. Trying harder will not substantially reduce error, but re-designing systems to make them inherently less error-prone will.

Berwick has popularized the quote, attributed to Einstein, that, "Madness is doing the same thing over and over again and expecting a different result." We will not reduce drug error until we change the way we give drugs. This will include embracing technological solutions of one sort or another. However, it will also mean complying with these solutions. It is unlikely that forcing functions will ever make drug error in anesthesia impossible. It is certain, however, that redesigning the system can make errors much less probable—provided anesthesiologists and nurse anesthetists actually make the effort to take proper advantage of the innovations.

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## Data and Proposals Support Safer Drug Administration

"Errors," From Preceding Page

Table 1. Prospective estimates of rates of drug administration error in anesthesia (1978-present)

Study	Sample	No. of Anesthetics	No. of Drug Errors	Drug Error Rate
Craig & Wilson <sup>10</sup>	6 Months	8312	12	0.14%
Kumar et al. <sup>11</sup>	April 1984-January 1985 and April 1985-January 1986	28965	31	0.11%
Short et al. <sup>12</sup>	1990	16739	26	0.16%
Fasting & Gisvold <sup>13</sup>	September 1996-October 1999	55426	63	0.11%
*Webster et al.8	February 1998-October 1999	10806	81	0.75%
*Bowdle et al.9	21 weeks	6709	41	0.61%

\* Studies that used the facilitated collection technique.

### Table 2. Strong safety recommendations based on a systematic review of the entire literature on drug administration error in anesthesia and as validated against actual incident reports

- 1. The label on any drug ampule or syringe should be carefully read before a drug is drawn up or injected.
- 2. Legibility and contents of labels on ampules and syringes should be optimized according to agreed standards in respect to some or all attributes of font, size, color, and the information included.
- 3. Syringes should be labeled (always or almost always).
- **4.** Formal organization of the drug drawers and workspace should be used with attention to tidiness, position of ampules and syringes, separation of similar or dangerous drugs, removal of dangerous drugs from the operating rooms.
- 5. Labels should be checked specifically with a second person or a device (such as a barcode reader linked to a computer) before a drug is drawn up or administered.

Table 3. Possible additional measures to promote safer drug administration in anesthesia

- 1. The provision of all labels in a standardized format emphasizing the class and generic names of each drug, incorporating a bar-code and class-specific color-code consistent with international drug labeling standards.<sup>27,30</sup>
- 2. The presentation of selected, commonly used drugs in pre-filled syringes prepared under quality assured conditions and pre-labeled as above.<sup>27</sup>
- 3. The use of a bar-code reader to scan the drug at the point of administration immediately before it is given, linked to an auditory prompt (i.e., the computer speaks the name of the scanned drug) and a visual prompt (i.e., the computer displays the name of the drug, in prominent color-coded format) to facilitate checking of the drug's identity.<sup>27</sup>
- 4. Integration of scanned information into an automated anesthetic record, facilitating accuracy of the drug information in the record and reducing the cognitive load on the anesthesia professional.<sup>27</sup>
- 5. The use of devices at the point of care to automatically measure the dose of drug administered.<sup>29</sup>
- The use of purpose designed drug trays to facilitate the layout of syringes and ampules and organization of the anesthesiologists' or nurse anesthetists' workspace.<sup>27</sup>
- 7. Infusion syringe labels consistent with the standardized labels described above, which incorporate a dosing nomograph into the label itself, thus removing the need for look-up tables or dose calculations and reducing the cognitive load on the anesthesia provider.<sup>31</sup>
- *8.* The use of automated medication dispensing systems with features such as single-issue drawers and barcode scanners to facilitate safer dispensing of drugs in the operating room.

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### **Sevoflurane: The Challenges of Safe Formulation**

#### by Evan D. Kharasch, MD, PhD

Sevoflurane is a widely used inhalational anesthetic, first introduced in 1990 by Maruishi Pharmaceuticals in Japan, and subsequently (1995) marketed by Abbott Laboratories in the United States as Ultane<sup>®</sup> and worldwide as Sevorane<sup>®</sup>. Beginning in 2006, generic versions of sevoflurane became available, first by Baxter Healthcare and then by Minrad International. Although Ultane<sup>®</sup> and the generic versions are considered by regulatory agencies to be therapeutically equivalent, there are potentially important differences between them. These include the methods of synthesis, impurities, the containers in which they are sold, and the formulation (sevoflurane itself and any additives).

