

NEWSLETTER

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Preventing Pediatric Transfusion-Associated Incidents of Hyperkalemic Cardiac Arrest *A Wake Up Safe Quality Improvement Initiative*

In the past 4 years, 7 cases of cardiac arrest or near-cardiac arrest associated with hyperkalemia during massive transfusion-of which 3 cases were associated with hyperkalemia and the remaining 4 cases were suspected of having hyperkalemiahave been reported to Wake Up Safe, a Quality Improvement Initiative of the Society for Pediatric Anesthesia. Wake Up Safe is a Patient Safety Organization that hosts a registry of serious adverse events among the now 25 pediatric hospitals that participate. The case profiles submitted were as follows: an infant undergoing myelomeningocele repair; an infant undergoing resection of an abdominal tumor; a premature neonate undergoing resection of sacrococcygeal teratoma; an infant undergoing sagittal synostectomy for craniosynostosis; a neonate undergoing resection of a facial mass; a child undergoing cardiac surgery with cardiopulmonary bypass support; a teenager in extremis undergoing emergency exploratory laparotomy for free air. In 2 of these patients, the serum potassium levels exceeded 8 mmol/L during transfusion of red blood cells (RBC) that were 21 and 28 days old in 1 patient and 23 days old in the other. In the third case, serum potassium level exceeded 6 mmol/L after transfusion of RBC that were 5 days old.¹ In the remaining 4 cases, other comorbid conditions were likely the primary cause of the cardiac arrest or near cardiac arrest, and/or more specific information was unavailable regarding the plasma potassium or units of RBC. Between 1998 and 2004, before the establishment of Wake Up Safe's registry, the Pediatric Perioperative Cardiac Arrest (POCA) registry received 8 reports of cases in which patients developed hyperkalemic cardiac arrest related to blood transfusion.²

These registry events spurred Wake Up Safe to look more closely at the existing literature on hyperkalemia during massive transfusion in children. Drawing on definitions available in adult literature and on massive transfusion protocols in by Angela C. Lee, MD, and Eugenie S. Heitmiller, MD

pediatric populations,³ we defined massive transfusion as the transfusion of > 70 mL/kg, or 1 blood volume, over a 24-hour period or > 35 mL/kg within 3 hours or less. Our literature search identified 2 registries and 6 clinical studies that examined potassium levels in pediatric massive transfusion. In addition, we examined 9 case reports, published between 1972 and 2007, of pediatric patients who had experienced cardiac arrest during massive transfusion. Serum potassium was reported in 8 of these case reports and had a mean of $9.2 \pm 1.8 \text{ mmol/L}$. Key points that emerged from the clinical studies and case reports were as follows: 1) The case reports were skewed toward infants and neonates in particular, and 2) the rate of blood transfusion (more so than total blood volume), cardiac output, and site of transfusion



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Mixed Simulators: Seamlessly Integrating Physical and Virtual Simulation for Training in Procedural Skills and Safety

by Sem Lampotang, PhD, David Lizdas, Albert R. Robinson III, MD, Olga Ihnatsenka, MD, Nikolaus Gravenstein, MD

Simulation has become an accepted component of education and training in health care to the point that a formative simulation session is now a part of the high-stakes Maintenance of Certification in Anesthesiology (MOCA) exam. The APSF played an influential and seminal role in the development of mannequin patient simulators (physical simulation) through steering the nascent anesthesia-centric mannequin patient simulator designs at Stanford University and the University of Florida to include vital signs such as breath and heart sounds, eye signs and chest movement.^{1,2} This heralded patient simulation through an anatomic and physiological design that would also address training needs of other health care disciplines outside anesthesia. The APSF was also instrumental through its research grant program in advancing virtual simulation in the form of the screen-based, web-enabled Virtual Anesthesia Machine simulation^{3,4} and other screen based simulators.⁵

Simulation is not an end in itself but a means to acquire skills that can be classified into 3 main types (affective, cognitive and psychomotor) that form the skills triangle (Figure 1). Affective skills are about interacting with other humans such as

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Technology's Escalating Impact on Perioperative Care: Clinical, Compliance, and Medicolegal Considerations

Vignette

A 57-year-old female presents for a laparoscopic cholecystectomy. Following the uneventful induction of general anesthesia, the patient is prepped and surgery begins.

Intraoperatively, the patient becomes acutely hypotensive and tachycardic. Despite intravenous fluids and phenylephrine, the hypotension persists. The patient is ultimately resuscitated but slow to awaken postoperatively. MRI of the head reveals an ischemic infarction. She regains consciousness on postoperative day 1, but has persistent right-sided weakness.

The spouse and surviving children bring suit against the anesthesiologist for failing to appropriately treat the hypotension resulting in a cerebrovascular accident. During discovery, the circulating nurse and scrub technician testify that the anesthesiologist was on her cell phone and checking e-mail immediately prior to the event. Plaintiff's attorney subpoenaed the cell phone and hospital computer records validating the allegation.

Comments – Cell phone and hospital computer records are discoverable and may be admissible evidence at trial. In this case, the anesthesiologist's defensible care is compromised by the proven allegation of electronic distraction during the anesthetic.

Introduction

The medical community has historically approached new technologies with a reasonable degree of circumspection. In 1985, an *Annals of Internal Medicine* article addressed uncertainties surrounding the growing use of computer applications in health care.¹ Specific concerns included ethics, confidentiality, regulatory measures, patient safety, and liability. Nearly 20 years later, these enduring issues remain topics of debate.

Benefits of Technology on Clinical Practice

Technology has changed the practice of medicine. Powerful handheld devices are serving escalating roles. These devices can seamlessly connect to information via the electronic medical record (EMR) and a host of other software applications. Benefits of this technology include improved communication, information access, and productivity. by Brian J. Cammarata, MD, and Brian J. Thomas, JD

Connectivity and Communication

Over a relatively brief period of time, physicians have grown accustomed to readily available connectivity and robust access to information. They now have the capacity to view critical information and prescribe therapy for anywhere in the world. The traditional location-centric approach to information acquisition has been replaced by a more user-centric model. For example, reviewing an echocardiogram no longer requires a walk to a specific department. Instead, the practitioner can view most studies from any computer inside or outside of the hospital.

Texting (including messages sent from mobile carrier websites, web-based paging applications, call centers, answering services, and hospital switchboards) can be a useful method of communication. In contrast to voice communication, text messaging is often more convenient for busy professionals' schedules and expedites daily work flows. Additionally, the capacity to send attachments (such as pictures or other pertinent documents) augments communication efficiency.

Connectivity promotes better resource matching and supports evolving practice models. In anesthesiology or critical care medicine, electronic access to information has augmented the ability to centrally monitor multiple patient-care locations and can promote improved attending physician resource utilization. On a larger scale, telemedicine is rapidly expanding and becoming a vehicle for care in outlying communities.

Detethering

Mobile solutions are evolving as a standard for information access and communication. Miniature devices now have computing power rivaling desktop tower workstations a few generations old. Many health care institutions are leveraging this technology and deploying fully mobile access solutions.

Beyond the provider-flexibility aspect, mobile solutions have other benefits for patient care. Radio-frequency identification (RFID) technology facilitates processes such as the efficient use of surgical equipment and pharmaceutical inventory management. RFID-labeled instruments and sponges yield prompt identification of retained surgical devices and improve patient safety.²⁻⁴

Anesthesia Information Management Systems

In many aspects, anesthesiology practice readily interfaces with automation. Anesthesia Information Management Systems (AIMS) can assist with escalating practice demands including immediate access to patient data, improved documentation legibility, contemporaneous documentation, and clinical decision support.⁵⁻⁷

Preoperatively, timely patient information enhances evaluation quality.⁸ Intraoperative functionality, such as automated electronic data acquisition, reduces clerical tasks and expedites data analysis.⁹ Throughout the perioperative period, clinical decision support (CDS) can potentially reduce errors and improve patient safety.¹⁰

Data

Electronic medical records have the capacity to support large-scale data acquisition and analysis.¹¹ Sophisticated data management and reporting facilitates compliance and safety initiatives such as the Surgical Care Improvement Project (SCIP), Patient Quality Reporting System (PQRS), and Anesthesia Quality Institute (AQI).

Technology and Patient Safety Concerns

In addition to the described benefits, technology has introduced new patient safety and ensuing medicolegal concerns. Medical staff and hospital leadership must establish guidelines, work flows, and processes to promote the rational use of these innovative tools. Table 1 lists common technology-related concerns and describes operational solutions.

Intraoperative Noise Pollution

Numerous sources of noise pollution exist in the operating suite environment. Some sources of noise pollution, such as patient monitors and surgical equipment, are unavoidable. Discretionary sources, such as personal communication devices and digital music players, require consideration. Despite limited studies on this topic, available evidence supports concerns that intraoperative noise can adversely impact patient safety.¹²⁻¹⁴

Digital devices and widely available portable docking stations have introduced music into almost every operating suite. Music can promote a pleasant working environment, improve productivity, and reduce patient anxiety.¹⁵ Depending upon the timing and volume, however, music can also become noise and a distraction. A laboratory study by Stevenson et al. determined that visual attentional loads and auditory distractions additively reduced anesthesiology residents' ability to detect changes in pulse oximeter tone.¹² A subsequent study by Way et al. concluded that ambient noise (specifically music) similarly reduced auditory performance by surgical residents.¹⁶

New Technology Leads to New Concerns and Considerations

"Technology Impact," From Preceding Page

Beyond medicine, other industries have identified occupational noise concerns as an important safety issue. The airline industry mandates that flight decks are free of distracting input during critical periods (a "sterile cockpit" in the vernacular).¹⁷ These critical periods include take off and landing. Critical intraoperative periods, such as anesthesia induction/emergence and unanticipated surgical events, should be treated with similar privilege. Ironically, Ginsberg et al. reported that ambient operating room noise volumes were consistently highest during critical anesthetic events.¹⁸

Other Operating Suite Distractions

Texting or talking on the phone negatively impacts the performance of common tasks such as operating a motor vehicle.¹⁹⁻²¹ The extent to which distracting activities influence anesthetic patient care is less clear. Slagle and Weinger evaluated the impact of reading during low-workload periods of the maintenance phase of anesthesia. The authors concluded that reading did not negatively impact objective vigilance measures.²² A second study by Wax et al. examined intraoperative electronic nonrecord keeping activities during anesthesia maintenance.²³ Comparable to intraoperative reading, the authors did not observe a correlation between the potentially distracting activity and increased hemodynamic variability.

