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# NEWSLETTER

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# APSF Stresses Use of Audible Monitor Alarms

*(Reprinted with permission from the* ASA NEWSLETTER, *2004;68(6):25-6.)*

*by Robert K. Stoelting, MD*

Monitoring the patient's physiologic function during anesthesia is intended to facilitate, but not replace, the constant vigilance of the anesthesiologist. In this regard, monitors may be viewed as adding an "additional safety net" for the vigilant anesthesiologist. Since the adoption of the ASA's "Standards for Basic Anesthesia Monitoring" by the House of Delegates on October 21, 1986, there has been an evolution of monitoring technology and consensus among anesthesiologists, which is reflected by the amendment of these monitoring standards on October 21, 1998, to include pulse oximetry and capnography.[1]

The existing Standards for Basic Anesthetic Monitoring include "an oxygen analyzer with a low oxygen concentration limit alarm" and "use of a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded." Since these standards were last amended, the development and availability of audible information signals as part of the physiologic monitors has continued to evolve. Further, one of the national patient safety goals of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is to "improve the effectiveness of clinical alarm systems."[2] This JCAHO safety goal includes the statement: "Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit."[2] The JCAHO's suggestions for meeting this goal and its recommendations are to "develop and implement policies that prevent turn-off capabilities for alarms."[2] In a report of 1000 anesthetic incidents, the fact that an "alarm sounded" was recognized as one of the most important factors in minimizing the severity of the incident.[3]

Despite the compelling logic for utilizing audible information signals to enhance the anesthesiologist's vigilance, the reality is that audible physiologic alarms may be viewed as distractive and disruptive by physicians, leading to the routine practice of "silencing" the alarms.[4] Audible alarms may not provide valid physiologic information and may be associated with patient interventions and events already known by the anesthesiologist. Furthermore, how many audible alarms (and their variety of tones) are really needed? These questions have led the Anesthesia Patient Safety Foundation (APSF) to announce the following initiative:

*The APSF will publish [in this edition of the* APSF Newsletter*] a discussion of the use of audible alarms on physiological monitors and the use of an audible beep tone from the pulse oximeter during all anesthetics. In addition, the APSF will sponsor an APSF Board of Directors' workshop on this topic on October 22, 2004, in Las Vegas, NV.*

Although the announced APSF initiative is focused on the operating rooms, the intent is for the discussion to extend beyond the operating room to include high-acuity monitoring areas in the hospital. The APSF will solicit input from anesthesiologists and the equipment industry to better understand the value (and flaws) of existing audible information signals, and how improvements can be made to decrease the perceived disruption and distraction that may be created by existing audible alarms.

**See "Audible Alarms," Page 19**

## Inside:



## *Gaba Appointed Simulation Dean*

*David M. Gaba, MD - New Associate Dean for Immersive and Simulation-Based Learning at Stanford University.*

David M. Gaba, MD, Director, Patient Safety Center of Inquiry at VA Palo Alto Health Care System and Professor, Department of Anesthesia, Stanford University, has been named to a new position as the Associate Dean for Immersive and Simulation-Based Learning at Stanford University effective July 1, 2004. In this role, Dr. Gaba will have the responsibility of defining how that institution should use immersive and simulation-based technologies to support clinical, research, and educational missions. This will include coordinating programs at the VA Hospital, and in the Departments of Surgery and Pediatrics. Dr. Gaba is a world-renowned expert on patient safety and simulation. He is a member of the APSF Board of Directors and Executive Committee and serves as the Secretary of the APSF. Dr. Gaba is to be congratulated for his career-long dedication to patient safety and this accomplishment, which represents one of the first simulation deanships in the United States.

*Lorri A. Lee, MD*

***Assistant Professor***
***Department of Anesthesia***
***University of Washington***

## *Recent Appointment to APSF Editorial Board*

## *Lorri A. Lee, MD*

Lorri A. Lee, MD, has recently been appointed to the Editorial Board of the Anesthesia Patient Safety Foundation. She has contributed a number of important articles to the *APSF Newsletter* and continues to be an important resource. Dr. Lee completed her anesthesiology training at the University of Washington in Seattle, Washington, and is currently an Assistant Professor in the Department of Anesthesiology at that institution. She is a member of the ASA Closed Claims Project Committee, which studies adverse patient outcomes and liability associated with anesthesia. Recent investigations from this group have included complications associated with regional anesthesia, central lines, and chronic pain management. Dr. Lee's primary area of interest is perioperative visual loss, and she is involved in both intraoperative and epidemiologic research focused on this topic. She is Director of the ASA Postoperative Visual Loss Registry, and a member of the newly formed ASA Perioperative Blindness Task Force. The APSF welcomes Dr. Lee to the Editorial Board.



# APSF Executive Committee Invites Collaboration

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


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# Audible Alarms Provide Safety Net

**"Audible Alarms," From Page 17**

Ultimately, any change in monitoring standards that speaks to the use of audible alarm signals will be based on consensus and cooperation between anesthesiologists and those manufacturers who incorporate audible information signals in physiologic monitors.

It is my personal bias that the audible presence of the "beep" tone from the pulse oximeter, plus knowing that the audible alarm on at least one physiologic monitor of the anesthesiologists' choice (oxygen saturation, end-tidal carbon dioxide, heart rate, blood pressure) is active, would provide the desired safety net to the anesthesiologists' eternal vigilance without the distraction that may be created by a "chorus" of alarms sounding without valid physiologic reasons.

