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NEWSLETTER

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Perioperative Hyperglycemia Raises Risks

Inflammation/Hormones Increase Adverse Outcomes

Ioanna Apostilidou, MD, and Richard C. Prielipp, MD

Hyperglycemia and glucose intolerance are common manifestations of perioperative stress in many hospitalized patients. Diabetic patients have more frequent, more prolonged, and more expensive hospital admissions that result in increased morbidity and mortality than nondiabetics. Diabetic patients also require more frequent surgical interventions and are more often admitted to the intensive care unit (ICU). Moreover, it is common for even nondiabetic surgical and ICU patients to develop acute hyperglycemia during stress. This hyperglycemia is mediated by the release of proinflammatory cytokines (e.g., TNF-alpha and IL-6) and elevated concentrations of catecholamines, growth hormone, glucagon, and glucocorticoids.[1] These mediators induce metabolic alterations in carbohydrate balance that alter peripheral glucose uptake and utilization, increase gluconeogenesis, depress glycogenesis, and induce glucose intolerance and insulin resistance.

Hyperglycemia produces deleterious effects on the immune system, neutrophil function, and on the response to endotoxin. As a consequence, acute hyperglycemia adversely affects patient outcomes. Diabetic patients undergoing cardiac surgery managed with tight perioperative glycemic control have a lower rate of sternal wound infection and hospital mortality.[2-4] In a large nonrandomized study, 2,467 diabetic cardiac surgical patients were classified in 2 sequential groups, the control group with "usual" sliding scale insulin glucose control and the study group with continuous intravenous insulin infusion to maintain blood glucose <200 mg/dL.[2] Continuous insulin infusion resulted in lower glucose levels and was associated with significantly lower incidence of sternal wound infection (0.8 vs. 2%) and lower postoperative mortality (2.5 vs. 5.3%). In a subsequent analysis of 4,864 diabetic patients who underwent open-heart procedures, the investigators reported that a 3-day continuous insulin infusion that kept glucose levels <150 mg/dL was a key factor in improved outcomes.[4] Modulation of the metabolic state during cardiac ischemia and inhibition of lipolysis by insulin stimulates nitric oxide production and may confer cardiac protection. For instance, in a prospective randomized study of 141 coronary artery bypass graft (CABG) patients, Lazar and colleagues found that tight glycemic control (serum glucose, 125-200 mg/dL) decreased the incidence of recurrent wound infections, episodes of recurrent ischemia, atrial fibrillation, and postoperative length of stay.[5] Outcome in patients without diabetes undergoing cardiac surgery also improve with tight glycemic control.[6-9] An increase of only ***20 mg/dL*** in the mean intraoperative glucose was linked to an increase of more than 30% in adverse outcomes.[8]

ICU and Similar Patient Groups

Numerous prospective, randomized trials confirm that maintenance of normoglycemia in critically ill patients (plasma glucose between 80-110 mg/dL) improves ICU outcomes.[6-14] Euglycemia can be achieved in ICU patients with insulin infusion protocols and reduces

- ICU mortality (-32%)
- in-hospital mortality (-34%)
- serious infections rate
- onset of acute renal failure
- neuropathy
- duration of ventilatory dependence.[10,11]

While these benefits are more difficult to document in medical ICU patients,[12] it is clear that appropriate use of insulin decreases complications from hyperglycemia associated with the response to acute disease, with or without a direct impact on the primary disease process itself.[12-14]

Other patients with acute illness and hyperglycemia are also at risk. The Diabetes and Insulin-Glucose Infusion in Acute Myocardial Infarction (DIGAMI 1) study revealed that intensive glycemic control during the peri-infarction period reduced long-term mortality rate (1 year, -28%; 3.4 years, -25%).[15] That benefit was evident regardless of the antidiabetic regimen used (DIGAMI 2) emphasizing the importance of maintaining euglycemia.[16] Acute stroke patients have higher mortality rates and poorer recovery when blood glucose exceeds 110 mg/dL.[17] Thus, evidence supports the use of aggressive insulin protocols to manage hyperglycemia in patients admitted to acute care hospitals for myocardial infarction, stroke, those with a previous diagnosis of diabetes, and those patients undergoing surgery.[18,19]

Management Caveats

Tight glucose control demands frequent measurement (at least hourly initially) of glucose concentration and a consistent approach to management. Ideally, a glucose control protocol must fulfill these criteria:

1. Ability to make rapid, precise, consistent modifications in blood sugar
2. Ability to maintain, increase, or decrease blood sugar depending on clinical situation
3. Ability to monitor glucose levels quickly, close to real time with trend detection to allow preemptive glucose management. (See the appendix on page 26 for a protocol example from the University of Minnesota.)

The risk of hypoglycemia and difficulty of attaining normoglycemia with a tight glycemic control protocol is an important safety concern in both cardiac and other ICU patients.[20] In 2 recent studies, a novel approach, the *hyperinsulinemic normoglycemic clamp technique,* achieved normoglycemia even during

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Inside:

ASA Publishes Practice Advisory for Perioperative Visual Loss Associated with Spine Surgery

by Robert C. Morell, MD

The American Society of Anesthesiologists has published a recent Practice Advisory pertaining to postoperative visual loss associated with spinal surgery. The purpose of the advisory is to increase awareness of permanent impairment and/or total loss of sight associated with spinal surgery performed under general anesthesia. Anterior ischemic optic neuropathy, posterior ischemic optic neuropathy, and central retinal artery occlusion are all discussed in this practice advisory, which is available on-line at www.asahq.org and has also been published in the June 2006 issue of *Anesthesiology*. The advisory is a report produced by the American Society of Anesthesiologists Task Force on Perioperative Blindness and was approved by the ASA House of Delegates on October 25, 2005. Primary findings of the task force are summarized as follows:

"There is a subset of patients who undergo spine procedures while they are positioned prone and receiving general anesthesia that has an increased risk for developing perioperative visual loss. This subset includes patients who are anticipated preoperatively to undergo procedures that are prolonged, have substantial blood loss, or both (high risk patients)."

"Consider informing high-risk patients that there is a small, unpredictable risk of perioperative visual loss."

"The use of deliberate hypotensive techniques during spine surgery has not been shown to be associated with the development of perioperative visual loss."

"Colloids should be used along with crystalloids to maintain intravascular volume in patients who have substantial blood loss."

"At this time there is no apparent transfusion threshold that would eliminate the risk of perioperative visual loss related to anemia."

"High-risk patients should be positioned so that their heads are level with or higher than the heart when possible. In addition, their heads should be maintained in a neutral forward position (e.g., without significant neck flexion, extension, lateral flexion, or rotation) when possible."

"Consideration should be given to the use of staged spine procedures in high-risk patients."

Readers are encouraged to read the full document for detailed information on this important advisory, which includes specific information regarding the methodology, application, sources and strength of evidence, and limitations of this practice advisory.

Dr. Morell is the editor of this newsletter, Clinical Associate Professor of Anesthesiology, Wake Forest University Health Sciences, Winston-Salem, NC, and Adjunct Clinical Associate Professor of Anesthesiology, University of Florida School of Medicine, Gainesville, FL. Dr. Morell is in the private practice of anesthesiology and resides in Niceville, FL.

A Statement by the Executive Committee of the APSF

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

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NEWSLETTER

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Address all *general, contributor, and subscription* correspondence to:

Administrator, Deanna Walker
Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922
e-mail address: walker@apsf.org

FAX: (317) 888-1482

Address *Newsletter* editorial comments, questions, letters, and suggestions to:

Robert C. Morell, MD
Editor, *APSF Newsletter*
c/o Addie Larimore, Editorial Assistant
Department of Anesthesiology
Wake Forest University School of Medicine
9th Floor CSB
Medical Center Boulevard
Winston-Salem, NC 27157-1009
e-mail: apsfeditor@yahoo.com

Methodology Might Be Debated, Clinical Endpoint Is Not

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periods of especially high stress such as cardiac surgery. This technique involves a fixed, relatively high-dose infusion of insulin and then uses a variable rate of glucose infusion to "clamp" the blood glucose concentration at an appropriate level.[21-23] However, this methodology is incredibly labor and time intensive too.

Although the methodology for administering insulin and glucose may be debated, the clinical endpoint is not. The American College of Endocrinology position statement recommends maintaining blood glucose ≤110 mg/dL (<6.1 mM) in intensive care patients to decrease perioperative complications and in-hospital morbidity and mortality.[24] Most insulin protocols for ICU patients target glucose levels in the physiologic range of 80-110 mg/dL.[10-12] However, we still need to elucidate the exact biochemical mechanisms by which the benefit of normoglycemia is actually conferred.[6] Indeed, although insulin is the primary agent available to lower blood sugar, recently available pharmacologic agents, such as the incretin mimetics, amylin and exenatide, which can actually lower glucagon release, may confer metabolic advantages distinct from insulin treatment alone. Other strategies to ameliorate the perioperative "stress response" in surgical patients include interventions like epidural or spinal blockade to reduce catecholamine secretion and improve insulin responsiveness.

In summary, we believe that whenever hyperglycemia and/or insulin resistance occur, early detection and effective insulin therapy is indicated. Clearly, the potential of hypoglycemia remains the most serious safety issue. Recent clinical reports suggest hypoglycemia may be associated wtih multiple factors, including misunderstanding of the insulin administration protocol, rebound response from concomitant intravenous bolus of corticosteroids, and other complex insulin and drug-patient interactions. Therefore, there is intense interest in continuous glucose level monitoring technology, which promises a means of avoiding, undiagnosed and untreated hypoglycemia. We also await the findings of additional important clinical studies regarding these issues.[25]

Dr. Apostolidou is Associate Professor of Anesthesiology at the University of Minnesota in Minneapolis, MN. Dr. Prielipp is Professor and Chair of the Department of Anesthesiology at that institution, and is also Chair of the APSF Committee on Education and Training and a member of the APSF Executive Committee.

