

National Partnership for Maternal Safety—Maternal Safety Bundles

by Jennifer M. Banayan, MD, and Barbara M. Scavone, MD

The United States is one of only eight countries worldwide and the only developed nation where maternal mortality has increased since 1990.¹ Parturients in this country are three times more likely to die from pregnancy-related complications than women in Britain, Germany, or Japan.¹ These findings are shocking, especially considering that prior to 1982 maternal mortality in the United States had improved dramatically over the last century.² Improvement in survival can be attributed to advances in medical care, more hospital deliveries by those trained in obstetrical care, and better aseptic technique.³

Traditionally, the most common causes of maternal death have been hemorrhage, hypertensive disorders, thromboembolic events, and infections.^{4,5} The proportion of deaths due to conventional causes is now declining and instead a significant proportion of maternal deaths are attributable to cardiovascular conditions and other co-existing medical diseases (Figure 1).^{5,6} Interestingly, anesthesia complications leading to mortality are becoming rarer. This change underscores the need for anesthesia professionals to not

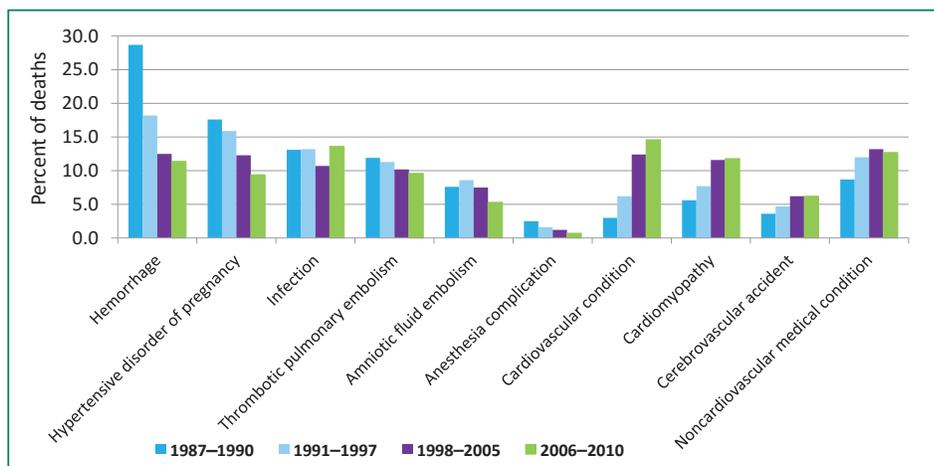


Figure 1. Cause-Specific Proportionate Pregnancy-Related Mortality: United States, 1987–2010.

only provide safe labor analgesia and anesthesia for cesarean delivery, but to broaden the scope of their attention to assist women through a safe pregnancy and birth.

Not only has maternal mortality increased, but severe maternal morbidity has more than doubled

in the 21st century, affecting 50,000 women every year.⁷ The reason for this change is unclear, but several possible explanations exist. First, we are observing an increased incidence of parturients in the United States with advanced maternal age,⁸

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American Society of Anesthesiologists

ASA/APSF Ellison C. Pierce Jr., MD Patient Safety Memorial Lecture

Safety Beyond Our Borders: Different but the Same



Alexander A. Hannenberg, MD

Annual Meeting of the American Society of Anesthesiologists

Saturday, October 22, 2016

McCormick Place Convention Center (Room W375abc)

10:45 AM–11:45 AM

Professional Certification in Patient Safety: An Opportunity for Expanding the Horizons for Anesthesia Professionals

by Patricia McGaffigan, RN, MS, and Jeffrey B. Cooper, PhD

Anesthesia professionals are leaders in patient safety and have been since before the Institute of Medicine brought widespread attention to the issue of medical error through its report, *To Err Is Human*. A combination of technological advances, education, awareness, and adoption of practices from other high-risk industries has resulted in anesthesiology becoming far safer today than it was 30 years ago.¹

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NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

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APSF Newsletter
guide for authors

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Letter to the Editor:**Clear Plastic Causes Obstruction of Breathing Circuit****To The Editor:**

After 10 uneventful ENT cases today, we had a near miss in the final case—a panendoscopy. I was supervising the room with a conscientious and capable CRNA who had done a quick pressure check of the circuit prior to moving in. The patient was induced and the anesthetist was unable to mask ventilate; however, intubation was easily accomplished with a 5.0 microlaryngeal tube. Visualization was considered to be a grade 1 view. We were still unable to ventilate. There were no breath sounds. I pulled the tube and attempted to mask ventilate unsuccessfully, so I reintubated with an 8.0 ETT and still was unable to ventilate. The surgeon took a quick look with a flexible scope, looking for possible subglottic obstruction, but upon disassembling the circuit, the y-piece separated inadvertently from the elbow, revealing a perfectly disguised piece of packaging plastic causing the obstruction. Upon reassembly, the patient was easily ventilated, and is, thankfully, no worse for the wear.

I have heard about similar occurrences in the past, but this was an eye opener for me. As I recreated the obstruction in PACU, I realized that if the plastic film was small enough, as this had been, there are no exposed ragged edges, and it is impossible to see the obstruction through the circuit.

I have always been cautious not to trap plastic when assembling circuits, but this part is preassembled. There are a lot of potential places between the manufacturer and the patient for a mishap to develop.

My suggestion is simple. Why don't we pressure manufacturers to wrap circuit components in a visible but translucent colored plastic wrap, so that it is more visible if inadvertently trapped in the circuit? It should be a low cost solution to a patient safety issue. I'd like to hear your thoughts.

Name and city withheld by request.

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Safety Foundation (APSF)
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Functional Check of the Breathing Circuit

A properly functioning breathing circuit is imperative for the care of patients receiving general anesthesia. On occasion, disposable breathing circuits may have manufacturing defects, scavenging system connections may be faulty, and other system components including human errors may impair the proper function of the breathing circuit. The best approach to uncovering these hidden hazardous issues is to perform a functional test of the breathing circuit prior to applying it to the patient.

Recommended procedure to be performed prior to each use of the breathing circuit

1. Connect the breathing circuit and all components that will be used for the case (e.g., elbow with CO₂ sampling line, circuit filters, flexible extension tubing, HME).
2. Remove the breathing bag from the bag arm and place it on the connector that will plug into the mask or connect to the endotracheal tube.
3. Turn the ventilator on and set the mode to Volume Controlled Ventilation and set the ventilator to the rate, tidal volume, and I:E that you might use for the next patient.
4. Depress the oxygen flush button until the bellows reach their maximum height.
5. Observe the breathing bag for normal operation (inhalation and exhalation of test lung) for at least eight respiratory cycles.
6. Observe the exhaled tidal volume—it should be close to the set tidal volume after eight cycles.
7. Observe the breathing circuit pressure—make sure that it is normal.
8. Observe the top of the bellows and determine if it always rises to the same location, or if there is a leak and the top of the bellows (height) is decreasing (may need to compensate for CO₂ sampling flow rate).

The APSF Committee on Technology believes that a functional test of the breathing circuit is important to perform before the circuit is applied to any patient. Numerous reports each year of defective plastic components in disposable breathing circuits, foreign materials restricting or obstructing gas flow, and misconnections have resulted in the inability to ventilate the patient during induction of anesthesia, a problem that cannot be detected by performing a simple leak check.



Anesthesia Patient Safety Foundation
ANNOUNCES THE PROCEDURE FOR SUBMITTING
GRANT APPLICATIONS

**DEADLINE TO SUBMIT THE LETTER OF INTENT (LOI)
FOR AN APSF GRANT AWARD TO BEGIN JANUARY 1, 2018 IS:
FEBRUARY 13, 2017**

- LOI will be accepted electronically beginning January 3, 2017.
- The maximum award is \$150,000 for a study conducted over a maximum of 2 years to begin January 1, 2018.
- Based on the APSF's Scientific Evaluation Committee's evaluation of these LOIs, a limited number of applicants will be invited to submit a full proposal.