The APSF intends to provide the forum for these discussions and urges input from anesthesiologists and manufacturers on this important anesthesia patient safety question.

*Dr. Stoelting is the President of the Anesthesia Patient Safety Foundation, former Chair of the Department of Anesthesia at Indiana University, and the author of numerous classic anesthesia textbooks.*

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[PRESS RELEASE]

# *ISMP Launches Medication Safety Self Assessment*

The Institute for Safe Medication Practices (ISMP), in partnership with the Health Research and Educational Trust (HRET), and the American Hospital Association (AHA), has launched the 2004 ISMP Medication Safety Self Assessment® for hospitals. The assessment is being distributed to hospitals across the country. ISMP estimates that the preliminary aggregate national data will be released in late 2004.

Conducted for the first time in 2000, the assessment allowed US hospitals to gauge their use of nearly 200 characteristics and practices that most significantly influence safe medication use and identify challenges and opportunities for change over time. In August 2003 ISMP received a grant from The Commonwealth Fund to fund the 2004 ISMP Medication Safety Self Assessment®. The 2004 assessment will help participating hospitals measure their progress in medication safety since the last survey and allow all hospitals to compare their current systems and practices to other demographically similar hospitals nationwide.

The 2004 ISMP Medication Safety Self Assessment® will also assist in the development of educational tools and training materials to further enhance safe medication administration.

"Hospitals and health systems share a fundamental commitment to providing every patient with safe, high-quality care. To meet that commitment we are continually examining the way care is delivered and looking for ways to improve," said Dick Davidson, president, AHA. "The 2004 Assessment will enable the field to identify where we've made progress in the past 4 years, as well as opportunities for improvement."

Michael Cohen, president, ISMP, said, "Much has happened in the area of patient safety since 2000, and we feel the 2004 assessment results will uncover the progress US hospitals have made over the last 3 years and help determine whether the current challenges in health care have affected medication safety systems."

"In an effort to regain the public's trust and to continue the journey of building a safer health care system, honest assessments of medication safety, such as this one, are needed to identify processes and organizational infrastructures that place patients at risk," said Mary Pittman, president, HRET.

Hospitals are being asked to convene multidisciplinary teams to respond to the survey and provide a wide range of perspectives for the most complete data set possible. The experience of completing the assessment will enrich a variety of health care providers' efforts to improve the safety of medication use practices. Hospitals should also be aware that the surveys are completely confidential and the identities of participating organizations will not be revealed, only aggregate data.

Many leading organizations have endorsed and supported the 2004 Assessment. For more information and for a list of the endorsing organizations, please visit www.ismp.org.

## The Institute for Safe Medication Practices (ISMP)

The Institute for Safe Medication Practices (ISMP) is a 501c(3) nonprofit organization that works closely with health care practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 30 years of experience in helping health care practitioners keep patients safe, and continues to lead efforts to improve the medication use process. In 2004, the Institute is celebrating the 10th anniversary of its official incorporation as a nonprofit organization. For more information on ISMP, visit www.ismp.org.

## Health Research and Educational Trust

Founded in 1944, the Health Research and Educational Trust (HRET) is a private, not-for-profit organization involved in research, education, and demonstration programs addressing health management and policy issues. HRET, an American Hospital Association affiliate, collaborates with health care, government, academic, business and community organizations across the United States to conduct research and disseminate findings that shape the future of health care. Visit HRET's website at www.hret.org.

## American Hospital Association

The American Hospital Association (AHA) is a nonprofit association of health care provider organizations and individuals that are committed to the health improvement of their communities. The AHA is the national advocate for its members, which includes almost 5,000 hospitals, health systems, networks and other providers of care and 37,000 individual members.

Founded in 1898, the AHA provides education for health care leaders and is a source of information on health care issues and trends. For more information, visit the AHA Website at www.aha.org.

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# Pulse-OX Tone Conveys Vital Information

*by Julian M. Goldman, MD, and Frederick A. Robertson, MD*

The value of audible clinical alarm signals is widely recognized.[1] As of January 1, 2004, all Joint Commission on Accreditation of Healthcare Organizations (JCAHO) health care facilities are required to comply with a set of 7 National Patient Safety Goals.[2] Goal #6 is to "improve the effectiveness of clinical alarm systems" and requires that alarms are "activated" and "are sufficiently audible." Integral to the ongoing national analysis of the JCAHO requirements is a question regarding the applicability of goal #6 when an "operator" (clinician) is present—such as in the OR.[3,4] Similarly, there is a long-standing debate among anesthesiologists about the utility of audible clinical alarm signals in the operating room.

The argument supporting the use of audible alarm signals is straightforward: Audible alarm signals can enhance vigilance by directing the clinician's attention to out-of-bounds parameters. Undoubtedly, we have all experienced the benefits of timely and effective audible clinical alarm signals in the OR.

The argument against the mandated use of audible clinical alarm signals in the OR is based on a subjective risk-benefit analysis of the alarms. Yes, alarms might be useful, the argument goes, but the cacophony of alarm signals during critical periods of anesthetic management may distract and overwhelm the clinician.[5] As a result of cognitive overload, vigilance may be diminished, not enhanced.[6] These perceptions of the performance of extant clinical alarm systems appear to be universally held. Thus, many anesthesiologists silence physiologic alarms.[7] Unfortunately, unlike machines, we are not eternally vigilant,[8,9] and the silencing of intraoperative physiologic alarm signals has resulted in clinical disasters.