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SOAP Panel Advocates Team Training in Obstetrics

by Stephen D. Pratt, MD

The idea that medical errors and the adverse events they cause are major public health concerns is not likely to be news to readers of this *Newsletter*. It has been seven years since the Institute of Medicine (IOM) highlighted the fact that up to 98,000 Americans die every year due to medical errors.[1] This places medical error as the leading cause of accidental death in the United States, surpassing the combined totals of motor vehicle accidents, fire, and drowning. Since then, similar data have been found in the Canadian health care system, with in-hospital adverse events accounting for between 9,200 and 24,000 deaths.[2] A recent report went so far as to suggest that limiting health care to the Medicare population may actually improve mortality rates by decreasing the number of medical errors to which the elderly will be exposed.[3]

Many potential solutions to the problem of medical error have been proposed, including computerized provider-order-entry,[4] site/side documentation for invasive procedures,[5] banning ambiguous abbreviations,[5] and many others. Teamwork, however, is perhaps the most recommended solution. Again, the idea that teamwork has the potential to improve patient safety is not news. The follow-up report from the IOM published in 2001, *Crossing the Quality Chasm*, recommended that health care teams better use the concepts of Crew Resource Management (CRM) to improve care.[6] There have been small steps in the right direction over the ensuing 5 years. Team training has been associated with improved attitudes, behaviors, and outcomes. Grogan demonstrated that an 8-hour course on teamwork and CRM concepts can improve staff attitudes toward safety and teamwork,[7] and the same group has found that team training has improved patient safety in the operating room (Seddon, personal communication). Morey et al. found that classroom-based team training effectively increased teamwork behaviors and improved outcomes.[8]

Unfortunately, successfully implementing a teamwork structure and changing the culture in which we practice is still the exception rather than the rule. Many forces are impeding the shift to a new, team-based, medical paradigm, including the logistical and financial requirements of such a change, fears that working as a team might increase malpractice exposure, and even intransigence to change itself. However, I believe there is a more fundamental factor at work. I believe that most clinicians simply do not understand what "teamwork" would mean in the medical environment. They do not understand how a medical team would act differently from the way medicine is currently practiced. Worse, since they do not know what the final product should look like, they have no idea how to start to makes the changes that would be necessary to get there. Although some literature does exist,[9,10] little has been published describing what teams do or what steps to take to implement teamwork. As a result, even those who might embrace the concepts of teamwork are often left unable even start the process.

In an attempt to help to fill this gap in understanding, the Society for Obstetric Anesthesia and Perinatology (SOAP) hosted a patient safety panel at its annual meeting in Hollywood, Florida, this year. Three national experts in medical teamwork training presented the training methods the use to train their staff to be a team on their labor and delivery units.

Dr. Benjamin Sachs, Chairman of the Department of Obstetric and Gynecology at Beth Israel Deaconess Medical Center (BIDMC) and Professor at Harvard Medical School presented first. Dr. Sachs indicated that his department began a strong commitment to patient safety after a major adverse event in 2000.[11] The training program used at BIDMC was developed in conjunction with the Department of Defense, Tricare, and the American Institute for Research, and with the help of such teamwork experts as Eduardo Salas. Originally developed as part of a multi-center prospective randomized trial on the effects of team training on obstetric outcome, the training course has gone through modifications based on the lessons learned from the study and the most recent understanding of what makes teams work well. The training includes a 4-hour classroom-based training session to teach the basic concepts of teamwork. These concepts include Leadership, Situation Monitoring, Mutual Support, and Communication. The didactic training is supported by the creation of 3 separate types of multidisciplinary teams. The first is the core team, those who administer direct patient care. The second team is the coordinating team, a group that helps to balance work loads and staffing, and is responsible for ensuring that teamwork behaviors such as team meetings and briefings occur. The third team is a pre-determined set of clinicians designated to respond to emergencies, the contingency team. Well-defined tools and behaviors, including team meetings and briefings, communication techniques, check lists, and feedback and conflict resolution strategies are used to remind staff how to act "teamly." Finally, a structured implementation process helps to bring these concepts, behaviors, and practices into the clinical environment. This implementation process includes a deliberate schedule for adopting each new behavior, a strong coaching effort, strategies for dealing with resistance, and periodic reinforcement of the behaviors to sustain the changes.

Dr. Sachs presented data demonstrating a 25% decrease in major adverse outcomes in their obstetric patients, with the best improvements coming in the high-risk preterm deliveries. In addition, his group found a nearly 50% reduction in malpractice cases since they implemented their teamwork system.

Dr. David Birnbach, Vice Chairman of the Department of Anesthesia and Director of the Center for Patient Safety at the University of Miami presented next. His group uses a high-fidelity simulator at Jackson Memorial Hospital to teach teamwork concepts. The simulation center at Jackson Memorial is state-of-the-art, costing more than $3 million annually in equipment and staffing. It includes an operating room environment, complete with surgical and anesthesia equipment, actors to play the obstetric and nursing staff, and a "dummy" patient that can be manipulated from a control room to simulate nearly any physiologic perturbation. This realistic environment allows staff to be immersed in "real life" obstetric scenarios and requires that they use and practice their teamwork skills. Dr. Birnbach showed multiple videotapes of actual cases from the simulator. These videos are used to debrief the sessions after the staff goes through the training. While clinical skills can be taught and honed in this environment, Dr. Birnbach indicated that the emphasis is on teamwork concepts, especially communication and resource management. Several of the scenarios depicted anesthesia staff getting into trouble and not even telling the rest of the team about the problem or much less asking for help. The hope is that by seeing themselves make these teamwork errors, staff will be able to change their behaviors and better use teamwork skills.

In a novel use of their simulator, Dr. Birnbach is creating "best practice" scenarios. He has taken patient complaints and re-enacted them in the simulator. Actors re-enact both the medical and interpersonal problems as they were described by the patient. A second version of the scenario is then created that demonstrates a better way that the situation could have been handled.

Dr. Paul Preston was the third panelist. Dr. Preston is a staff anesthesiologist at the University of California, San Francisco. He is a leader in developing team training educational programs in the Kaiser Permanente system. After working with Dr. David Gaba in the use of simulators to teach Anesthesia Crisis Resource Management and Dr. Michael Leonard in Humans Factors analysis and training, Dr. Preston has become an expert in teaching staff to work as a team. Dr. Preston presented a team-training model that incorporates both a classroom-based

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Crew Resource Management Integral to Training

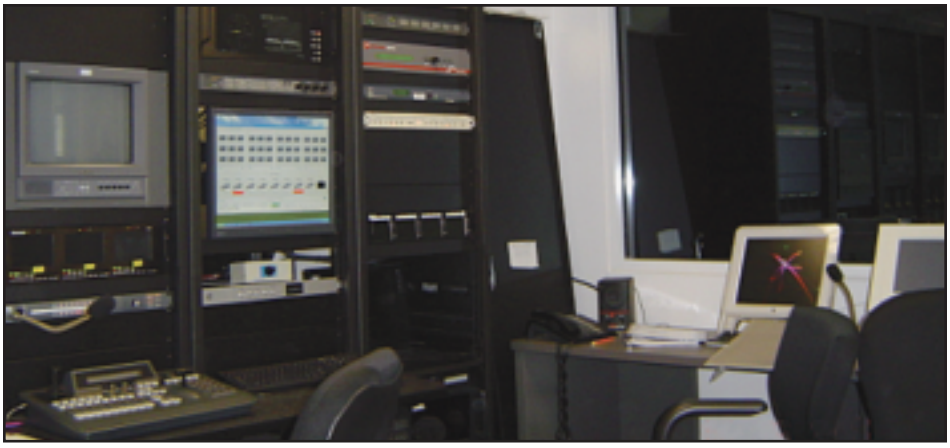
"Team," From Preceding Page

education and simulated crisis management scenarios. The training is a 4-hour course. He starts with a quick review of human factors and CRM concepts. These include briefings, communications skills, assertion for safety, situation awareness, leadership, and resource management. He then brings staff through simulated emergencies. He has a relatively "low-tech" simulator that he is able to bring to the hospital being trained. Thus, staff are able to practice the crisis management scenarios in their usual environment with their colleagues. The simulated cases are based on real cases that focus on potential or identified weaknesses in the system. He has more than 2 dozen obstetric and general medical or surgical emergencies. He videotapes these sessions and then debriefs the staff. Again, these debriefings focus on systems issues, communication, and teamwork, and not clinical skills.

Based on the experience bringing this simulated environment into many hospitals, Dr. Preston was able to present some important lessons learned. These include some not-so-surprising facts (obstetricians are often overloaded and do not communicate well), important leadership facts (nursing leaders are invaluable in getting a "big picture" of the unit and helping the obstetric providers maintain situation awareness), and even rather mundane practical facts (moving to the OR in a stat situation works best if the piggybacked IVs are all unplugged, the epidural is placed on the bed, and one person is in charge of telling people when to go). Dr. Preston stated that perhaps the most powerful effect of the team training is the consistent way that it encourages the clinicians to come together to communicate and to fix problems.

A lively discussion and question and answer period followed the panelists' presentations. In addition, the Board of SOAP decided to create a patient safety committee in order to ensure that future meetings include similar educational activities.

The 3 presenters on this panel have successfully brought teamwork into their work environments. More importantly, they have created educational systems that help clinicians to understand what teamwork means in the medical environment and how to gain the skills necessary to become a good team member. The 3 systems are quite different, but each incorporates the necessary components of CRM and has been used successfully. One hopes that those in attendance returned to their practices with a better understanding of what teamwork and CRM mean in medicine and how they can be taught and implemented. With this important step, perhaps many more units can make the necessary changes to a safer team-based practice.



A snapshot of the control panel and "O.R." in the simulator at Jackson Memorial Hospital.

Dr. Pratt is an Instructor at the Beth Israel Deaconess Medical Center in Boston, MA.

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A birth in the Kaiser Simulator.

University of Minnesota Provides Protocol

"Hyperglycemia," From Page 23

UMMC Continuous Intravenous INSULIN Infusion Orders; ADULT (>45 kg)

GOAL: Maintain glucose level between 80–100 mg/dL. Start protocol only if glucose >110 mg/dL x 2. This protocol is not to be used for patients in Diabetic Ketoacidosis (DKA).