*Instructions for submitting a Letter of Intent can be found at:
http://www.apsf.org/grants_application_instructions.php*

Improving Maternal Safety: States Take The Initiative

“Maternal Safety,” From Cover Page

but this trend is also seen in other parts of the world where mortality rates are not increasing. Second, we are performing a disproportionately high rate of cesarean deliveries as compared to other developed countries,⁹ which leads to a variety of complications including an increased incidence of placental implantation abnormalities such as placenta accreta.¹⁰ Or, the most compelling explanation is the surge of chronic health conditions such as obesity, hypertension, diabetes, and chronic heart disease in the parturient.^{6,7,11,12}

In response to the increase in maternal mortality and morbidity in this country, a national imperative exists to identify and evaluate the causes of these deaths as well as identify preventable factors. Remarkable progress has been made in the state of California where more than 10% of American births take place. Data published on maternal deaths in California between 2002 and 2004 documented 207 deaths, with nearly 40% of those deaths potentially preventable.¹³ Three conditions were found to have the greatest level of preventability: obstetric hemorrhage, deep vein thrombosis, and preeclampsia/eclampsia. In response to these findings, the California Maternal Quality Care Collaborative created free online “toolkits” available to anyone. Toolkits include a collection of articles, guidelines, implementation guides, and educational documents with the goal of preventing death in the parturient. The first toolkit released was on obstetric hemorrhage. Many hos-

pitals in California used the toolkit to implement efforts at their institutions to actively decrease maternal hemorrhage and morbidity and mortality stemming from it. Over the next five years, maternal mortality in California decreased dramatically as compared to the national maternal mortality rate that continued to increase from 2008 to 2013 (Figure 2).

The effectiveness of instituting protocols with the intention of reducing maternal hemorrhage has been evaluated. Looking at over 32,000 deliveries during the periods before and after institution of a hemorrhage protocol, one group of investigators observed a significant reduction in blood products transfused and a nonsignificant reduction in the number of puerperal hysterectomies performed.¹⁴ These findings provide the best evidence to date that increasing education and resources and providing toolkits may have a real impact on patient outcomes.

New York took its own initiative to decrease maternal mortality. In 2013, a group of clinicians met together with leaders from The American Congress of Obstetricians and Gynecologists (ACOG) District II, an area covering the state of New York, to create the Safe Motherhood Initiative (SMI). They were encouraged by success stories of systematic educational interventions that led to decreased mortality elsewhere. For example, the United Kingdom created a national effort to reduce the incidence of pulmonary embolism in pregnancy, and mortality from embolic disease subsequently

decreased.¹⁵ Consequently, SMI included standardized risk-assessment tables, protocols, checklists, and algorithms to minimize variability in practice. Finally, three bundles were created: one on hemorrhage, one on hypertension, and one on venous thromboembolism (VTE). They then created bundle boxes under the safe motherhood website and even offered Continuing Medical Education to encourage clinicians to visit their website. Bundle boxes include a binder with implementation guidance, including posters, brochures, checklists, algorithms, and tables. They also offer a variety of PowerPoint and audio recordings archived on the website to assist in learning. Those who developed and implemented the bundles provide practical advice on implementation.

Four years after he led the efforts in California, Dr. Eliot Main issued a call to action to bring similar resources and infrastructure to a national stage. Representatives from a variety of organizations met in Atlanta in 2012 to create a collaborative approach to optimize maternal health and improve maternal care. The group set priorities for implementation and deployment of efforts focusing on obstetric safety. These meetings resulted in formation of the National Partnership for Maternal Safety (NPMS), housed within the Council on Patient Safety in Women’s Healthcare. Its mission is to “continually improve patient safety in women’s health care through multidisciplinary collaboration that drives cultural change.” An important element of the NPMS is the wide range of professional organizations included in this coalition (Table 1).

The NPMS goal is to reduce maternal morbidity and mortality in the United States by 50%. One means of accomplishing that was to create bundles—evidence-based interventions that are designed to be implemented together resulting in improved outcomes¹⁶—similar to those created in California. NPMS began by creating materials on three topics: hemorrhage, hypertension in pregnancy, and VTE, and published their findings on the website: <http://www.safehealthcareforeverywoman.org/>. All the information on the website is free and available to the public, but a login and password is needed to access the site to help the NPMS keep track of who utilizes the information.

The process of making the bundles available to the public is a stepwise process. First, a one-page document is published online which includes links to critical information and implementation guidance. Then, a formal detailed article is published in a variety of high-impact journals. The core of the NPMS is its commitment to being a multidisciplinary group. The publication of the bundles in a variety of sources including anesthesia, obstetrics, nursing, and midwifery journals is a testament to this commitment.

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Maternal Mortality Rate, California and United States, 1999–2013.



Figure 2. Source: State of California, Department of Public Health, California Birth and Death Statistical Master Files, 1999–2013. Maternal mortality for California (deaths \leq 43 days postpartum) was calculated using ICD-10 cause of death classification (codes A34, O00–O95–O99). United States data and HP2020 Objective use the same codes. U.S. maternal mortality data are published by the National Center for Health Statistics (NCHS) through 2007 only. U.S. maternal mortality rates from 2008 through 2013 were calculated using the CDC Wonder Online Database, accessed at <http://wonder.cdc.gov> on March 11, 2015. Produced by California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division, May, 2015. (<https://www.cdph.ca.gov/data/statistics/Documents/2013MaternalMortalityRates-SlideSet%20for%20MCAH%20Website.pdf> - Last accessed 08/09/2016)

Bundles Help Providers Manage Maternal Complications

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Although ACOG has published practice bulletins and committee opinions for years, they have not been multidisciplinary in nature. Bundles are a way of providing a variety of existing evidence-based recommendations, such as ACOG practice bulletins, into an organized and accessible format. Additionally, there is a real emphasis on allowing the individual facility to modify and tailor the bundle to meet local needs. The bundles give examples of different ways of managing and responding to maternal complications that are known to cause significant maternal morbidity and mortality. Each bundle is formatted into four sections: Readiness, Recognition and Prevention, Response, and Reporting/System Learning.

The first bundle, the Obstetric Hemorrhage Patient Safety Bundle, was initially published on the website. Then a more detailed document was published in 2015 in four high-impact journals simultaneously: *Anesthesia & Analgesia*,¹⁷ *Obstetrics and Gynecology*,¹⁸ *Journal of Obstetric, Gynecologic, & Neonatal Nursing*,¹⁹ and *Journal of Midwifery and Women’s Health*.²⁰ Obstetric hemorrhage is the most common complication of childbirth, but much of hemorrhage-related morbidity and mortality is considered preventable.^{21,22} Areas for improvement include better recognition and quantitative appreciation of blood loss, increased attention to clinical signs of hemorrhage, quicker restoration of blood volume, and greater emphasis on intervening decisively.²³ Goals of the hemorrhage bundle include limiting the proportion of hemorrhage episodes that become severe, decreasing the need for blood product transfusion, and decreasing the frequency of coagulopathy.

The Readiness section of the hemorrhage bundle includes a list of supplies and systems needed to prepare for hemorrhage, such as a hemorrhage cart and hemorrhage medications. The Recognition and Prevention section includes those assessments that should be performed for every patient, such as accurate measurement of cumulative blood loss. Response includes stage-based obstetric hemorrhage emergency management plans. And finally, the Reporting/System Learning includes recommendations on how to conduct multidisciplinary reviews after severe hemorrhage episodes, including tips for debriefing and perinatal quality improvement committees (Figure 3).

