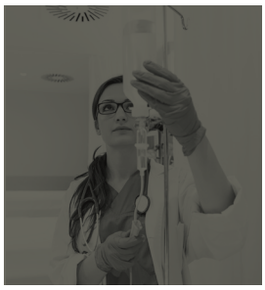

PENNSYLVANIA *society of* ANESTHESIOLOGISTS

***SPRING 2018** NEWSLETTER*

SENTINEL

Tom Witkowski, M.D.
PSA PRESIDENT

This article is something I selected from the archives. It is just as important now as when it was first published. We need to take the message to heart if we are to preserve physician led anesthesia care.

President's Message

Silence is not Golden

"Ten people who speak make more noise than ten thousand who are silent."
-Napoleon Bonaparte

Even though we may be ambivalent about his legacy, there can be no question Napoleon understood how governments operate and what motivates the people they govern. He knew instinctively how leaders influence the masses and how the people influence their leaders.

"The heart of a statesman must be in his head," the famed military strategist once said. With those 10 words, he admonished generations of government bodies to emphasize rational thought over impulse and emotion.

Two hundred years later, physicians practice "evidence-based medicine." We are trained to make decisions through rational thought. The pursuit of rationality is what most often motivates us to communicate with elected officials.

Yet, we have become accustomed to a daily bombardment of news reports of government gridlock and conflict arising from divisions within our legislative bodies. An endless stream of self-interested groups push, shout and point fingers, always ready to say that, if anything at all was accomplished, it wasn't the right way to go.

Too often frustration dampens any motivation to let our elected leaders know what is best for our patients and medical practices. Consequently, we say and do nothing.

We cannot allow frustration to turn into self-censorship. Silence will be our Waterloo.

Physician anesthesiologists are to be taken seriously. We are the most extensively trained providers of anesthesia in the United States – the only ones trained in the full scope of perioperative medicine. These credentials notwithstanding, laws and regulations that affect what we do are not automatically shaped as we might like them.

In many other states, groups including nurse anesthetists have pushed hard for legislation expanding their scopes of practice to include writing prescriptions and administering anesthesia without a physician present. Physicians, with varying degrees of success, have opposed these bills.

Logic would dictate having the most extensively trained professionals in charge when lives are on the line. But legislators respond to the cries of their constituents; emotion plays a role. A room full of nurse anesthetists insisting, unchallenged, that they can perform as well as physicians is persuasive, despite the obvious flaws in logic.

If we want our lawmakers and government administrators to be responsible, to lead with reason, we need to be at their sides to remind them of their obligation to protect the safety of their constituents. We need to show them not only how we would like things to be, but why it makes the most sense.

As a society of physicians, we have the rationale to be correct in our position and the credentials to be believed. There is only one way to bring this credibility to bear: we have to speak up – in large numbers.

When votes are critical, groups who don't agree with us will try to out shout us. If we let them, they will win.

A phone call to a legislator doesn't take a lot of time, but it can make all the difference. ■

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PENNSYLVANIA *society of* ANESTHESIOLOGISTS

***SENTINEL** NEWSLETTER*

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The PSA Newsletter is an official publication of the Pennsylvania Society of Anesthesiologists Inc. Opinions expressed in this newsletter do not necessarily reflect the Society's point of view. All correspondence should be directed to:

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IN THIS EDITION

Richard O'Flynn, M.D.
EDITOR

As I write this, we have just celebrated Physician Anesthesiologist week (January 28 – February 3) which followed CRNA week (January 21 – January 27). You should be reading this as we just passed Doctors' Day on March 30.

You have to wonder the impact of these dedicated days/weeks. Does anyone really pay notice to the State proclamations or are these simply symbolic "feel good" events? It seems that every day is part of national something day, week or month. It has almost gone to the ridiculous. There is National Donald Duck Day (June 9), Winnie the Pooh Day (January 18), Dog Biscuit Appreciation Day (February 23) and Dress Up Your Pet Day (January 14) to name but a few. Doctor Day shares the day with Take a Walk in the Park Day, National Pencil Day and National Turkey Neck Soup Day.

The point is that it is not about a single day or week, we need to remember what our real purpose is. Let's celebrate the day/week but remember the real purpose of our calling, the reason that we chose our profession is that we wanted to care for our patients.