GENERAL

- ✔ ☐ Discontinue all currently active insulin orders.
- ✔ ☐ Insulin infusions will be provided as 1 unit of regular insulin/mL in 0.9% Sodium Chloride, in 30 mL syringes, unless otherwise requested.
- ✔ ☐ If patients are on Parenteral Nutrition/Enteral Feeding, and they are held or cycled, contact MD for specific instructions regarding the insulin infusion.
- ✔ ☐ If subcutaneous insulin (correction scale or scheduled) is ordered, discontinue the insulin infusion 2 hr after the 1st dose of Sub-Q insulin.
- ✔ ☐ Discontinue this protocol when the patient has achieved glycemic control, and is being transitioned to subcutaneous insulin or no longer requires insulin therapy. See Transition Insulin Orders.

GLUCOSE MONITORING

- ✔ ☐ Bedside glucose monitor (whole blood glucose) Q1H until glucose is stable within 80-110 mg/dL x 4, then Q2H until insulin infusion is discontinued. If subsequent glucose values are outside the 80-110 mg/dL range, measure whole blood glucose Q1H.
- ✔ ☐ Obtain a STAT plasma glucose for changes in mental status, diaphoresis, or unexplained tachycardia.

INITIATION OF CONTINUOUS INSULIN INFUSION PROTOCOL

STEP ONE. For initial glucose value, start insulin infusion according to scale below:

Initial glucose value	Action taken
111–140 mg/dL	Start insulin infusion @ 1 unit/hour.
141–175 mg/dL	Start insulin infusion @ 2 units/hour.
176–220 mg/dL	Give 2 units IV bolus of regular insulin and start insulin infusion @ 2 units/hour.
221–300 mg/dL	Give 4 units IV bolus of regular insulin and start insulin infusion @ 3 units/hour.
301–400 mg/dL	Give 10 units IV bolus of regular insulin and start insulin infusion @ 4 units/hour.

INITIATION OF CONTINUOUS INSULIN INFUSION PROTOCOL, continued

STEP TWO. For 2nd blood glucose value, adjust insulin infusion according to scale below:

Second glucose value	Action taken
<80 mg/dL	Follow instructions for blood glucose value in Step Three.
80–110 mg/dL	No changes. Continue current infusion rate.
111–400 mg/dL	Increase insulin infusion BY 2 units / hour.
>400 mg/dL	Notify MD.

STEP THREE. For all blood glucose values after the 2nd reading, adjust insulin infusion according to scale below:

Blood glucose value	Action taken
<40 mg/dL	Hold insulin infusion. Notify MD. Give 50 mL IV of Dextrose 50%. Recheck blood glucose in 15 min. If <80 mg/dL, repeat 50 ml Dextrose 50%. If recheck glucose > 80 mg/dL, then restart insulin infusion at half previous rate.
40–59 mg/dL	Hold insulin infusion. Give 25 mL IV of Dextrose 50%. Recheck blood glucose in 15 minutes. If <80 mg/dL, repeat 25 mL of Dextrose 50%. If recheck glucose >80 mg/dL, then restart insulin infusion at half previous rate.
60–79 mg/dL	Hold insulin infusion. Recheck blood glucose in 1 hour. If <80 mg/dL, follow STEP 3 protocol. If recheck glucose >80 mg/dL, then restart infusion at half previous rate.
80–110 mg/dL	No changes if blood glucose stable within range. If blood glucose is fluctuating within range, titrate in 0.5 unit increments based on patient response to keep within range.
111–175 mg/dL	Increase insulin infusion BY 0.5–1 unit/hour.
176–220 mg/dL	Increase insulin infusion BY 1–2 units/hour.
221–260 mg/dL	Increase insulin infusion BY 2–3 units/hour.
261–300 mg/dL	Increase insulin infusion BY 4 units/hour.
301–350 mg/dL	Increase insulin infusion BY 5 units/hour.
351–400 mg/dL	Increase insulin infusion BY 6 units/hour.
>400 mg/dL	Notify MD

MD SIGNATURE: _____ PAGER #: _____ DATE: _____

Appendix 1: A continuous intravenous insulin infusion protocol from the University of Minnesota Medical Center.

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Dear SIRS

Line Isolation Still Important

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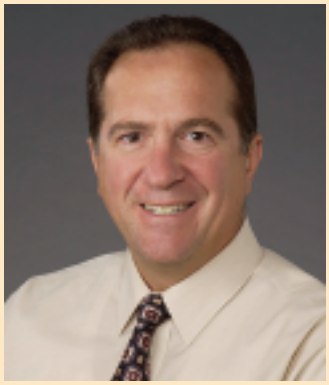

Michael Olympio, MD,
Chair of the APSF Committee on Technology and Co-Founder of the Dear SIRS Initiative.

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 Drs. Michael Olympio, Chair of the Committee on Technology, and Robert Morell, Editor of this newsletter. Dr. Olympio is overseeing the column and coordinating the readers' inquiries and the responses from industry. **Dear SIRS** made its debut in the Spring 2003 issue.

Dear SIRS:

Has there been a change in the recommended use of line isolation monitors? We had an alarm today and we were told by our engineering department to essentially ignore it, as they are not even being placed in new ORs. They say the equipment maintenance and use of ground fault circuit interrupters (GFCIs) has virtually eliminated any chance of patient harm.

Could you update me on this, or point me to a link on how we should be approaching this issue in 2006? Thanks so much.

Patrick Noud, MD

In Reply:

Dear SIRS:

1) We are a Federal (VA) Hospital. About 11 years ago we designed a new building that opened about 9 years ago. We were told that isolated power was no longer required by code, but we could choose it if we wanted to.

2) I chose isolated power in the OR because:

   A) It is a passive safety system that does not depend on an active component (GFCI) on every circuit. It is built into the isolation from ground.

   B) If a medical device has a first-fault, the circuit remains ON and all items on that circuit have the same level of safety as with standard 3-wire circuitry AND you are alerted to a problem; this is useful as other devices might still be on the same circuit. With a GFCI, the circuit "pops" to off so that all devices on it are without power. Further, you may not be immediately aware as to whether the failure was due to a ground fault or some other problem.

   C) I myself would consider the OR a "wet location." Most big cases have lots of blood and saline squirted around, not to mention the possibility of patient sweating, and rare circumstances that are not usually wet could become so in unusual situations. I think that ICUs could also fall into this category, but they may not traditionally use isolated power.

3) My guess is that the cost differential is small WHEN AMORTIZED over the lifetime of the OR suite. I'm not sure that there isn't more expense with a building full of GFCIs in trouble-shooting them and the like vs. an isolated line system.

4) I believe that in such matters knowledgeable clinicians should essentially have the final say, in consultation with the engineers, not the other way around. Building only to code may NOT necessarily be the optimal thing for patient safety.

5) Even with an isolated power system, you do STILL need to ensure that all devices have a ground wire. This will handle (at least for macroshock protection) a double fault, as well as any leakage currents.

David Gaba, MD
Professor of Anesthesia
Associate Dean for Immersive and Simulation-based Learning
Stanford University
VA Palo Alto Healthcare System

Dear SIRS:

First, the national requirements for isolated power, and for ground fault interruption, come, to the best of my knowledge, from the NFPA. The applicable standard is NFPA 99 - Standard for Health Care Facilities 2005 edition, Chapter 4 - Electrical Systems. The particular sections that are relevant to this discussion are 4.3.2.2.8 (Wet Locations), 4.3.2.2.9 (Isolated Power Systems), and 4.3.2.6.3 (Line Isolation Monitors).

These standards are available on the NFPA web site www.nfpa.org in "read only," copyrighted format. However, as I understand them for *wet locations*, they require either isolated power systems, or ground fault circuit interruption (GFCI); and it qualifies GFCI to situations where power interruption is tolerable (in the case of a short circuit).

Obviously, as you know, local and state standards may vary from the NFPA. Finally, the ASA itself does not get more specific than to say, in its "Guidelines for Non-operating Room Anesthetizing Locations," that "In any anesthetizing location determined by the health care facility to be a 'wet location' (e.g., for cystoscopy, arthroscopy, or birthing room in

See "Line Isolation," Next Page

New ORs Should Have Isolated Power

"Line Isolation," From Preceding Page

labor and delivery), either isolated power or electric circuits with ground fault circuit interrupters should be provided."

I'll copy this email to Dr. Jan Ehrenwerth, our representative to NFPA, for his additions or corrections. Thanks, and good luck with your OR construction!

Don Martin, MD
Chair, Committee on Equipment and Facilities
American Society of Anesthesiologists

Dear SIRS:

I am happy to provide you with information about isolated power and line isolation monitors (LIMs). I am the ASA representative to NFPA, and have written and lectured on the subject many times. For reference, please see my chapter (#8) on "Electrical Safety" in Barash's *Clinical Anesthesia*. In 1983, the NFPA (which sets most fire standards) removed the requirement for isolated power and LIMs from ORs that do not use flammable anesthetic agents. This rule was originally developed as a fire safety standard. Therefore, no explosion risk, no need to keep the rule. It made sense to them. What they did not account for, was the huge increase in electrical equipment, often with very wet floors.

Note, however, that NFPA did not say, "Do *not* use isolated power," but rather, "It is not required, but optional."

Since isolated power is somewhat more expensive (the incremental cost is about $3000-5000 per OR), many hospitals have taken the shortsighted view to leave it out. Therefore, most ORs have no more electrical safety protection than your dining room. Even your kitchen and bath have GFCIs, which are better than nothing. I feel strongly that isolated power should be retained. Hospital engineers are often misinformed or wrong, and use made-up facts to support their argument. As an example, at Yale University in the past 10 years, we have built or remodeled 24 ORs and ALL HAVE ISOLATED POWER AND LIMs.