The second bundle, Severe Hypertension in Pregnancy, was recently made available on the above mentioned website. Failure to adequately control blood pressure or recognize the clinical manifestation of preeclampsia such as hemolysis, thrombocytopenia, elevated liver enzymes, and pulmonary edema are leading sources of error leading to grave complications.²³ Furthermore,

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Table 1. Voting Membership Council for Patient Safety in Women’s Health Care

• American Academy of Family Physicians (AAFP)
• American Association of Nurse Anesthetists (AANA)
• American Board of Obstetrics and Gynecology (ABO+G)
• American College of Nurse-Midwives (ACNM)
• American College of Obstetricians and Gynecologists (ACOG)
• American College of Osteopathic Obstetricians and Gynecologists (ACOOG)
• American Society of Anesthesiologists (ASA)
• American Society for Reproductive Medicine (ASRM)
• American Urogynecologic Society (AUGS)
• Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN)
• Committee on Patient Safety and Quality Improvement (ACOG)
• Junior Fellow (ACOG)
• National Association of Nurse Practitioners in Women’s Health (NPWH)
• Patient Advocate (2 seats)
• Preeclampsia Foundation
• Society for Academic Specialists in General Obstetrics and Gynecology (SASGOG)
• Society of Gynecologic Oncology (SGO)
• Society for Maternal-Fetal Medicine (SMFM)
• Society for Obstetric Anesthesia and Perinatology (SOAP)
• Society of OB/Gyn Hospitalists (SOGH)
• Society for Reproductive Endocrinology and Infertility (SREI)

**COUNCIL ON PATIENT SAFETY
IN WOMEN'S HEALTH CARE**
safe health care for every woman

READINESS

Every unit

- Hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compressions stitches
- Immediate access to hemorrhage medications (kit or equivalent)
- Establish a response team - who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)
- Unit education on protocols, unit-based drills (with post-drill debriefs)

RECOGNITION & PREVENTION

Every patient

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
- Measurement of cumulative blood loss (formal, as quantitative as possible)
- Active management of the 3rd stage of labor (department-wide protocol)

RESPONSE

Every hemorrhage

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
- Support program for patients, families, and staff for all significant hemorrhages

REPORTING/SYSTEMS LEARNING

Every unit

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of serious hemorrhages for systems issues
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee

PATIENT SAFETY BUNDLE

Obstetric Hemorrhage

Figure 3. Maternal Safety Bundle on Proactive Establishment of Resources for Management of Obstetric Hemorrhage.

Anesthesia Professionals Can Make A Difference In Improving Maternal Safety



READINESS

Every Unit

- Standards for early warning signs, diagnostic criteria, monitoring and treatment of severe preeclampsia/eclampsia (include order sets and algorithms)
- Unit education on protocols, unit-based drills (with post-drill debriefs)
- Process for timely triage and evaluation of pregnant and postpartum women with hypertension including ED and outpatient areas
- Rapid access to medications used for severe hypertension/eclampsia: Medications should be stocked and immediately available on L&D and in other areas where patients may be treated. Include brief guide for administration and dosage.
- System plan for escalation, obtaining appropriate consultation, and maternal transport, as needed

RECOGNITION & PREVENTION

Every Patient

- Standard protocol for measurement and assessment of BP and urine protein for all pregnant and postpartum women
- Standard response to maternal early warning signs including listening to and investigating patient symptoms and assessment of labs (e.g. CBC with platelets, AST and ALT)
- Facility-wide standards for educating prenatal and postpartum women on signs and symptoms of hypertension and preeclampsia



RESPONSE

Every case of severe hypertension/preeclampsia

- Facility-wide standard protocols with checklists and escalation policies for management and treatment of:
 - Severe hypertension
 - Eclampsia, seizure prophylaxis, and magnesium over-dosage
 - Postpartum presentation of severe hypertension/preeclampsia
- Minimum requirements for protocol:
 - Notification of physician or primary care provider if systolic BP \geq 160 or diastolic BP \geq 110 for two measurements within 15 minutes
 - After the second elevated reading, treatment should be initiated ASAP (preferably within 60 minutes of verification)
 - Includes onset and duration of magnesium sulfate therapy
 - Includes escalation measures for those unresponsive to standard treatment
 - Describes manner and verification of follow-up within 7 to 14 days postpartum
 - Describe postpartum patient education for women with preeclampsia
- Support plan for patients, families, and staff for ICU admissions and serious complications of severe hypertension

REPORTING/SYSTEMS LEARNING

Every unit

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of all severe hypertension/eclampsia cases admitted to ICU for systems issues
- Monitor outcomes and process metrics

Note: "Facility-wide" indicates all areas where pregnant or postpartum women receive care. (E.g. L&D, postpartum critical care, emergency department, and others depending on the facility).

PATIENT SAFETY BUNDLE

Hypertension

Figure 4. Maternal Safety Bundle for Establishing Protocol and Resources for Management of Hypertension/Preeclampsia.

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the systolic blood pressure in preeclamptic patients is an important indicator of stroke.²⁴ Therefore, administration of anti-hypertensives in a timely fashion is essential and potentially lifesaving. ACOG has published dosing regimens for labetalol and hydralazine for the initial management of acute severe hypertension in pregnancy, and this guidance has been incorporated into the hypertension in pregnancy bundle.

Like the hemorrhage bundle, the document is divided into four subgroups: Readiness, Recognition and Prevention, Response, and Report/Systems Learning. The Readiness section includes diagnostic criteria and guidance on antihypertensive medications including dosages and administration. The Recognition and Prevention section includes protocols for measurement and evaluations of blood pressure. Response includes management plans for patients with severe hypertension and eclampsia. And, again, Reporting/System Learning includes recommendations on multidisciplinary reviews including debriefing (Figure 4).

As for the VTE draft, it is available on the website now, and the more detailed version is currently being created and due for publication soon. VTE is one of the leading causes of maternal mortality and severe morbidity, but it is largely considered preventable.⁴ Diligence in administering adequate anticoagulation is crucial. Encouraging data from the United Kingdom demonstrated a reduction in maternal death after implementation of more widespread VTE prophylaxis.¹⁵ The Joint Commission requires compression devices on parturients at risk for pulmonary embolism during their cesarean procedure. They also require that high-risk antepartum and postpartum patients be anti-coagulated. The NPMS VTE bundle will include recommendations on who is considered high risk and who should receive VTE prophylaxis. It also will encourage early ambulation and the use of compression devices (Figure 5).

Recognizing that a large percentage of maternal mortality and morbidity is preventable is the key to improving outcomes in the United States. Managing patients with life-threatening emergencies requires clinicians with expertise in resuscitation and criti-

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READINESS

Every Unit

- Use a standardized thromboembolism risk assessment tool for VTE during:
 - Outpatient prenatal care
 - Antepartum hospitalization
 - Hospitalization after cesarean or vaginal deliveries
 - Postpartum period (up to 6 weeks after delivery)

RECOGNITION & PREVENTION

Every Patient

- Apply standardized tool to all patients to assess VTE risk at time points designated under “Readiness”
- Apply standardized tool to identify appropriate patients for thromboprophylaxis
- Provide patient education
- Provide all healthcare providers education regarding risk assessment tools and recommended thromboprophylaxis

RESPONSE

Every Unit

- Use standardized recommendations for mechanical thromboprophylaxis
- Use standardized recommendations for dosing of prophylactic and therapeutic pharmacologic anticoagulation
- Use standardized recommendations for appropriate timing of pharmacologic prophylaxis with neuraxial anesthesia

REPORTING/SYSTEMS LEARNING

Every Unit

- Review all thromboembolism events for systems issues and compliance with protocols
- Monitor process metrics and outcomes in a standardized fashion
- Assess for complications of pharmacologic thromboprophylaxis

Standardization of health care processes and reduced variation has been shown to improve outcomes and quality of care. The Council on Patient Safety in Women's Health Care disseminates patient safety bundles to help facilitate the standardization process. This bundle reflects emerging clinical, scientific, and patient safety advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Although the components of a particular bundle may be adapted to local resources, standardization within an institution is strongly encouraged.

The Council on Patient Safety in Women's Health Care is a broad consortium of organizations across the spectrum of women's health for the promotion of safe health care for every woman.

For more information visit the Council's website at www.safehealthcareforeverywoman.org

PATIENT SAFETY BUNDLE

Maternal Venous Thromboembolism Prevention

Figure 5. Maternal Safety Bundle for Prevention of Maternal Venous Thromboembolism.

Taking an Active Stance to Limit Maternal Morbidity and Mortality

“Maternal Safety,” From Preceding Page

cal care. Anesthesia professionals are therefore a vital part of the peripartum team and should take an active stance to limit maternal morbidity and mortality. Now, more than ever, anesthesiologists should act as peripartum physicians and participate with other caregivers to optimize maternal safety and reduce morbidity and mortality.

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Certification Program Was Introduced in 2012

“Certification,” From Cover Page

Still, we have a long way to go; health care is not yet as safe as it could be.² The National Patient Safety Foundation (NPSF), like the Anesthesia Patient Safety Foundation (APSF), has a broad agenda for working with multiple stakeholders to advance progress in patient safety. And, like APSF, NPSF is committed to encouraging, promoting, and supporting the professional development of patient safety leaders. The leadership of APSF sees development of a cadre of anesthesia patient safety leaders as one of its most important strategic goals.

