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NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 23, No. 3, 37-48 | Circulation 84,122 | Fall 2008

Medication Errors Persist

Summit Addresses Intravenous Safety

by Donald E. Martin, MD

Intravenous medications have saved the lives of millions of patients. However, partly because of the huge number of doses and the number of different medications given daily, errors in IV medication administration still represent a significant health care problem in the United States today. It has been almost 9 years since the Institute of Medicine's Report "To Err is Human" shocked the public consciousness and the medical establishment in 1999.[1] Since then, much has been said and written about the problem, and there have been some significant steps forward. The Joint Commission has made reduction of medical errors one of its national patient safety goals for the past several years. In 2006, the FDA mandated that manufacturers include a machine readable bar code on the label of the containers of many prescription drugs. New technology such as bar codes, radio frequency identification (RFID), and computerized order entry (CPOE) systems have all come on the horizon as technological solutions, only to create different problems which may be almost as big as those they are intended to solve.

It is painfully obvious that we are as yet nowhere near a solution, even for the so called "high alert" medications! The administration of flush solution with a heparin concentration 1000-times that intended to 17 Texas neonates in Corpus Christi on July 4 this year is just one very recent example of how far we have to go.

According to the 2006 Institute of Medicine Report "Preventing Medical Errors," on average, a hospitalized patient is subject to at least 1 medication error per day, with at least 1.5 million preventable adverse drug reactions occurring each year. These reactions lead to an estimated $3.5 billion in additional health care costs annually to hospitalized patients alone, and reactions to drugs represent between the fourth and sixth leading cause of deaths in hospitalized patients.

According to an analysis of over 73,000 intravenous drug errors reported to the US Pharmacopoeia MedMarx database between 2000 and 2004, more than 50% of errors were in the process of actually administering medications, and 60% of these errors occurred in the intravenous administration of 1 of 20 "high alert" medications (Table 1). Between 3% and 5% of these reported errors led to patient harm.

In the MedMarx database, one-half of errors occurred on patient units or nursing floors. However, 5% occurred in the operating room or in the pre- or post-anesthesia care units, where anesthesiologists and nurse anesthetists routinely practice. In the operating room, it has been estimated that 1 drug administration error occurs for every 133 anesthetics.[2] Approximately 1% of these errors actually cause patient harm. Therefore, elimination of medication errors represents a tremendous opportunity to save lives and improve patient care in the OR as well as in the remainder of the hospital.

Table 1
20 "High Alert" Medications Most Frequently Involved with Harmful Intravenous Drug Errors

Medication	% of Harmful Errors
Morphine Sulphate	8.5
Heparin	8.3
Hydromorphone	6.1
Insulin	4.9
Vancomycin	3.9
Fentanyl	3.8
Furosemide	2.3
Potassium Chloride	2.2
Meperidine	2.1
Methylprednisolone	1.8
Lorazepam	1.7
Cefazolin	1.7
Loversol	1.7
Midazolam	1.7
Dopamine	1.6
Diltiazem	1.5
Total Parenteral Nutrition	1.4
Phenytoin	1.4
Piperacillin/Tazobactam	1.4

(Based on 3,184 reports submitted to Med Marx involving the parenteral routes [epidural, intrathecal, intravascular and intravenous] during the years 2000 to 2004.)

In order to save lives and prevent harm to patients, far reaching changes are needed in the way medications are prepared and administered. The persistence of the problem has led to a new sense of urgency on the part of many organizations dedicated to patient safety, including the Institute of Medicine (IOM), the Institute for Safe Medical Practice (ISMP), Emergency Care Research Institute (ECRI), Joint

See "Errors," Page 39

Inside:

Letters to the Editor:

Is Chlorhexidine Prep Appropriate for Peridural Anesthesia?

To the Editor:

Hebl in 2006 stated in a review article published in *Regional Anesthesia and Pain Medicine* that chlorhexidine-based solutions should be considered the antiseptic of choice for regional anesthetic procedures and that its use be considered a Grade A recommendation. [1] In a previous *APSF Newsletter* these solutions have also been recommended, based on effectiveness, for skin preparation prior to insertion of invasive intravascular catheters to reduce the risk of catheter-related bloodstream infections.[2]

In spite of this, still in 2008 the Chloraprep "One-Step" applicator (Medi-flex, Overland, KS) has written in its contraindications in the back, that this solution should not be used when working in close proximity to meningeal structures.

In my opinion this remains a tremendous problem because we have conflicting data and the clinician remains in the middle unable to convincingly follow the published guidelines from the *American Society of Regional Anesthesia and Pain Medicine* or follow the recommendations from the manufacturer. So in the context of safety what should we do?

Felipe Urdaneta, MD
Gainesville, FL

References

1. Hebl JR. The importance and implications of aseptic techniques during regional anesthesia. *Reg Anesth Pain Med* 2006;31: 311-23.

2. Wagner CE, Prielipp RC. Chlorhexidine prep decreases catheter-related infections. *APSF Newsletter* 2003;18:2.

To the Editor:

I would like to thank you for the opportunity to respond to Dr. Urdaneta's question, "Should We Follow These Guidelines and Recommendations or Not?" It is a valid question that has been posed many times.