Despite the aforementioned studies, the topic of intraoperative distraction is complex and remains controversial. Elective multitasking may negatively impact previously unmeasured aspects of anesthetic care. Functional magnetic resonance imaging reveals that non-distracted information processing and storage involves the hippocampus. During multitasking, the striatum is activated and replaces hippocampal engagement. The latter condition may negatively impact creativity and adaptive problem solving.²¹

The ASA Closed claims database reports a relatively small (13 of 5822) number of adverse outcomes related to provider distraction.²⁰ These included reading printed material, phone calls and loud music. Distraction-related events were more commonly judged as substandard care and were associated with payments in over 80% occurrences. As the vignette accompanying this article highlights, patients expect the full attention of each operative team member throughout surgery.

Intraoperative Nursing Workflows

Nursing workflows are designed to focus on patient care. Intraoperatively, the circulating nurse is often expected to answer cell phones, return calls, or read texts. These activities interrupt workflows and potentially detract from critical patient care events.

Table 1. Technology Concerns and Solutions

TECHNOLOGY CONCERN	IMPLEMENTABLE SOLUTION			
Excessive noise during critical periods	Control non-essential noise levels during all phases of each procedure allowing team members to effectively bi-directionally communicate			
	Eliminate all discretionary sources of noise during prescribed "sterile" periods and any unanticipated event requiring additional team communication			
ading, Phone Calls and	Avoid discretionary internet-based activities during patient care			
Texting	Limit multitasking to brief, necessary events			
	Provide OR internet access only to patient-care related websites			
	Adhere to Professional Society guidelines addressing appropriate device use and minimizing distraction			
Intraoperative nursing	Maintain a culture of "patient first" for the entire surgical team			
workflows	Avoid placing an expectation of managing mobile devices on the circulating RN or other team members			
AIMS	Ubiquitous user involvement throughout the AIMS lifecycle			
	Reasonable, but consistent, education for all end users as a contingency of practicing in your facility			
	Encourage and expect only original documentation for all end users			
	Collaborate with IS and HIM departments regarding EMR data retention practices and policies			
Alert Fatigue	Replace "informational" alerts with an "actionable" version			
	Implement an iterative process for evaluating individual alert effectiveness and modifying to effectively achieve the desired patient-safety goal			
Compliance	Never send PHI of any variety over an unsecured texting platform			
	IS and clinical department collaboration regarding the security needs to protect patient information			

Abbreviations: OR, operating room; RN, registered nurse; AIMS, anesthesia information management system; IS, information systems; HIM, health information management; EMR, electronic medical record; PHI, patient health information.

Unsecured Texting and the New HIPAA Rule

Patient privacy is a compliance mandate and a periodically neglected aspect of patient care. Privacy violations often occur insidiously, such as through texting. Unsecured texting of protected health information (PHI) can result in potentially significant liability risks, federal compliance investigations, and civil monetary penalties.²⁴ The final HIPAA omnibus rule creates a presumption in favor of notification of any breach of unsecured PHI. The HIPAA Privacy and Security Rules generally require covered entities and their business associates to implement appropriate physical, administrative, and technical safeguards to ensure confidentiality, integrity, and availability of all electronic PHI it creates, receives, maintains, or transmits.²⁵ Secure passwords and encryption are common technical safeguards. PHI should neither be transmitted via an unsecured platform nor stored on public "cloud" archives.

Anesthesia Information Management Systems

Increasing AIMS implementations have introduced new concerns for patient safety. AIMS applications and workstations are highly configurable. Robust and mandatory training is critical. From an organizational perspective, case law has supported health care facility requirements to uphold adequate end-users training.²⁶

Despite overwhelming concerns of technologyrelated safety issues, the most common sources of errors are user driven. While aberrant readings can occur, these can be corrected and updated by the vigilant provider. Prevalent intraoperative errors include incorrect medications, inaccurate timing, or even charting on the wrong patient. Copying and pasting within, and sometimes across, patient records is an undesirable but common occurrence and potential source of errors.²⁷

End user notifications, sometimes called clinical decision support (CDS), are intended to miti-

Draft Documents May Persist in Electronic Database

"Technology Impact," From Preceding Page

gate critical user errors. Misguided overuse of this technology can result in end user alert fatigue and compromise the tool's effectiveness. Alert fatigue results in end users disregarding up to 9 out of 10 notifications at some facilities.²⁸ Strategies for effective CDS include the judicious deployment of actionable alerts and recurring institutional evaluation regarding individual alert effectiveness.

The New Medical Record

Long after the patient's surgical procedure is complete, the medical record preserves critical event details. The emergence of the EMR has eliminated what traditionalists would call the "patient chart." Instead, vast amounts of data are electronically acquired and stored throughout the patient's hospitalization. This electronic warehouse can include the patient's medical history, billing information, consents, imaging studies, medication administration, computer-generated advisories, risk management data, research data, race data, religion data, and almost certainly a whole host of other "fields" that most of us may never even suspect exist. Elements of these data are then extracted and placed into reports creating a facsimile of the traditional record.

One of the selling points of the EMR is that it becomes a clearinghouse for patient care considerations and to support the business aspect of medical care. For example, an anesthesia provider may manually or automatically enter procedure start and end times into the EMR for patient care reasons. Following the procedure, members within other hospital departments will almost certainly access this information for related services. A common scenario could involve the hospital's coding and billing department. However, an activity as benign as a hospital coder's entering the database to review start and end times for billing purposes could be used by creative plaintiff's lawyers to argue a potential opportunity for falsification or alteration of the medical record.

More troubling still is the reality that draft versions of electronic documentation, prior to "signoff," may remain buried in the electronic data. For example, if a provider begins charting a narrative, then decides to change the word choice or provide additional information, the provider may be under the assumption that only the "final" version is saved in the EMR when the provider hits "save" or "sign-off" on the entry. For any serious and aggressive plaintiff attorney years later, the prior edits may still be available and regarded as valuable information. The concept is similar to those who were trained not to chart in pencil because it can be erased. The mere imprint of erasure makes what was previously written look potentially damaging.

The message from this reality is that when a health care provider does chart, one must choose their words carefully. Always assume that drafts of the entry can potentially be reconstructed with enough effort somewhere down the road. Physician administrators, health information management departments and information system professionals should prospectively collaborate and establish policies regarding mutually agreed upon data retention practices. This approach will promote reasonable documentation practices and information sharing.

Summary

Technology has improved multiple facets of medical practice. Predictably, technology has also been accompanied by new challenges requiring active management. Practitioners must have an understanding of technology-related topics ranging from the impact of distraction to compliance. Anesthesiology, surgery, perioperative, and information technology departments should cooperatively establish policies and procedures governing the acceptable use of technology in the operating suite. Multiple professional medical organizations have either created, or are in the process of creating, similar guidelines.

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Anticipation of Massive Transfusion May Allow Preventive Measures

"Pediatric Hyperkalemic Arrest," From Page 1

(with central venous access being higher risk) were key factors in the development of transfusion-associated hyperkalemic cardiac arrest (TAHCA).

In an editorial, Strauss⁴ recommended that RBC be infused at 0.5 mL/kg/min in order to avoid hyperkalemia. However, the clinical situation may dictate exceeding this rate. Although massive transfusion in the perioperative setting is often in the context of hypovolemia from blood loss with ensuing fluctuations in hemodynamics and electrolytes, anesthesia providers can take measures to reduce the likelihood of TAHCA. We recommend that anesthesia professionals anticipate blood loss and transfuse before significant hemodynamic compromise occurs. In a hypovolemic, low-cardiac-output state, the body's ability to redistribute the potassium load present in stored blood is compromised, resulting in clinically significant hyperkalemia. It is hoped that early transfusion will allow for a slower rate of transfusion and prevent the need for rapid infusions. Identifying patients with baseline electrolyte abnormalities or compromised renal function is important as well, based on the patient's known comorbidities and the type of surgery planned. We recommend that electrolytes be checked and corrected frequently to prevent the metabolic changes, such as hypocalcemia and acidemia, that often accompany massive transfusion. In terms of route, we recommend using peripheral intravenous (IV) catheters rather than central venous lines for massive transfusions. Five of the 9 case reports in our review involved primary transfusion via a central line. Theoretically, peripheral infusion will also allow for a longer redistribution time of the potassium load present in stored RBC before it reaches central circulation and exerts cardiogenic effects. Furthermore, in in vitro studies, larger bore (>23G) peripheral IV catheters were shown to cause less RBC hemolysis than were small-bore IV catheters.⁵

When massive transfusion is anticipated, a Transfusion Medicine consult is beneficial in determining what the transfusion policy is for the hospital and what effective measures are available to reduce the potassium level in the RBC products dispensed from the Blood Bank, particularly in a scenario where hyperkalemia becomes clinically significant.6 One option may be to use "fresh" RBC for massive transfusion; the definition of fresh is arbitrary and often refers to RBC stored less than 7 days after collection. However, these fresh units may be in limited supply or completely unavailable. Depending on the Blood Bank, measures to reduce the potassium level in stored RBC include plasma volume reduction, reduction of additive solution, washing of RBC, and minimization of the time interval between irradiation and transfusion. Again, these measures to process stored RBC take time and are specific to certain institutions. Timely communication among the surgeon, anesthesia professional, and Blood Bank is crucial to prevent any one group from making decisions unilaterally, to optimize the use of available resources, and to minimize the risks for hyperkalemic cardiac arrest in the bleeding patient who requires massive transfusion.