A recent publication by Dr. Max Baker, professor of anesthesiology at the University of Iowa, thoroughly reviewed the differences in sevoflurane products, and the potential patient safety implications.<sup>1</sup> Dr. Baker is an accomplished chemist, holding patents on the synthesis of volatile anesthetics, and has written previously on the challenges of drug formulation.<sup>2</sup> The methods for synthesizing sevoflurane differ between manufacturers, resulting in differing impurities and their amounts. The good news is that, as Dr. Baker states, "the quantities of impurities are low and qualitative differences minor" and are "not expected to be of clinical significance, *if they remain so*" (italics mine).

It is this last caveat that is the focus of the remainder of the Baker paper. Sevoflurane is susceptible to various types of chemical degradation. Most pertinent is the degradation of sevoflurane by Lewis acids (such as metal oxides and metal halides), to hydrofluoric acid, and to other toxic compounds. Hydrofluoric acid (HF), even in minute amounts, is highly reactive, corrosive, profoundly toxic, and can cause respiratory irritation or pulmonary hemorrhage.<sup>3,4</sup>

An incident of Lewis acid mediated sevoflurane degradation occurred in 1996.5,6 Several bottles of sevoflurane had cloudy drug, a pungent odor, marked acidity (pH <1), and high fluoride (863 ppm), all indicating substantial anesthetic degradation and formation of HF, in quantities far exceeding the safe limits of 3 ppm over an 8 hr average. Abbott subsequently determined that increasing the water content in sevoflurane formulations decreased Lewis acid-dependent sevoflurane degradation.7 They changed the sevoflurane formulation to contain at least 300 ppm water, in order to prevent Lewis acid degradation and formation of toxic degradants. The new "waterenhanced" sevoflurane formulation was approved later that year by the U.S. Food and Drug Administration (FDA), and awarded patent protection.

Why is all this important? Generic sevoflurane formulations do not contain Lewis acid inhibitors,

nor can they contain water in concentrations higher than 130 ppm. As Dr. Baker concludes, "a potential remains for sevoflurane instability, . . . therefore some vigilance regarding product integrity remains prudent."<sup>1</sup>

Recent information from the European Medicines and Healthcare Products Regulatory Agency,8 and in abstract form,<sup>9,10</sup> reinforces the need for such vigilance. The Penlon Sigma Delta sevoflurane vaporizer, distributed by Baxter, was found to interact with lower-water sevoflurane formulations, with the production of certain degradation byproducts. This caused etching of the vaporizer sight glass and partial disintegration of the indicator ball, etching of the metal filling port shoe, corrosion of the plastic keyed-filler stoppers with resulting leakage of anesthetic, and yellow discoloration of the sevoflurane. Sight glass etching made the sevoflurane liquid levels in the vaporizer hard to read. The European Agency recommended that the vaporizers be removed from use. Although the degradants were not identified in the above reports, sight glass etching suggests the potential formation of hydrofluoric acid.

Recent laboratory findings also reinforce the need for vigilance.11-13 Vaporizers from various manufacturers were disassembled and found to contain potential Lewis acids (metal oxides) on surfaces that contact both liquid or vapor sevoflurane. Degradation of lower-water generic sevoflurane by aluminum oxide, a prototypic Lewis acid, was up to 90-fold greater than that of higher-water Ultane® sevoflurane. Lower-water generic sevoflurane, but not higher-water Ultane®, when stored in Penlon Sigma Delta vaporizers under accelerated storage conditions, underwent substantial degradation. There were substantial increases in fluoride (as high as 600 ppm) and reduced pH (as low as 3), as well as sight glass etching and metal filler shoe corrosion. Thus, lower-water generic sevoflurane underwent Lewis-acid mediated degradation to HF. The absence of such degradation with water-added Ultane® sevoflurane is consistent with the known ability of water to prevent Lewis acid-mediated sevoflurane degradation.