To be clear, the debate about the usage of audible clinical alarms applies primarily to physiologic alarm conditions (e.g., ECG rhythm, blood pressure) and not to some of the "equipment" technical alarm conditions that are integral to medical devices. For example, the US national safety and performance standard for anesthesia workstations requires an audible alarm signal to indicate failure of the oxygen supply and the presence of sub-atmospheric breathing system pressure, among other conditions.[10]

The complexity of deploying effective clinical alarm systems that have adequate sensitivity and specificity for the detection of clinically significant events is becoming widely recognized.[11] Various "intelligent" alarm systems have been considered for years.[12-14] In fact, the newly published international alarm system standard has a section (201.2) dedicated to intelligent alarm systems.[15] However, the intelligence of alarm systems is hampered by their inability to be "aware" of the context of clinical management.[16] For example, absence of contextual awareness may prevent an "intelligent" alarm system from correctly displaying the alarm message generated by a hypotensive non-pulsatile arterial blood pressure tracing. For this situation, is the appropriate alarm urgency "high priority" to direct our attention to unexpected cardiac arrest; "medium priority" for a partially occluded arterial catheter; or is no alarm necessary since the changes are due to the initiation of cardiopulmonary bypass?

Despite the limitations of current clinical alarm systems, anesthesiologists have enthusiastically embraced one clinical alarm sound that isn't strictly an alarm: it is an information signal. The audible "pulse tone," "saturation tone," or "beep tone" of the pulse oximeters has become indispensable for modern anesthetic practice. According to the requirements of the US national standard for pulse oximeters, the variable pitch tone (if present) must parallel the $SpO_2$ reading.[17] Thus, the pulse tone conveys pulse rate, pulse regularity, and changes in $SpO_2$. The matching of changes in pulse tone to changes in $SpO_2$ seems to be based on an intuitive relationship that appeals to "clinical sense." And, by virtue of conveying this information, the pulse oximeter fulfills the definition of an alarm, which is "communicating information that requires a response or awareness by the operator."[18] The pulse oximeter's values can be affected by a variety of physiological changes, so the high-level information conveyed by the instrument must be interpreted with other data to provide a diagnosis and guide corrective action. Nevertheless, it is precisely the real-time, high-level assessment of general cardiopulmonary performance that underlies the instrument's value. Consequently, as anesthesia providers, we are not the only clinicians in the OR to respond to the pulse tone. Surgeons routinely use the tone to guide interventions.

With due respect to the long-standing debate about the "limited proven clinical value" of pulse oximetry for intraoperative management, the jury of clinicians has spoken: pulse oximetry has become the de-facto standard of care for intraoperative monitoring of oxygenation, and the pulse tone is the one monitor that is always heard in almost every operating room. Isn't it time that we mandate the use of the pulse oximeter pulse tone for the monitoring of all patients undergoing general anesthesia and incorporate this requirement in the ASA Standards for Basic Anesthetic Monitoring?[19] If so, we must explore related issues, such as the necessity of standardizing the pulse oximeter's pitch-saturation values.

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**See "Pulse Oximeter," Page 23**

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## Dear SIRS

# $O_2$ Blender Causes Concern

**S** AFETY
**I** NFORMATION
**R** ESPONSE
**S** YSTEM

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

**Dear SIRS** refers to the **Safety Information Response System**. The purpose of this column is to expeditiously communicate 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:

Is it fair to assume that a gas outlet fitting indexed to the oxygen diameter index safety system (DISS) should guarantee that 100% high pressure oxygen is indeed delivered at its output? Is it acceptable that an air-oxygen blender output is indexed to this oxygen standard, yet 21% oxygen can be delivered by this connection?

I ask these questions because we have recently had an incident at my hospital in Kettering, Ohio, where an anesthesia machine was connected to such a blender via a standard oxygen hose. This happened in an MRI unit that recently acquired an anesthesia machine to initiate the provision of general anesthesia. The blender was set at 21%. Of course, the low oxygen alarm within the anesthesia machine sounded shortly after the start of the anesthetic, and fairly quickly the problem was discovered.

I'm alarmed that the position statement of other departmental administrators is that we just pay attention to what we hook up (granted). They see no concern about the bigger issue of why the DISS is not protecting us against the delivery of unintended gas. Have the manufacturers of oxygen blenders subverted the system, or is this just a glitch in the standard? Should this go out as a sentinel event? I'd appreciate your input.

*Randy Ralston, MD*
*Chief of Anesthesia*
*Kettering Memorial Hospital*
*Kettering, OH*

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**Editor's Note:** *Responses from several blender distributors acknowledged that these blenders do have male DISS oxygen outlet fittings. Below we reproduce a particularly helpful response from Mr. Tom Green of Paragon Service, a distributor of oxygen blenders. He speaks in reference to his particular SmartBlend blender, but the points are valid for this discussion.*

### Dear SIRS (In Reply):

1. Fittings on anesthesia machines and blenders are diameter index safety system (DISS). On the rear of an anesthesia machine or blender are fittings specified to medical air, oxygen, etc. All anesthesia machines have a male DISS on the rear. Our SmartBlend blender has a male air DISS and a female oxygen DISS. Crossing gas connections would be difficult. The opposite end of our hoses would also be specific to air or oxygen.
2. The SmartBlend uses pipeline medical air, not room air. The setting on the SmartBlend is dialed in to 21-100% oxygen output. An integral digital oxygen monitor (with high and low alarms) is part of the unit. Should there be no air or oxygen available into the unit, it can only give either 21% or 100% oxygen, and will be confirmed by the oxygen monitor.
3. The outlet fittings on the SmartBlend are Oxygen DISS. We have attached a 1-15 LPM oxygen flowmeter. We could and would be willing to install an air flowmeter. There are no flowmeters available for air/oxygen mixture. I was told that "enriched" air is considered oxygen, which may be debatable and arguable. We will supply either at the customer's request. There are air flowmeters available with DISS fittings. We remove the male oxygen DISS outlet fitting and put a male/male 1/8" NPT fitting into the flowmeter.