If significant hyperkalemia does occur, some treatment options include the following:¹

- Calcium chloride 10-20 mg/kg (max 1 g) or calcium gluconate 30-100 mg/kg (max 3 g)
- 1-2 g/kg IV dextrose (using 10% dextrose in neonates and 25% dextrose in older children) and insulin 0.1 units/kg IV
- Bicarbonate 1 mEq/kg IV
- Kayexalate 1-2 g/kg/dose via gastric tube or per rectum
- Discontinue potassium-containing IV fluids and replace with normal saline
- Albuterol
- Hyperventilation.

Most transfusions administered for anemia can be given without concern for TAHCA. However, in the small subset of pediatric patients identified to be at risk, anesthesia professionals should anticipate and prepare for hyperkalemia in the context of massive transfusion.

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Surgical Team Debriefing and Follow-Up: Creating an Efficient, Positive Operating Room Environment to Improve Patient Safety

Experience from the Memorial Healthcare System, Florida

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Abstract

Crew Resource Management (CRM) training includes teamwork, communication, decision making, and the routine usage of checklists and protocols. The principles of CRM were developed in high-risk, high-reliability industries where mistakes cause disastrous consequences. In recent years, CRM practices have been introduced to hospitals to improve patient safety. This paper examines the role of debriefing in the operating room, in helping to make the surgical suite safer for patients. As one of CRM's most powerful tools, debriefing improves communication across disciplines, provides a means for practice improvement, and assures that equipment, personnel, and technology issues are identified and addressed. Communication among professionals in the operating room and the practice of debriefing will be discussed through an examination of the experience of the anesthesia and surgical teams at Memorial Regional Hospital and Joe DiMaggio Children's Hospital in Hollywood, Florida. It was found that the debriefing tool supports continuous process improvement by encouraging each team member to creatively identify solutions to issues encountered during the perioperative period.

Keywords: Briefing-debriefing; Crew resource management; Patient safety

Introduction

Despite continuous improvements in surgical and anesthesia techniques, including the use of less invasive surgical approaches,¹ preventable medical errors account for more deaths annually than breast cancer, automobile accidents, or drowning.² Poor communication among health care workers is widely recognized as the most common cause of these errors,³ with estimates ranging from 43% to 91% of adverse events and near misses in the operating room (OR) attributable to miscommunication.⁴⁻⁶ In response to preventable surgical errors, the Joint Commission Board of Commissioners has mandated strategies for improving communication, including the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery[™] (2003) which emphasizes pre-procedure verification, site marking, and a time out.^{7,8}

Hospitals have a vested interest in improving the communications among OR staff, but admonitions and behavioral sanctions are seldom sufficiently effective to reduce OR-related errors and the facility's concomitant malpractice risk. All too often, the spirit of teamwork and collaboration is not present in a typical operating room setting due to an uneven power dichotomy: the surgeon is the one in charge; other staff members are present to support the surgeon's role. But this one-sided approach discounts the insights and wisdom of others in the room, sometimes to the detriment of the patient.

The surgical arena is not the only environment that requires thorough communications, teamwork, and decision-making to ensure safety, but other industries have integrated Crew Resource Management (CRM) into their daily practices as a way to promote teamwork, communication, decision making, and the usage of checklists, specific protocols, and algorithms.

CRM-based team training has an excellent track record in overcoming communication and collaboration causes of adverse events in such high-risk, high-reliability industries as aviation, nuclear power, and military operations.⁹⁻¹¹ In these industries, CRM has contributed to an 86% decrease in the risk of dying on a U.S. major jet air carrier since the 1990s,¹² a 52% reduction of military transport squadrons accidents, and an 81% decrease in U.S. Navy Intruder squadrons accidents, among others.¹³

With miscommunication significantly contributing to the volume of preventable medical errors, some hospitals have begun to tap into CRM training in recent years and document its positive effects on reducing both surgical mortality and OR delays.¹⁴⁻¹⁶ While full CRM implementation is multi-faceted, this paper addresses how surgical team debriefing following the completion of a surgical procedure is key to creating a culture that continuously improves patient safety.

Materials and Methods Setting

Memorial Healthcare System ("Memorial"), the fifth-largest public health care system in the nation, has a reputation for providing advanced medicine and technology, and high quality health care services to South Florida residents through its 6 hospital facilities. Memorial and its facilities have earned many awards and accolades including the American Hospital Association's "Living with the Vision" and Foster G. McGaw awards, for which Memorial was selected from more than 5,000 hospitals as the national model for improving the health of the community. Memorial Regional Hospital, the flagship facility of the health care system and one of the largest hospitals in Florida, offers extensive health care services including Memorial Cardiac and Vascular Institute, Memorial Cancer Institute, and Memorial Neuroscience Center. The value of debriefing and communication was explored among OR professionals from Memorial Regional Hospital and Joe DiMaggio Children's Hospital.

CRM Tools

CRM training was introduced within Memorial in late 2007 with the goals of creating a culture for patient safety through improved communication, teamwork, and decision making among professionals in its operating suites. The assistance of a hospital consulting group with considerable experience in CRM Patient Safety programs was enlisted to help improve patient safety throughout the hospital system. Hospital executives and physician department chairs, in concert with Memorial's consultants, began introducing teamwork and communication training to each department. Since buy-in from hospital leaders and key physicians was priority, Memorial's team members worked together to develop specific tools and expected behaviors that would help each of them position patient safety at the forefront of everyone's job.

A key element in the communication rigor established through CRM is the time out, which empowers each team member to be responsible for patient safety. Conducted just prior to surgical incision, the time-out statement concludes with the safety reminder: "If you see anything you think is unsafe, I expect you to speak up, look for red flags, and use the word 'delta!' anytime a full stop is needed." When any member of the team calls 'delta,' that statement requires all action to cease because a team member has identified a serious patient safety issue that requires assessment by the team before proceeding. The willingness of staff to speak out in this way is predicated on strong commitment by top personnel to build an institutional culture for patient safety.

Other CRM tools, such as debriefing, are aimed at increasing communication across disciplines. In a study by Zuckerman, et al., debriefing is described as a process that allows individuals to discuss team performance in a constructive, supportive environment—a process which has been linked to improvements in specific procedures, teamwork and communication, and error identification.¹⁷ The Bandari et al. study demonstrated that briefings and debriefings were a practical and

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successful means of identifying both clinical and operational errors in surgical care.

The OR team debriefing is a very fast postoperative meeting with all members present from a surgery. The lead surgeon calls for input and, with an intentional twist on convention, the least senior member of the team is invited to speak first. The questions to be addressed during the debriefing are:

- What went well?
- What needs improvement (in terms of systems, supplies, staffing, and communications issues)?
- How can these improvements happen?

As demonstrated in these questions, the practice of debriefing provides an opportunity for all involved to identify both what went right with the case and what aspects could have been improved, as also noted in a study by Ahmed et al. that identifies best practices in surgical debriefing across 3 continents. In this manner, the intent is to hardwire teamwork behaviors and open communication into the daily standard of care.

Implicit in the practice of debriefing is the act of follow-up by the institution. Follow through provides an opportunity for continuous improvement not only from the perspective of the team members' performance but also for the identification of environmental aspects (equipment, supplies, physical layout, etc.) that require attention before the next surgery. Items generated from the previous day's debriefing are reviewed in the morning OR report by the surgical director, giving staff the assurance that the work they are doing in the debriefing is being put to good use. It is the responsibility of the circulator to communicate specific problems identified in the debriefing session to specific individual(s) who would be responsible for taking corrective action, generally within 12-48 hours. For example, if missing equipment or instruments were noted, those items would be reported to the equipment sterile processing department. If one of the team members could not properly operate a piece of equipment, that person would be referred to the person in charge of OR personnel for follow-up education. Likewise, Bandari et al. describe how the list of defects identified during briefing and debriefing should be sent to administrative personnel on a weekly basis and to the hospital administration on a monthly basis.¹⁸ (An example form used during the debriefing process is shown in Figure 1, and an example of how the circulator will communicate follow-up issues to the various hospital departments is shown in Figures 2 and 3 on the following pages) As in Berenholtz's study, Memorial's staff members use this information Debrief Action Items (Owned by Circulator)

	e: E	oked Room:		Booking #:	Booking #:	
Time	Time on grid: Gender:			Age:		
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Figure 1. Example of debriefing form.

for continuous process improvement and feedback to hospital personel.

Results

Through CRM training that emphasizes communication and standardized processes, Memorial has experienced outcomes that include improved quality, improved safety, reduced untoward outcomes and sentinel events, improved patient experience, and improved patient satisfaction. Although it is a natural and inevitable human condition to revert back to poor habits, CRM eliminates such process and protocol variability, substantially reducing this creep towards previous habits by requiring conscious effort and concentration at the point of care.

Memorial saw significant increases in safety, communication, and satisfaction in every hospital as a result of implementing CRM and as evidenced through Memorial's safety culture survey scores. A year following the implementation of CRM training, physician satisfaction increased

CRM Can Improve Handoffs and Transitions

Surgeon

Referred to

Preference Card Update

Account

Number

Date

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substantially in every category, including perception of overall quality, place to practice, patient safety, teamwork collaboration with nursing, and communication with nursing.