As a means toward these ends, in 2011, NPSF formed the Certification Board for Professionals in Patient Safety to develop and oversee the Certified Professional in Patient Safety (CPPS) credentialing program. This article discusses the importance of certification in patient safety for health professionals, including anesthesia professionals.

The Value of Certification of Patient Safety Professionals

Patient safety concepts and practices have spread to virtually every specialty and practice setting. Where 30 years ago, few (if any) hospitals had an employee dedicated to patient safety, now it is not uncommon to see patient safety departments, committees, and officers at the highest levels of leadership. Patient safety is now recognized as a science and a unique discipline.³

For any health professional, patient safety knowledge—and the ability to apply it—are critical competencies. NPSF recognized that a process of certification of patient safety professionals would be one of the best ways to encourage and foster the acquisition of that knowledge and the application skills.

A professional certification in patient safety serves multiple purposes:⁴

- To establish core standards for the field of patient safety, benchmark requirements necessary for certified professionals, and set an expected proficiency level
- To provide health professionals a means to demonstrate their proficiency and skill in the discipline of patient safety and create for them a specific aspirational goal
- To provide a way for employers to validate a potential candidate’s patient safety knowledge and skill base.

Since the certification program was introduced in 2012, more than 1,300 health professionals have successfully completed the requirements of the program and are entitled to use the Certified Professional in Patient Safety (CPPS) credential. By profession, they include physicians (of varying

specialties including anesthesiologists), nursing professionals (including CRNAs), pharmacists, safety, quality, and risk management professionals, health care executives, and others who hold the requisite education and experience required to sit for the exam.

Developing an Evidence-Based Examination

The certification examination was developed through a rigorous process that started with a job analysis first conducted in 2011. An advisory committee representing various health care settings in the U.S. created the job analysis survey, which was sent to a wide range of health professionals. The information gathered from the analysis was used to develop a relevant, valid certification examination supported by evidence-based data.

The CPPS Expert Oversight Committee (EOC) is responsible for overseeing the examination and re-credentialing processes for the CPPS credential, and assuring that certification continues to meet the high standards required for the profession. In keeping with the need to remain current in the field, a second job analysis survey was conducted in 2014, and included global representation, resulting in updates to the examination and the current content domains:

- Culture
- Leadership
- Patient Safety Risks & Solutions
- Measuring & Improving Performance
- Systems Thinking & Design/Human Factors.

Candidates are eligible to sit for the CPPS examination if they possess academic and professional experience at one of the following levels:

- Baccalaureate degree or higher plus three years of experience (includes time spent in clinical rotations and residency programs) in a health care setting or with a provider of services to the health care industry
- Associate degree or equivalent plus five years of experience (includes time spent in clinical rotations) in a health care setting or with a provider of services to the health care industry.

“The CPPS examination provides a common denominator for all disciplines and backgrounds of patient safety practitioners,” said Kathryn Rapala, DNP, JD, RN, CPPS, vice president, Clinical Risk Management, Aurora Health Care, and chair of the CPPS Expert Oversight Committee. “We really want to see this certification integrated within the broader health care community.”

As would be expected, the commitment of time necessary to prepare for certification varies based on the individual’s background and experience. In a

personal interview, Kenneth Rothfield, MD, CPPS, former chairman of the Department of Anesthesiology at Ascension’s Saint Agnes Hospital in Baltimore, Maryland, and chief medical officer and chief quality officer at St. Vincent’s HealthCare, part of Ascension Healthcare, notes that the preparatory work would not be “exhaustive” for those already working in some areas of patient safety.

“Those interested in getting certified are likely already very involved in safety activities, but maybe haven’t gotten the depth of experience in every aspect required for certification,” he says. Candidates who sit for the exam are asked to complete an exit survey. From January 2015 through July 2016, the survey was sent to 860 candidates, with 389 responding (45% response rate). These candidates report using preparatory materials ranging from an online Self-Assessment Exam (76%) or a review course offered by NPSF (60%), to studying the exam content outline (55%), resource list (36%), and other reference books or study guides (16%).

CPPS and Anesthesia Professionals

With a strong focus on safety in their training and throughout their careers, anesthesia professionals are natural leaders for patient safety in perioperative care and beyond. What, you may ask, is the value of a specific certification in patient safety?

Erin White Pukenas, MD, FAACP, CPPS, a pediatric anesthesiologist who wears multiple hats, has an answer. She is System Patient Safety officer; director, Anesthesia Quality and Patient Safety; and associate director of Pediatric Anesthesiology at Cooper University Health Care as well as assistant professor of Anesthesiology at Cooper Medical School of Rowan University. In a personal interview, Dr. Pukenas explained that she sees this certification as a natural extension of the anesthesia professional’s development.

“I’m fortunate to be an anesthesiologist and to have had the opportunity to learn extensively about patient safety. In my view, certification is a tangible way to demonstrate skills to our colleagues who have studied quality, safety science, or human factors engineering exclusively,” says Dr. Pukenas. “As the science and demands of quality and safety in health care grow, so too will the workforce trained in it. For me, certification was one way to show that I have a solid, learned, and practiced set of skills that I can apply successfully in today’s health care environment. CPPS certification builds on my training as an anesthesiologist and cultivates additional skills that I can use to lead our safety teams. Our specialty is uniquely positioned to create the vision for safe

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Becoming an Effective Patient Safety Agent

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patient care, and we must continue to demonstrate our capacity to do so.”

A similar sentiment comes from Patrick J. Loynd, DNP, CRNA, CPPS, of Capital Health System in New Jersey, where the Anesthesia Department is an integral part of the patient safety program.

“Patient safety and injury intervention is achieved through anesthesia professionals’ participation in hospital patient safety committees; policy and procedure development; root cause analysis; and the establishment of evidence-based practice parameters,” says Dr. Loynd, who has been involved in many such efforts. “It is an honor and a privilege. Setting out to achieve a CPPS certification was my way of complementing my anesthesia expertise with the knowledge and skills required to be an effective patient safety practitioner.”

Given the broad scope of practice across the care continuum and in all settings and the developing interest in the perioperative surgical home, anesthesia professionals have much to contribute to patient safety. Certification in patient safety demonstrates knowledge of systems issues, human factors, and culture, and it amplifies the attention to safety that is already so deeply embedded in the anesthesia profession. We hope that many more of you will investigate if and how this certification can be of value to your hospital, your career achievements and satisfaction and most of all to your patients.

To learn more about this professional certification, visit www.cbpps.org.

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The Effect of General Anesthesia on the Developing Brain: Appreciating Parent Concerns While Allaying Their Fears

by Luke S. Janik, MD

More than one million children under the age of five undergo surgery annually in the United States.^{1,2} The most common procedures are myringotomy tubes, tonsillectomy/adenoidectomy, hernia repairs, and circumcisions. Recently, the issue of anesthesia-related neurotoxicity has been in the media limelight, and parents are appropriately fearful about the effects of general anesthesia on their child's brain development.

Any anesthesia professional who cares for children has undoubtedly faced the question, "Will anesthesia harm my child's brain?" It is no wonder parents are frightened about the effects of general anesthesia on the developing brain. A quick Google search of this very question yields over 400,000 results, with attention grabbing headlines such as, "Anesthesia May Harm Children's Brains" (WebMD)³ and "Researchers Warn on Anesthesia, Unsure of Risk to Children" (NY Times).⁴ Are these concerns justified or is this media sensationalism? As anesthesia professionals, what are our responsibilities to the parents in discussing the risks of general anesthesia? The following review on this topic will address the pre-clinical evidence, observational studies, and the most recent research efforts.

Pre-Clinical Evidence

In 2000, Ikonomidou et al. published a landmark article in *Science* investigating the mechanism of ethanol in the development of Fetal Alcohol Syndrome (FAS).⁵ By treating rat pups with ethanol during the peak period of brain synaptogenesis, they were able to replicate the effects of FAS including generalized loss of brain mass and neuronal apoptosis. They discovered that ethanol causes widespread apoptotic neurodegeneration by two distinct mechanisms: N-methyl-D-aspartate (NMDA) antagonism, and γ -aminobutyric acid receptor (GABA_A) activation.⁵ Not surprisingly, this study caught the attention of the anesthesia community, as many of our anesthetic agents and sedatives act by one or both of these mechanisms.