There are 2 ways to proceed, if you feel as I do, that this is an important safety feature. One is to say, "This is what we want, and we have to have it!" I feel the better approach is for the Anesthesia and Surgery Departments to jointly declare that the ORs are WET LOCATIONS (the same as your kitchen or bathroom). This is easy to do: Think of cystoscopy, irrigation fluids, trauma blood loss, etc.). I am not sure what code they are using that says ORs are *not* wet locations. However, local practice can always overrule a national code, especially if one is going to a safer system. I think that you have to be insistent on the OR being a wet location. Once that is accepted then the CODE states that they MUST use isolated power (LIMs) or GFCIs. GFCIs are generally felt *not* to be acceptable in ORs, because they cause interruption of power. This is fine in a bathroom, but in the OR it can be hazardous. If the GFCI trips, the faulty piece of equipment must first be identified and then unplugged, before the circuit breaker can be reset. This is complicated by the fact that most new ORs have the circuit breaker panel located outside the OR, and it can be difficult to identify which panel controls a given OR. The only safe way to use GFCIs in the OR is to make every electrical outlet its own branch circuit. This is probably more expensive than isolated power.

In response to the question of responding to a LIM alarm – the answer is absolutely! The person who said to ignore it should be sent back to school, or not be working in an OR. The alarm is almost always significant, if the LIM is a newer generation that alarms at 5 milliamps. The very old LIM, which alarms at 2 milliamps, may give a false alarm. Obviously if you have isolated power in the OR, you would not have a GFCI at the time.

It is important to fight this battle early in the design process, since once the walls are up, it is too late and too expensive to change. I am happy to speak with anyone about this at any time.

Jan Ehrenwerth, MD
Professor of Anesthesiology
Yale University

Dear SIRS:

The advantage of isolated power systems for critical locations in hospitals is that they provide safe dependable power that is not interrupted by trips. Instead, the LIM gives an indication that there is a leakage problem before there is any loss of power. The leakage is cumulative. When looking for the cause of an alarm it's generally the last item plugged in! The alarm threshold was increased from 2 Ma to 5 Ma in 1978. If a system is experiencing a high number of alarms it should be checked to assure that it is not using the pre-1978 threshold.

Mike Mahan, PE
North Carolina Baptist Hospital
Winston-Salem, NC

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NEW

Q&A

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

Q Dear Q&A:

In our operating rooms, we are exclusively using Datex-Ohmeda vaporizers: isoflurane in Isotec 4 and 5, sevoflurane in Sevotec 5, and desflurane in Tec 6.

Obviously, the agent in the vaporizer should be in date, but our question concerns the draining of vaporizers at various intervals. The Datex-Ohmeda Tec 5 manual suggests draining the agent every 2 weeks or an unspecified interval for agents without additives. The Tec 6 apparently cannot be drained at all. We have never before drained our vaporizers and don't know of any other anesthesia department following these guidelines. The effort, waste, and environmental issues are of concern to us, particularly in regards to the recommended high frequency of drainage.

Any help regarding this issue is greatly appreciated, as we are now required to create a policy for our vaporizer maintenance.

Jay Jordan, MSN, CRNA
Rowan Regional Medical Center
Salisbury, North Carolina

A Dear Mr. Jordan:

We've discussed the issue of draining vaporizers with people here in Madison. While the desflurane vaporizers are not meant to be drained in the field, the other vaporizers may be drained. The User Reference Manual for Tec 5 and Tec 7 vaporizers states:

Maintenance intervals:

Prior to performing any maintenance procedures or returning to a service center for repairs, clean and disinfect the vaporizer.

Every 2 weeks:

When the agent is low, drain the contents of the vaporizer into an appropriately marked container and discard the agent. For halothane vaporizers check the output of anesthetic agent periodically with an agent monitor. See note below.

Note:

The decomposition of halothane causes the release of halides, which may corrode metal components particularly in the presence of moisture. Also, a preservative added to halothane by its manufacturers to impede decomposition can leave a residue, which may cause vaporizer components to stick. If halothane is used infrequently the vaporizer should be drained after use.

I've asked around and no one knows why the recommendation is the same for isoflurane, sevoflurane, and enflurane vaporizers as it should be for halothane, except the common practice some years back was to share vaporizers among many different machines and all the user reference manuals stem from one master manual addressing worst-case scenarios. With sharing vaporizers common and with the possibility than any given vaporizer may be sitting on a shelf someplace and not routinely used, draining remained recommended; the user would not know how long a vaporizer was standing idle so the recommendation was as stated above. Most departments today have sufficient vaporizers to supply 1 for each machine. The issue remains, however, what is the quality of the agent in the vaporizer? Draining them periodically and refilling them assures a more uniform product in the vaporizer. Of course the thymol issue with halothane makes draining these vaporizers advisable.

Thank you for your question.

The Committee on Technology

Q Dear Q&A:

How would you dispose of waste anesthesia agent? I am a biomedical technician working for a third party company. I was asked this question by an administrative officer in one of our client accounts.

Richard Shreve

A Dear Mr. Shreve,

My answer would be to obtain advice from the engineering department of the hospital first, suggesting that you would like to use the hospital evacuation system to "suction" the liquid (vapor) from the waste container. I would make this suggestion based upon the current method of scavenging waste anesthetic gas, via suction and expulsion out the roof of the building, as I was told by our own engineers. Would suction of the liquid itself be feasible and allowable by engineering?

- In the past we had built an evaporator for this purpose that was connected to the hospital scavenging system. The evaporator was an Erlenmeyer flask into which the liquid agent was poured. The rubber stopper for the flask had 2 glass tubes, one short one that barely went through the rubber stopper that was connected to hospital suction (suction and scavenging were the same system in our hospital). The other glass tube was about 1/4 inch from the bottom of the flask and ran up through the rubber stopper and stuck up in the air, and sucked room air into the flask. This prevented liquid from entering the suction system and in the case of halothane left the thymol in the flask (very low vapor pressure) as the halothane evaporated (keeping thymol out of the suction system is important). We were also located at the end of the suction system so there was flow from many sources to dilute the anesthetic gas from our evaporator. The difficulty is that some anesthetic agents, although not considered flammable, will burn if mixed in correct proportions with oxygen or nitrous oxide – these are outside of the anesthetic concentrations of these agents. For example, sevoflurane is at the lower flammability level at 11 volumes-percent in oxygen and 10 volumes-percent in nitrous oxide,[1] far outside of the anesthetic concentrations we use, but with a vapor pressure of approximately 200 mmHg at 25°C and an efficient evaporator we can achieve maximum concentrations of 26.3% at sea level. Typically these concentrations from the evaporator will be diluted in the vacuum piping system such

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NEW Q&A

"Q&A", From Preceding Page

that very, very low levels of sevoflurane would reach the vacuum pump. Smaller hospitals may have difficulty with limited suction flow dilution depending upon the time of day that the evaporation was occurring.

- The other issue that has been receiving much attention lately is the high oxygen concentrations reaching oil-lubricated suction pumps and causing flash fires and explosions that completely destroyed the pumps.[2] The addition of combustible concentrations of anesthetic agents may represent serious hazards if attention is not paid to the physical characteristics of the suction system. Some hospitals use separate high flow low pressure scavenging systems that are not part of the suction system and may represent very little hazard. My advice is to learn about your scavenging system before your use a device like the evaporator described above. The evaporator has the advantage that it uses air rather than oxygen or nitrous oxide, but it will depend upon dilution with other gases downstream that may increase the oxygen concentration but additionally may further decrease the agent concentration. The evaporator can be used safely under almost all circumstances.
- Pharmacy hoods are usually not evacuated but are pressurized to prevent contamination. They are similar to the positive pressure orthopedic rooms. I would also suggest that not all suction is evacuated in a safe fashion outside the building with respect to inhalation agents. Some hospitals have special evacuation paths to present the anesthesia waste where no one can breathe it. Regular suction may, or may not, be expelled in a similar fashion. The NFPA has standards for the appropriate evacuation of waste anesthesia gases. Some appropriate waste gas systems may not be able to handle liquid agent; rather they can handle vapor. So that really leaves disposal of the agent by vaporizing into something that is evacuated according to the NFPA standards.
- Depending on where the waste agent resides I see a couple of possibilities.

  1) Quick and dirty method: put it in a negative pressure vent – if available in the hospital.

  2) Ask the manufacturer. In Germany and EU countries, they have to provide guidelines for disposal in the safety datasheets of the agents. Often it says there: Carry it to your next local collection point for harmful substances.

Thank you.
The Committee on Technology

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2. Allen M, Lees DE. Fires in medical vacuum pumps: do you need to be concerned? *ASA Newsletter* 2004;68(10). Available online at: http://www.asahq.org/Newsletters/2004/10_04/allen.html. Accessed June 19, 2006.

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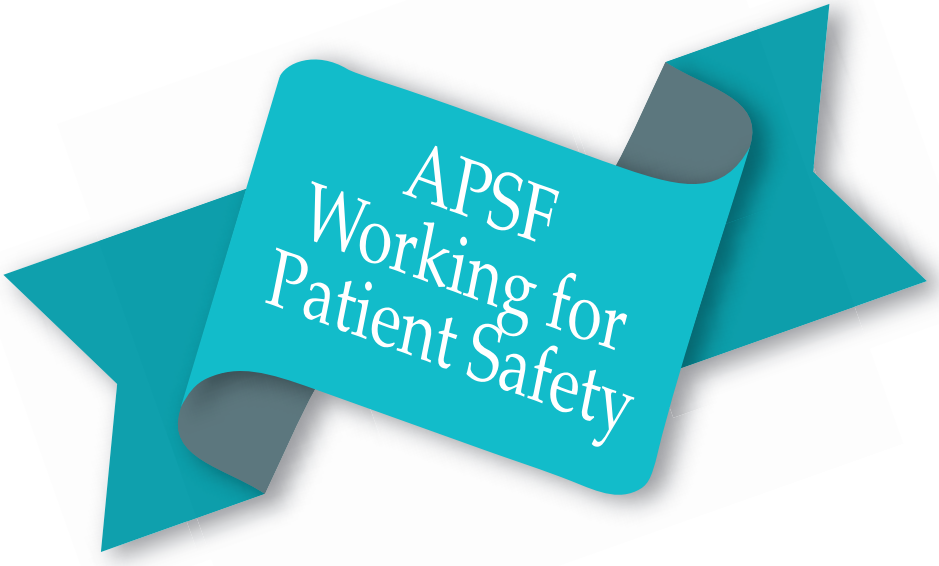

Contact Information

Anesthesia Patient Safety Foundation
Building One, Suite Two
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Administrator: Deanna M. Walker

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Malignant Hyperthermia Death Holds Many Lessons

by Henry Rosenberg, MD and Al Rothstein

The death of a young, vigorous, healthy individual during routine surgery is an emotionally devastating event. The family and friends of the person are shocked, angry, depressed, beset by guilt, frustration, and thousands of questions. Was there something they could have done to prevent the death? Should the surgery have occurred? Did the physicians and nurses miss something or act inappropriately?