In addition to physician satisfaction, Memorial's staff members developed an extraordinary sense of teamwork combined with a high degree of personal responsibility to assure patient safety, as demonstrated by the 2010 safety survey. Here, teamwork within units and employee satisfaction experienced significant increases across every hospital. In this way, the standardization of communication procedures that CRM facilitated has created an environment where all employees are able to proactively contribute to patient safety.

CRM also contributed to significant improvement in terms of handoffs and transitions as well as improvements across other departments that utilized CRM training, including the radiation oncology department. Since implementing CRM in the radiation oncology department, none of its treatments have deviated from the treatment plan, and the department has been able to identify situations where ambiguity or conflicting documentation could have resulted in inappropriate treatment or significant patient harm.

However, not all departments saw significant increases. While moderate or mild increases were also common, pockets of low performance did exist, too. These pockets of low performance may be due to lack of management commitment or support, fewer experienced employees, or other external events. Although some departments demonstrated weaker results than others, CRM has greatly affected each of Memorial's 6 hospitals by instituting a wide-ranging organizational culture change.

Examples

To further demonstrate how debriefing works to facilitate teamwork and promote a better culture for patient safety, we present several examples-some fairly straightforward and some that address the very core of teamwork and communication issues within the operating suite. It is our intent to demonstrate how the actions generated from debriefing can range from quick fixes to much more detailed solutions.

Environmental Factors

During open-heart surgery, a monitor measures brain function and blood flow to the brain during cardiopulmonary bypass procedures. In one such procedure, the view of this monitor was obstructed by other equipment. Since the monitor's information was not visible to all the staff, appropriate adjustments during the surgery were not made as quickly as they otherwise would have been. In the debrief, the OR staff noted this and

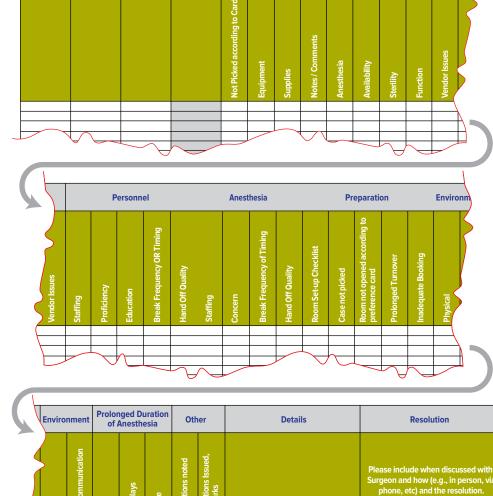


Figure 2. Example of form used to facilitate follow-up communication.

made a recommendation for future equipment placement that is visible to all staff throughout the procedure.

Protocol Development

After separating a pediatric patient from cardiopulmonary bypass and experiencing difficulty ventilating the patient, the anesthesia team recognized that they should perform more frequent blood gas analysis to ensure that the patient is appropriately ventilating and oxygenating post bypass. In the debriefing that followed, the anesthesia team developed a protocol that is now used

routinely to ensure optimal ventilator management for the patient after separation from cardiopulmonary bypass.

Briefing Information

In one cardiac debriefing session, the team identified that by routinely addressing the type of anticoagulant the patient is taking during the presurgical briefing sessions, each team member would be more alert as to how it might affect the patient's response to surgery. By incorporating information about the type of anticoagulant the

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CRM Creates Collaborative Culture

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patient has been taking and whether that anticoagulant is still in the patient's system at the time of the surgery, greater focus can be brought to this issue prior to the procedure.

Tunnel Vision

A female patient was to receive a tracheostomy as a palliative measure. As is typical the surgical team expected a 30-minute procedure. However, the surgeon encountered difficult anatomy and consequently performed a major neck dissection and at one point considered aborting the procedure. After 90 minutes of surgery, convinced that he had identified the trachea, the surgeon placed a tracheostomy tube and asked that ventilation be initiated via the newly placed tracheostomy tube. It was immediately obvious that the tube was misplaced as there was no clinical evidence of ventilation and at this point the 3 anesthesiologists in the OR asked the surgeon to remove the tracheal tube so that the patient could be intubated transorally and ventilated. The surgeon insisted that he was in the airway.

Despite the anesthesiologists' multiple invocations of delta (the signal to stop everything), he did not stop surgery and would not remove his hands from the field. The nursing staff present additionally invoked delta, but the surgeon did not respond to the other team members and continued with this course of action. The patient suffered a cardiac arrest secondary to progressive hypoxia. In desperation, one of the anesthesiologists reached with an unsterile hand into the surgical field and physically removed the surgeon's hands so that the patient could be intubated transorally. The patient could not be resuscitated.

Here, the debriefing documented that the surgeon did not honor the delta. As a result, the Director of Medical Affairs counseled with the surgeon to make clear the expectations for communications in the operating room and response to delta. Moving forward, other operating room personnel have become empowered to move up the chain of command quickly whenever there is a concern about the effects of tunnel vision and a provider ignores delta.

Staff Empowerment

Upon arriving to the OR at 6:30 a.m., the anesthesia attending was greeted by 3 agitated nurses who had assisted with a combined neurosurgery, plastics, and ENT case that had begun the previous morning, approximately 22 hours ago. While obtaining a report from the departing night nurses, they were concerned about surgeon fatigue, the need to assess the patient's status, the need for patient repositioning, and the appropriateness of keeping the patient under anesthesia for such a long period of time. With the knowl-

Debrief with fix Friday 3/2/12 2849746 Dr B-Equipment No backup CO₂ cartridge in Back-up CO₂ cartridge function NOVA SURE machine Positive debrief Tuesday 3/6/12 714021 Dr C-Positive comments for Dr's team D–, M–, M–, A–, and K– who POSITIVE displayed outstanding team-wor to provide very good care to their patients. The team did not have to leave the room for a single thing! Debrief with fix Friday 3/2/12 6820296 Dr G-Carecast would not open in OR #5 Equipment function room also.

Figure 3. Portion of form used to follow-up debriefing which documents resolution of identified issues.

edge that the Chief of Anesthesia was out of town, the attending realized that it was their responsibility to address this situation.

The anesthesiologist recounts that they marshaled courage to question the surgeon and call for a delta. The anesthesiologist indicated that they were documenting their request for a time out to ask some specific questions: Do you need extra help? Do you need another surgeon? Do you need any extra equipment? The anesthesiologist also requested that the patient's coagulation and hematologic status be assessed, the patient be repositioned, and the advisability of proceeding to operate be discussed. The surgeon responded appropriately to the delta, the patient was assessed and repositioned, and the surgery was concluded quickly thereafter.

In this case, the debriefing session identified such issues as the risks of keeping the patient under prolonged anesthesia, the need for periodic repositioning, and the importance of periodic reassessment when the procedure is prolonged. Additional cross departmental meetings led to the development of a protocol that requires an automatic delta after 8 hours for reassessment and joint planning. This new protocol will guide staff the next time a similar situation occurs.

The anesthesiologist noted that the CRM training and strong support of superiors created a collaborative culture that empowered them to act on behalf of the patient and staff.

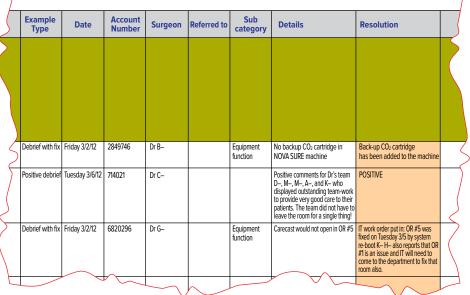
Interventional Radiology Suites In addition to Memorial's OR suite, quality and safety in Memorial's Interventional Radiology Suites were improved due to the increases unifor-

mity that the CRM process encourages. The reduction of untoward outcomes and sentinel events, improved experience and improved patient satisfaction were the result of the patient being included as a team member who could participate in the pause and call out any red flags of concern. Empowering the patient to ask questions has been found to increase the patient's confidence in the physicians, team members, and overall experience.

Discussion

At the outset of the implementation of the CRM Patient Safety System at Memorial, a point of resistance by surgeons and anesthesiologists was the concern that debriefing would add time in the OR after the conclusion of the case. While the value of the routine use of debriefing is huge, the time required to do it is modest. In a study involving more than 37,000 cases in a large medical center, Berenholtz et al. found that debriefing took an average of 2.5 minutes to complete. Contrary to expectations, what Memorial's OR teams have found is that debriefing actually makes their surgeries more efficient and take less time because less time is spent leaving the sterile field to acquire additional needed instruments or assemble equipment. In this way, the pivotal nature of the debriefing tool has been a major driver of change both in the daily practice of Memorial's surgical suites, in terms of making things work more efficiently and effectively and in bringing about specific changes to protocols to assure patient safety.

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Egalitarianism Raises New Challenges

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Parallels with Military Debriefing

Debriefing has been an important performance tool in the military since World War II when it was used to question soldiers at the conclusion of a mission.¹⁹ and it continues to be routinely used today by military flight personnel at the conclusion of every flight and mission. Drawing the parallel between military pilots and surgical teams, Zuckerman et al. notes that mistakes have drastic consequences, so the goal of debriefing is to minimize mistakes and to repeat them with lessening frequency.¹⁷

The act of reflection has been shown to be a critical element in adult learning,²⁰ so it is not surprising that debriefing after military operations emphasizes the significance of learning from the experience.²¹ Furthermore, the more that people associate debriefing with ordinary events, the better debriefing can be integrated into a company's everyday activities.²²

Airborne Warning and Control System (AWACS) navigators, for instance, manage to keep debriefing top of mind throughout their missions, noting any problems encountered, especially if the problems will impact later parts of the mission.23 As noted by Armistead, the debriefing process may occur at multiple intersections during a mission: if the weapons unit is not controlling fighters, they will debrief their missions internally and prepare debriefs to send to the fighter pilots; during the flight home, the technicians will note any problems to debrief with maintenance. Then, after the crew secures the aircraft, they debrief among themselves to evaluate how well they accomplished their training objectives. In this way, AWACS navigators utilize 2 forms of debriefing: the individual crews have the mission debrief on the plane, and then each crew comes together to have a debriefing session as a whole.