Over the following years, hundreds of studies in various animal models including rodents and non-human primates convincingly demonstrated a link between anesthetic agents and neuroapoptosis.⁶⁻⁸ Nearly all of our commonly used anesthetic agents have been identified as culprits, including benzodiazepines, propofol, ketamine, volatile anesthetics, and nitrous oxide.^{1,6-8}

Do the findings of these animal studies translate to the effects on humans undergoing anesthesia? The dose and duration of anesthetic exposure

in the animal models is considerably higher than what an infant is typically exposed to in the operating room. In addition, there is interspecies variability in drug potencies, toxicities, and side effect profiles. Furthermore, each animal model has a different window of brain vulnerability and different rates of brain maturation. These challenges significantly limit our ability to draw a meaningful conclusion, not to mention the fact that animal models often lack the precise physiologic monitoring, resuscitation efforts, and controlled ventilation that are utilized in real time clinical practice.

Observational Studies

Given the inherent limitations of animal models, focus shifted from the laboratory towards human clinical trials. Numerous retrospective observational studies were published that suggested anesthesia exposure early in life was a risk factor for learning disabilities later in life. Ing et al. reviewed test scores of language, cognition, motor skills, and behavior in a cohort of three hundred 10-year-olds who were exposed to anesthesia before age 3. These children were found to have a higher risk of language and abstract-reasoning deficits than unexposed matched controls.⁹ Flick et al. compared a similar cohort of children exposed to anesthesia prior to age 2 to unexposed matched controls. They suggested that exposure to multiple—but not single—anesthetics was an independent risk factor for the later development of learning disabilities.¹⁰ Wilder and colleagues also found that exposure to multiple anesthetics before the age of 4 was a significant risk factor for the development of learning disabilities.¹¹

While many observational studies support a link between exposure and disability, a similar number of studies refute this claim. In 2011, Hansen and colleagues reviewed ninth grade standardized test scores in over 2,500 children who underwent inguinal hernia repair in infancy, and found that compared to age-matched controls, there was no evidence of increased learning disabilities when adjusting for known confounders.¹² The same author later showed that over 700 infants exposed to anesthesia for pyloric stenosis repair before 3 months of age had similar educational test scores in adolescence compared to the unexposed controls.¹³ Bartels and colleagues performed a monozygotic concordant-discordant twin study of over 1,000 twin pairs in which one sibling was exposed to anesthesia prior to age 3 and the other was unexposed. They found the exposed twin had similar scores on standardized tests at age 12 as the genetically identical unex-

posed twin, suggesting that anesthesia exposure was not a risk factor for poor test scores.¹⁴

The results of these small observational studies are conflicting, and do not provide a definitive answer to the question at hand. Rather, the conflicting data highlight the weaknesses of retrospective studies. Controlling for potential confounders including birth weight, gestational age, parental age and education, socioeconomic status, income, and ethnicity, proves to be very difficult. In addition, utilizing standardized achievement tests as outcome measures may not detect subtle neurocognitive deficits. Moreover, given the nature of retrospective studies, the individual anesthetic records are usually not available for review, so the anesthetic agent(s), dose, and duration of exposure are often unknown.

Recent Advances

Three recent large, well-designed studies have furthered our understanding of how general anesthesia impacts neurodevelopment. The General Anesthesia compared to Spinal Anesthesia (GAS) trial is an international, multicenter, observer-blinded, randomized controlled trial in which infants (less than 60 weeks postmenstrual age, born greater than 25 weeks gestation) undergoing inguinal hernia repair were randomly assigned to receive either sevoflurane general anesthesia or awake-regional anesthesia by spinal, caudal, or combined spinal-caudal technique.¹⁵ The primary outcome is the score on a validated Intelligence Quotient (IQ) test administered at age 5, and is pending study completion in 2017. The secondary outcome was recently reported in *Lancet*, assessing neurodevelopment at age 2 by grading cognitive tasks such as attention, memory, and problem solving, in addition to motor and language skills. Davidson et al. found no evidence that less than one hour of sevoflurane anesthesia in infancy increases the risk of adverse neurodevelopmental outcome at age 2 compared to the awake-regional group.¹⁵

Sun et al. recently published another landmark trial, the Pediatric Anesthesia Neurodevelopment Assessment (PANDA) study.² This study compared neurocognitive and behavior outcomes in children aged 8–15 years old exposed to a single general anesthetic for inguinal hernia surgery prior to age 3 to their unexposed sibling. The results suggested no statistically significant difference in full-scale IQ score between the exposed and unexposed siblings.² There were also no statistically significant differences between groups in

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Studies Address the Effect of General Anesthesia on Pediatric Brain Development

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scores of memory, executive function, motor and processing speed, language, attention, visuospatial function, or behavior.² The results reported were strengthened by the study’s use of sibling-matched controls (which reduced confounders, e.g., genetics, socioeconomic status, and parental educational level) and the ability to review the anesthetic record, which provided insight into the type and duration of anesthetic exposure.

Most recently, O’Leary et al. published a large population-based cohort study assessing developmental outcomes at primary school entry (age 5–6) in over 28,000 children exposed to general anesthesia compared to more than 55,000 matched controls.¹⁶ In the first “big data” study in this field, they found no evidence of adverse developmental outcomes in children exposed to anesthesia before age 2, or in those with multiple exposures to anesthesia. While there was a very small risk of adverse developmental outcomes in children exposed after age 2, the significance and cause of this finding remains unclear.¹⁶ Perhaps this is a result of the anesthesia, but seeing that there was no adverse developmental outcome in over 10,000 children exposed under age 2—considered the “window of vulnerability” in human neurodevelopment—we can speculate that another cause may be responsible (e.g., the underlying disease process or other unaccounted for confounding variables). As alluded to in the previous section, one inherent limitation of observational studies is that they cannot prove causality.

Discussion

Many pediatric anesthesia professionals are reassured by the results of the recent studies discussed above, but recognize that the data are not conclusive, and further research is necessary before we can definitively state that a single exposure to a short anesthetic has no adverse effect on neurodevelopment. Until then, how can anesthesia professionals ease the concern among parents whose children must undergo procedures requiring anesthesia? First, we can stress to parents that it is widely accepted that infants and children require anesthesia for a variety of common procedures and that delaying these procedures has clear inherent risks as well.^{17,18} Next, we can highlight that to date, the most recent well-designed, large-scale studies reassuringly show minimal or no impairment in neurocognitive development in children who received general anesthesia (though we still await the primary endpoint in the GAS study).^{2,15,16} Lastly, we can discuss that there is no evidence suggesting that one anesthetic tech-

nique is preferred over another. Therefore, the choice of anesthetic technique should be left up to the discretion of the anesthesia team on a case-by-case basis.

Anesthesia professionals can point parents to the SmartTots website (www.smarttots.org), which is a collaboration between the International Anesthesia Research Society and the FDA to coordinate and fund research on the topic of anesthesia and neurodevelopment. This website contains useful resources and a consensus statement created by experts in the field on this topic for both parents and professionals.¹ As anesthesia professionals, we should listen to parents and acknowledge their fears, while providing them with evidenced-based recommendations and credible resources. This may help to earn their trust, while mitigating their fears related to the effects of anesthesia on their child’s developing brain.

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The Role of Capnography to Prevent Postoperative Respiratory Adverse Events

by Sofia Geralemmou, MD; Stephen Probst, MD; and Tong Joo Gan, MD, MHS, FRCA

As perioperative physicians, we are largely concerned with postoperative respiratory compromise because of its impact on morbidity and mortality, as well as on healthcare costs. Respiratory compromise following surgery and/or sedation is an umbrella definition that encompasses causes of both hypoxia and hypoventilation. Without intervention, respiratory compromise can lead to a variety of complications including pneumonia, reintubation and respiratory arrest. Such complications can be attributed to the type of surgery, anesthesia, and/or patient risk factors. Some studies have found that up to 14.2% of all surgical patients experience postoperative pulmonary complications, particularly those with open upper abdominal procedures.¹ It is widely believed that the induction and maintenance of anesthesia may be a contributing factor to the development of postoperative pulmonary complications due to the “disruption of the normal activity of the respiratory muscles,”² ultimately leading to atelectasis and hypoxia.