These were the feelings and emotions experienced by the family and friends of Steven Nook, a 20-year-old athletic, affable, young man who died following surgery to repair an injury to his shoulder experienced during a skiing accident on January 5, 2005.

Steven had so much to live for. He was a popular sophomore at University of Wisconsin-LaCrosse and aspired to be a physical education teacher and football coach. He made friends easily and was outgoing.

What happened and why did it happen? Steven died as a result of malignant hyperthermia (MH) syndrome, a rare reaction to commonly used anesthetic agents. This syndrome, first recognized in 1960, results from alterations to a specific gene. Unlike many other inherited (genetic) disorders though, these rarely produce symptoms or signs until the patient receives a general anesthetic agent. It is like a viper lying in wait for the right circumstances to strike.

In the 1960s and '70s the diagnosis of MH during surgery was a virtual death sentence; 80% of patients died after experiencing MH. However, thanks to the efforts of many anesthesiologists and other physicians and scientists around the world, deaths from this disorder now occur infrequently during or following the 30 million or so anesthetics administered in the US every year. Anesthesiologists and nurse anesthetists have so many sensitive devices to monitor vital functions—respiration, oxygenation, cardiac function, temperature, and kidney function—that deaths related to anesthesia have become very uncommon, perhaps 1 in 250,000 healthy patients. Therefore, when a death occurs it is a shock and trauma to the entire anesthesia, operating room, and surgical teams. This story focuses on the short- and long-term reactions of the caregivers when a healthy patient succumbs despite the best treatments available.

Where did the term *MH* come from? When the disorder was first formally described, the dramatic and unusual feature of the reaction was an elevation of body temperature to levels incompatible with survival—107-109°F or higher—in medical terms, hyperthermia. Since 80% of patients diagnosed with the disorder died, it was a malignant disorder, hence the name. The reaction was especially impressive because, as a rule, a patient's body temperature has a tendency to drop during anesthesia.

The basic problem in MH is an increase in metabolic rate in response to most gas anesthetic agents, such as sevoflurane and desflurane, and a particular paralyzing drug called succinylcholine. Further details concerning the mechanism of the increase in metabolism may be found on the website of the Malignant Hyperthermia Association of the United States (MHAUS), a not-for-profit patient advocacy group formed by a relative of a young man who died from MH in 1981 (www.mhaus.org).

What has made death from MH a rarity at this time? Three main factors: education of the anesthesia community to screen patients for family histories of MH susceptibility and to recognize the early signs of MH, the routine measurement of exhaled carbon dioxide (CO_2 rises rapidly when metabolism increases) and body temperature, and the US FDA approval of dantrolene sodium IV for the treatment of MH in 1979.

Dantrolene was indeed present in the OR when Steven developed MH, and it was administered to him rapidly and in sufficient doses; however, his case was one of those very unusual circumstances because the development of full-blown MH occurred very late, more than 3 hours into the surgery. Carbon dioxide levels rose very slowly initially, and then raced ahead explosively when the syndrome took hold. Elevation of body temperature, always a later sign of MH, was especially late in his case. So, by the time the anesthesia team determined that MH was occurring and dantrolene should be given, the train had left the station and was racing down the tracks. In fact, the antidote drug did retard the metabolic changes, but unfortunately damage to vital body functions had taken place and over the ensuing 2 days, and despite heroic efforts, Steven's coagulation system went awry and led to massive, uncontrolled hemorrhage.

Steven was not the stereotypical physical education major. He was not afraid to express himself in poetry. For example,

People say, "I'm sorry" when I say I was born on 9/11. . .

But today is a day to be proud of. . .

Today, my birthday, America united

—"9/11" by Steven Nook

"The most shocking things were the subtle clues that this might be malignant hyperthermia (MH)," says Tami Ulatowski, MD, an anesthesiologist with Summit Anesthesiology group who was quickly called in when the staff began to suspect that Steven was displaying signs of MH.

"The younger nurses thought of him as a peer, the older nurses as their son," remembers Kathy Delleman, Intensive Care Unit Manager for Aurora Sinai Medical Center in Milwaukee, WI. Delleman says that it is unusual to identify so closely with a patient, but because of his age, personality, and skiing accident, Steven had qualities that the staff could identify with.

One of the first steps that was taken once the diagnosis was made was to call a special "hotline" established in 1982 by MHAUS in order to help anesthesia caregivers deal with the emergency management of this complex disorder. This free service is staffed by approximately 30 anesthesiologists expert in the management of MH. Three are available at any one time on a 24/7 basis.

Andrew Herlich, DMD, MD, was the MH Hotline consultant at the time. Herlich is Professor of Anesthesiology, Otolaryngology, and Pediatrics, and Medical Director of the Human Simulation Center at the Temple University School of Medicine. Herlich was reassuring to Steven's medical team and was on the phone with them several times a day, having given them his personal home number and beeper number. Dr. Herlich's message was one of support, advice, and reality.

"He told us not to be discouraged even though Steven's temperature reached 109°," says Dr. Wilfrido Castillo, chief of the anesthesiology department at Aurora Sinai. "We knew what we were up against, but because of Dr. Herlich's guidance we knew that we were doing everything we could, and this prepared us in case of a bad outcome."

"I tried to be strong and reassure Steven each time I was with him that he would get through this," recalls Steven's mother, Jacque Nook. "I believe he heard my voice and it gave him some comfort. He must have been so scared. It helped me to know that the monitor on his forehead (that measures the level of consciousness) indicated that Steven was most likely aware of my voice. I rejoiced each time the numbers on the monitor suggested that Steven was hearing me. He knows his mother's voice! So I held it together as best I could, but I was screaming inside."

The hospital staff was still hopeful that Steven would survive, but he wasn't showing signs of improvement. "We felt helpless," says Delleman. "We wanted our interventions to work and they weren't."

A Devastated Medical Staff

As the situation worsened for Steven, it did the same for the medical staff. Despite their professionalism and disciplined approach from years of medical

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Emotional Effects of Loss Are Extensive

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training, an unfortunate MH death can have a devastating, personal effect. An effect that takes time to surmount—one that motivates staff to recheck every move, and in the end, look for new ways to prepare for another MH case.

Stephanie Kassulke was the anesthesia recovery room nurse and because she could identify so well with Steven, she was starting to have a difficult personal time when she saw that Steven was not improving. "When I went home that night, when Steven was still alive, I was crying so hard in the car that I almost had an accident. My kids are that age. They are young healthy kids. You put all of your effort into it to help him make it, and you hope you will get a miracle."

Two days after Steven entered the hospital, he passed away.

Dr. Herlich summarizes, "When Steven's temperature precipitously rose in the OR, the anesthesiologist immediately called for help. He proceeded to treat him by discontinuing the volatile anesthetic, cooling him by all means possible, administering intravenous dantrolene, and correcting the metabolic abnormalities revealed by blood tests. However, over the ensuing hours after transfer to the intensive care unit, Steven developed a severe bleeding problem as well as a problem with heart function."

"As a result of the stress of the MH, Steven developed severe heart and kidney failure over the course of the next 2 days. The bleeding disorder worsened and was unresponsive to even the most advanced of therapies, including dialysis and the administration of many medications and blood products that stabilize blood clotting. During this period, dantrolene was continuously administered to maintain Steven's temperature and blood chemistries as close to normal as possible, which was obviously impossible."

"They (the hospital staff) made every effort to tell us what they were doing, how he was responding, and give us any little hope they could muster," remembers Mrs. Nook, herself a nurse. "However, I could see the frustration in their eyes, when Steven kept getting worse despite their efforts. They wanted to see improvement as much as we did, and it didn't come."

"When they called the code on Friday I knew it was him," says Kassulke. "When he died, I felt a lot of anger."

"This came out of nowhere," says Delleman. "No warning."

Before the procedure, his anesthesiologist had questioned Steven about whether there had been any family history of adverse reactions to anesthesia. This question is part of the screening process for MH and should be asked of all patients about to receive a general anesthetic. In Steven's case, the answer to the question was no known family history. Many MH susceptibles have a benign family history for the disorder because MH does not manifest with every exposure to anesthesia. This fact made the medical staff feel even more shocked, because they had followed the proper screening procedure with Steven.

"The day he passed, there were a lot of tears," says Delleman. "I don't think there were a lot of words. There were more hugs and putting arms around shoulders. Not everybody recovered in the same way. Some were able to move on immediately. For others, it was foremost in their mind. Some are still dealing with it several months later."

"That following Sunday I went to church and cried through the sermon. I would be in the grocery store and the thoughts would infiltrate. It happened during routine things."

Delleman and Kassulke say that the medical staff who have children close to Steven's age had the toughest time recovering. Delleman added, "I myself have a son a couple of years older. When I go home, I look at him in a different light. He had surgery a year ago and could have responded that way."

Kassulke remembers, "I went home that night and I hugged both of my kids and told them I loved them. There were about 2 weeks when you sit down and cry right away just by thinking about it. What I have had to deal with is the lack of control, watching this young man slip through our fingers.

"I'm still having a hard time getting over it. You know in certain circumstances that there is nothing you can do, but this wasn't cancer or hemorrhaging. There was no previously known disease process to help you prepare for what might happen. I went back to work on Monday, but people were asking me what was wrong because I was down, subdued for awhile."