The length of such AWACS missions may be analogous to a long transplant case where the surgeon will remain in surgery but the teams change, including anesthesia providers and other surgical team members, thereby having different crews start and finish the procedure. In cases like this, with extended timeframes and multiple "crews," a joint mission debriefing at the end may be beneficial to ensure critical findings are not missed.

Short cases raise similar yet opposing questions about the need for debriefing. When asking whether or not debriefing is necessary after every short case when the same team is present, one can refer to the process of stealth fighters who often land and take off again without turning the engine off yet still complete a minute debrief over the radio. In the same manner, if a procedure takes a matter of minutes in the OR, the team should still quickly note if improvements or problems were found, and at the end of a series of 4 or 5 cases, the OR team can then take a more thorough look at the cases.

Egalitarianism and Tunnel Vision

The emphasis on egalitarianism within the operating suite has not been without its challenges. Anesthesia professionals routinely provide debriefing to their trainees, making it ingrained in the culture of their specialty, but the same was not found to be true among surgeons, as Ahmed et al. noted.²⁴ Although top down change is a challenging transistion for surgeons who are accustomed to being in charge, Memorial's commitment to the speedy resolution of problems identified in the debriefing process has real appeal for them.

Unfortunately, in example #4, Tunnel Vision, the surgeon had lacked situational awareness and had developed tunnel vision. This singular focus on one aspect, to the exclusion of everything else, is also noted by the National Transportation Safety Board (NTSB) as the reason for the crash of Eastern Airlines Flight 401 near the Miami airport in 1972. Members of that crew were so preoccupied with a malfunctioning indicator that they failed to monitor other instrumentation that would have informed them of their unexpected descent soon enough to prevent a crash into the ground. The plane was destroyed; of the 163 people aboard, 101 died from their injuries. The NTSB report observed that distraction, confusion, and lack of effective coordination among the crew led to the event.²⁵ In our surgical example, the invocation of delta was an attempt to interrupt the surgeon's tunnel vision, but that same distracted preoccupation led to fatal results.

Continual Process Improvement

As outlined by the methods and results in this paper, Memorial emphasized that each team member, regardless of his or her discipline or status, had an important voice and role in ensuring a safe outcome for the patient. The same dedication to safety holds true in other high risk settings, including military operations where military ranks are temporarily ignored to allow each member to become an equal witness for the duration of the debriefing, as noted by Armistead.

In both industries, recording action items from the debriefing session has proven to be a rewarding process in itself because it leads to continual process improvement. In Memorial's OR environment, for instance, the right instruments for the specific surgeon and procedure are now prepared correctly the next time and the equipment found to be deficient the previous week is now corrected in advance. When deficiencies are corrected

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promptly and consistently, trust between staff and the hospital builds, and the surgeons are more likely to participate in other aspects of the CRM process as well.

Still, unwavering, impassioned commitment from all senior health care system executives has been the key to implementing the CRM Patient Safety System. From Memorial's Chief Executive Officer to the Chief Medical Officer, Chief of the Department of Anesthesia, and Chiefs of all surgical departments, their commitment to cultural change in the interest of patient safety has set the tone for conduct within the operating suites. Reinforcement from the top produces changes that support the collaborative culture necessary for improved patient safety. In this way, patients are receiving safer care, and all of Memorial's staff members are challenged to bring their very best efforts each day on behalf of their patients.

Conclusion

With dysfunctional communication patterns responsible for a considerable portion of adverse events in the hospital setting, effective CRM training in other high risk industries is gaining appeal. But change routinely meets with resistance. Strong leadership from the top levels of the organization has proven to be the key to effective implementation within Memorial. By concentrating on the successes garnered through a well implemented debrief and follow-up process, surgeons, anesthesia professionals, and staff are more likely to be open to the other aspects of the CRM Patient Safety System. By encouraging all members of the team to be fully involved in assuring the patient's safety, hospitals can draw on the full capabilities of their team members to continually improve their practice. Memorial highly recommends this approach to creating a culture of patient safety.

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Improving Patient Safety: Collaboration, Innovation, Connection Organization Provides Information on New Connector ISO Standards

When the "Luer" connector was developed more than a century ago, its genius was its simplicity. The universal design of this small-bore connector made it easy to administer medication, oxygen, and fluids, among many other therapeutic uses. However, its universal design also introduced vulnerabilities by allowing connection between devices that were not intended to connect (e.g., feeding tube to a ventilator in-line suction catheter; feeding tube in a tracheotomy tube; blood pressure monitor into an IV line, etc.).

Misconnections are rare—many clinicians go their entire career without experiencing an incident—but when misconnections do occur, they may be damaging and even fatal.

These misconnections may occur for a variety of reasons, such as line confusion when multiple medical devices are being used, difficulty in distinguishing the proper connection in low-light conditions, and even the well-intentioned helper misconnecting lines after unintentional disconnection.

New design standards for connectors that are nearing completion will answer a legislative mandate from California and an outcry from health care delivery organizations that have had adverse incidents. Once the new connectors make their way into the supply chain, the "universality" of the Luer connector will be history. The new, safer connectors will be differently dimensioned for each application, eliminating the universality of the current, one-size-fits-all connectors. by Mary Logan, JD, CAE, and Tom Hancock

The Current Situation

We don't know exactly how many misconnections are happening today—because we believe incidents are under-reported—but we do know exactly how dangerous they can be. When a noninvasive blood pressure inflation tube gets connected to an IV line, it delivers air under pressure into the bloodstream and causes an air embolus. When nutritional formula intended to go to the stomach through a feeding tube is connected to an IV line, it delivers the formula into the bloodstream causing embolus and sepsis. When IV fluids are connected to the inflation cuff on a breathing tube and deliver a large volume of fluid to a fixed volume device designed to be filled with air, it creates an airway obstruction.

The push to reduce tubing misconnections already includes alerts and guidance documents, educational materials, practice standards, and protocols, such as tracing a line back to its origin, putting tubes with different purposes on different sides of the body, color-coding connectors, or developing alternate connectors. But eliminating the risk of misconnection required something more comprehensive—a complete design change specified by a series of standards, adopted across the industry.

Success of such a feat has required a shift both in thinking and operating—from competition to collaboration. The first major sign of success came in December 2010, when an international group of clinicians, manufacturers, and regulators,



Manufacturers will begin launching new enteral device connections in 2014.

in collaboration with AAMI and ISO, completed and published a foundational standard (ISO 80369-1) that sets general requirements for safer connectors for the highest risk health care applications. It also establishes a framework for testing connectors to ensure non-interconnectability of unrelated delivery systems (e.g., vascular and enteral). Standards for system-specific applications are still in development, but new connectors are expected to reach the market as early as 4th Quarter 2014 for enteral devices.

Beginning in 2015, additional standards in the series will focus on connectors for specific clinical applications—such as breathing systems and driving gases, limb cuff inflation, neuraxial, and intravascular-hypodermic—and will be released as they are completed. The key point here is that the dimensions of each connector application will be different. Once the new connectors are available, the existing Luer connector will be maintained only for the intravascular and hypodermic applications. All other tubing connectors will be designed to make sure they are not compatible with the intravascular (Luer) connector, or any of the other new connector designs for other delivery systems.

The Promise of a New Design

The beauty of the new connectors is that they echo the simplicity that the original Luer connector delivered—ensuring compatibility and consistency—but with a much lower risk of misconnections. New connectors will provide greater ability for different manufacturers' devices to integrate, while making it much more difficult, if not impossible, for unrelated delivery systems to be connected. Standardized connections across health care settings will lessen the likelihood of therapy interruption due to connector incompatibility or unavailability.

A Phased Introduction

Manufacturers are committed to launching the new connectors with minimal disruption to supply and clinical practice and to working through existing inventory. There will definitely be "pain points" through the supply chain for health care delivery organizations, though. Change is always hard, and this will be a change as "big," or bigger than, as when single-use needles were introduced. The better you and your organizations understand the process, the easier the transition will be.

Be Aware: Prepare and Adopt

"Improving Safety," From Preceding Page

A phased approach will start with enteral devices in 2014. The enteral devices that will be impacted include feeding tubes, administration sets, and syringes. Manufacturers will incorporate the new connectors into their existing offerings where applicable. By working closely with their suppliers, health care facilities or providers should be able to convert on a timeline that best suits their needs and those of their patients.

The introduction will include guiding health care providers through a careful transition plan; developing and executing a coordinated joint communications plan; and identifying each unique connector with a common name to be used by all suppliers of devices for each respective delivery system.

While there are no federal mandates around safer connectors, effective January 1, 2016, California law will prohibit general acute care, acute psychiatric, and special hospitals from using an epidural, intravenous, or enteral feeding connector that fits into a connection port other than the type for which it is intended.

You Can Help: Aware, Prepare, Adopt

The Global Enteral Device Supplier Association (GEDSA), a nonprofit trade association, was formed to introduce the new standards. Partnering with experts from leading industry organizations, GEDSA developed "Stay Connected," a 3-phased communications program—*Aware*, *Prepare*, and Adopt—to ensure a successful transition to safer connectors. Just as the development of the new design standards was a coordinated effort, so too is the market adoption of the safer connectors. You are the key to a successful transition.