Degradation of lower-water sevoflurane to toxic compounds is a potential patient safety issue. The 1996 Lewis acid degradation of original low-water sevoflurane to HF was considered a clinically significant safety issue prompting widespread practitioner notification and reformulation of sevoflurane to contain at least 300 ppm water as a Lewis acid inhibitor. Recent clinical and laboratory reports of new lowerwater sevoflurane formulation degradation in Penlon vaporizers to HF recapitulate those of 1996. Patient harm was not needed in 1996 in order to generate safety concerns about degradation of lowerwater sevoflurane, and lead to its replacement with higher-water sevoflurane. Therefore, the absence of reports (to date) of patient harm with currently marketed lower-water sevoflurane should not mitigate appropriate concerns about the degradation and safety of lower-water sevoflurane.

The FDA defines drugs as pharmaceutical equivalents if they 1) contain the same active ingredient(s), 2) are of the same dosage form and route of administration, and 3) are identical in strength or concentration.<sup>14</sup> The FDA also defines drugs as therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.<sup>15</sup>

Although the active ingredient (sevoflurane) in various manufacturers' formulations is chemically identical, the formulations differ in their water content. Recently approved lower-water sevoflurane formulations do not contain enough water to prevent Lewis acid-mediated degradation and the production of toxic hydrogen fluoride. Nevertheless, lowwater sevoflurane is considered therapeutically equivalent (AN rated) to high-water sevoflurane. Recent laboratory and clinical case reports that demonstrate degradation of lower-water sevoflurane to toxic and corrosive hydrogen fluoride, and damage to vaporizers, suggest that the higher- and lower-water sevoflurane formulations may not have the same safety profile. While they may be considered pharmaceutical equivalents, they may not be therapeutic equivalents. Again, vigilance, the maxim of anesthesiology, is warranted.

Dr. Kharasch is the Russell D. and Mary B. Shelden Professor of Anesthesiology, Director, Division of Clinical and Translational Research, Department of Anesthesiology, Washington University, St. Louis, MO.

DISCLOSURE: Dr. Kharasch is also an occasional consultant to Abbott, a manufacturer of sevoflurane.

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### Featuring Contributions from the Society for Technology in Anesthesia

The Anesthesia Patient Safety Foundation's Committee on Technology would like to thank those members of the Society for Technology in Anesthesia (STA) who contributed to the discussion below. This string was originally posted to their listserv, and the STA Board of Directors graciously allowed the APSF to edit and publish the following commentary.

### **Computer Controlled Systems Replace Conventional Needle Valves**

### Q Dear Q&A,

In looking at the schematics of some of the newest anesthesia machines (e.g., Aisys and Avance, GE Healthcare, Inc., and the former Julian, Dräger Medical, Inc.), I am struck by how they have finally eliminated the hydraulic flow controls (i.e., needle valves) for computer controlled valves. This means, in the absence of power, no gas will flow, except for the redundant oxygen system. The question I'd like opinions on from the group is, "What has driven this change in anesthesia machine design?" I have several hypotheses (locally generated), but I'd like input from a wider group. I'll share my ideas afterwards so as not to bias anyone's thoughts.

James F. Szocik, MD University of Michigan

### A Dear Dr. Szocik,

One can postulate many reasons for the change. The primary rationale is likely the ability to control and measure fresh gas flow by software. In recent years the most notable change in the anesthesia delivery system design has revolved around the anesthesia ventilator. Looking forward, designs that allow more efficient delivery of anesthetic vapor would be the next evolutionary step. Platforms which utilize mechanical fresh gas flow delivery will be more difficult or impossible to evolve into designs that can manipulate the fresh gas/anesthetic vapor concentration relationship to achieve more efficient vapor delivery. Electronic fresh gas control opens up the possibility of engineering that relationship.

From a safety point of view, all of the machines on the market provide some means of direct oxygen delivery in the event of electrical failure even if it is an oxygen flow meter mounted to the machine. One question is whether or not you want to deliver vapor if electricity fails. Interesting question to raise!

Jeffrey M. Feldman, MD University of Pennsylvania School of Medicine

### A Dear Dr. Szocik,

I am reminded of the story, a few years ago, in which the anesthesia machine engineers from a certain company went out to various hospitals to ask anesthesiologists what they did not like about their anesthesia machines and what new features they wanted.