As pointed out by Dr. Urdaneta, a 2006 review article published in Regional Anesthesia and Pain Medicine, stated that chlorhexidine-based solutions should be considered the antiseptic of choice for regional anesthetic procedures and that its use be considered a Grade A recommendation.[1] As of 2008 all chlorhexidine-based topical cutaneous skin antiseptics have the warning "do not use for lumbar puncture or in contact with the meninges"[2] or "do not use in contact with the meninges."[3]

The Food and Drug Administration (FDA) approval of a drug is based on the data submitted by the manufacturer. The FDA requires that substantial evidence resulting from adequate and well-controlled investigations demonstrate that a drug will have the effect it purports or is represented to have under the conditions or use prescribed, recommended, or suggested in the proposed labeling. Once the FDA determines that a drug is safe and effective the manufacturer can only advertise or promote the drug for the indication approved by the FDA, and all promotion must be based on information that was submitted for review.[4]

A physician's discretionary use of that product (the practice of medicine) is not restricted to the uses

See "Chlorhexidine," Page 47

Karen Posner Named to Laura Cheney Professorship in Anesthesia Patient Safety

Dr. Karen Posner has been named to The Laura Cheney Professorship in Anesthesia Patient Safety, launched by Dr. Frederick Cheney, former chair of the department of anesthesia at the University of Washington in Seattle. This professorship is named after Dr. Cheney's mother, a nurse who encouraged him to go into the field of medicine. The Professorship provides a cornerstone for the department's patient safety research program and will provide a permanent source of research funding for anesthesia patient safety. Dr. Posner is honored as the first holder of this endowed position.

While Dr. Posner's activities continue with the ASA Closed Claims Project, some endowment funds have been committed to a junior investigator starter grant within the University of Washington's department of anesthesiology to promote patient safety research among junior faculty. Fundraising continues, with the goal of converting the professorship into an endowed chair position that would enable expansion of patient safety research activities.

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The **Anesthesia Patient Safety Foundation Newsletter** is the official publication of the nonprofit Anesthesia Patient Safety Foundation and is published quarterly at Wilmington, Delaware. Annual contributor cost: Individual–$100, Corporate–$500. This and any additional contributions to the Foundation are tax deductible.

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

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Recommendations Under Development

"Errors," From Page 37

Commission, Food and Drug Administration (FDA), Centers for Medicaid and Medicare Services (CMS), National Patient Safety Foundation (NPSF), United States Pharmacopeia (USP), Agency for Healthcare Research and Quality (AHRQ), the Institute For Healthcare Improvement (IHI), the National Quality Forum (NQF), and many other professional and specialty organizations.

Representatives of these and other national organizations joined in an intensive 2-day Intravenous Safety Summit convened by the American Society of Health System Pharmacists (ASHP) in Rockville, MD, on July 14-15 to recommend very specific and attainable changes in practice that will be effective in preventing medication errors and saving lives now lost to adverse drug events. One of the real strengths of this summit was the integral involvement of front-line practitioners—nurses, physicians, and pharmacists, as well as vendors, health system experts, and researchers. Three participants in the summit represented the specialty of anesthesiology: Jeffrey B. Cooper, PhD, represented the Anesthesia Patient Safety Foundation; Donald E. Martin, MD, represented the American Society of Anesthesiologists; and Nathaniel M. Sins, MD, represented Partners Healthcare and brought unique expertise in the emerging "smart pump" technology.

Specific recommendations from the summit are yet to be finalized. However, the themes for these recommendations were clear from the discussion and included

1. The standardization of infusion concentrations and the units or format used to order or prescribe intravenous medication infusions (such as mcgm/min vs. mcgm/kg/min).
2. Simplifying the administration process, with preference for the preparation of intravenous medication in the pharmacy rather than at the point of care.
3. Obtaining the maximum benefit from technology in the form of bar codes, computerized order entry, and smart pumps.
4. Establishing a culture conducive to medication safety.

The specialty of anesthesiology and the practice of nurse anesthesia are both in very good positions to take leading roles in research, practice changes, and cultural changes needed to save lives now lost due to medication errors. Anesthesiologists are one of the few groups of physicians who are personally responsible for drug administration. Historically, our specialty has been able to effectively design monitors and ventilation systems and to greatly reduce death due to hypoxia or ventilatory failure in anesthetized patients. Anesthesiologists already have effective patient safety, "standards," and "practice advisory" infrastructures in place. Significant research has already been done to evaluate drug administration procedures and technology to improve safety of drug administration during anesthesia (Table 2). All of these improvements have a potential to improve the process of drug administration in the operating room, which is a complex collection of more than 40 steps, if used to enable anesthesia providers to work more safely, as well as more quickly and efficiently.

Establishing a "culture of safety," however, may be more difficult than developing technology. Stabile, Webster, and Merry, in the Fall 2007 issue of the *Anesthesia Patient Safety Foundation Newsletter*, called for just such a cultural shift in medicine, from a culture of productivity to a culture of safety. In their words, "safety should be funded because it is the right thing to do, not because of any ROI directives." Commercial aviation and other similarly complex yet high-risk industries adopted a culture of safety years ago. Medicine can do no less.

Therefore, as a very important next step, the Anesthesia Patient Safety Foundation is planning a Board of Directors' Workshop for Friday, October 17 in Orlando, FL, entitled "Innovations in Medication Safety in the Operating Room." The workshop is designed to identify solutions for medication errors in the operating room that are currently technologically feasible, as well as ideas for potential new processes to be developed and explored. Participants in this workshop will include physicians, pharmacists, health systems and technology researchers, as well as representatives from the Joint Commission and other regulatory agencies. The very practical solutions coming from this workshop, as well as the ASHP IV Medication Safety Summit may well provide the innovations in drug administration processes, as well as insight into the human factors responsible for inevitable human errors, which are needed to bring about a true reduction in medication errors in the operating room.