The first step is to generate *awareness* of the impending changes across your organization. The new connectors will impact clinicians and administrators, risk management, materials management, quality and safety, health care technology management (i.e., clinical engineering), and other support staff. Choose a team within the organization to stay informed as plans progress, use that team to develop your implementation plan, and communicate updates to the rest of the organization as often as possible.

Preparation will smooth the way for the transition, so clinical teams need to assess existing systems, processes, and protocols that may need to change, focusing on areas of highest risk that have the most immediate need to convert to the new connectors. Work with supplier representatives and adopt their product-specific transition plan. Train clinicians and materials/inventory management staff for impending changes.

Successful *adoption* requires, when the new connectors enter the work stream, that you reinforce to your organization the long-term benefits over the short-term inconvenience of the transition process itself. Transitions can increase or introduce new risk, so awareness of and preparation for what's coming are key to strong adoption strategies.

Working together and taking careful steps to make sure we do it the right way, we will be on our way toward reducing risk and improving patient safety by eliminating the potential for misconnections.

For more information:

http://www.aami.org/hottopics/connectors/ index.html (see especially the new FAQs)

About AAMI

The Association for the Advancement of Medical Instrumentation (AAMI), is a nonprofit organization founded in 1967. It is a diverse community of nearly 7,000 health care technology professionals united by one important mission—supporting the health care community in the development, management, and use of safe and effective medical technology.

About GEDSA

The Global Enteral Device Supplier Association (GEDSA) is a nonprofit trade association formed to introduce international standards for health care tubing connectors. Comprised of manufacturers, distributors, and suppliers worldwide, GEDSA facilitates information flow about the initiative, which is designed to increase patient safety and optimal delivery of enteral feeding by reducing the risk of tubing misconnections. GEDSA partners with leading experts from The Joint Commission, AAMI, American Society of Parenteral and Enteral Nutrition, The Institute for Safe Medication Practices, Premier Safety Institute, Novation, and more to develop and execute a communication plan. Led by GEDSA, this group helps organizations, clinicians, administrators, supply chain, and others transition to new ISO standard connectors. GEDSA invites everyone to "Stay Connected" as the tubing connectors are introduced to ensure a successful transition to safer connections.

The authors are grateful for the work of Colleen Elliott, standards director at AAMI, for her work with the standards committee and input on this article.

Mary Logan, JD, CAE is President of AAMI and Thomas Hancock is Executive Director of GEDSA.

Letter to the Editor: Cap Obstructs CO₂ Sampling

To the Editor:

We recently discovered an interesting finding with our circuit after failing to document endtidal CO2 during bag-mask ventilation after induction. Upon further inspection of the circuit, we noted a blue cap inside the elbow connector (DynJaa, Medline Circuit, see Figure 1). It was soon realized that the blue cap that normally comes attached to the outside of the elbow connector, where the sampling line attaches, was actually inverted and pushed inside the connector. After a vigorous tapping of the elbow connector, the blue cap fell out, and we reattached our sampling line and confirmed end-tidal CO₂. Thankfully, no adverse outcomes were encountered, but we could easily imagine a scenario during bag mask-ventilation, where the cap could fall straight down into the patient's oropharyngeal cavity, possibly leading to aspiration. We can only speculate as to how the cap ended up inside the elbow connector (new anesthesia tech, accidental loss of the cap), but wanted to share this finding with the readers of the APSF Newsletter. A preoperative machine check was done; however, this event was not detected since the cap obstructed CO2 sampling but did not obstruct airflow within the circuit.

Davide Cattano, MD, PhD, Samir J. Gandhi, MD, Katherine C. Normand, MD

Department of Anesthesiology, the University of Texas HSC at Houston.



Figure 1. The CO_2 connector (elbow) and the misadventurous cap on the wrong side.

Medical Gases: Time to Adopt the Global Standard?

Standardization has long been accepted as a fundamental element of patient safety by the APSF and others. The International Organization for Standardization (ISO) was established in Geneva in February 1947 initially to help standardize industrial development. Since then the scope of ISO has expanded to cover, among many other matters, anesthesia apparatus. As the world becomes a smaller place with regard to the manufacture of such equipment, it is becoming commonplace for many components of anesthesia workstations to be manufactured with a global market in mind. This takes on greater significance as health care staff become increasingly able to move around the world to practice their specialites. It therefore seems even more appropriate in 2014 that all ISO standards should be adopted globally.

Anesthesia, which is recognized as leading the way on patient safety, already has some global standards e.g., user applied medication labels¹ and the International Standards for safe practice of anesthesia.² As the specialty continues to promote patient safety, it seems incongruous that the published international standards of our basic primary/core complement of oxygen, medical gases, and suction are not adopted by all countries. Indeed, without such a fundamental adoption, our speciality's credibility in this aspect of our work would seem to be called into question.

One of the earliest ISO standards defined the colors to be associated with medical gases³ and also the introduction of pin indexing.⁴ Prior to the adoption of these, there had been many accidents due to missed connection of gases.⁵ The problems associated with color coding of cylinders became the basis for a very popular crime novel and film, *Green for Danger*, by Christiana Brand.⁶

At this time around the world there still appear to be some major differences in the way that medical gases are presented, with the most important of these being the color coding of oxygen for both cylinders and pipelines, which can be white, green, or blue even within the same country (see Figure 1)! Such differences are made potentially much more dangerous by the increasing ability of anaesthesia personnel to travel and work from country to country.⁷

Different colors may not be seen as a major problem in elective work although deaths still occur.⁵ Yet, when an emergency or anesthetic crisis occurs, reflex actions are more likely to be taken and this could result in serious harm.

This problem was highlighted at the most recent World Congress of Anaesthesiologists in Buenos Aires Argentina in 2012 when all the delegates from over 120 member societies of the World Federation of Societies of Anaesthesiologists voted unaniby David K. Whitaker and David J. Wilkinson

mously in favour of the adoption of a worldwide standard color system for medical gases.

The WFSA Assembly fully supports the principle of one global standard for the colors and labelling of cylinders and pipelines used for the supply of oxygen and other medical gases.

The WFSA Assembly calls upon our colleagues in industry, government and other relevant bodies to join with us and take all the necessary steps to achieve this single standard for the safety of patients all around the world.

It has been suggested that there is no real problem perceived at present and if countries which did not currently follow ISO standards were to change then this might create considerable risks that might impact on patient safety. This is an interesting risk/ benefit debate. Any widespread changes would require careful management, but these should not be a reason to resist improvement in care. The ISO standards for medical gases have been modified several times since they were first published, and the implementation of these changes did not result in any problems as far as the authors are aware. Is it not reasonable and logical to assume that, in the future, color coding of medical gases will be standardized? So the sooner this change is made, the better. As the world's population continues to increase dramatically, any problems in implementing the change to a global system (and we believe there need not be many) will potentially increase every year they remain unchanged and be much greater in future years. Anesthetic and surgical actitivity is expected to increase significantly. In 2004 it was estimated there were 230 million operations.8 In 30 years, even if only the low-expenditure countries rate of surgery per 100,000 population increases to that of the middle-expenditure countries, with the world's population then at 9 billion a conservative estimate would suggest 380 million operations per year. Before this expansion takes place it would seems sensible to have these ISO standards adopted ahead of this almost doubling of worldwide investment in new anesthetic and surgical facilities.

There are lessons in the example of changing the side of the road on which one drives. That is an



Figure 1. Around the world there still appear to be some major differences in the way that medical gases are presented, with the most important of these being the color coding of oxygen for both cylinders and pipelines, which can be white, green, or blue even within the same country.

even more challenging matter, which surely would be associated with absolute mayhem and multiple terrible deaths. In Sweden on September 3, 1967, "*Hogertrafikomlaggningen*" took place when the whole country transferred to driving on the right hand side of the road. The mortality rate from traffic accidents fell immediately and it took 2 years before rates were back to the pre-change level.⁹ There is no expectation that any changes resulting from the adoption of the ISO standards would take place overnight, but this Swedish example provides concrete evidence that radical changes can be implemented when there is agreement and determination to carry them out.

In recent memory Switzerland, Germany, and Austria changed to the ISO standards for medical gas cylinders and no problems were reported. Discussions with our industrial partners who manufacture and supply medical gases and anesthesia apparatus indicate that they would fully support the implementation of one global standard.¹⁰ Why wouldn't they? It is a no-brainer that particularly in difficult economic times they would want to only have to manufacture and distribute one series of products, again increasing safety and reliability for them as well as patients and anesthesia professionals.

Any changes could be carefully planned and managed across health care systems. Most of the costs could be covered by routine maintenance. Gas cylinders are regularly returned to be refilled and

ISO Standards Exist for Color Coding of Gas Cylinders

"Medical Gases," From Preceding Page

could be repainted then. The color-coded, lowpressure, flexible hoses that connect the machines to the gas pipelines-system wear and deteriorate and need changing every 5 years for safety, so their replacement could be easily be coordinated appropriately in a hospital. Similarly, wall connectors that get changed less frequently for engineering developments could certainly be incorporated in all new buildings/refurbishments. As with the adoption of other standards hospitals will have to plan their introduction locally. This rarely happens overnight and the full involvement of our manufacturing colleagues, who will also benefit from a simplified/standardized production and supply chain will be vital.

So is there a way forward? Superficial consideration makes some pessimistic colleagues think it may be insurmountable. But with cooperation, initiative and goodwill it could be exceedingly easy.

There already is an ISO standard for color coding of gas cylinders, which has been adopted by many countries.³ We would like to see all anesthesia providers around the world adopt this standard and lobby for its introduction in their own country by a specific date. If the profession as a whole could successfully coordinate and lead to deliver this it will be a wonderful achievement to demonstrate our speciality's global commitment to patient safety and a milestone and model for others to follow.