The engineers WANTED people to tell them they needed electronic flow meters, electronic vaporizers, electronic ventilators, new ventilator modes, etc. Instead, the anesthesiologists complained the wheels did not roll very well they should be redesigned and equipped with "cow-catchers" to push cables and hoses out of the way. The drawer space was inadequate. A pull-out writing desk was needed. A small auxiliary light was needed for endoscopy cases so the anesthesia record could be seen in the dark. And so on.

Of course, the engineers departed in a mood of frustration, because what the anesthesiologists asked for was NOT what they wanted to build.

It should be noted that one CAN design controls that can be both manually operated and electronically operated. For instance I can increase or decrease the volume on my home stereo system by manually turning the big volume knob on the receiver, or by pushing the buttons on the remote control and watching the knob "turn itself" from across the room. It is easy to imagine a combination manual-automated system to adjust gas flows and vaporizer settings. The precise gas flow can be measured by electronic flow meters (or even by a simple system that measures the pressure drop across a known resistance). This measurement can be used to provide feedback for the flow meter controller.

One challenge for the new machines is that the old, mechanical machines had become nearly 100% safe—nearly 100% failure-free. With new complexity, there are new opportunities for failure, new opportunities that we may not have even thought of yet!

Frank Block, MD University of Arkansas for Medical Sciences

### A Dear Dr. Szocik,

I also agree that there is much to be gained by adding electronic controls to the anesthesia machines if they enhance patient safety and improve the delivery of anesthesia. We need to have a machine that defaults to a safe basic machine, at least until the new controllers, software, and hardware have a very low probability of failure; and clinicians must feel comfortable using them under all circumstances. I favor parallel controls, like the electronic flow control in line with the needle valve. Permitting clinicians to use as much or as little of the new technology, in the beginning, is a wise marketing strategy in addition to providing a safe environment for the patient.

#### See "Q&A," Next Page

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

The information provided in this column is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of APSF. It is not the intention of APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.



### What Has Driven This Change in Anesthesia Machine Design?

#### "Q&A," From Preceding Page

We don't need additional catastrophic failure modes, which represent the worst outcome of replacing needle valves with electronic valves. Clinicians need to have enough familiarity with more advanced machines, that they can use it out of the box, like making Xerox copies or driving away in a new rental car, and then move into the more advanced features as they gain confidence.

I would like to see an affordable machine that makes the successful transition to a new and safer technology, even for the Luddites\* among us. Don't we have a responsibility to the lowest common denominator of user?

Bill Paulsen, MMSc, PhD, CCE, AAC South University School of Health Professions Mercer University School of Medicine

### A Dear Dr. Paulsen,

The important aspect of your last paragraph is "affordable." Every feature costs money and at the end of the day the companies always wonder if people will pay for what is included in the machine. In an ideal world an evolutionary approach that incorporates the old and the new would be appealing. Economics speak against it. Dr. Block made a good point that what excites an engineer is not always what excites a user.

Jeffrey M. Feldman, MD University of Pennsylvania School of Medicine

#### A Dear Dr. Szocik,

I agree with Dr. Feldman that one of the main reasons for considering computer controlled

valves is control, but I think the other is something else. For billing purposes, vendors want users to be able to measure how much vapor they use, measure how much gas they use, and then bill for those as they would for any other service. To make it even more efficient, you transfer control to the machine itself so that it can adjust gas flows and agent concentration while monitoring "MAC" with other parameters.

Obviously, inherent machine control is not so obvious. I want such mechanisms to be proven reliable. And, I would rather buy a machine where the underlying control platform was already well established, before it controlled newly developed computerized valves.

Ryan Forde Massachusetts General Hospital

### A Dear Dr. Szocik,

I think the reasons for going to electronically controlled flow include 1) a pathway to automated control of flow, 2) input for the electronic record and cost calculations, 3) input for fresh gas flow compensation for the ventilator and vaporizer, and 4) decreased maintenance requirement for electronic versus glass flow meters. It is interesting that anesthesiologists are so wary of electronic flow meters. Microprocessor-based ICU ventilators have been the standard for almost 20 years. All of the new anesthesia machines have battery backup, and most hospitals have emergency generators, so power loss at the electrical outlet is not really a concern.