### Subsequent information from Tom Green follows:

The issue that has arisen is which fittings/connectors should be used on a blender. The factory fittings are oxygen male DISS with check valve. We removed one of the oxygen DISS fittings and installed an oxygen flowmeter. I had a discussion with Bruce Brierley, President of Maxtec (Salt Lake City, UT), who said that an enriched (>21%) mixture is considered oxygen in the respiratory therapy environment.

The opposite could be argued. We could install an air flowmeter, but air is 21%. So that is not completely accurate either. Since there is not a flowmeter for a mixture of 21-100% oxygen, one of the two needs to be chosen. Both are correct, and both are wrong. We have chosen the oxygen flowmeter for the SmartBlend at this time.

I believe the much more important discussion needs to revolve around the SmartBlend itself and the safety features of the SmartBlend. It is the first device that allows anesthesia providers the capability of delivering an auxiliary mixture of 21-100% oxygen of their choosing (e.g., during MAC with a nasal cannula). Currently, most use only the 100% auxiliary oxygen flowmeter attached to the anesthesia machine. One hundred percent oxygen is not required for most patients via a nasal cannula and is very hazardous in case of a fire.

*Tom Green*
*Paragon Service*

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**Editor's Note:** *The* APSF Newsletter *and the APSF Committee on Technology wish to solicit input from readers, specifically asking if others have had similar problems, experiences, or concerns. Do you think we need a new standard DISS fitting, and thus new blended flowmeters for oxygen/air mixtures?*

**See "$O_2$ Blender," Next Page**

# Blender Manufacturer & Distributor Reply

**"$O_2$ Blender," From Preceding Page**

*Oxygen blender showing Oxygen DISS outlet fitting (left), and machine mounted blender showing auxilliary flowmeter (right).*

## Dear SIRS:

The following information may be useful in the discussion regarding outlet fittings on air/oxygen blenders. You may want to preface the information by indicating it comes from the world's largest manufacturer and original patent holder of medical gas blenders, Bird Products Corporation, a subsidiary of VIASYS Health care.

Air/oxygen blenders were developed more than 30 years ago for use predominantly in conjunction with mechanical respirators. When developed, the decision to utilize oxygen DISS outlets seemed logical based on the fact that the gas being delivered from the blender would, in most cases, have a higher concentration than 21%. Since there is no DISS standard for a "mixed" gas, it was reasoned that using an air fitting would be more misleading than using the oxygen fitting, and thus a standard was established.

The oxygen DISS outlet fitting is used on all medical gas blenders worldwide, including blenders used for nitrous oxide/oxygen mixing. With an estimated installed base of more than 250,000 gas blenders in the respiratory care market, the use of the oxygen DISS fitting has become accepted as the standard and is used by all known blender manufacturers.

*Kris Ukkestad*
*Director, Sales Operations*
*VIASYS Critical Care*
*Palm Springs, CA*

## Dear SIRS:

The Smartblend system incorporates the use of the Maxblend low flow blender which has a 0-30 LPM maximum flow range. Since the gas machine $O_2$ inlet requires 50 psi, it would have warnings that would indicate to the user that the $O_2$ supply is not adequate. Therefore, I would recommend to people interested in blenders for anesthesia that low flow is preferred.

The reasons a clinician would want to have a blending device in the OR are

1. The ability to give less than 100% oxygen easily through an auxillary flowmeter, which is important for neonates or fire prevention protocols for some procedures.
2. Perfusion equipment.

Let me know if I can provide anything else for you.

**Bruce Brierley**
*President*
*MAXTec, Inc..*

Editor's Note: ***While these letters make several valid and important points, it is important to NOT withhold supplemental oxygen from those patients for whom it is indicated by clinical judgment. The APSF Newsletter invites readers' thoughts and comments on this topic.***

***Check out the upcoming Fall Issue for a preview of the 2004 ASA Safety Highlights.***

# New APSF Contact Information

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# Pulse Oximeter References Continue

**"Pulse Oximeter," From Page 20**

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Letter to the Editor:

# Deriving the Most Benefit from Bar Coded Medication Administration

**To the Editor:**

Dr. McLesky's article "Bar Coding May Reduce Drugs Errors" was remarkable for its optimism about this technology. The few research-based examinations of the efficacy of these systems do not support such an optimistic view. Instead, they indicate that, like other complex information technology, bar coded medication administration (BCMA) is likely to create new problems, open new pathways to failure, and generate a new variety of counter-productive incentives in an environment already rather well-burdened with them.