Dr. Martin is Professor of Anesthesia at Penn State University College of Medicine in Hershey, PA. Dr. Martin is also Chair of the ASA Committee on Equipment and Facilities.

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Table 2
Error Reduction Techniques

Error Reduction Technique	Supporting References
Pre-filled syringes	3
Distinctive drug labels	2,3,4,5
Colored drug Labels	2,3,4,6
Check labels with second observer	3,6
Double check ampoule before labeling syringe, and syringe label before administration	2,3,6
Do not store concentrated solutions of hazardous medications (KCl) in OR	1,3
Standardization – drug preparation procedures	2
Standardization of layout of drug workspace	2,3,5,6
Standardization – syringe sizes	2,6
Bar codes on drug labels with audible reader	3,4,7,8,9,10

Patient Safety Topics Abound at 2008 ASA Meeting

The 2008 American Society of Anesthesiologists annual meeting will be held in Orlando, FL, beginning on October 18, 2008. Safety related topics will be presented in a variety of formats, including refresher course lectures, poster sessions and discussions, breakfast panels and symposia. Highlights of these presentations are summarized in tabular form for reference and ease of use. Saturday's refresher courses include Dr. Ehrenwerth presenting O.R. fires, Dr. Benumof reviewing the ASA Guidelines for patients with obstructive sleep apnea, and Dr. Palmer delivering obstetric emergencies. On Sunday, safety related refresher courses begin with discussing management of the difficult airway, followed by Dr. Rathmell presenting complications of pain management. Dr. Warner will also present the ever popular topic of perioperative positioning complications on Sunday afternoon. Monday refresher courses include discussion of dangerous drug interactions by Dr. Klock as well as the ramifications of morbid obesity by Dr. Ebert. On Tuesday Dr. Levy will gauge our reactions to anaphylaxis and adverse drug events and Dr. Crosby will address postoperative cognitive dysfunction. Tuesday afternoon brings us data from the closed claims registries including awareness, postoperative visual loss, and pediatric cardiac arrect, all moderated by Dr. Domino. Dr. Argalious will also follow up with PACU emergencies including their diagnosis and treatment. Finally, on Wednesday refresher courses conclude with sleep apnea in outpatient surgery, by Dr. Joshi, and awareness during general anesthesia, by Dr. Orser and Dr. Todd presenting management of the patient with cervical spine instability. Participants are encouraged to check out the numerous safety related abstracts and posters that will be presented throughout the ASA. Have a great meeting!

DATE / TIME	LOCATION	LECTURE TYPE	TOPIC: SPEAKER	OVERVIEW*
Friday 10/17				
13:00 – 17:00	**Rosen Centre Hotel** 9840 International Blvd	APSF BOD Workshop	**Medication Errors:** *J. Cooper, moderator*	Discuss factors involved with medication errors and scope of injury with potential industry and hospital solutions for prevention.
Saturday 10/18				
08:00 – 08:50	Rm W311 EF	RF	**OR Fires:** *J. Ehrenwerth*	Factors involved in OR fires and how to prevent and treat them.
08:00 – 09:30	Rm 230D	Poster Discussion	**Patient Safety:** *Practice Management*	Respiratory depression and monitors to prevent respiratory arrests. Factors influencing morbidity and mortality with emergency surgery and total knee and hip surgery.
09:00 – 11:00	Hall E2	Poster Session	**Patient Safety:** *Practice Management*	OR efficiency; preoperative assessment; cost comparisons of TIVA vs. volatile anesthesia and target controlled infusions.
09:10 – 10:00	Rm W315 AB	RF	**The ASA OSA Guideline:** *J. Benumof*	Discuss scope of problem with perioperative complications of OSA patients and the new ASA Guideline for OSA patients
13:00 – 13:50	Rm W315AB	RF	**OB Emergencies:** *C. Palmer*	Discuss anesthetic management of OB emergencies.
13:00 – 14:30	Rm 230C	Poster Discussion	**Patient Safety:** *Practice Management*	Factors affecting perioperative surgical infection and how to implement protocols; prevention of infection of i.v. tubing using TIVA.
14:00 – 16:00	Hall E2	Poster Session	**Patient Safety:** *Practice Management*	Patient complications and outcomes: MRI, regional anesthesia; peripheral nerve injuries; malignant hyperthermia.
14:10 – 15:00	Rm W311 AB	RF	**New Drugs & Delivery Systems:** *E. Viscusi*	Update on newer drugs and their delivery systems for pain management.
Sunday 10/19				
07:00 – 08:15	Rosen Centre Hotel	Breakfast Panel	**Critical Care in the PACU**	ASCCA: Use of non-invasive respiratory support devices; beta blockade, and acute postoperative delirium.
08:00 – 08:50	Rm W311 AB	RF	**Office Based Anesthesia:** *R. Twersky*	Discussion of challenges in office-based anesthesia; outcomes; and how to prevent complications by appropriate patient selection and best anesthetic techniques.
08:00 – 08:50	Rm W31 GH	RF	**Difficult Airway Management:** *C. Hagberg*	Current techniques for safely intubating the difficult airway patient and optimal perioperative management.
08:00 – 09:30	Rm 230D	Poster Discussion	**Patient Safety:** *Practice Management*	Improving utilization and flow in the OR.
09:10 – 10:00	Rm W311 CD	RF	**Complications in Pain Medicine:** *J. Rathmell*	Discuss problems and complications of managing pain patients and how to prevent them.
10:20 – 11:10	Rm W311 EF	RF	**Pediatric Emergencies:** *A. Ross*	Discuss anesthetic management of common pediatric anesthetic emergencies.
11:30 – 12:20	Rm W314 AB	RF	**OB Anesthesia Problems:** *D. Chestnut*	Discuss high acuity problems in OB anesthesia: diagnoses, management, and treatment; prevention of complications.
14:00 – 16:00	Hall E2	Poster Session	**Patient Safety:** *Practice Management*	Medication errors; resident education.
14:10 – 15:00	Rm W311 CD	RF	**PALS 2008 Update:** *J. Deshpande*	Discuss 2008 updates to pediatric advanced life support.
14:10 – 15:00	Rm W311 EF	RF	**Anesthesia for Radiology Procedures:** *C. Scher*	Discuss challenges of out of OR procedures in radiology—common complications and how to prevent them.