With the proliferation of individuals in hospitals introducing themselves as "doctor", it is important to remember, and remind hospital administrators if needed, that National Doctor Day is to honor physicians. The start can be traced back to 1933 and it became a national holiday in 1991 when Congress passed Proclamation 6253. Maybe it is now time to change the name to National Physician's Day as doctor is becoming so ubiquitous.

In this issue of the *Sentinel* we start a new series, Know Your Equipment. The first article is on pulse oximetry. While the article describes the basics of pulse oximetry, a more detailed article can be found on the PSA website.

In addition to the equipment article, PSA President, Dr. Witkowski and PSA District Director, Dr. Sullivan provide PSA and ASA updates and Z-PAC treasurer, Dr. Muetterties gives the PAC report. Kevin Harley of Quantum Communications, our legislative counsel updates what is happening in Harrisburg. PSA attorney, Charles Artz provides insight on two recent court cases and how that affects our practices.

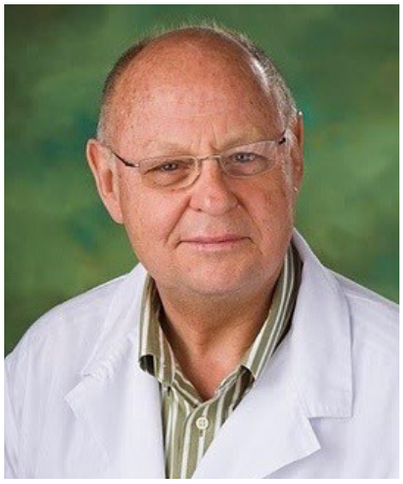
Attorney Mark Weiss provides us with another excellent article on practice management, giving a realistic view of the RFP process that so many of our colleagues deal with on a regular basis. Drs. Atkins and Martin report on the Pennsylvania Patient Safety Authority activity regarding wrong site procedures, including nerve blocks, something that I'm sure we all think only happens to others who are not "careful" like us.

The resident report in this issue, while very important to residents as they go through this stressful period reminds us all about the importance of our own well-being and the necessity to take care of ourselves.

I also encourage you to read Dr. Muetterties' article describing his experience aboard the Mercy Ship. As anesthesiologists there are many opportunities to volunteer and everyone who does it says that it is one of the most fulfilling experiences of their careers. ■

The *Sentinel* is your journal. We encourage submissions, suggestions or comments. Write us at cbenson@pamedsoc.org.

Where Has All the Z–PAC Support Gone?



Craig Muetterties, M.D.
PSA TREASURER

I started to write this article and was planning on describing the function of your Political Action Committee. I scrapped the article after nearly finishing it.

I believe we all know that our voice needs to be heard by legislators who are enacting laws that may radically change your practice of medicine and your own future as a patient. I have been an officer of this Society for over 20 years and have never seen a year when we have not faced coordinated attacks on the practice of medicine by groups that seek out legislators that are willing to listen to them and support their cause. This year is no different.

What is different is that there is apathy in our Society. In Pennsylvania, only 16% of anesthesiologists who are members of our Society contribute to Z-PAC each year. This means that the burden of raising funds to support your profession is being carried by a small number of your colleagues. My call to you is to increase this percentage by personally sending a check to:

Z-PAC | P.O. Box 325 | Media, PA 19063

Please be sure to include the name of your employer since this is a government requirement for contributions. You can also donate online using the link from our website, www.psanes.org. Follow the link for donating to the PAC or use the QR code on this page. Please note that donations that are made through a credit card are somewhat less effective since the credit card company will deduct a processing fee from the donation.

I look forward to reporting that the percentage of participating anesthesiologists has dramatically increased when I write the next report. ■

The Physician and the COST-BENEFIT RATIO

Joseph A. Answine, M.D., FASA

As written in the modern version of the Hippocratic Oath: "...I will apply, for the benefit of the sick, all measures [that] are required..."

As written in *Consumer Reports* (2014): "Person for person, health care in the U.S. costs about twice as much as it does in the rest of the developed world. In fact, if our $3 trillion health care sector were its own country, it would be the world's fifth-largest economy."

The definition of cost-benefit ratio: An indicator, used in the formal discipline of cost-benefit analysis, that attempts to summarize the overall VALUE for money of a project or proposal.

The definition of value: NOUN / The regard that something is held to deserve; the importance, worth, or usefulness of something. VERB / Estimate the monetary worth of something.

That "something" as mentioned in the definition of value for the sake of this article is "life" and "quality of life".