**S** AFETY

NFORMATION

**R** ESPONSE

**S** YSTEM

**Dear SIRS** 

As our description of the Dear SIRS column states, "The purpose of this column is to allow expeditious communication of technology-related safety concerns . . . with input and responses from manufacturers and industry representatives." What the description does not state, however, is how complicated it can be for Dear SIRS to bring clinician and industry together to formulate not only meaningful dialogue, but to effect some type of change that improves

patient safety. Although we are working on several new Dear SIRS issues, they simply are not optimal for current publication. We look forward to presenting helpful information whenever it is available. Stay tuned!

Drs. Olympio and Morell

I am more worried about the complex ventilation modes that are found in the new machines. This is where the "Luddites" will get into trouble, in my opinion.

Robert "Butch" Loeb, MD University of Arizona

#### A In Reply to All,

Our 2 local hypotheses for the progression to complete electronic control are 1) the continuing search for good information to put into the electronic medical record, and 2) "Technological Inertia," analogous to Newton's law, whereby the system and engineering were already on a roll in this direction, and would likely take a large amount of energy to stop or redirect it.

The biggest issue I have with the electronic control is the "failure" mode with prolonged power outage. With the great Eastern power outage a few years ago, we came within hours of running out of fuel for the generators. Cylinder oxygen is finite as well, but can be rationed better than generator power, and TIVA pump batteries will last about 3 days. I'd be interested to know what plans others have for regional wide disasters, wherein the infrastructure is also disrupted.

James F. Szocik, MD University of Michigan

\*Lud-dite [luhd-ahyt] – noun: A member of any of various bands of workers in England (1811–16) organized to destroy manufacturing machinery, under the belief that its use diminished employment. [Dictionary.com Unabridged (v1.1)]



Photograph showing electronic selection of the second gas (e.g., nitrous oxide or air), electronic metering of fresh gas flow (0.7 and 0.3 l/min, respectively), electronic selection of desired oxygen concentration (29%), and the electronic selection of volatile agent (Iso) and desired percent (1.0). Corresponding buttons are depressed, and selections are made with the com wheel (not shown). (This is a photograph of the GE Healthcare, Inc. Aisys anesthesia workstation control panel.)

### Letter to the Editor

## Labetalol May Decrease Cerebral Perfusion in Beach Chair Position

#### To the Editor:

I read with interest the 2 case reports and discussion by Drs. Cullen and Kirby of central nervous system (CNS) catastrophes that occurred in patients undergoing shoulder procedures in the beach chair position.<sup>1</sup> I noticed that the 2 cases had another common factor that was not discussed in their article; both patients had received labetalol while in the operating room. According to the original article, the first patient was given 50 mg of labetalol to treat high blood pressure readings obtained immediately prior to induction<sup>2</sup>—while the second patient received 20 mg of labetalol in divided doses as part of a deliberate hypotensive technique. Interestingly, neither patient had a history of hypertension.<sup>2</sup>

Labetalol is marketed for control of blood pressure in severe hypertension. It combines selective alpha<sub>1</sub> blocking action with non-selective beta<sub>1</sub> and beta<sub>2</sub> blockade. The ratio of alpha to beta blockade is 1:7 when used intravenously.3,4 Relatively weak alpha<sub>1</sub> blockade causes vasodilation, while stronger beta<sub>1</sub> blocking decreases heart rate and contractility. Beta<sub>2</sub> blocking prevents sympathetically mediated vasodilation and bronchodilation. Labetalol itself produces postural hypotension. The package inserts report a 58% incidence of "symptomatic postural hypotension" in awake patients when tilted or placed upright following labetalol injection, presumably referring to complaints of lightheadedness or dizziness. This is a sufficiently concerning effect that the administration guideline reads: "Patients should always be kept in a supine position during the period of intravenous drug administration."3,4 Manufacturers' recommendations do not constitute a legal standard of care, and the fact remains that many anesthesiologists do administer labetalol intravenously in patients in beach chair positions without complications. I personally question, however, whether this could be a contributing factor to some instances of CNS infarcts, such as the 2 presented in the Newsletter article.