According to Zhan et al., postoperative respiratory failure (not including pulmonary embolism) added approximately 9 hospital days to hospital length of stay, greater than \$53,000 to hospital costs, and an almost 22% increase in mortality.³ It is thus evident that postoperative respiratory complications have significant and widespread sequelae for both the patient and the health care system.

Several independent risk factors for postoperative pulmonary failure have been identified. In a greater than 80,000 subject study, Arozullah et al. found that 3.4% of patients undergoing noncardiac surgery suffered postoperative pulmonary failure. Respiratory failure was defined as “mechanical ventilation for more than 48 hours after surgery or the need for reintubation after postoperative extubation.”⁴ Examples of such risk factors are hypoalbuminemia, advanced age (>70 years old), renal insufficiency, type of surgery (i.e., AAA, thoracic), emergency surgery, general anesthesia, COPD, and dependency status.⁴

Numerous risk factors for postoperative opioid-induced respiratory depression have been identified including older age, very young age, obesity, obstructive sleep apnea, neurologic disease, cardiovascular disease, and others.^{4,5} In fact, so many risk factors have been identified that many experts believe that all patients receiving opioids postoperatively should be monitored for respiratory depression. This argument to monitor all patients postoperatively is further strengthened when one considers all the risk factors for postoperative pulmonary complications that are not related to opioid administration.^{5,6}

With the evolution of technology, noninvasive measures of end-tidal carbon dioxide are now available in the perioperative setting. In addition to mainstream sampling, which detects carbon dioxide levels at the endotracheal tube, side stream sampling via a cannula-like device can be used for both intubated and non-intubated patients. A numerical value and graph are displayed (Figure 1). The waveform itself can also be used as a diagnostic tool with minimum training. For example, an up sloping graph may indicate acute bronchospasm.

An increasing amount of evidence supports the use of capnography for earlier and more reliable warnings of respiratory depression for procedural sedation.⁷ The argument made in favor of capnography often cites that changes in capnography will precede changes in pulse oximetry. In a study by Burton et al., emergency department physicians administering procedural sedation were blinded to the use of capnography, as it was not the standard of care. Thirty-three percent of the cases had an adverse respiratory event (defined as a change in etCO_2 of 10mmHg or greater). Of these, 70% were detected by capnography 12 to 271 seconds before changes in pulse oximetry or respiratory rate.⁸

It is common practice to monitor patients in the acute postoperative period with pulse oximetry and respiratory rate. This, however, may not be adequate. Many have suggested that supplemental oxygen and the presence of the PACU nurse may be potential confounders in the accurate assessment of a patient’s respiratory status. A patient may maintain his/her oxygen saturation for quite some time with supplemental oxygen despite inadequate ventilation. Moreover, hypoventilation from excessive sedation with or without upper airway obstruction may be masked by periodic stimulation by the nurse. When the nurse walks away, bradypnea, poor inspiratory effort, and/or upper airway obstruction once again ensues, leading to hypercarbia and subsequent increasing somnolence. Thus, although current guidelines recommend pulse oximetry in the immediate postoperative period, many argue that capnography may be a more reliable and sensitive predictor of hypoventilation and an earlier detector for potential respiratory adverse events (RAEs). Because it is a breath-by-breath monitor, capnography provides an earlier indication of impending respiratory compromise. What is the evidence? A study conducted by McCarter et al. (n=634) found that capnography was more effective than pulse oximetry in providing early warning of respiratory depression in postoperative patients receiving supplemental oxygen.⁹ In all cases, capnography but not pulse oximetry alerted the nurse that respiratory compromise was impending. It is this breath-by-breath monitoring that better predicted the need for intervention.

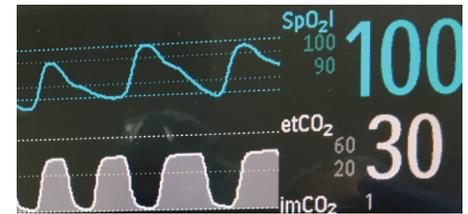


Figure 1. Pulse oximetry and capnography waveforms.

The American Society of Anesthesiologists (ASA)—Standards for Basic Anesthetic Monitoring, updated in 2010, now states that the adequacy of ventilation during general anesthesia and moderate/deep sedation shall be continually evaluated by both qualitative clinical signs and monitoring of expired carbon dioxide.¹⁰ This identifies the monitoring of expired carbon dioxide as a means to assess the adequacy of ventilation and has been implemented in part due to the risks associated with procedural sedation.¹⁰

Surrogates such as respiratory rate are measures that do not necessarily determine the adequacy of ventilation. A capnometer provides a quantitative measurement of the presence of exhaled carbon dioxide as well as a measure of the respiratory rate, though it does not provide information about the tidal volume. Carbon dioxide monitoring is required based upon the level of sedation, moderate or deep, and is irrespective of the location or type of anesthesia used. We would make an argument that a similar degree of monitoring should be maintained in the postoperative environment where most patients are still in a sedated state, especially in patients at high-risk for respiratory compromise.

In a small prospective randomized study of 54 opioid-naïve postoperative orthopedic patients, capnography resulted in greater detection of respiratory depression.¹¹ The authors concluded that capnography might be more appropriate for use with postsurgical high-risk patients taking opioids on a general care nursing unit.¹¹ Concerns regarding this technology include consistent appropriate positioning of the end-tidal CO_2 monitoring device in awake extubated patients, patient comfort, and less familiarity with this device compared to pulse oximetry by nursing staff. These issues can be addressed by both patient and nursing education.

In summary, improving patient safety and health care costs are two prominent goals of most policy change. The issue of adverse postoperative respiratory events has come center stage again as technological advancements allow for easy additional monitoring in the perioperative setting. Pulse oximetry has become standard of care in many areas outside of the operating rooms; we

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Postoperative Capnography: Modality for Earlier Detection of Adverse Respiratory Events

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believe that postoperative capnography should also be adopted in the postoperative environment for continuous monitoring of end-tidal CO₂ and earlier detection of catastrophic respiratory events.

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Implementation of Emergency Manuals in China

by Jeffrey Huang, MD

In aviation and nuclear power industries, emergency manuals have proven to be helpful tools during critical events. These emergency manuals are integrated into training, and are expected to be used whenever they are needed.

Gawande’s *The Checklist Manifesto* emphasized that perioperative checklists improved surgical safety.¹ The evidence proved the value of using checklists in medicine. Gawande et al. published a study result in the *New England Journal of Medicine*.² Implementation of the World Health Organization surgical safety checklist reduced the mortality and inpatient complications rate significantly. In 2013, a simulation-based trial demonstrated that teams missed 6% vs. 23% of critical actions during a variety of operating room critical events when emergency manuals were used versus not.³ In the United States, most institutions have gradually achieved significant cultural acceptance to integrate emergency manuals into their practice and training.

Can emergency manuals be implemented in other countries? Recognizing the importance of the implementation of emergency manuals, I contacted the Stanford Anesthesia Cognitive Aids Group, Harvard Ariadne Lab, and the Society for Pediatric Anesthesia to acquire the official permission for translating their manuals. All three organizations strongly supported my request and granted the permission. Leading developers of emergency manuals worked with me to support translation of these emergency aids under creative commons licenses.

Translation

Subsequently, two translation teams were organized. One team was led by Dr. Hui Zhang (Department of Anesthesiology, School of Stomatology, The Fourth Military Medical University, Xian, China). The other team was led by Dr. Zhiqiang Liu (Department of Anesthesiology, Shanghai 1st Maternity and Infant Hospital, Shanghai, China). Dr. Zhang’s team was responsible for Stanford Operating Room Emergency Manuals and Harvard

Ariadne Lab Operating Room Crisis Checklists. Dr. Liu’s team was responsible for Society for Pediatric Anesthesia Pediatric Critical Events Cards. The teams were composed of anesthesiologists from their respective department and other institutes. The workload was distributed among the team members with each translator responsible for translating one to two pages. They were required to ensure that the translation was as accurate, precise and as fine-tuned as possible. Professional editors were hired to do editing for OR Crisis Checklists and Pediatric Critical Event Cards. The organization, format, color coding, and text size were mandated to be consistent with the English version. The Stanford Emergency Manual was edited by Stanford Anesthesia Informatics and Media Lab under the direction of Dr. Larry Chu.