In Remembrance, a child does not age

And so they never leave,

They're in your heart at every stage

Of their life they weave.

—"Remembrance" by Steven Nook, December 2004

Dr. Castillo says that his main concern was with Steven's anesthesiologist: "It was obvious he was having a hard time. There is a decompression time, just like for a policeman or fireman involved in a crisis in the line of duty. He took some time off to be with his family."

Dr. Ulatowski says, "It's the one thing anesthesiologists fear, the MH episode. I think it is every anesthesiologist's worst nightmare. To lose a young, healthy patient in the OR in this day and age is virtually unimaginable, but that is what can happen with MH."

Dr. Herlich says that it can be much more shocking to a medical staff when a young, healthy man walks into a hospital and does not walk out, than if a 90-year-old with pre-existing conditions succumbs. Although saddened by that death as well, he says medical professionals are not as emotionally burdened because the patient has lived a full life, Herlich states.

Dr. Castillo believes that most doctors feel they can carry on after a situation like this, "but we need to admit to ourselves that we are human, and we need to realize that we may not respond in the normal way in the immediate future. We need to give ourselves time to recover. Physicians should be honest with themselves." The same may be said for all those who care for such patients.

Dr. Castillo initially had to push his own emotions aside, and let part of his recovery process include preparing for the next time this might happen. "There are a lot of technical questions: Why did this happen? What did we do? What could we have done? Although I was not emotionally involved because Steven was not my patient, I became involved emotionally with the family later. I shed a lot of tears when I sat down with the family, but one way I dealt with this was to be super prepared for such an event the next time."

The close-knit Nook family itself was a source of support for the hospital staff. Dr. Castillo remembers that the staff and the family supported each other a lot, the first time he had ever seen a family support a staff so strongly. The Nook family even e-mailed poetry and anecdotes to the staff. "My strength comes from inside me and my love for my sons, from my strong faith, and from my wonderful family and friends," Mrs. Nook says. "I attribute my ability to help the staff afterwards, to the fact that we shared this awful, gut-wrenching experience with them, and bonded with them," says Mrs. Nook. "I felt a camaraderie with them I can't explain. They had all the best critical care skills, but saving Steven was out of everyone's reach. We were all in this horrible pain together. I KNEW they were doing the best they could. They used all the best resources available to them."

So when you're lost, or
don't know what to do,

Remember . . .

Life brings with it, what you want it to.

—Untitled poem by Steven Nook

For the family and hospital staff, there was discourse about sadness, support from the hospital chaplain, psychologists, and the Crisis Intervention

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Malignant Hyperthermia Education Must Continue

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Department. The medical staff found that going to Steven's funeral and giving a creative memorial gift helped them recover. "There were several of us who went," says Delleman. "Steven's favorite color was blue, so we purchased a blue candle a foot high in a hurricane glass, with a ring of blue flowers. A surgery nurse and I drove to Steven's aunt's house to present it."

"When we talk about crisis events, for some of the medical staff the sharp professional edge is dulled until the recovery is over," says Marcia Williams, LPC (Licensed Professional Counselor) and Clinical Nurse Specialist in Crisis Intervention and Traumatic Grief at Aurora St. Luke's Medical Center. "One measure of the recovery process is how much the crisis continues to intrude into their daily lives. The disruption is real. So with most traumatic events the recovery time may be 4–6 weeks, but for some it can actually get better within a week."

Ed Foster, the Chaplain Supervisor at Aurora-Sinai, points out that even when a medical professional thinks they have recovered, the sad feelings can be triggered again. "It could be that another person resembling Steven comes in and it brings up all of those feelings again. The trouble is that folks want to judge themselves harshly and think that there is something wrong with them. In that case they may really need to talk about it with another medical professional or even consider therapy. They don't want to take the approach that they have talked about it enough."

Preparing for Next Time

Part of the recovery process involves preparation for another possible MH episode. For example, the staff is planning to have a mock MH drill at least once per year, reinforcing all of the proper steps needed to respond to an MH crisis. These mock drills are emphasized and covered thoroughly in the MH procedure manuals for hospitals, ambulatory surgery centers, and surgical offices produced by MHAUS.

Steps include

- assign specific tasks to staff
- provide checklists and worksheets
- emphasize frequent mock drills.

A slide show called "Managing Malignant Hyperthermia Risk in Today's Surgical Environment" is also available through MHAUS. The slide show assists in developing standard of care practice guidelines and algorithms to ensure that patients will have access to appropriate interventions for treating MH.

Dr. Herlich suggests that MH drills should include failure to control the syndrome with the first lines of therapy. "For instance you are giving your first or second dose of dantrolene and the temperature is still rising, the calcium values are decreasing, the potassium values are rising, and the patient's coagulation is starting to deteriorate. Don't go through a drill as if giving 1 or 2 doses of dantrolene means everything is hunky-dory and the patient walks out the door 1 or 2 days later."

Recovery room nurse Kassulke advises hospitals to increase awareness within all of the inpatient units. For example, if a pregnant woman is about to undergo general anesthesia, ask the father about MH as well to see whether it might affect the baby. She also emphasizes the importance of the immediate availability of an adequate supply of dantrolene. In Steven's case, 90 bottles (450 milligrams) were used in the initial 2 hours of the crisis. "We are fortunate at Sinai because we could pull dantrolene from 5 different hospitals. One of the reasons Steven made it out of OR and into critical care for 2 days is because we were able to get all of that dantrolene. We wiped out just about all of the supply in the Milwaukee region."

Dr. Ulatowski's message from Steven's death is that, "The work of educating and understanding the presentation and optimal treatment of MH is not yet done. Not until there are no more deaths from the disorder."

Dr. Herlich advises the OR team to call the MH Hotline as early as possible. "It is analogous to many other emergency situations. If you think it, you call. Don't wait. If in your mind you have a situation that you can't explain and MH might be occurring, even though the likelihood is low, you should call the MH Hotline."

Mrs. Nook advises patients who are unfamiliar with anesthetics to be aware of any family history of anesthesia problems, and not to take the experience of undergoing general anesthesia lightly. "Little did Steven or anyone else know that this would be an issue. But, just maybe, knowing MH could happen would make the OR team feel the patient's skin a little more often, or maybe, just maybe, catch something going wrong a little sooner."

Conclusion

Over the past 3 decades, the mortality rate for MH has dropped dramatically. However, as we see from Steven's case, death from MH can still occur, even in the best of hands. When it does, it can have a dramatic, traumatic effect on the entire medical staff, one that can bring with it a long recovery time. However, something positive can result. For example a scholarship in Steven's name has been established at his high school, Wauwatosa West, which already has garnered more than $10,000 of community support. Also, the Nook family is participating in the newly available molecular genetics testing procedure to help determine MH susceptibility in other family members. Information as to the diagnosis of MH by laboratory testing may be found at

http://www.mhaus.org/index.cfm/fuseaction/Content.Display/PagePK/MolecularGenetics.cfm.

If the experience of Aurora-Sinai results in more awareness of and preparation for other medical facilities, the MH mortality rate should continue to drop. It is hoped that the experience of the Nook family and the Aurora Sinai staff will perhaps save others from experiencing the same emotional devastation.

So do children, seem to grow

Pretty soon they're on their way

And so you see them pack and go

It may seem a most lonesome day.

But know this is not the case

For they really never leave

Because memories have their place

And leave no room to grieve.

--"Remembrance" by Steven Nook, December 2004

Henry Rosenberg is the President of the Malignant Hyperthermia Association of the United States and Director of Medical Education and Clinical Research at Saint Barnabas Medical Center, Livingston, NJ.
Al Rothstein is the public relations consultant for the Malignant Hyperthermia Association of the United States.

Steven Nook —A victim of MH

Letters to the Editor

Readers Sponsor Successful Legislation

To the Editor:

I could not agree more with the article in the Spring 2006 *APSF Newsletter* entitled "Adverse Events Require Communication and Disclosure."[1] As a current applicant to Indiana University School of Medicine, I think legislation banning the use of an apology or other statements of sympathy as evidence of fault in medical malpractice lawsuits is crucial for the future of medicine. One such example of such legislation was House Enrolled Act No. 1112, co-authored by my grandmother, representative Phyllis Pond, and signed by Indiana governor Mitch Daniels to become effective on July 1, 2006. Of the 4 house co-authors (Foley, Thomas, Kuzman, and Pond), 3 are attorneys and 1 is an educator. Both sponsors in the senate (Kenley and Bray) are attorneys. It was a bipartisan effort to allow a person to express true concern in case of an accident or adverse medical outcome. The bill specifically states in chapter 1, section 3 that "any statement, gesture, act, conduct, or a writing that expresses sympathy, an apology, or a general sense of benevolence" may not be used as evidence in an accident or medical malpractice suit. The bill does, however, still allow admission of "a statement of fault into evidence."[2] I think it is absurd that in many states health care providers feel they cannot express sympathy for fear of a lawsuit. With malpractice patient compensation reaching an all time high, $104 million in 2004 in the state of Indiana alone,[3] legislation allowing caregivers to communicate sympathy to patients without fear of a lawsuit may greatly reduce this figure across the board and foster better physician patient relations. Remember communications of sympathy are not admissible; however, admission of fault may still be admitted into evidence.

Gregory C. Pond
Fort Wayne, IN

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Determination of Physician Competency is Complex

To the Editor:

I read with interest the unfortunate circumstances surrounding the anesthetic mishaps recounted in a recent issue of the *APSF Newsletter* (20(4):61–68), and the equally disastrous ways the hospitals and internal legal advisors handled the mishaps. However, I do disagree with the implied suggestions that the physicians and hospitals failed somehow to ensure that "incompetent" practitioners are weeded out and not allowed to practice. In my opinion, this is an unjustified criticism.