One published study of the Veterans Administration BCMA system shows that BCMA application produces rigid sequencing of work, narrow "keyhole" computer generated views of work process, and potential for precise timing and tracking of bar code reading activities—all characteristics that poorly match the needs of workers in busy clinical settings.[1]

For example, BCMA may increase both the pressure to produce records showing "on-time" delivery and the penalties for failing to do so. The time delays associated with ordinary order entry, processing, review by pharmacy, and medication "delivery" to the caregiver fluctuate with the tempo of operations. Confronted with interruptions or critical needs, caregivers may divert the drug from one patient to another. From a BCMA perspective, this is either wrong drug or wrong patient, and generates a time-stamp that is difficult or impossible to reconcile.

Similarly, apparent improved performance on "right time" measures may reflect work-arounds as much as real progress. We have been told of instances where nurses have photocopied patient wristbands and scanned them to generate "right time" documentation for the computer while actually delivering the medication at a different time. The incentives to do this are the difficulty in working with balky equipment, the rigid structure of work enforced by the information technology, and the potential for becoming a statistical quality control point outside "acceptable limits." The important patient safety consequence is the loss of BCMA's potential value in assuring the "right drug" delivered to the "right patient." There are no data on how often this sort of work around is actually used; it is likely more common than we could be comfortable with.

Audits of administration time made possible by BCMA are a potent incentive for practitioners to adopt practices that increase their "on time delivery," but undo the potential increase in safety from such systems. But what are the underlying drivers for the practices that we perceive to be unsafe? Is it laziness? Moral turpitude? Willful disregard of safety by capricious practitioners? We think not. Instead, the causes of this behavior include ongoing short-staffing of nurses, the lack of high quality support tools to manage work at the bedside, and so forth. None of these are addressed by the institution of BCMA.

## Authors advocate eliminating timing data

Avoiding perverse incentives may mean sacrificing lower priority goals for higher ones. We have a concrete recommendation for proponents of BCMA. Throw away the timing data. The pressing motivation for BCMA was the desire to prevent wrong medications being given by providing computer-based matching of patient with drug. Make that the cornerstone of the BCMA safety program. Rather than have the computer record the time the band was "scanned," have it record only that the drug was given sometime during the shift. Eliminate all automated recording of timing. Allow workers to enter the actual time if they choose to do so. Doing this will remove the incentive to "game" the system, and send a clear message about what really matters—that matching drugs and patients is vastly more important than small discrepancies in administration times.

## Greatest value is insuring the right drug for the right patient

The introduction of BCMA into more widespread clinical use will reduce the incidence of some problems and create new ones. Careful design of such systems and deliberate avoidance of perverse incentives will increase the chances that they improve safety rather than hamper it.

*Michael F. O'Connor, MD*
*Mark Nunnally, MD*
*Richard I. Cook, MD*
*Chicago, IL*

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Letter to the Editor:

# Surgeon Patient Suffers Poor Quality Care — Advocates for Professionalism

I would like to relate an experience I recently had at what is felt to be the premier hospital in our region. I am a surgeon at another institution and had a major elective procedure performed that was not available at my hospital. I participated in the usual preoperative screening and reported at 5:30 a.m. for my planned 7:30 case.

While in the holding area, a man pulled my chart, and on questioning, stated he was an anesthesiologist. He did not ask any questions, nor did he examine me in any way. After replacing my chart, he wandered off. A middle-aged woman next pulled my chart, and on questioning replied to me she was a nurse anesthetist. She asked no questions, neither did she check my airway or examine me in any way.

A few minutes later, the anesthesiologist came back with Versed and administered 1 mg (I asked). I have no memory lapse for that time period. Several minutes later, the crew came to take me into the OR. A completely new young man stated, as he pushed something else in my IV, that he was the student nurse anaesthetist. From that moment on, I have no recall of events until PACU.

I am a physician, and even as such, to this day I have no idea who actually administered my anesthetic, nor what was done. I am grateful there were no complications, as no one questioned nor examined me, much less informed me of the plan, options, or risks.

I feel this is an example of bad care and dangerous medicine. If anesthesia providers want to function as simply a machine that performs a task, they should expect to be treated, and reimbursed as such.

As a surgeon, I consider my anesthesia providers partners in the care of the patient. I am present for the induction and wake-up of my patients, and feel I can speak with some authority on the subject. I could not and would not take patients to an institution where what I experienced was thought to be an acceptable standard of care.

*Name withheld by request.*

**The Editor of the *APSF Newsletter* invites readers' comments on this letter and this physician's experience.**

# HRO is Key Concept for Health Care

*by Jackie Luchsinger RN, MS, and Carolyn Pexton*

While debate continues over various estimates on the number of medical errors occurring in the United States, there seems to be general consensus that health care is not as safe and reliable as it should be. One of the notable exceptions in recent years is anesthesiology. Improvements made over the past decade have reduced the number of deaths attributed to anesthesia 25-fold from 1 in 10,000 anesthetics to 1 in 250,000 today. As reported in the January 26, 2004, issue of *Newsweek*, Americans now have 40 million surgical procedures under anesthesia each year, and only about 160 die of anesthesia-related complications.

Yet when those deaths occur, especially in high profile cases such as *First Wives Club* author, Olivia Goldsmith, who died recently during a cosmetic procedure, the organization and the industry are understandably scrutinized regarding the risks involved with even minor surgery, and involving even a relatively "safe" procedure such as anesthesia.

Strategies for measuring and mitigating risk have received increasing attention in many industries including law enforcement, fire service, and medicine. Since the tragic events of 9/11, America's efforts toward ensuring homeland security have been strengthened, covering multiple areas, requiring significant resources, and involving far more than the raising or lowering of the nation's threat level. In aviation, despite a few well-publicized exceptions, the industry has effectively minimized the number of fatal accidents, allowing thousands of daily flights to take-off and land safely without incident.