See "Topics," Next Page

"Topics," From Preceding Page

DATE / TIME	LOCATION	LECTURE TYPE	TOPIC: SPEAKER	OVERVIEW*
Sunday 10/19, continued				
14:10 – 15:00	Rm W14 AB	RF	**Pregnant Patient for Non-OB Surgery:** *J. Hawkins*	Discuss optimal timing and management of anesthesia for the pregnant patient having non-OB surgery.
15:20 – 16:10	Rm W311 AB	RF	**Neuroanesthesia Misconceptions:** *J. Drummond*	Discuss misconceptions in neuroanesthesia, complications, and how to avoid them.
15:20 – 16:10	Rm W311 EF	RF	**Positioning Problems:** *M. Warner*	Perioperative complications associated with positioning: how to avoid them and how to work up and treat injuries.
Monday 10/20				
07:00 – 08:15	**Rosen Centre Hotel**	Breakfast Panel	**Ambulatory Patient Outcomes**	SAMBA: Measuring and improving patient outcomes in the ambulatory setting.
07:00 – 08:15	**Rosen Centre Hotel**	Breakfast Panel	**Perioperative Management of Heart Failure Patients**	SCA: Discuss current prevalence, treatment, and best management of the patient with heart failure.
08:00 – 08:50	Rm W311 EF	RF	**EBM and Perioperative Care:** *B. Fahy*	Discuss how evidence-based medicine fits in to your perioperative care plan—how you can make a difference.
09:00 – 11:00	Hall E2	Poster Session	**Patient Safety:** *Practice Management*	Prediction of blood transfusion in major surgery; adherence to guidelines for cardiac assessment in non-cardiac surgery; difficult intubation.
09:10 – 10:00	Rm W311 CD	RF	**Drug Interactions:** *P. Klock*	Discuss dangerous drug interactions in anesthesia and how to avoid them.
13:00 – 13:50	Rm W315 AB	RF	**Morbid Obesity:** *T. Ebert*	Discuss pathophysiology of morbid obesity associated illnesses, how it impacts your clinical care, and how to avoid complications.
14:00 – 16:00	Hal l E2	Poster Session	**Patient Safety:** *Practice Management*	Effects of drugs on end organ function; diagnosing allergies to medications.
Tuesday 10/21				
08:00 – 08:50	Rm W314 AB	RF	**Anaphylaxis & Adverse Drug Reactions:** *J Levy*	How to rapidly diagnose and treat anaphylaxis and other adverse drug reactions.
08:00 – 11:00	Chapin Theatre	Journal Symposium	**Diagnosis & Management of Difficult Airways and Sleep Apnea**	Assessment, testing, perioperative management of sleep apnea patients and patients with difficult airways.
09:00 – 11:00	Hall E2	Poster Session	**Patient Safety:** *Practice Management*	Tobacco interventions by anesthesiologists; PONV; awareness.
09:10 – 10:00	Rm W311 CD	RF	**Postoperative Cognitive Dysfunction:** *G. Crosby*	Discuss risk factors for postoperative cognitive dysfunction and issues surrounding definitions, testing, and control groups.
09:10 – 10:00	Rm W314 AB	RF	**Preoperative Assessment for the Cardiac Patient:** *L Fleisher*	Update on the appropriate workup for cardiac patients and effect on outcome.
13:00 – 15:00	Rm W315 AB	RF	**ASA Closed Claims Registries:** *K. Domino, moderator*	Discuss findings from the various ASA Closed Claims registries including pediatric cardiac arrest, postoperative visual loss, and the new awareness registry.
14:10 – 15:00	Rm W311 EF	RF	**PACU Emergencies:** *M. Argalious*	Discuss common PACU emergencies, how to evaluate and diagnose problems, and avoid complications.
Wednesday 10/22				
07:00 – 08:15	Rosen Centre Hotel	Breakfast Panel	**Risk and the Pediatric Patient**	SPA: How to recognize, assess, and manage the pediatric patient at high risk for anesthetic complications.
08:00 – 08:50	Rm W311 AB	RF	**Sleep Apnea Patients for Outpatient Surgery:** *G. Joshi*	Common problems associated with sleep apnea patients; how to minimize postoperative risks; and appropriate discharge criteria.
08:00 – 09:30	Rm 225B	Poster Discussion	**Patient Safety:** *Practice Management*	AIMS, Simulation, Video assessment of preoperative trauma care.
09:00 – 11:00	Hall E2	Poster Session	**Patient Safety:** *Practice Management*	Intubation techniques and devices for the difficult airway.
09:10 – 10:00	Rm W311 AB	RF	**Awareness with General Anesthesia:** *B. Orser*	Discuss factors associated with awareness under general anesthesia, appropriate preventative strategies and treatment.
09:10 – 10:00	Rm W311 CD	RF	**Cervical Spine Instability:** *M. Todd*	Discuss the unstable cervical spine; cervical spine disease for surgery; and cervical spine motion with different intubation techniques.