Despite autoregulation, in the standing position, cerebral blood flow (CBF) in healthy individuals falls by 14-21% of supine values.<sup>5</sup> Only with tilts up to 20 degrees does CBF remain constant. There is evidence that in the upright position, CBF is more dependent on the arterial-venous pressure gradient than it is on mean arterial pressure,<sup>5</sup> so extra caution might be advisable when using drugs that alter hemodynamics under these circumstances, especially when measuring cuff pressures alone. Labetalol injection has already been shown to act synergistically with at least 2 potent inhalational anesthetics in producing

hypotension, reducing cardiac output, and increasing CVP.<sup>34,6</sup> Since 1996, package inserts for the drug have included the following warning: "Several deaths have occurred when Labetalol HCl injection was used during surgery (including when used in cases to control bleeding)."<sup>34,7</sup>

I first became interested in the clinical pharmacology of labetalol after reviewing a number of anesthesiology malpractice claims in which otherwise healthy patients became bradycardic and arrested within 20 minutes of being given the drug to treat epinephrine-induced hypertension. I was surprised to find that literature regarding the physiologic explanation for this is available,8-11 although it remains a rather underappreciated phenomenon in much of the anesthesia community. In the presence of epinephrine, norepinephrine, or phenylephrine, the weak alpha-adrenergic blockade of labetalol, in addition to strong combined beta-blockade, allows for unopposed adrenergic stimulation. This can result in severe increases in systemic vascular resistance along with declines in cardiac output, and has been associated with cases of pulmonary edema and death-even in healthy adults and children.8 In the current article, while discussing patient safety in the beach chair position, the authors suggest using "vasopressor infusion, as needed during the time of the procedure when the patient is upright and at risk." I am concerned that the infusion of phenylephrine or epinephrine in a patient who has already received labetalol (or another beta-blocker) might potentially produce the life-threatening complication described above.

Labetalol is not a short-acting drug, and its effects would likely have lasted the duration of both surgeries described in the article—and substantially into the postoperative periods. Its elimination half-life after IV administration is estimated at 5.5 hours. In drug company studies, it took an average of 16 to 18 hours for blood pressure to return to pretreatment values.<sup>3,4</sup> Accordingly, the not uncommon practice of using labetalol to treat transient episodes of high blood pressure and tachycardia in otherwise nonhypertensive patients that result from preoperative anxiety, intubation stimuli, or surgical stress, strikes me as odd, considering its pharmacology. There are certainly other means available to treat temporarily high heart rates and vasoconstriction.

While the beach chair position has now become standard of care for shoulder procedures in many orthopedic practices, the addition of labetalol to general anesthesia adds another layer of complexity to physiology in the upright position, with implications that have yet to be fully determined. I agree with the authors that the use of the beach chair position combined with deliberate hypotension will likely compromise cerebral perfusion. But using labetalol for any reason—thereby blocking all of the body's usual responses to postural change: vasoconstriction, increased heart rate, and increased contractility might also affect cerebral perfusion in patients who are positioned head-up. I applaud Drs. Cullen and Kirby for spotlighting many of the potential problems with this situation and for advocating caution whenever one is positioning a patient in beach chair. Let us hope we can continue to identify ways of decreasing the anesthesia risk for a patient position that improves surgical technique.

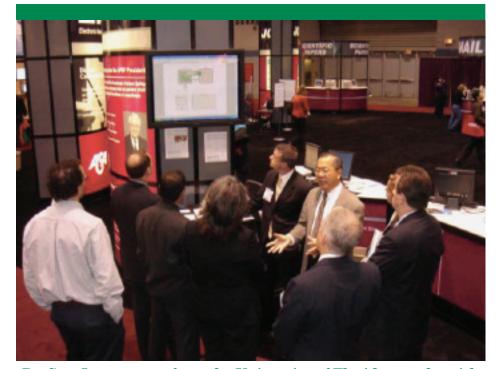
Ann S. Lofsky, MD Santa Monica, CA

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Team training is an ideal process to improve communication, which is a vital link in the delivery of safe, effective health care. Therefore, the APSF will cosponsor a workshop at the ASA Annual Meeting in San Francisco to foster strategies of team training (#817, Monday, October 15, 2:00-5:00 pm, Moscone Center West, Rm 2001). Although a variety of available programs will be discussed, the focus will be introduction of a cost-effective mechanism of team training via a curriculum that is available in the public domain after development by the Department of Defense (DoD) and the Agency for Healthcare Research and Quality (AHRQ). This unique workshop should attract the attention of anesthesiology clinicians, medical center leaders, and other health care educators and researchers. Experts in the field of patient safety and team training will share their practical experience and identify best practices based on the science of teamwork and training. Those who wish to conduct teamwork training within their own institutions will find the workshop particularly valuable. The objective will be to describe a large-scale DoD initiative to reduce medical error by embracing and applying team training programs. This initiative was developed based on extensive experience gathered during application of this approach for anesthesiologists, intensivists, and other health care leaders.