Health care has gotten a lot of attention lately for mistakes that adversely affect both quality and cost. An item in the *Philadelphia Inquirer* (2/1/04), reported research from the federal Agency for Health care Research and Quality (AHRQ) finding that US surgical teams leave instruments inside patients 2,700 times per year, creating a total annual cost of $36 million. This is despite the fact that such errors are classified by the National Quality Forum as being among 27 medical events that "should never occur in health care," and that surgical teams count items (often as many as 200 to 500 per procedure) to ensure they are not left in patients. Even with strong patient safety programs in place, such errors can occur.

There is no "silver bullet" to completely eliminate risk, but there are steps that can be taken to create a culture of safety and develop a high reliability organization (HRO). HROs have been defined as organizations that have been able to consistently reduce the number of expected or "normal" accidents—through culture change, technology, and other means—despite an inherently high-stress, high-tempo environment. Researchers have studied such organizations to uncover best practices that can be more widely applied.

Achieving HRO status in an environment such as health care, which is fairly unpredictable and increasingly complex, is not an easy task. But efforts to nudge the industry in this direction have been mounting, especially since the release of the IOM reports on medical error rates. A wide and growing array of agencies, such as the Anesthesia Patient Safety Foundation, Leapfrog, the Institute for Safe Medication Practices, the National Quality Forum, and the National Patient Safety Foundation, are dedicated in one way or another to the pursuit of quality and risk management in health care.

Among such organizations there is general consensus on the goal to improve safety, yet differences of opinion remain on the precise path to reach that goal. In many cases, traditional methods such as TQM (Total Quality Management), PDCA (Plan-Do-Check-Act) and CQI (Continuous Quality Improvement), have fallen short of their original expectations. Despite an increasing push for accountability and transparency in medicine, errors are difficult to capture and quantify, and can include everything from not following a patient's dietary guidelines, to mistakes in medication administration or failure to match blood type during a transfusion. Finding a way to improve even a single process within a hospital, however, can yield measurable benefits in terms of both cost and quality.

For example, a recent Six Sigma project that targeted the reduction of bloodstream infections in 1 intensive care unit (ICU) allowed the hospital to exceed CDC guidelines, reduce infection rates by 75%, and generate an estimated $1.2 million per year in savings. There was a statistically significant improvement in 1 SICU, based on approximately 75 central line catheters per month between January and August and an expected 2 infections per month.

Some factors behind the success of this project include the following:

- Clear standard operating procedures were established for each step of the process.
- Audiovisual training in addition to traditional training methods was provided for all staff.
- New barrier precaution kits were assembled.
- Patient satisfaction, literature, and the need to control cost created a common or shared need to drive change.
- Multiple change management tools were used to gain participation and cooperation of nurse and physician staff.
- Recognition of efforts helped build on success and drove the desire to continue the change initiative.
- Continued monitoring and communication of key metrics maintain the results.
- The project team garnered support for the project objectives prior to implementation.
- Precaution kit best practice is being implemented in other departments.

Extrapolating results from a single process improvement effort to develop a HRO is achievable within health care, but requires technical and cultural change management strategies like Six Sigma, Lean, and Work-Out.

### What is Six Sigma?

Six Sigma originated in manufacturing in the 1980s and has been described as a measure of quality, a statistical process for continuous improvement, and an enabler for culture change. It is a highly structured method for defining, measuring, eliminating and controlling defects and process variance.

Quantitatively, a process performing at Six Sigma will generate fewer than 3.4 defects per million opportunities. As Figure 1 indicates, moving from 3 Sigma to 6 Sigma represents a 20,000 times improvement in quality. Culturally, becoming a Six Sigma organization is like becoming an HRO in the provision of a framework that targets and encourages flawless performance.

| Σ | Defects Per Million Opportunities |
|---|---|
| 1 | 697,672.15 |
| 2 | 308,770.21 |
| 3 | 66,810.63 |
| 4 | 6,209.70 |
| 5 | 232.67 |
| 6 | 3.40 |

Six Sigma levels and DPMO

**Figure 1.** *The relationship between Sigma level and the number of defects per million opportunities.*

**See "HRO," Next Page**

# Six Sigma Offers Important Methodology

**"HRO," From Preceding Page**

The Six Sigma DMAIC methodology (Define, Measure, Improve, and Control), applies to any existing process with measurable response variables. Figure 2 demonstrates this highly structured, five-phase approach and analytical data analysis. Using DMAIC, a number of hospitals have been able to document impressive benefits. Projects span the organization and have included decreasing patient wait time in the emergency department, optimizing processes surrounding advanced technologies, improving admissions, increasing capacity and access to care, and reducing medication errors.

In the example cited at the outset of this article, the level of errors per million procedures under anesthesia puts this particular process at 5.97 Sigma, or nearly perfect. Figure 2 illustrates the impact of various Sigma levels on other common processes in a health care environment.

Achieving high reliability in health care demands a relentless focus on underlying, systemic causes for variation. This is unfortunately the opposite of the way many organizations approach errors or quality issues. Often there is a tendency to blame the people involved while retaining the same processes and systems that allowed the error to occur in the first place. This theme is evident in a new book written by two University of California-San Francisco Medical Center physicians entitled, *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes*. Through a case-based approach, authors Robert M. Wachter, MD, UCSF Professor of Medicine, Chief of the M Service, and Chair of the Patient Safety Committee at UCSF Medical Center, and co-author Kaveh G. Shojania, MD, UCSF Assistant Professor of Medicine, share vital lessons about patient safety with the medical community and public at large.