An initial move might be the organization of a Medical Gas Summit which brings together all those with an interest in this field, anesthesia professionals, manufacturers, and safety experts, etc., to have face to face discussions on how this might be implemented.

If anesthesia can achieve this it will send an important signal to all the other specialities in medicine and other professions that such important global standardizations can be achieved for universal benefit and make our increasingly smaller world a safer place.

Acknowledgment

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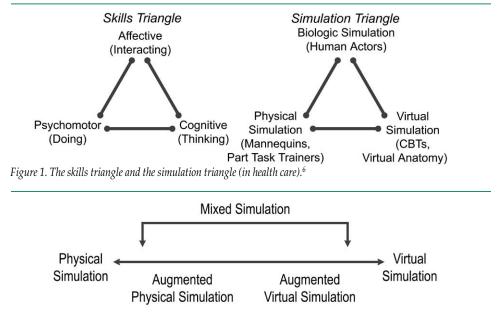
Mixed Simulators Contain Both Virtual and Physical Components

"Mixed Simulators," From Page 1

interpersonal skills, leadership, and teamwork. Cognitive skills involve thinking and the application of knowledge, e.g., decision making, strategy, risk assessment, and risk mitigation. Psychomotor skills center on qualities of "doing" or performance such as manual dexterity, hand-eye coordination, and spatial ability.

The simulation technologies used to acquire all 3 types of skills in health care fall into 3 main classes (biologic, virtual and physical) that constitute the simulation triangle (Figure 1). The 2 triangles, as represented in Figure 1, map well onto each other. A physical simulator devoid of virtual elements (such as an intubation head or mannequin patient simulator) is ideal for learning psychomotor skills such as intubation or CPR. A virtual simulator such as a computer based trainer (CBT) has no physical, tangible elements. Interactions are mediated via pointing devices such as a mouse or joystick as in the web-enabled Virtual Anesthesia Machine (VAM) simulation.⁴ Virtual simulators are well suited to convey cognitive skills and knowledge; e.g., they provide the ability to virtually peel off layers of a human body or a piece of equipment to provide insight into hidden or invisible internal anatomy, structures, mechanisms, and processes.⁴ Standardized patients (human actors having, or pretending to have, a disease condition) are also considered a form of simulation (biologic) and provide an excellent way to hone affective skills such as bedside manners and conducting a history and physical or an anesthesia preoperative assessment. A logical conclusion of our lab's APSF-funded research in physical and virtual simulations was to combine both forms of simulation to benefit from the advantages of each in a seamlessly integrated mixed simulator (Figure 2).

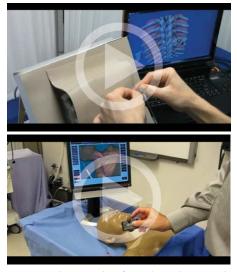
What is a mixed simulator? A mixed simulator, as the name implies, contains both physical and virtual components.6 A lay example of a mixed environment is the yellow first down line when watching American football on TV. The yellow first down line is virtual and does not physically exist; spectators in the football stadium do not (yet) see a yellow first down line. For the mixed environment to work, the virtual component must be precisely registered (an engineering term) to its physical environment; that is, it should appear to be in the precise location that it would have been had it been physical. Taking the yellow first down line again as an example, if it was superposed a yard off from where it needed to be it would mislead rather than augment our ability to appreciate the game. Within the context of mixed simulators for medical procedures, the precision of the registration must be submillimeter; we do not want the wall of a virtual vein to be off by more than 1 mm from where it would be relative to, for example, a virtual lung or a physical rib in a mixed simulator. In addition, in a mixed simulator that represents anatomy, the vir-



*Figure 2. The taxonomy for the physicality-virtuality continuum in simulation*⁶ *that forms the base of the simulation triangle depicted in Figure 1.*

tual components such as the brain, lungs, veins, arteries, nerves, and ligaments are 3-dimensional with sometimes complex, convoluted surfaces compared to a one-dimensional first down line.

The safe and efficient performance of medical procedures such as central venous access (CVA) and regional anesthesia (RA) requires both 1) cognitive skills (e.g., correct mental model of complex 3D anatomy, defensive strategy [If I miss the vein, will I strike the first rib or the lung along this trajectory?], and correct interpretation of a cross-section produced by handheld ultrasonography during guided procedures) and 2) psychomotor facility



Concrete video examples of mixed simulators can be found at http://simulation.health. ufl.edu/research/cvl_ intro.wmv and http://simulation.health.ufl.edu/ research/ra_sim.wmv.

(right and left hand dexterity, coordination in advancing the needle and moving the US probe simultaneously while keeping the needle tip visible in the insonation plane, and spatial ability to think and visualize in 3 dimensions).Thus, procedural simulators are a good fit for mixed simulators that combine the 2 forms of simulation technology (physical and virtual) best suited for acquisition of procedural skills (psychomotor and cognitive respectively). Concrete examples of mixed simulators are a CVA7 and an RA simulator; see videos at http://simulation.health.ufl.edu/research/cvl_ intro.wmv and http://simulation.health.ufl.edu/ research/ra_sim.wmv.

Both the RA and CVA mixed simulators are anatomically authentic as the 3D anatomical components are derived from medical imaging (MRI, CT). The physical components of the mixed simulator such as the ribs, skull, and skin are reproduced via a 3D printer that creates a high fidelity replica of the human model. Many medical procedures involve a needle or catheter with a metal stylet. The tip position (x,y,z) and orientation (roll, yaw, pitch) of a physical needle are tracked with a miniature magnetic sensor with sub-millimeter resolution so that if the tip is inside the space occupied by a virtual 3D component such as a vein, then the correct feedback such as a blue-tinged flashback in the syringe can be simulated. A 3D color visualization (real-time visual augmentation) is part of the mixed simulator design and allows users to visualize a virtual replica of the needle interacting with the internal components in both "blind" and guided procedures. The simulator captures all the user's actions during

See "Mixed Simulators," Next Page

CVA Simulator Awarded Best Scientific Exhibit at 2011 ASA and RA Simulator Wins EC Pierce Award

"Mixed Simulators," From Preceding Page

the procedure, enabling playback of the procedure for after action review (debriefing) as well as an automated, objective, and transparent scoring algorithm. In general, the soft tissues are simulated as virtual components while the bony structures such as the clavicle, sternal notch, and spinous processes are implemented as physical components and can be palpated and sometimes used as anatomical landmarks. The mechanical interaction between the physical needle and the physical structures in the mixed simulator provide an inexpensive method to provide tactile feedback to users without needing a haptic device. Ultrasonography, used for guided procedures such as CVA and RA, is readily incorporated into a mixed simulation and further enhances the capabilities and realism of the mixed simulator.

The CVA simulator was awarded the First prize for the Best Scientific and Educational Exhibit at ASA 2011 and the RA simulator the APSF Ellison Pierce Award for Best Patient Safety Exhibit at ASA 2013. In

a simulated environment, the CVA simulator reduced the incidence of iatrogenic pneumothorax during central venous access,⁷ a complication recently classified as a Serious Reportable Event (formerly known as a "never event"). By combining the best of virtual and physical simulation, mixed simulators represent the next generation of patient simulators and training tools and hold the promise of further enhancing patient safety by enhancing cognitive (better mental model of 3D anatomy and safe techniques through visualization) and psychomotor skills (keeping the needle tip in the insonation plane) during medical procedures. The crucial and timely funding provided by the APSF research grant program to nurture simulation research continues to bear fruit and advance patient safety.

Sem Lampotang, PhD, David Lizdas, Albert R. Robinson III, MD, Olga Ihnatsenka, MD, Nikolaus Gravenstein, MD, Department of Anesthesiology, Center for Safety, Simulation & Advanced Learning Technologies, University of Florida.

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Letter to the Editor: Increased Awareness of Processing Risks with Laryngeal Mask Airways

Laryngeal Mask Airways (LMAs) are used routinely during general anesthesia. Vigilance toward possible airway obstruction is important even when LMAs are optimally placed. A broad differential diagnosis, if respiratory insufficiency occurs with an LMA in place, should include equipment failure, as the following case highlights.

A healthy, young female with a upper respiratory tract infection undergoing a radiofrequency ablation of a femoral tumor under CT guidance had an LMA placed uneventfully following intravenous (IV) induction with fentanyl and propofol. Immediately after placement of the LMA, elevated airway pressures of >41 cm H₂O were noticed, along with an upward sloping capnograph tracing and small tidal volumes of approximately 135 ml. The chest was silent to auscultation. Bronchospasm, laryngospasm, and LMA malposition were included in the differential. Treatment was undertaken, including ascertaining proper LMA placement, of 20 mg of succinylcholine (IV) and repeated administration of aerosolized salbutamol, without improvement. When the patient began breathing spontaneously, she showed signs of respiratory distress with significant intercostal retractions and use of accessory muscles of respiration. She remained hemodynamically stable with SpO₂ of 99% during the entire episode. Attempted introduction of a Fiberoptic Bronchoscope through the LMA was not possible due to the presence of an obstructing piece of plastic wedged within the lumen of the LMA. The LMA was removed, replaced with another, and the procedure was completed uneventfully.

The plastic piece was a cap (see Photos 1-3), which had fallen off a reusable facemask sometime during processing or sterilization at the hospital. At our institution, facemasks and LMAs are often placed in the same kidney basin to be sent for processing. Presumably, the cap from a facemask came off and became lodged in the LMA's lumen during the course of processing. It was not readily apparent upon visual inspection of the LMA preinsertion (see Photo 1).