Experts in the field of team training as well as individuals involved in the development of the curriculum will present their past experience and future expectations for perioperative team training. Background information includes an overview of the military health system and its specific challenges, with insights into how the DoD became a lead organization promoting safer health care. Initial and current DoD team training initiatives will be described, including a comprehensive analysis using case studies. The current program, called "TeamSTEPPS" (Team Strategies and Tools to Enhance Performance and Patient Safety) will be described, along with a review of its strengths and limitations. Course materials are available for public use and lessons learned by the program developers will be reviewed. Attendees will hear the experience at one Midwestern academic medical center (Creighton University) during implementation of TeamSTEPPS. Important elements include benchmarks and measurement tools to determine effectiveness of program interventions. An adjunct to the curriculum highlights how simulation is integrated into team training modules. Practical pointers include a number of "lessons learned" during launch of a large-scale health care initiative from those most familiar with the program. Lastly, issues and questions for future research will be identified with input from workshop attendees. Join us!



Dr. Sem Lampotang, from the University of Florida, speaks with visitors to the APSF Booth at a recent ASA meeting.

#### Presenters:

- Robert J. McQuillan, MD, Associate Professor and Chair, Department of Anesthesia, Creighton University (moderator)
- Heidi King, Tricare Management Activity, Office of the Chief Medical Officer
- Eduardo Salas, PhD, Department of Psychology and Institute for Simulation and Training, University of Central Florida
- Mary Salisbury, RN, The Cedar Institute, Providence, Rhode Island
- David Gaba, MD, Professor of Anesthesia and Associate Dean for Immersive and Simulation Based Learning, Stanford University
- Kim Galt, PharmD, Associate Dean of Research, School of Pharmacy and Health Professions/Director of Creighton Health Research Program, Creighton University

The workshop will be held during the ASA meeting on Monday, October 15, 2007, Moscone Center.

### COT Selects Paulsen and Reilly for New Leadership Positions

Dr. Michael Olympio, chair of the Committee on Technology (COT) is pleased to announce the selection of Dr. William A. Paulsen, MMSc, PhD, CCE, AAC, as the first Vice Chairman of COT. Dr. Paulsen has served COT for a number of years, most recently and actively within the Q&A column and the Technology Training Initiative. Bill is professor and chair of the Department of Anesthesia Sciences at South University in Savannah, GA, and brings quite extensive technical and leadership skill to this position. Dr. Paulsen will assume direct management of COT's Q&A Column within the APSF Newsletter, and will develop and coordinate the technology safety initiatives of individual COT members. We are equally pleased to announce the selection of Patricia Mullen Reilly, CRNA, BSN, as the first COT Strategic Relations Director. Ms. Reilly has extensive experience on the COT, most recently and actively within the Technology Training Initiative. She brings a wealth of clinical, managerial, and interpersonal experience to this position and will help COT reach out to its membership to improve communications, recruitment, and developmental strategies. Welcome to Dr. Paulson and Ms. Reilly.

## **Important New Safety Issues to Be Discussed at the 2007 ASA Convention**

### "2007 ASA," From Page 43

on-time antibiotic administration and administration of antiemetics for prophylaxis (A2142, A2144), 2 papers on using simulation to decrease anesthesia risk with the introduction of new procedures (A2138) and to practice health care team training (A2145), and 1 paper on the value of an educational lecture prior to an anesthesia machine check (A2143).