*Overview provides partial list of posters in poster discussions and sessions; RF, refresher course.

Dear SIRS

Machine Failure Caused by Keyboard Damage

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

Dear SIRS refers to the Safety Information Response System. The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. This process was developed by 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 2004 issue.

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

Dear SIRS:

I am the head of cardiothoracic anesthesia at St. John's Mercy Medical Center in St. Louis and have had a unique failure of one of our newer anesthesia machines that I (and our equipment committee chairman) believe has not been reported. The machine features a keyboard-driven interface that controls all monitors, gas flows, and all ventilator functions. In short, the ventilator/vaporizer screen became unresponsive to all input and therefore the vaporizer and ventilator controls could not be changed in the middle of a case. I changed out machines (with lots of help) uneventfully, and our equipment technician and biomed person discovered that the designers had installed a number of hidden keys (for future upgrades) one of which became intermittently activated by surface damage. When activated, it locked out all the other controls thereby locking the ventilator and the vaporizer controls.

I would be very grateful for your advice in this matter.

Sincerely,
Kit Young, MD
St. Louis, MO

Dear Dr. Young:

The failure was indeed caused by damage to the keypad, as you reported. This damage could have resulted in failure of the keypad regardless of whether it occurred on an unlabeled ("hidden") key area or on a labeled key. It is unfortunate that it was difficult to detect because the visible signs of the damage were small, and the damage was apparently not reported when it occurred. Subsequent examination of the sample you provided revealed a small hole in the keypad. The object that created this small hole was inserted with enough force to push the metal shield on the circuit board into the circuit layer of the keypad, causing an electrical short circuit (see Figures 1a and 1b). It was this electrical short circuit that caused the keypad to fail.

Membrane-type keypads are commonly used in many types of approved medical equipment and are generally quite durable, rugged, and reliable.

While anesthesia machines are designed to be rugged, they unfortunately cannot be made to be completely indestructible. It is true that some types of damage could lead to failure of a machine component. The design process for an anesthesia machine includes a Hazard Analysis and FMEA (Failure Mode and Effects Analysis), with the intent that a failure of any component will not result in a direct hazard, whether it be to the patient, machine operator, or others in the area. In this case the machine performed as designed when faced with a failure of the keypad—it continued to operate with the last known

See "Keyboard," Next Page

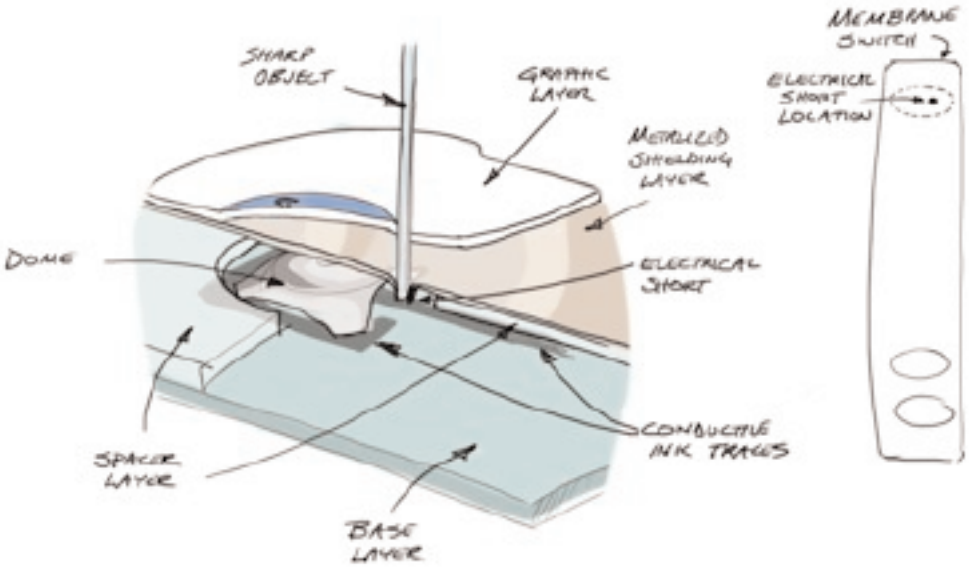

Figure 1a: Sharp object inserted into the keypad. This pushed the metal shielding layer through the spacer layer and into the conductive trace, causing an electrical short circuit.

Damage Should Be Reported If Detected or Suspected

"Keyboard," From Preceding Page

ventilation, fresh gas, and vaporization settings. Switching to manual (bag) ventilation is always an available option if needed. Switching to 100% oxygen is also available through an alternate, adjustable O_2 delivery system, which concurrently discontinues vaporization. And discontinuation of vaporization alone (with retention of second gas) is accomplished by removal of the agent cassette.

This case does illustrate the importance of reporting any damage when it occurs, even if it appears small and the device seems to function correctly. Best course of action is to have the device checked thoroughly by a qualified service person or trained biomedical engineer before placing it back in service. Hidden damage can lead to possible component failure or degradation at a later time, as indeed happened in this case. This applies to any component of the machine, not just to the keypad.