Education

While the teams were working on translation, I traveled to China and did several presentations on

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Permission to Translate



Cover page of Stanford Emergency Manual translated into Chinese.



Figure 2. Cover page of Harvard Ariadne Labs Crisis Checklist translated into Chinese.

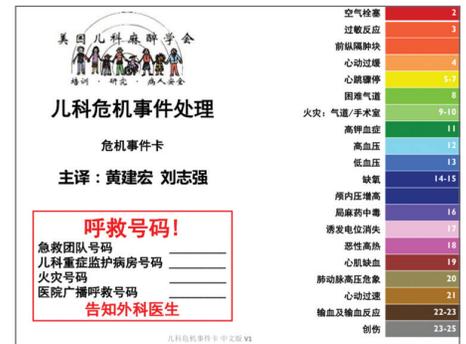


Figure 3. Society of Pediatric Anesthesia Pediatric Critical Event Card index translated into Chinese.

125,000 Manuals Downloaded in 6 Months

“China,” From Preceding Page

the importance of using emergency manuals in the operating room. Presentations were made in the Zhejiang Province Anesthesia Quality Annual meeting. The presentation was recorded and aired in the New Youth Anesthesia Forum. Subsequently, I also presented in several hospitals, and at The Chinese Society of Anesthesiology (CSA) annual meeting in Xi'an. The presentations highlighted the importance and the upcoming availability of the Chinese versions of emergency manuals. The webinar presentation to the New Youth Anesthesia forum was viewed by more than 47,000 members.

Publication

The New Youth Anesthesia Forum, the largest anesthesia network in China, is publishing three Chinese language translations of the emergency manuals. It has more than 127,000 registered members. The website director, Dr. Xianyong Zhou (Department of Anesthesiology, the 2nd Affiliated Hospital, Zhejiang University, Hangzhou, China), was personally responsible for the publication process. An introductory letter about the Chinese versions of the emergency manuals was created, and a separate web page was generated. The web page was designed to record how many copies of each book were downloaded. A feedback letter was generated for readers to make comments regarding the books and report successful implementation and use.

Metrics of Successful Implementation

Since all three books are free to download in the US, the Chinese versions are also free to download in China. We decided to publish on Christmas Day 2015 and offer the books as Christmas presents for Chinese anesthesiologists. New Youth Anesthesia Forum published the manuals on the website as the top news item for website registered members (<http://xqnmz.com/thread-70751-1-1.html>). In the meantime, New Youth Anesthesia Forum published this news on their mobile web for the members who used mobile devices. They can link to the downloaded site through their mobile devices. The New Youth Anesthesia Forum ensured that every member was aware of the publication.

These manuals are equally applicable for acute events in emergency departments, labor and delivery, medical, pediatric, and intensive care units. They can also be adopted for use in other hospital locations. To encourage other health care professionals to adopt use of the manuals, I also contacted a popular Chinese surgical website, obgyncn.com, resulting in rapid availability of manuals to surgical colleagues.

Within 6 months of publication, almost 125,000 copies have been downloaded. The actual distri-



Figure 4. Members of the first implementation workshop in Peking University People's Hospital

bution is likely much larger because many members received their copies by email and via social networking. The members highly appreciated the emergency manuals' publication. New Youth Anesthesia Forum received many notes of gratitude from their membership.

Training

Experience with the WHO surgical checklist shows that just tacking a checklist on the wall doesn't create effective use and subsequent positive change in team behaviors. According to the Emergency Manuals Implementation Collaborative (EMIC), availability of emergency manuals is not enough to improve performance. Training and familiarization are necessary to enable clinicians to become proficient in using emergency manuals.

Peking University People's Hospital is one of the most prominent hospitals in China. The hospital has over 2,000 beds, and is located in the heart of Beijing. The hospital simulation center is the first Society of Simulation in Healthcare accredited simulation medical education center in China. The simulation center facility provides 1,300 square meters of space and access to state of the art simulation technology for health care training. The anesthesia department was determined to implement emergency manuals. The department chair, Dr. Yi Feng, strongly supports the implementation project. They printed out the books and kept one copy at each anesthesia station. They were also enthusiastic about establishing a train-the-trainer project. The project leader, Dr. Hui Ju, and I worked together to create detailed education material and organized a training program and are developing a simulation-based team-training curriculum to train participants in the simulation center.

The first implementation workshop was carried out on April 11, 2016, in Peking University People's Hospital simulation center. About a dozen participants joined the workshop, with 50% of them coming from different areas and facilities. An introduction was presented as to why, how, and when to use emergency manuals. Scenarios demonstrated the importance of participant engagement. The participants engaged in their roles and team communication, and a simulation training session was demonstrated for all trainees. The same critical event was presented with and without the use of emergency manuals. This introductory demonstration simulation helps participants to witness relevant elements of team communication in a crisis and the use of an emergency manual. The demonstration will be aired on the hospital website as an implementation of emergency manuals education resource. A second implementation workshop is scheduled for April of 2017.

To assess the impact of the training on learner attitudes and knowledge, a survey form was developed. The participants were surveyed regarding their perceptions of the usefulness and clinical relevance of the emergency manuals on a scale of 1 to 5. The participants strongly believed that OR emergency manuals are excellent tools to learn how to manage OR crises and improve outcomes. They will use emergency manuals and will organize a local formal familiarization session in their hospitals.

Tongji Hospital, Tongji Medical College, and Huazhong University of Science & Technology are comprised of 52 clinical and paramedical

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Emergency Manuals Gaining Wide Support in China

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departments with a total of 4,000 beds. Their anesthesia department has become one of the most prestigious anesthesia programs in China. Tongji Hospital has 70 operating rooms and performs about 70,000 anesthesia cases annually. The department chair, Dr. Ailin Luo, strongly supports the implementation of emergency manuals. Dr. Xianwei Zhang participated in the translation of the book, and organized implementation of emergency manuals. A group of anesthesiologists in the department were working on developing a training curriculum. They used a simple CPR mannequin and were able to create “realistic-enough” scenarios. The anesthesia department has a tradition of providing excellent education for its trainees. Their training curriculum can be used for the anesthesiologists from hospitals without a simulation lab.

Support From Official Organization

The Chinese Association of Anesthesiologists (CAA) is a division of the Chinese Medical Doctor Association. CAA is one of the largest anesthesiologists societies in China. The president of CAA, Dr. Weifeng Yu, supported the implementation of emergency manuals. The secretary of CAA, Dr. Zhijie Lu, arranged an implementation of emergency manuals presentation in the Congress of CAA. Based on the available evidence demonstrating the value of checklist use and team training, CAA encourages Chinese anesthesiologists to adopt the use of emergency manuals in the management of critical events with appropriate multidisciplinary training in their use.

The Chinese Society of Anesthesiology (CSA) is a branch of the Chinese Medical Association. The president of CSA, Dr. Lize Xiong, supported the implementation of emergency manuals and recommends that all Chinese anesthesiologists receive appropriate training and adopt the use of operating room emergency manuals with the goal of anesthesiologists being able to enhance their crisis management skills.

In Conclusion

Emergency manuals have been well received by Chinese anesthesiologists. Many hospitals have one copy at each anesthesia station. After multidisciplinary training, clinicians can become proficient in using emergency manuals. Chinese clinicians will achieve cultural acceptance to integrate emergency manuals into their practice and training.

Dr. Huang is a member of Anesthesiologists of Greater Orlando, a Division of Sheridan Healthcare and Associate Professor at the University of Central Florida College of Medicine and a member of the APSF Committee on Education and Training.