## Summary

Initial skepticism over any new improvement initiative is understandable, since most health care organizations have not been able to sustain results from previous programs like TQM, CQI, and PDCA. In fact, studies have shown that approximately 62% of change initiatives are destined to fail. Reasons for this may include a lack of leadership support, absence of control mechanisms to monitor change on an ongoing basis, less statistical rigor targeting standard deviation and not just averages, and failure to address the cultural or human side of change. Combining strong technical strategies such as Six Sigma and Lean with proven cultural strategies like Work-Out and Change Acceleration Process, is one approach that can take a hospital further down the path to HRO status.

Debate over particular solutions is healthy and should be driven by an accumulation of evidence. Denial that serious deficiencies exist, however, is no longer a fantasy we can afford. Becoming a HRO, like aiming for Six Sigma levels of excellence, is a worthy goal, one that can be supported by studying achievements in other industries such as aviation and examining success stories from "early adopter" hospitals and health systems.

At the risk of repeating a familiar phrase, it is not simply a matter of working harder, but working smarter. When discussing the need for change in health care, providers may bristle at words like "efficiency" and "productivity," which imply slack that does not exist in most daily schedules. Cultural transformation involves putting a framework in place that makes it easier to do the right thing and far more difficult for errors to occur. Several critical attributes and capabilities can deliver results and support the quest to become a HRO:

- Acknowledgment of the need for change
- Data-driven methods for reducing process variation, defects, and waste
- Cultural techniques for acceptance building and change acceleration
- Measurable and accountable leadership development
- Well-defined and thoroughly utilized operating mechanisms
- Improvement initiatives visibly supported by management and clearly aligned with organizational objectives and values
- Ability to leverage and expand access to new technologies
- Collaboration and best practice sharing across and beyond health care.

Adapting stronger systems for identifying and eliminating risk should be seen as complementary to medical science. Implementing effective strategies to create highly reliable processes and organizations is imperative for the viability of the health system as well as the sake of the patient.

**See "HRO," Next Page**

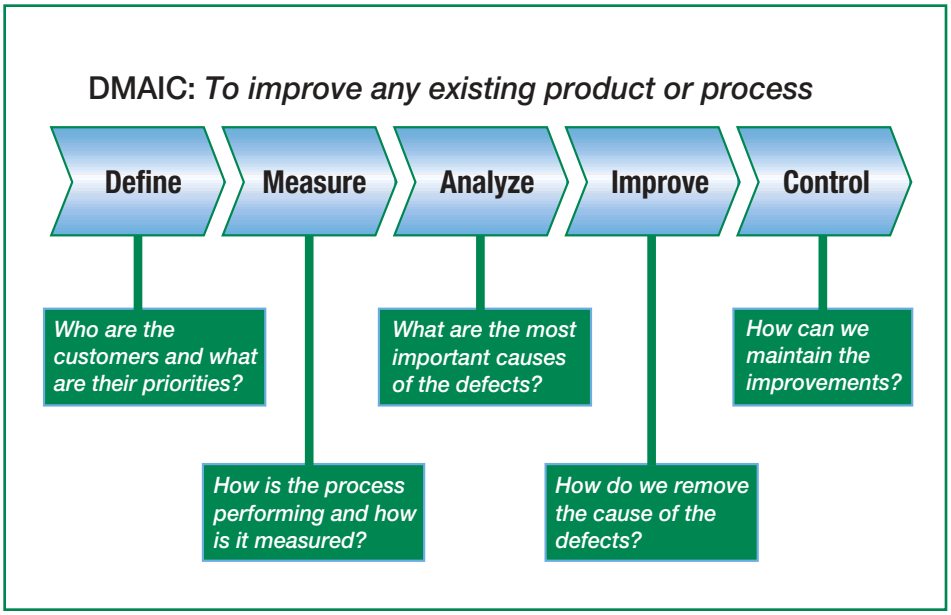


**Figure 2.** *DMAIC flow chart demonstrating the steps to improve any existing product or process.*

# 99% is Just Not Good Enough

### "HRO," From Preceding Page

Without overlooking its unique challenges and obligations, health care can learn from best practices that have been successfully applied in other high-risk industries. We are all stakeholders when it comes to health care. Uniting the best of medical science and management science could be the marriage that saves the system.

*Ms. Luchsinger is Principal, West Consulting, GE Healthcare. Ms. Pexton is Director of Communications, Performance Solutions with GE Healthcare Services in San Ramon, CA.*

#### Suggested Reading/General References


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**Websites for more information**