### Numerous Panels Focus on Patient Safety

Numerous panels at this year's ASA Annual Meeting focus on patient safety starting <u>Saturday</u>, <u>October 13</u>, with Dr. Michael O'Reilly and Clinical Anesthesia Decision Support: Fact or Fantasy (#PN12, 1:30-3:00 pm, Rm 307, Moscone Center South). On <u>Sunday, October 14</u>, Dr. William Furman will discuss Anesthesia Information Systems (AIMS) and Care Improvement (#PN20, 9:00-11:00 am, Rm 308, Moscone Center South). Later in the afternoon, Dr. Tracy Stierer will moderate a panel on Identification and Management of Patients with Obstructive Sleep Apnea (#PN24, 1:30-3:30 pm, Rm 305, Moscone Center South). Monday, October 15, Dr. Norman Cohen will participate in a panel on The Pay-For-Performance Train Has Left the Station: Now What? (#PN33, 9:00-11:00 am, Rm 307, Moscone Center South). Tuesday, October 16, Dr. Daniel Sessler will moderate a panel on Prevention of Surgical Wound Infections (#PN45, 9:00-11:00 am, Rm 305, Moscone Center South), followed in the afternoon by Dr. Gregory Crosby moderating a panel on General Anesthetic Neurotoxicity: Can It Be Bad When It's So Good? (#PN55, 1:30-3:30 pm, Rm 308, Moscone Center South). The patient safety panels conclude on Wednesday, October 17, with Dr. Lee Fleisher moderating Strategies To Improve Perioperative Outcomes (#PN57, 9:00-11:00 am, Rm 303, Moscone Center South), followed by Dr. Dorothy Pavlin moderating a session on improving ambulatory patient safety

and recovery (#PN64, 1:30-3:30 pm, Rm 303, Moscone Center South).

### Rovenstine Lecture to Discuss Anesthetic Morbidity and Mortality

Dr. James Cottrell, this year's presenter of the Emery A. Rovenstine Lecture (Monday, October 15, 11:15-12:20 pm, Rm 134, Moscone Center North), will discuss the complications and adverse effects of anesthetics in his lecture entitled "We Care, Therefore We Are: Anesthesia-Related Morbidity and Mortality."

From the preceding list of exciting presentations, it is clear that patient safety remains in the forefront of research and clinical endeavors for anesthesiologists. We have provided only some highlights of patient safety-related lectures and presentations. Please visit the ASA website or review the meeting program for a complete list of topics and schedules.

## Support <u>Your</u> **APSF!**

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- Important Safety Initiatives
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### Make a Donation

- By Mail
- At the APSF Booth at the 2007 ASA in San Francisco

## Letter to the Editor Labeling Syringes

### To the Editor,

I write in response to the letter by Dr. John Beauregard (*APSF Newsletter*, Spring 2007) about labeling medications. Recently the Washington State Department of Health cited our hospital because we (the anesthesiologists) do not label syringes of propofol. We are an MD-only anesthesia group that draws up and administers our own drugs, we lock the syringed in a Pyxis so they are constantly under our control, and we do our own cases "start to finish."

The inspectors cited JCAHO standards and NPSG Requirement 3D, which refers to the labeling of "high alert" medications. These regulations do not endorse the ASA Standards on Labeling of Pharmaceuticals for Use in Anesthesiology or the ASTM color coded label system we use currently. Instead, JCAHO Standard MM4.30 must be adhered to (drug name, strength, and amount). I contacted JCAHO and received the following e-mail reply on July 5, 2007:

The National patient safety goals are very specific with regards to what must be included in the labeling of medications on and off the sterile field. Color coding, etc., are not now nor were they ever allowed under this goal. Membership on the Sentinel Event advisory council that does the research and development of the goals does include the ASA.

We have 45 days to comply with the DOH. There is no appeal process.

Greg Allen, MD, FRCPC Olympia, WA





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Please address all inquires by email (apsfoffice@aol.com) or facsimile (317-888-1482).

Check out the Virtual Anesthesia Machine Website and the APSF Anesthesia Machine Workbook at www.anest.ufl.edu/vam



### **References Document Formulation Concerns**

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### APSF Executive Committee Invites Collaboration

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, 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.



### Anesthesia Patient Safety Foundation

is pleased to announce the APSF/American Society of Anesthesiologists (ASA) Endowed Research Award

in full support (\$150,000) of a grant to be awarded in October 2007 for initiation in January 2008.

The funds for this named grant will be provided from the APSF Endowment Fund, which was made possible by the generous contributions of ASA to APSF over the last several years.



APSF Booth at a recent ASA meeting.

Be sure to visit the APSF Booth located in the exhibit hall at the Moscone Center during the 2007 ASA Annual Meeting, October 13-17, 2007, in San Francisco, CA.

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