It is important that all individuals who work around medical devices, especially life support equipment, are aware of the need to immediately report any damage or suspected damage to the equipment. Perhaps this case can serve as an illustration to re-emphasize the need for this knowledge and awareness. Thank you for sharing your experience.

Sincerely,
Kevin Tissot
Engineering Manager, Anesthesia Platforms
Life Support Solutions - GE Healthcare

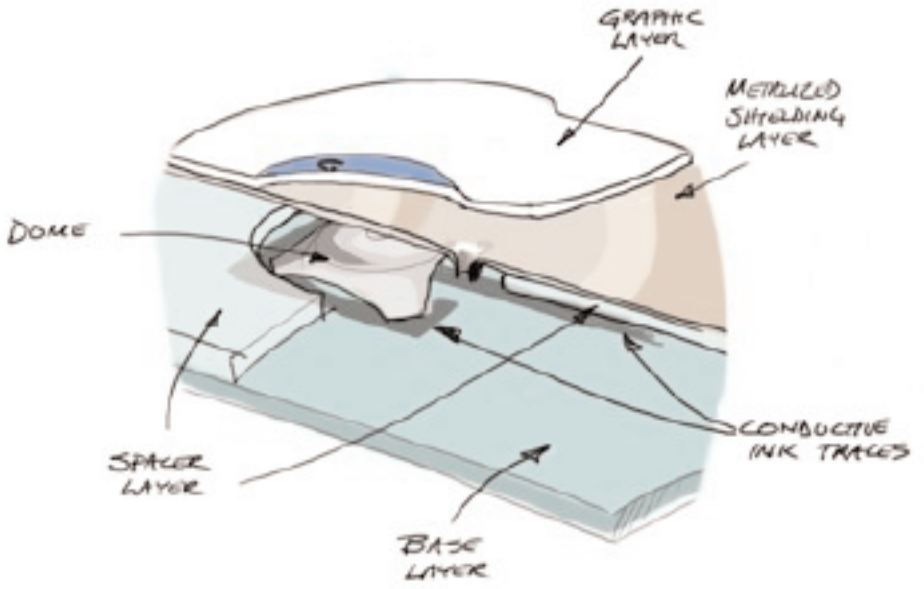

Figure 1b: After the sharp object was removed. Note the electrical short circuit caused by contact of the metal shielding layer to the conductive ink trace is still there. The short circuit in this case was intermittent.

Support your APSF—*The address for donations is*
APSF, 520 N. Northwest Highway, Park Ridge, IL 60068-2573

Q&A

Can One Drive a Jet Ventilator From the Common Gas Outlet?

Q Dear Q&A,

I have a question about how to ventilate a patient via emergency cricothyrotomy in the OR setting in the absence of a common gas outlet (CGO) on the anesthesia machine. I refer to our Datex-Ohmeda GE Healthcare, Inc. Avance anesthesia machine, which does not have the auxiliary (A)CGO option. However, even if it did, the user manual clearly states, "Do not use the ACGO to drive external ventilators or for jet ventilation." Do you have recommendations for management of ventilation via cricothyrotomy when using the Avance GE machine? Thank you ahead of time for your help with this concern.

Sharon Christian
Springfield, MA

A Dear Ms. Christian,

Thank you very much for your question to the APSF. The common gas outlets in various machines can be complicated by the presence of check valves and/or pressure relief valves of differing magnitudes. One question back to you now is whether or not you are attempting manual ventilation via the cricothyrotomy device with the manual ventilation bag/circuit, or whether you are trying to jet ventilate through it. This may be dependent upon the type of device used for the cricothyrotomy. Can you specify the situation you are referring to?

Dr. Olympio
Co-Editor, Q&A Column

Q Dear Q&A,

Thank you for responding to our question. We currently are not necessarily trying to do either of the options you ask about, but rather are trying to ascertain the most appropriate way to provide emergency ventilation through a cricothyroid puncture with the new Avance machines. It has been a long-standing safety practice within our department to have available in each anesthesia machine an emergency "kit" for cricothyroid puncture/ "jet" ventilation. This "kit" consists of a 14 gauge intravenous catheter with a luer connection to a length of oxygen tubing, with a 15 mm. metal connector at the other end that would fit into our older machines' common gas outlet. Staff had been instructed that, should emergency cricothyroid puncture become necessary, oxygenation should be performed by "jet" ventilation by intermittently pressing the oxygen flush valve.

Since the Avance machines lack a common gas outlet, what is the best means of providing emergency ventilation and/or oxygenation? Are other devices necessary aside from the "kit" I described? Can/should our "kit" be hooked up to the breathing circuit, with the pop-off valve closed while the oxygen flush valve is depressed? The bottom line is what device/procedure is recommended to provide emergency oxygenation and/or ventilation, should cricothyroid puncture become necessary, using the Avance machines?

Thank you for your interest and help.