One only needs to compare the 2 systems of justice meted out for an attorney accused of incompetence, and the physician accused of incompetence. I have been involved as a witness in both types of cases. At least in Florida, the system for the attorney is much simpler, and relies on evaluations by peer attorneys, the state bar, and the appointment of a legal hearing officer (usually a retired judge). After a hearing, a recommendation is made by the hearing officer to the state Supreme Court, and a decision is then made by the state Supreme Court regarding the attorney's continued right to practice. The process ends there. There is no right of appeal to another court of law.

A physician has a far lengthier process to go through, both with the hospital, and/or with the state board of medical examiners. This is justified in many ways in order to ensure that a physician's error in judgment is not used as "proof" of general incompetence for purely economic reasons. The federal Healthcare Quality Improvement Act of 1986 established many ground rules for fair hearings for physicians before their privileges can be restricted or revoked by hospitals. Among other provisions, these ground rules limit severely the ability of those with an economic interest in the outcome from having a role in determining the outcome, and guarantees the physician's right of representation by an attorney at all levels of fair hearings. Similarly, it limits the liability of hearing committee members, providing they act in good faith. There is also an appellate process afforded a physician whose privileges have been restricted or revoked. In addition, a series of court challenges usually follows any official action by a hospital board, which, unlike the attorney's situation, does not ensure a trial by the physician's *professional* peers.

It should be understood that these 2 processes are the processes through which attorneys and physicians have their privileges or licensure revoked or modified, and are independent of the tort trials regarding accusations of malpractice. Regarding limitations of practice rights, the legal system is far more streamlined for the attorney, which may or may not be in the individual attorney's best interest. Although the system for the physicians seems to better serve the interests of the individual physician, it also involves many attorneys at all levels of the proceedings, is slow and tedious, is very expensive for all parties except the participating attorneys, and often gives rise to the unjustified criticism that "physicians do not do a good job of policing themselves."

Given the strong economic competitiveness between physicians in the marketplace today, should physicians and hospitals have more autonomy in the revocation or limitation of physicians' privileges and licensure? Having such autonomy, I believe, would lead to abuse in many instances, and ultimately would not serve the best interests of the public at large or the medical community. In spite of such potential abuse, if the public truly wishes the medical community to have a greater ability to regulate itself, the medical community has no ability to do so under the current legal system. Changes in the system would need to be made, and the power to make those changes rests with the federal and state legislatures, one hopes, with responsible medical community input and participation. However, in light of the economic impact of the strong participation by attorneys in the physician hearing process, does anyone seriously think that the legal system wants the medical community to have more autonomy in determining the privileges or licensure of a given physician? Given the current legal processes and economic climate, the criticism of the medical community's "failure to police itself" should be redirected toward better public education about the justified legal limits on the medical community's autonomy in deciding its members' right to practice.

David A. Cross, MD
Scott and White Memorial Hospital and Clinic
Associate Professor of Anesthesiology
Texas A&M Health Sciences Center
Temple, TX

Letter to the Editor

Reader Seeks Balance in Disclosure Requirements

To the Editor:

I was deeply troubled by the "Adverse Events Require Communication and Disclosure" article in the Spring *Newsletter*. I am, like many other physicians, extremely conscientious about patient care and have an excellent rapport with most all my patients. I am completely honest with patients and their families when unexpected complications develop, and am a huge proponent of direct conversations with patients during their hospitalization and with family members immediately after surgery if problems do arise. However, I am in complete opposition to mandated disclosure requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and The Medical Care Availability and Reduction of Error Act in Pennsylvania.

Ms. Trombly, an attorney, starts the article by stating that formalizing the handling of near misses and actual adverse events has become commonplace in other industries such as aviation and manufacturing. This certainly is true, but the airline industry is not mandated to send a formalized letter out to every passenger 7 days after it lands if it had to change the course of another plane to avoid a head-on collision at 30,000 feet. These complications are all handled "in house" unless the industry itself determines it is best to handle them otherwise or is mandated by a court to do so—there is no legal statute requiring this disclosure.

The article continues and describes JCAHO 's institution of a requirement for disclosure of "unanticipated outcomes." She then talks about the legislation passed in Pennsylvania in 2002, entitled "The Medical Care Availability and Reduction of Error Act," which requires a hospital, an ambulatory surgery facility, or a birth center to notify a patient (or patient's family) of a "serious event" in writing within 7 days. The Act defines serious event as "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in the death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient."

Here we go again! Physicians are being treated like second-class citizens in this country. All we have heard for the last 5 years is the protection of individual patient's privacy. Patients can knowingly carry the AIDS virus and never divulge it to anyone. If they are embarrassed that they take an MAO inhibitor for depression they do not have to tell their health care provider if they choose not to. If they were treated for a cocaine overdose last week at another hospital and do not want the records transferred to the hospital that is now taking care of them, they are completely within their rights. We now cannot put their names up on any board that can be seen by other patients and sometimes have almost taken the wrong patient back to the OR so that we can "respect" their privacy. Yet, a physician is supposed to divulge every detail of virtually any unexpected event, regardless of how harmless or mundane it may be, within 7 days after it occurs in writing to the patient. Fairness to the physician—certainly not!

When I took civic class in middle school I learned that we had 3 branches of government (judicial, executive, and legislative) so that there was a checks and balances system to our government. However, the JCAHO has no checks and balances system. If the hospital or outpatient facility fails their inspection or does not heed their request it will not receive Medicare funding. Lord Acton in 1887 described this type of power the best: "Power tends to corrupt, and absolute power corrupts absolutely." The JCAHO requirement for disclosure and The Medical Care Availability and Reduction of Error Act are an infringement of the Fifth Amendment to the Constitution. Despite what attorneys and JCAHO may believe, physicians do not forfeit their civil liberties in this country when they take the Hippocratic oath.

I will quote this relevant portion of the Fifth Amendment: "(No person) shall be compelled in any criminal case to be a witness against himself." At first glance many will say we are not talking about a crime. That is not completely true. First, the constitution is saying that even a criminal should be extended this right. If that is true, and it is true, a physician should at least expect this concession. Secondly, if the physician sends a mandated letter to the patient or their family and attempts to explain his role in the unexpected poor outcome of this event and it is suspected from this explanation that the physician acted in a negligent manner, it can quickly become a criminal lawsuit. Finally, by enacting a law that mandates disclosure, if disclosure is not forthcoming, that individual has now committed a criminal act. The power of the JCAHO and the Pennsylvania legislature does not supercede the power of the framers of our Constitution.

The last topic I will address is the belief that it is possible not to increase your litigation liability with these mandated disclosure requirements. If I ask you to place a black box in your car that only registers times you exceed 75 miles per hour and then ask you to turn this into your State Patrol office at the end of each month, do you think you would increase the likelihood of being issued a citation for speeding? If you went into your local county police station and told them that you often smoked pot and used methamphetamine on the weekends, but had never been charged with drug possession, do you think that the next time your local police officer stops you for a traffic violation that there would be a greater likelihood he would ask for a blood test and/or search your vehicle for drugs? If you put a breathalyzer on your automobile to record your alcohol level every time you started your car and you kept a record of this for a year and at the end of that year a police officer looked at the levels of alcohol you were driving under, do you think there would be a greater likelihood you would be issued a DUI citation than if you were being stopped on a random basis by your local police? Would it not be a reasonable request to put breathalyzers on all vehicles to prevent so many DUI fatalities? The ACLU would say that this encroaches on our civil liberties, even if it is beneficial to the public. Anyone who believes that mandatory disclosure legislation will not increase our legal liability and jeopardize our ability to practice medicine is either being disingenuous or is certifiably insane.

Let me be crystal clear. I am a strong advocate of telling the patient and their family about any complications that arise during a surgical procedure, especially if unanticipated. I also believe that you should present this information to the patient and their family members with compassion and sincerity. However, I do not believe that this disclosure should be mandated. The decision of when and if disclosure is to be made to the patient or their family members should be retained by the physician unless we as a society wish to alter the Fifth Amendment of the Constitution. We should always strive for improvement, and in my opinion this can be obtained through M&M conferences that are sheltered from litigation, and a continuous quality improvements assessment of our practices. To advocate mandatory disclosure for virtually all unexpected/unanticipated events will only lead to a quagmire of what events must be disclosed, fines for not reporting certain events, and more determinations made by a jury of our "peers."

Keith McLendon, MD
Atlanta, GA

Letter to the Editor

ICU Patients Need Careful Monitoring in the MRI

To the Editor:

Dr. Flowerdew's recent letter regarding physical presence during the administration of anesthesia appropriately addresses the issues involved in radiation therapy patients and also recognizes the need for physical presence to "actually administer the anesthetic."[1] The inherent danger from radiation to the provider exists (should one remain present in the room during treatment) and justifies monitoring from a safe distance. This is NOT true for MRI anesthesia, as no significant or recognized physical danger exists in the scanner room to justify monitoring from the next room. The nature of our invasive profession demands rapid evaluation and direct access to patients, ventilators and monitoring equipment, whenever possible. Clearly, when a qualified provider (i.e., CRNA) is physically present to provide continuous patient care at the bedside, an attending physician can provide direction/supervision from outside the room.

To suggest that intensive care physicians be available for electronic remote consultation can, however, detract attention from the paramount need to have an anesthesia caregiver at the bedside, to continually monitor as per ASA basic standards and guidelines. One might hope that ICU patients in Maine also have ICU nurses in close proximity to the patient, especially with their physicians at great distances. Dr. Flowerdew's inference, however, does describe the type of contemporary care ICU patients receive in MRI scanners, when anesthesia is not administered by anesthetists: patients are alone in the scanner, on ventilators with very limited capabilities and alarms, often with sedation and vasoactive infusions, and often without end tidal CO_2 or all other "routine monitors" (i.e., arterial pressure traces and volumetric pumps) they were afforded previously in the ICU and during transport. Removal of all primary providers from the scanner room further decreases safety, as I have previously reported, especially when the scanner room door is closed and opening this door requires the scan to be interrupted.[2]

Mark Warner, MD, may have challenged the audience of his 2005 Rovenstine Lecture to look for new ways to deliver anesthesia care as Dr. Flowerdew reported, but I do not think Dr. Warner intended safety to be actively compromised. We as a profession have been intimately involved with standards for safe sedation in all other hospital areas. I personally view the contemporary challenge to be in insuring the safety of all patients in MRI scanners, by promoting specific national standards for this unique and increasingly commonplace procedure, whenever any form of life support or sedation is employed. This requires defining the benchmark of care via our specialty; thus, raising the threshold for all specialties to follow, by "standing near by in the MRI" and with every appropriate monitor used by conventional standard or during prior care/transport.