Fortunately, the cap did not enter the patient's airway, and the patient did not suffer injury. Following this incident, we have changed our facemasks to a model without removable plastic caps. We have also added the process of passing a brush through the lumen of LMAs during the cleaning process. A quick pre-use inspection of reusable LMAs is also encouraged as it may reveal damage or the presence of an intraluminal foreign body.

An understanding of processing procedures of reusable equipment is important for the clinician. The inadvertent introduction of foreign materials during processing of reusable airway devices, such as occurred with the LMA of our patient, is a rare but preventable complication, which is potentially harmful or even fatal.

Sylvain Gagne MD FRCPC, University of Ottawa, Ottawa, Canada.



Photo 1. Cap wedged in lumen of Ambu LMA.



Photo 2. View of cap in lumen of Ambu LMA.



Photo 3. LMA cut open to extract cap (in foreground).

Letter to the Editor:

When Compromise is Not Good: Safety Hazards of Cracked and Broken Bottles

A 59-year-old female was scheduled at our outpatient surgery center for a left breast lumpectomy for recurrent breast carcinoma. Our anesthetic plan included the intravenous administration of acetaminophen (Ofirmev[®]) as a pain adjuvant. Acetaminophen was obtained from the Pyxis[®] unit. Upon inspection of the acetaminophen bottle, a white powdery substance was noted to be adherent to the outside of the bottle and 2 linear cracks spanning the length of the vial were observed (Figure 1). In 2 unrelated incidents, previous to this, a cracked bottle of ketamine and a shattered bottle with spilled acetaminophen were found in 2 other Pyxis drawers (Figures 2 and 3).

A thorough literature search was conducted but few studies or reports were found concerning medication safety, packaging, or transportation and broken or cracked vials. These reports describe broken vials after obtaining access with a pressurized syringe and coring of the rubber stopper with the risk of embolization after intravenous administration.^{1,2,3} The integrity of glass vials recently came to the attention of the FDA and another manufacturer, Hospira. Subsequently, Hospira has recalled a lot of lidocaine vials in 28 states. The recall was initiated for a reddishorange particulate found on the inner surface and floating in the solution thought to be related to a supplier's glass defect.^{5,6}

We hypothesized on possible mechanisms for the occurrence of bottle breakage: glass bottle manufacturing defect, transport damage (manufacturer to pharmacy and pharmacy to Pyxis®), and damage from repeated opening and closing of Pyxis® drawers. After discussion with our pharmacy, we learned Ofirmev® bottles are securely padded when shipped and that large cracks, when removing the bottles from the packaging or placing them in the Pyxis[®] drawers, have not been noted. As the lidocaine reference above suggests, defective manufacturing processes of glass vials can compromise medications in vials or lead to breakages similar to our recent findings. We have discussed these incidents with Ofirmev's® manufacturer Cadence Pharmaceutical's quality associates; they state cracks in the glass allow oxygen to enter the vial turning the solution yellow and permit possible particulate matter formation. Furthermore, the vials are inspected prior to shipment and any subsequent cracks are usually incurred during shipment of the medication.

In these cited cases, we report macroscopic bottle damages that compromised our medications' sterility. These findings should make end-users aware of the possibility of microscopic bottle damage that may contribute to medication compromise and potential patient harm. One would surmise that the breakage of medication vials is more likely with more fragile glass vials, especially with pre-scored tops, than with these larger, sturdier glass bottles. However, as illustrated above, these larger bottles are also susceptible to breakage.

Although medication safety and sterility should always be on the minds of anesthesia providers, The Joint Commission's (TJC) recent emphasis on the strategic importance of medication management (which includes medication security, safety, and integrity) reconfirms our need for vigilance. In recent TJC medical facility accreditation site visits, one of the most common areas of non-compliance and, therefore, reasons for citation, is the secure storage of medications.⁴ To comply with this rule, many facilities are installing automated medication management systems in their operating rooms. Our experience underscores the need for pharmacy personnel to be attentive to the details of medication storage in



Figure 1. Large linear crack in intravenous acetaminophen vial.

these units. Because drawers in these units are accessed numerous times on a daily basis, the significance of medication alignment is obvious;

See "Broken Bottles," Page 23



Figure 2. Diminished level of medication without any visibile cracks. Inset—White powdery substance adherent to outside of vial.

Which System Should be Used for Waste Anesthetic Gas Disposal?

Q Dear Q&A,

Is there any literature or documentation that speaks about the benefits or hazards of a waste anesthetic gas disposal (WAGD) outlet versus a vacuum outlet for scavenging? The manufacturer of our anesthesia machines states that it does not matter which source we use.

Robert Welninski Chicago, Illinois

A Dear Mr. Welninski,

BeaconMedaes has produced a paper on waste anesthetic gas disposal (WAGD). There is a reference to NFPA-99 that carries a warning about mixing of WAGD and medical vacuum, primarily focused on high oxygen concentrations from WAGD in the oil based suction pumps. There is no proof, however, that this has created any real problems in actual use.

http://www.beaconmedaes.com/pdfs/WAGD.pdf

Figure 1 illustrates the ideal system where there are separate main lines for WAGD and vacuum. In this case all suction comes from the main vacuum line and the waste anesthetic gas goes into the WAGD main line. In this case all suction devices and the WAGD system are operating at full capacity.

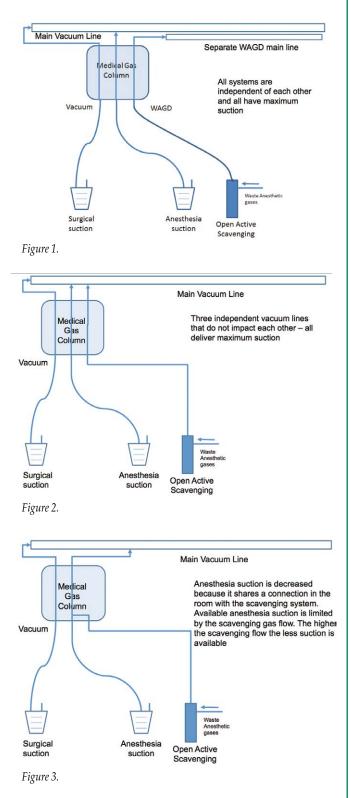
Figure 2 illustrates the case where there is no main WAGD line, and the anesthesia machine scavenging interface connects to a main vacuum line. When all of these lines have separate pipelines from the gas outlets in the utility column to the main Vacuum lines, there is again no degradation of performance in any of the suction systems or the WAGD interface.

Figure 3 illustrates a scenario where the WAGD is plugged into the same pipeline as the anesthesia suction because the gas outlets are connected together in the gas utility column. In this case if the WADG flow were high the anesthesia suction would be compromised. Ideally, the scavenging flow would be equal to the total fresh gas flow set on the anesthesia machine plus the excess drive gas from the bellows plus the waste gas from the respiratory gas analyzer. This flow will have limited impact on suction flow of 140 liters/minute. However, if the WAGD flow was half of the total suction flow, the suction would drop from 140 liters/minute to 70 liters/minute.

See "Q&A," Next Page

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

The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of the APSF. It is not the intention of the 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 the 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.



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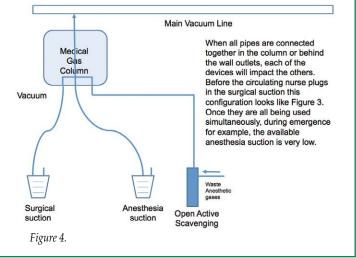
Single Pipe Can Degrade Suction

"Q&A," From Preceding Page

Figure 4 illustrates the case where the surgical suction, anesthesia suction, and the WAGD flows are all connected together in the gas utility column. A single pipe from the outlets in the gas utility column to the main vacuum line will cause all suction to be degraded. Imagine at the end of the case when the surgical suction is running full open, the scavenging system is running and the patient begins active regurgitation and your suction flows which are supposed to be at 140 liters/minute, are below 45 liters/minute with concomitant decreases in pressure.

When a manufacturer tells you that you can use either a WAGD outlet or a vacuum outlet, they are referring to Figure 1 or Figure 2. Avoiding Figures 3 and 4 would be advantageous and permit full suction capabilities through soft tip or Yankauer suctions tips.

The APSF Committee on Technology



Integrity of Medications Must Be Safeguarded

"Broken Bottles," From Page 21

proper attention and consideration to medication placement and alignment by the pharmacy staff during stocking should occur. TJC also states that the integrity of medications must be safeguarded.⁴ Thus, it is not only the pharmacists' responsibility, but also that of all anesthesia providers to inspect bottles and vials for microscopic damage prior to medication administration. As we observed, a breach of a medication's integrity may first be suspected by noting that a new medication vial is only partially full (In Figure 2, note the diminished medication level in the unopened ketamine vial). Equally concerning is the potential risk, primarily for anesthesia providers, of these cracked vials rupturing or splintering in their hands and cutting them when they attempt to spike or access a cracked bottle prior to medication administration.

With the assistance of our operating room pharmacists, we reconfigured our medication drawers to reduce medication movement during opening and closing of Pyxis[®] drawers. In addition, we have instructed all anesthesia providers to carefully inspect medication vials and bottles prior to medication administration. Confirming all medications' integrity prior to administration is an important step we can and should take to provide safe anesthesia to all our patients. In doing this, we exemplify vigilance, the hallmark of safe patient care.

Andrew Crabbe, MD Thomas Tinker, MD Alberto DeArmendi, MD University of Oklahoma College of Medicine Oklahoma City, OK



Figure 3. Shattered vial of intravenous acetaminophen.

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The Anesthesia Patient Safety Foundation (APSF) announces the availability of the 18 minute educational video:

Prevention and Management of Operating Room Fires



 $\label{eq:View the DVD on the APSF website} \\ (www.apsf.org)$

Request a complimentary copy of the DVD on the APSF website (www.apsf.org)

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