Sincerely,
Alan C. Weintraub, MD
Springfield, MA

A Dear Ms. Christian and Dr. Weintraub,

This subject was one of great interest to me in years past, as the anatomy of the common gas outlet changed with each new Ohmeda machine, in particular. I have a personal, original drawing reproduced here in Figure 1, which represents the relative positions of check valves and low pressure relief valves in the Ohmeda MODULUS I, MODULUS I Selectatec, MODULUS II, MODULUS II Plus, MODULUS CD, and EXCEL. The question was always, "Which one could provide effective pressure for jet ventilation?" The relief valves were either 2.9 or 5.5 psig in those models. According to Rosenblatt and Benumof[1], 50 psig is suggested for effective jet ventilation with a 14G catheter or smaller. If the check valve was proximal to the relief valve, then jet vent would not be possible. However, if the relief valve was shielded from the 50 psig wall inlet source by the distal check valve, then it would be possible. The Dräger Medical, Inc. NARKOMED had a higher relief valve setting of 18 psig under the vaporizer dial, without any check valve, which might then allow some degree of jet ventilation.

It is my understanding that the Avance would not support jet ventilation, with or without the auxilliary common gas outlet, because of a similar 5.5 psig low pressure relief valve that is distal to a vaporizer manifold back-check valve.

If you have the auxiliary oxygen flowmeter on your Avance, it is my understanding that the supply to that flowmeter is down-regulated from the cylinder and/or pipeline

See "Q&A," Next Page

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

More Q&A

Ability to Jet Ventilate is Machine Specific

"Q&A," From Preceding Page

source, to a value of 35 psig, and is always pressurized without the need to turn on the system switch. Your biomedical technician can check that outlet pressure very easily with a gauge while occluding the outlet port. Whether or not the maximum flow from that flowmeter is adequate at 35 psig to oxygenate or ventilate is the greater question, and depends upon the restrictor size and details described in the Rosenblatt/Benumof reference. The typical wall source of oxygen in the operating room is 50 psig and could be used with a flowmeter to provide adequate pressure and flow, or it could be accessed through an anesthesia machine "power outlet" with a commercial jet ventilator, if the outlet was available. I would also direct your attention to the Spring 2007 issue of our Q&A column, which describes ancillary sources of jet ventilation capabilities when the machine is not available or does not have such capability: http://www.apsf.org/resource_center/newsletter/2007/spring/15_qanda.htm

Although technical means and various devices exist to provide adequate pressure and flow, a direct connection of high pressure to the bronchial tree, without adequate egress or with excessive entrainment of room air could have significant risks, as described in the reference (35psig is approximately 2.3ATM whereby a clinical inflation pressure of 35 cm H_2O is approximately 0.035 ATM). Finally, the reference also describes the different capabilities of ventilation and oxygenation through various cricothyrotomy devices.

Sincerely,
Dr. Michael A. Olympio
Chair, Committee on Technology, APSF

Reference

1. Rosenblatt WH and Benumof JL. Transtracheal jet ventilation via percutaneous catheter and high-pressure source. In: Hagberg, CA. Benumof's airway management: principles and practice. 2nd ed. St. Louis: Mosby-Elsevier, 2007.

Check Valves, Relief Valves and Jet Vent

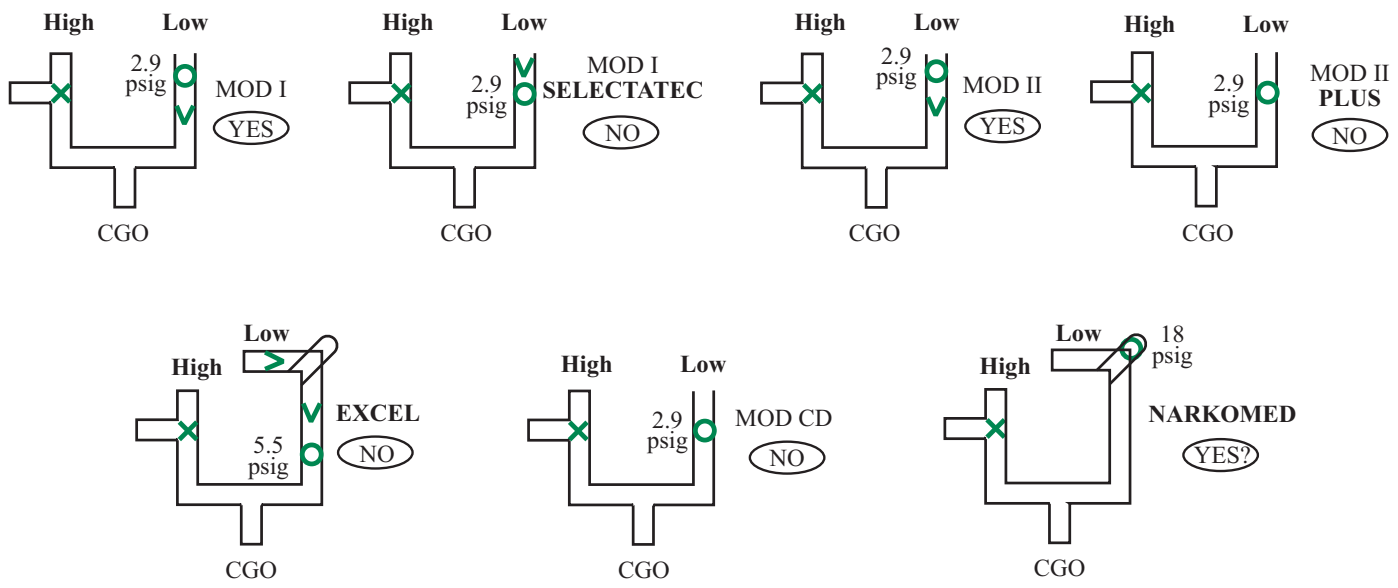

Figure 1. *Adaptation of an original personal drawing by Dr. Olympio that shows the relative relationships of the low-pressure relief valve and the one-way check valve. For example, in the Ohmeda MOD I, top left, the high pressure flush of 50 psig oxygen on the left limb would fully exit the CGO as the check valve on the right limb would close, thus preventing loss of pressure through the 2.9 psig relief valve.*