In the same issue of this *Newsletter*, the new ASA and AANA guidelines requiring audible alarms for pulse oximetry and CO_2 monitors have been introduced and raise a new question: Will/do current available models reliably provide volumes adequate to overcome the MRI noise and earplugs used while in the scanner rooms?[3] Possibly sound amplification, optical alarms, or other new technologies (i.e., with speakers inside protective headsets) may be needed in this special environment to insure a high level of care inside the scanner room. Similarly, if ICU (or anesthetized) patients continue to be monitored from outside the scanner room, will these monitors be required to alarm to the adjacent room, or will they be turned on, or even be utilized/connected when no one is in the scanner room to react to them? We all recognize the shortcomings of ECG monitors during MRI scanning and the inability of audible alarms to ring to the next room through the closed doors of an MRI scanner. Just what are the "national standards" for MRI monitoring, alarm settings, response times, and qualifications of the "monitoring personnel," especially when an ICU patient on vasoactive infusions is placed on a ventilator in a MRI scanner? I think adequate "standards" remain to be adequately defined for ICU patients. Scanner technicians are not typically trained nurses or otherwise qualified to monitor intensive care patients or sedation from the scanner room. Are gravity infusions via "dial-a-flow" or micro-drip sets with intermittent NIBP measurements used when MRI compatible pumps and pressure transducers are not available? Should this be acceptable now, when modern technology is at hand? Shouldn't nurses and respiratory technicians be physically present in the scanner to monitor their patients and equipment, just as in the ICU? The radiology physicians are furthermore not typically present or particularly familiar/engaged with life support equipment either, especially in the "off hours," when scanners run around the clock to amortize their acquisition costs.

Paul M. Kempen, MD, PhD
Pittsburgh, PA

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FDA and NIOSH Issue Warning About Oxygen Regulator Fires and Incorrect Use of Seals

The following report was issued on April 24, 2006, to warn providers of fires that may occur at the interface of oxygen regulators and cylinder valves resulting from the incorrect use of CGA 870 seals.

FDA has received 12 reports in which regulators used with oxygen cylinders have burned or exploded, in some cases injuring personnel. Some of the incidents occurred during emergency medical use or during routine equipment checks. FDA and NIOSH believe that improper use of gaskets/washers in these regulators was a major factor in both the ignition and severity of the fires, although there are likely other contributing factors.

Two types of washers, referred to as CGA 870 seals, are commonly used to create the seal at the cylinder valve / regulator interface: The type required by many regulator manufacturers is a metal-bound elastomeric **sealing washer** that is designed for multiple use applications. The other common type, often supplied free-of-charge with refilled oxygen cylinders, is a plastic (usually Nylon®) **crush gasket** suitable for single use applications.

The nylon crush gaskets require higher torque than the elastomeric sealing washers in order to seal the cylinder valve / regulator interface, and if they are used again, they require more torque with each successive use. The cylinder valve / regulator connection is designed to be hand-tightened. If the crush gaskets are re-used, the need for increased torque may require using a wrench or other hand tool, which can deform the crush gasket and damage the cylinder valve and regulator. This can result in leakage of oxygen past the cylinder valve seat and across the nylon crush gasket. According to a forensic analysis supported by FDA and NIOSH, "flow friction" caused by this leakage of compressed oxygen across the surface of the crush gasket may produce enough thermal energy to spontaneously ignite the nylon gasket material.

Recommendations

FDA and NIOSH recommend that plastic crush gaskets never be reused, as they may require additional torque to obtain the necessary seal with each subsequent use. This can deform the gasket, increasing the likelihood that oxygen will leak around the seal and ignite.

The following general safety precautions should also be taken to avoid explosions, tank ruptures, and fires from oxygen regulators.

- Always "crack" cylinder valves (open the valve just enough to allow gas to escape for a very short time) before attaching regulators in order to expel foreign matter from the outlet port of the valve.
- Always follow the regulator manufacturer's instructions for attaching the regulator to an oxygen cylinder.
- Always use the sealing gasket specified by the regulator manufacturer.
- Always inspect the regulator and CGA 870 seal before attaching it to the valve to insure that the regulator and seal are in good condition and the regulator is equipped with only one integral metal and rubber seal that is in good condition. Avoid plastic seals.
- Tighten the T-handle firmly by hand, but do not use wrenches or other hand tools that may over-torque the handle.
- Open the post valve slowly, while maintaining a grip on the valve wrench so that it can be closed quickly if gas escapes at the juncture of the regulator and valve.

Reporting to FDA

To report your experience regarding the devices in this Notification, please use MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm.

Getting More Information

If you have questions about this notification, please contact April Stubbs-Smith, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voicemail message at 301-594-0650 and we will return your call as soon as possible.

See "Fires," Next Page

"Fires," From Preceding Page

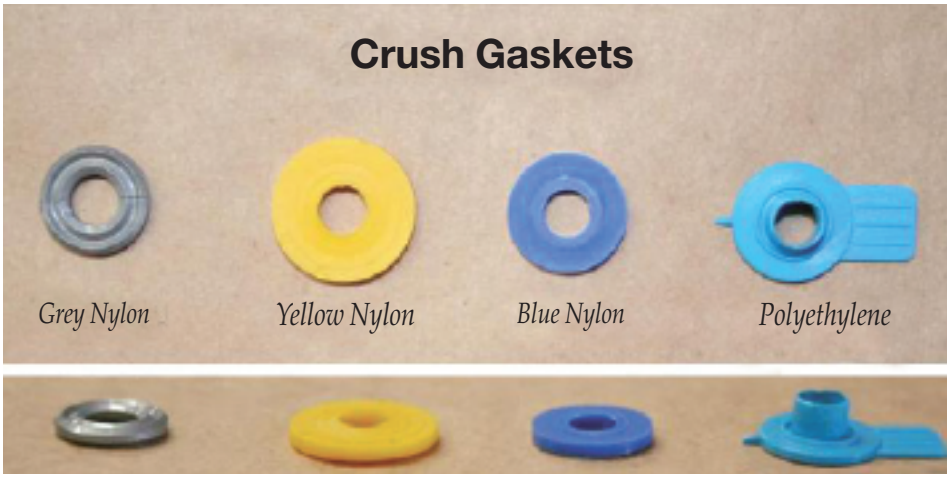

Figure 1 : Examples of crush gaskets available for CGA 870 type medical post valves.

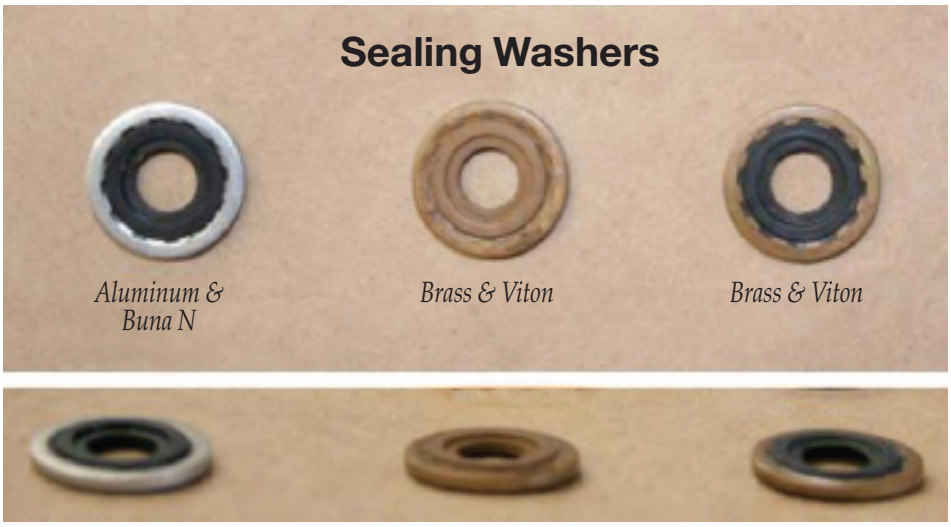

Figure 2: Examples of some sealing washers available for CGA 870 Style medical post valves.

FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html. You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit http://list.nih.gov/archives/dev-alert.html.

Editor's Note:

The preceding warning and recommendations were issued by Daniel Schultz, MD, Director, Center for Devices and Radiological Health, Food and Drug Administration and Nancy Stout, EdD, Director, Division of Safety Research, CDC, NIOSH.

The letter encouraged all readers to copy and distribute this information. The *APSF Newsletter* is pleased to be able to assist in the dissemination of this important safety information.

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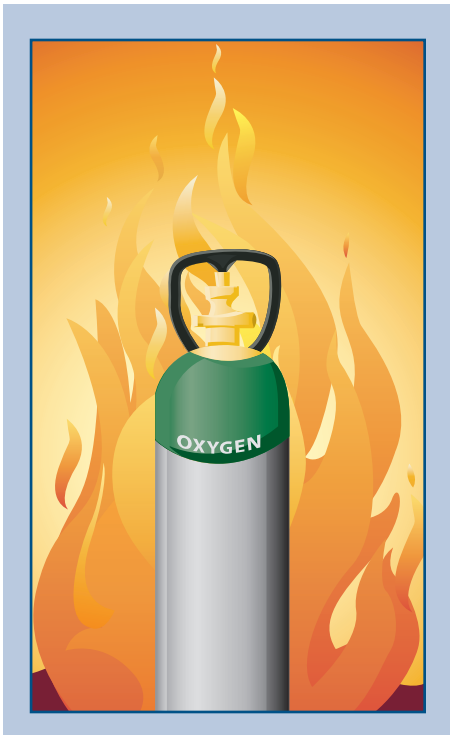

Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922

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