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A Statement by the Executive Committee of the APSF

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

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Letter to the Editor:**The Future of Emergency Manuals and Cognitive Aids: Integration Within Anesthesia Information Management Systems**

We read with great interest your recent article “APSF Sponsors Workshop on Implementing Emergency Manuals,”¹ which focused on broadening the implementation of cognitive aids by perioperative care teams. We commend the collaborative efforts of the workshop to ascertain the best method of delivery and presentation of cognitive aids in clinical practice. The workshop participants appeared to favor hard-copy emergency manuals to material that would be presented to a user digitally. We wanted to highlight what we believe to be a significant advantage of embedding digital decision support tools within an Anesthesia Information Management System (AIMS).

The utilization of electronic health records (EHR) such as AIMS has grown greatly with 75% of academic anesthesiology departments adopting AIMS by 2014, up from 16% in 2007.² In addition to the growing adoption of AIMS, the forward march of quality improvement initiatives such as the Health Information Technology for Economic and Clinical Health (HITECH) Act should lead to further improvements in AIMS through the Meaningful Use (MU) program.³ The ability of AIMS (as part of a hospital-wide EHR) to incorporate data input from a patient’s health record (baseline vital sign ranges, laboratory values, medication administration records, etc.) allows for large scale data analyses upon which can be built predictive algorithms for the presentation of timely clinical decision support tools.

Many AIMS have already evolved from a simple digital translation of a paper anesthesia record to an interactive tool allowing improvement of the anesthesia professional’s performance.⁴ While there are some advantages in ease of use and familiarity of paper anesthetic records, AIMS allows for full utilization of artificial intelligence in computing. A relatively simple example can be highlighted by examining a hypothetical patient of male gender with baseline hypertension and anemia undergoing an intraperitoneal surgical procedure. If such a patient would experience periods of hypotension, he would be placed at increased risk of developing acute kidney injury (AKI).⁵ A well-designed decision support tool built within AIMS would identify such a patient as being a higher risk for developing AKI, and notify the anesthesia professional of the need for more aggressive management of intraoperative hypotension. This example demonstrates the potential for predictive algorithms to provide the necessary tools for prevention and management of an imminent crisis.

The benefits of checklist utilization in anesthesia care and crises management have previously been validated by a number of studies.^{6–8} Successfully implementing cognitive aids can be a complex endeavor and involves four vital elements: creation, familiarization, use, and integration.⁹ In another study, the largest obstacles to utilization of decision support tools were factors that limit “thoughtful integration into the anesthesia workplace” and “ease to use (design & length of checklist).”¹⁰ A great number of these obstacles can be potentially addressed by conceiving a more sophisticated AIMS that provides a digital support tool to the user at the most appropriate time. The goal would be for the artificial intelligence of AIMS to present the emergency manual automatically rather than depend on a variety of human factors. A crude example of such an AIMS design is one that would recognize intraoperative tachycardia (HR >100 for 1 minute) and present a screen shot of the tachycardia algorithm of choice. This design would overcome several barriers to effective cognitive aid utilization. First, the algorithm could notify the user of the hemodynamic abnormality signaling the potential for progression into an emergency situation. Second, such a design does not rely on the user to initiate accessing the appropriate cognitive aid; rather the cognitive aid of choice becomes immediately available on the AIMS screen. Third, the cognitive aid is inserted within the natural field of view of an anesthesia professional—a computer monitor that is visually referenced on a minute-by-minute basis. Finally, such innovation could introduce a more interactive relationship between the user and AIMS, encouraging greater future adoption. In our opinion, this kind of design would promote improved familiarization, use, and integration of cognitive aids.

In the APSF-sponsored workshop on implementing emergency manuals, 92% of participants believed that more studies are needed to assess the best application of emergency manuals.¹ Additionally, it has been demonstrated that decision support tools should be vigorously tested during simulated emergencies to aid in the design of such tools.^{9,11} For these reasons, our simulation group has begun to develop proof of concept studies aiming to show improvement in anesthesia professional performance when presented with emergency manuals that could be integrated into the AIMS.

While industry and business have mostly adopted application of data science, health care has lagged behind despite the tremendous potential for

big data analytics to improve outcomes and lower costs.¹² There are great technical and design challenges to utilization of big data in medicine as a whole. Specifically, embedding digital decision support systems within AIMS has a variety of obstacles to overcome prior to moving forward. There are uncertainties as to the scope of regulation of the US Food and Drug Administration (FDA) medical device regulation as it applies to real-time decision support tools.⁴ There are also technical challenges to such a model: accessing the data warehouses in real-time, maintenance through various version upgrades, and support for troubleshooting when problems inevitably arise.⁴ As new data emerges AIMS will have to be updated to continue to provide standard of care information to practitioners. Finally, how can we implement a uniform system with so many different types of AIMS in use? It seems impractical and time consuming for each individual system to innovate and design decision support tools for use within only a single AIMS. However, the ability to demonstrate quality of care improvements with the added benefit of cost savings through better outcomes will, one hopes, give AIMS manufacturers the needed push to innovate a more interactive, user-friendly experience between anesthesia professionals and AIMS.

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References to Support Letter on Cognitive Aids

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Letter to the Editor:

Rupture of Obstructed Nasal Cannula

To The Editor:

Today, I provided IV sedation to a patient who was having a closed reduction of a nasal fracture. I placed a nasal cannula with oxygen and etCO₂ monitoring in the patient's mouth. While the surgeon was infiltrating the nose with local anesthesia, I noticed that the patient's SpO₂ had decreased and the adjunct oxygen flow meter that had been set at 4 liters/min was now set at zero. I attempted unsuccessfully to increase the oxygen flow. Failure of the oxygen supply was ruled out because the oxygen flow meter on the anesthesia machine was working. Subsequently, there was a loud pop that got everyone's attention.

As you can see from the photo that is attached, the nasal cannula ruptured. The patient had clenched his teeth on the nasal prongs, biting off a small piece. The surgeon retrieved the piece of plastic from the patient's tongue. We suspect that when the cannula was occluded, enough pressure from the flow of oxygen caused the cannula to rupture.

Although I have placed the nasal cannula in the mouth many times for nasal procedures, this had never occurred. In the future, I intend to use an oral airway or bite block if the cannula cannot be placed in the nose.

Sincerely,
Diane Foos, CRNA
Abington Surgical Center
Willow Grove, PA



Figure 1. Ruptured Nasal Canula.

Letter to the Editor:

Fluid Management Redux

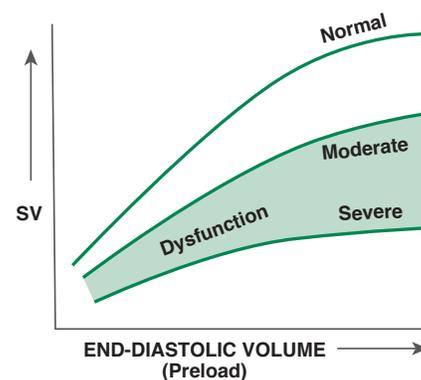
To the Editors:

In response to Drs. Mythen and Grocott...

For over 30 years of practicing anesthesiology, I have considered the following physiologic principle when trying to optimize fluid management. Based on the Starling Curve, it is apparent that patients with normal systolic ventricular contractility should be more "fluid responsive" than patients with poor systolic contractility. I believe that much of the recent research and discussion about fluid management has ignored this concept. Patients with poor systolic function are likely to increase their stroke volume over a smaller range of fluid challenges and more likely to develop heart failure and pulmonary edema with larger fluid boluses.

I believe that one of the reasons it is difficult to "optimize" fluid therapy is that we need to consider underlying contractility. Normal ventricles are preload dependent and poor ventricles are less preload dependent and more afterload dependent.

Frank — Starling Curves



Another reason we have had difficulty in proving that fluid management/"goal-directed therapy" can improve stroke volume and "perfusion" in sepsis is that several existing studies have set lofty and perhaps unreachable goals in their experimental design. Knowing that contractility may be impaired in sepsis, it may be difficult to push the stroke volume to "normal" with just fluid. Inotropes may need to be added for contractile support.

Using goal-directed therapy models to characterize fluid responsiveness and being more generous in those patients with normal systolic function seems prudent. Consideration for judicious fluid administration with the potential addition of inotropes in patients with poor systolic function should be considered. ONE SIZE DOES NOT FIT ALL.

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Saturday, October 22, 2016**

McCormick Place Convention Center
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