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Letters to the Editor:

Chlorhexidine Question May Be For FDA

"Chlorhexidine," From Page 38

indicated on FDA-regulated labels. Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.[5] The policy statement from the American Academy of Pediatrics for Unapproved Uses of Approved Drugs states, "An unapproved use of an approved drug refers to a use that is not included or that is disclaimed in the approved labeling. Unapproved use does not imply an improper use and certainly does not imply an illegal use. The term 'unapproved' is used merely to indicate lack of approval, not to imply disapproval or contraindication based on evidence of a lack of safety or efficacy. The distinction between contraindication and unapproved is important medically and legally". . . ."New uses, doses, or indications will not be approved by the FDA until substantial evidence of safety and efficacy for the indication or age group is submitted to the FDA. This may take years or may never occur."[4]

Since the consensus position of the American Society of Regional Anesthesia publication in the 2006 Hebl review article stating that chlorhexidine-based solutions should be considered the antiseptic of choice for regional anesthetic procedures, there has been discordance between the evidence-based practice of many clinical providers of regional anesthesia and chlorhexidine-based antiseptic product labeling. Dr. David Hepner published a correspondence in the April 2007 issue of *Anesthesiology* that stated the expert panel for *Regional Anesthesia and Pain Medicine* "felt strongly that although the US Food and Drug Administration has not approved chlorhexidine before lumbar puncture, it has a significant advantage over povidone iodine because of its onset, efficacy, and potency" and commented that "interestingly, povidone iodine is also not approved for lumbar puncture."[6] Chlorhexidine (CHG) or tinctures of CHG antiseptic solutions have been used extensively in and outside the United States for regional anesthesia procedures.[7]

The US Physician Desk Reference (PDR), as of 1984, warns that "chlorhexidine gluconate is for external use only. Keep out of eyes and ears and avoid contact with meninges." Before 1984, the PDR did not have the "avoid contact with meninges" warning. There are 2 referenced articles for neurotoxicity, both of which are animal studies. One article, published in 1955, was a study with many chemicals and detergent compounds that were injected into the cerebral spinal fluid of monkeys; neurotoxicity was seen with all compounds.[8] A second study published in 1984, based on a rat model, involved injecting a CHG solution into the anterior chamber of the eye. This study showed degeneration of adrenergic nerves and suggested that neurotoxic effects on thin myelinated fiber systems in the CNS should be investigated.[9] Since the publication of the 1984 PDR warning, a number of articles have appeared describing the use and efficacy of CHG in regional anesthesia and conclude that it is the preferred skin disinfectant.[10,11,12] These papers and accumulated clinical experience have been sufficient to persuade the major specialty society (ASRA) and the majority of clinicians to adopt CHG as the preferred skin disinfectant in the setting of regional anesthesia. To view this from the perspective of the FDA, their reluctance to specifically suggest a label change perhaps arises out of a philosophical reluctance, no perceived need from their perspective, and inadequately powered prospective evaluation of CHG in the setting of regional anesthesia (especially epidural and spinal) to reach their threshold for a labeling change.[13] From the perspective of a manufacturer of a CHG skin prep, the expense associated with obtaining a label change is prohibitive. Evidence based guidelines, like those in the Hebl article, make a manufacturer initiated labeling change unlikely. The question raised by Dr Urdaneta should perhaps best be posed to the FDA.

Cynthia T Crosby
VP Global Medical Affairs
Cardinal Health
Leawood, KS

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Errors Difficult to Completely Eliminate

To the Editor:

Dr. Workhoven is of course correct that no one should ever administer a medication based on color or shape clues without reading the label. However, it is unrealistic to predict that using words alone, written or spoken, will prevent all drug error.

Many drug names look alike (e.g., hydralazine and hydroxyzine, amrinone and amiodarone), especially if your reading glasses are smudged. The words even sound alike, when spoken in noisy operating rooms, especially those wired with the kind of hard-rock soundtracks favored by orthopedic and chest surgeons. The spoken word can also be misunderstood when expressions like "the bolus," "the antibiotic," or "start 2 of epi" are used.

Real life does not end at the operating room (OR) door, and misunderstandings will never end—despite our best efforts. The only solution I can envision is the development of a new type of OR specialist who checks every medication before it is administered and confirms the identity of every vessel before it is ligated.

Howard Schranz, MD
New York, NY

Eliminate Pattern to Prevent Drug Errors

To the Editor:

Dr. Schranz makes many good points about some of the causes for drug error in the operating room (OR). There are many distractions, and production pressure is also a major cause, I am sure. No time to "read" the label, only time to recognize the color and shape pattern.

It just seems to me that the human mind is rather adept at, and seemingly eager to use, pattern recognition for many visual tasks in and out of the OR. It is, perhaps, easier than reading the small print on the label, less time consuming, and works well, but sometimes not so very well, if your glasses are smudged or bespattered or you can't hear the surgeon well over the cacophony of sound and fury that is the modern day, boom box embattled OR.

So, eliminate the pattern, force all attention to the label and the letters printed on it. Perhaps it can serve as a small step forward in the perpetual effort to eliminate drug error.

Nick Workhoven
Coos Bay, OR

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ASA Annual Meeting - October 18, 2008

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