**IsixSigma:**
**www.healthcare.isixsigma.com**

**International Society of Six Sigma Professionals:**
**www.isssp.com**

**GE Healthcare Services Performance Solutions:**
**www.gemedicalhcs.com**

**Agency for Healthcare Research and Quality:**
**www.ahrq.org**

**Health Care Processes by Sigma Level**

| Sigma | Patient Personal Items | Coding Processing | Scheduling Time | DPMO | % Yield |
|---|---|---|---|---|---|
| 3 | 3,660 Patients with Misplaced Personal Items Every Day | 700 Coding Errors Every Day Require Correction | 257 Calls Each Day Exceed The Two Minutes On Hold Time | 66,800 | 99.32000% |
| 4 | 340 Patients with Misplaced Personal Items Every Day | 72 Coding Errors Every Day Require Correction | 24 Calls Each Day Exceed The Two Minutes On Hold Time | 6,210 | 99.3490% |
| 5 | 12 Patients with Misplaced Personal Items Every Day | 13 Coding Errors Every Day Require Correction | 5 Calls Each Day Exceed The Two Minutes On Hold Time | 230 | 99.97700% |
| 6 | 6 Patients with Misplaced Personal Items Every Day | During The Year, Only 10 Coding Errors Require Correction | During The Year, 3 Calls Exceed The Two Minutes of Hold Time | 3.4 | 99.99966 % |

**Sometimes 99% Is Just Not Good Enough**

Source: OE Medical Systems

**Figure 3.** *Examples of Health Care Process by Sigma Levels.*

## Letter to the Editor: TRI: *Position vs. Dilution*

### To the Editor:

I read the letter from Dr. Lambert[1] and the response by Drs. Pollock and Horlocker[2] in the fall 2003 issue of the *APSF Newsletter* with interest.

Over a 6-month period I have used 50-100 mg of lidocaine (subarachnoid) (Abbott 1% MPF lidocaine or AstraZeneca 2% MPF Xylocaine) in over 50 supine patients (mostly knee arthroscopy), and I followed up with a telephone interview. All had satisfactory anesthesia, and no patient had any significant complaint. However, I did not ask questions specific to transient radicular irritation (TRI).

Is it possible that the dilution of "hyperbaric" lidocaine (specific gravity = 1.034 -1.011) reported by Pollock et al.[3] was ineffective in reducing the incidence of TRI because a hyperbaric solution is more likely to pool in the sacral region and expose the cauda equina to the lidocaine for periods longer than might occur with an "isobaric" or "hypobaric" solution? Even minimally hyperbaric solutions are likely to pool in the sacral region. Unlike the hyperbaric solutions that Pollock et al.[3] used, my solutions (specific gravity around 1.0007) were isobaric or even hypobaric. Therefore, they would be more likely to distribute over a different area in the CSF in the supine patient and be less likely to "pool" in the cauda equina region.[4,5]

Interestingly Alley and Pollock reported on a patient given a hypobaric lidocaine spinal anesthetic (1% lidocaine, s.g. not measured) and placed in the prone jack-knife for pilonidal cyst excision who developed TRI.[6] This would seem to contradict my hypothesis that hypobaric lidocaine might prevent TRI. Indeed, Alley and Pollock propose that sciatic stretch rather than "maldistribution" caused the TRI in their patient. However, in the jack-knife position, the hypobaric solution likely gravitates to the sacral region (the same way that a hyperbaric solution does during a "saddle block"). This exposes the cauda equina to lidocaine for a longer interval than would be the case if the patient were positioned supine after the injection the way that my patients were positioned.

The title of the Pollock and Horlocker letter[2] states, "More research on TRI is needed." A starting point might be a randomized and blinded study of the effect of the dilution of isobaric lidocaine on the incidence of TRI.

*Steven Funk, MD*
*Ogden, Utah*

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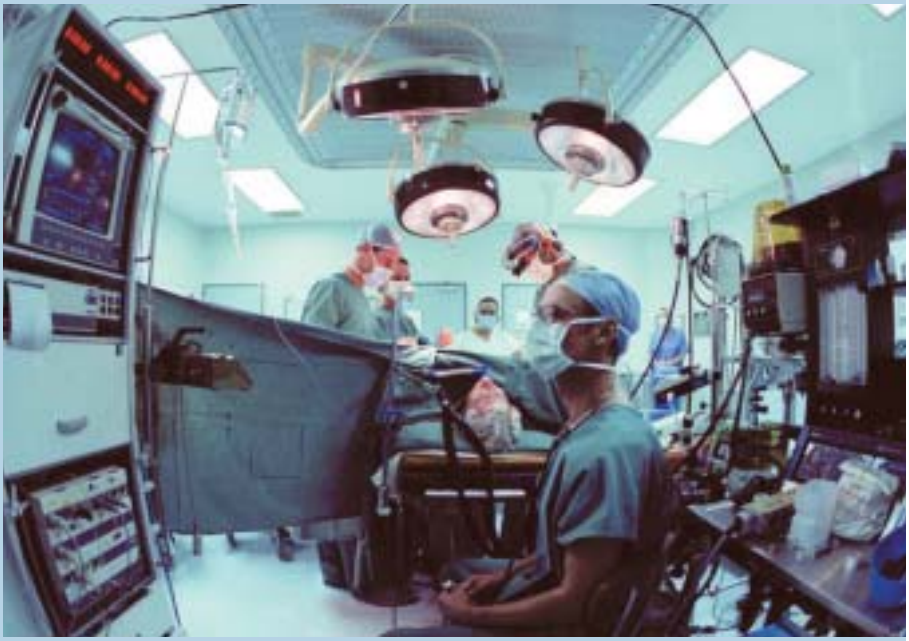
# Highlights:

- *Clinical Alarms Initiative*
- *Pulse Oximeter Tone Conveys Vital Information*
- *Dear SIRS: $O_2$ Blender Causes Concern*
- *HRO is Key Concept for Health Care*

**S** AFETY
**I** NFORMATION
**R** ESPONSE
**S** YSTEM



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