The quotes and definitions above have led to a paradox for physicians. Today, the cost-benefit ratio is heavily involved with the implementation of health care. The system in the United States, to survive due to continuously rising costs, demands that this be true.

But, what part should we as physicians play within the system? I am continuously frustrated when, after reviewing the literature, I ask for a new medication or piece of equipment, and the first question that I get is "What is the cost?" Would it be terrible if I say that I don't care? When I took on this responsibility as a young physician it was my understanding, my belief and my desire to put patients first when making any decision. It made sense when I was in medical school, and it still makes sense to me now. At what point does cost become more important than the patient? $1,000? $1,000,000? Never? Of course, our knee-jerk reaction is to say never, but the truth is it obviously does to some out there that have a say; whether administration, legislators, insurers or some of us.

Now, I am not talking about the ethical question of surgery or comfort care for an elderly person with multiple co-morbidities such as dementia. But, the intervention, based on the evidence, will decrease morbidity or mortality by say 1 in 10,000. However, the cost will never be recouped by the healthcare system.

We are constantly being asked as anesthesiologists to control costs for medications and equipment. We are all painfully aware that the cost is not insignificant even for oldest, generic medications. Newer medications and advancements in technology have obviously driven the costs even higher.

Anesthesiologists have, with great pride, been the front runners in medical innovation. The arterial oxygen saturation monitor, propofol, and invasive and noninvasive hemodynamic parameter monitoring are part of our daily world. When I take care of a patient, I commonly ask myself, "what I would do if this was a family member of mine?" and act accordingly. So, if I know something better is out there, why wouldn't I want it regardless of a petty obstacle such as cost? I bring many medications to my hospital pharmacy and therapeutics committee and I commonly ask administration for the acquisition of new monitoring equipment.

My track record for success is dismal to say the least. I just don't see it. I struggle to see why I cannot have IV acetaminophen, or Exparel, or Entereg for my enhanced recovery patients. Or, why I cannot use Sugammadex without having to write a note to my teacher apologizing for my indiscretions when the data insanely (not just a little) favors the benefits of the drug over previous agents used. Why do I need to repeatedly explain the necessity of quantitative TOF monitors, cerebral oximeters and noninvasive hemodynamic monitors? Doesn't anyone read the literature? Doesn't anyone else care? I know there are budgets, and profits versus expenses. But the burning question is, as a provider and patient advocate, should I care? And, when does the physician stop and the businessperson take over? Should I be so hard on those who are trying to keep their institutions afloat? Am I as narrowminded as they say I am?

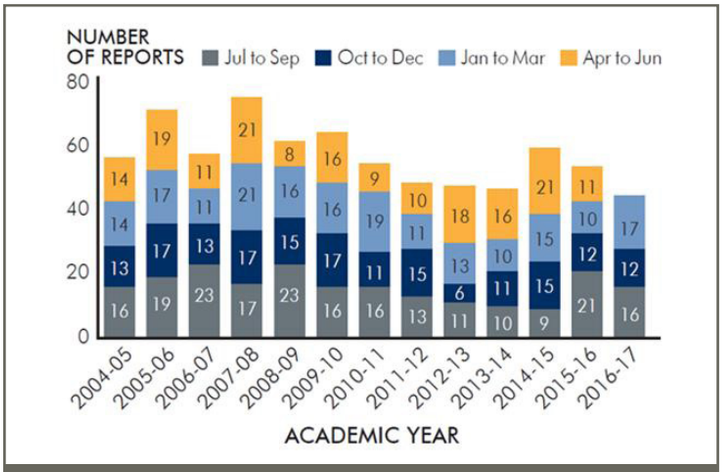
I argue that there are enough people on the other side. There are enough people protecting the pennies and the solvency of the institution and the health care system. So, I think I'm going to stick to being argumentative, narrowminded, and that unyielding physician anesthesiologist that puts the patient first. ■

Reliable Performance of Correct-Site Nerve Blocks

PENNSYLVANIA PATIENT SAFETY AUTHORITY | PENNSYLVANIA SOCIETY OF ANESTHESIOLOGISTS
Joshua Atkins, M.D., PhD. and Donald Martin, M.D.

Wrong site procedures represent the fourth most common *Sentinel* event reported to the Joint Commission through October of 2017 and constitute approximately 13% of all *Sentinel* Events reported to The Joint Commission in the last decade.

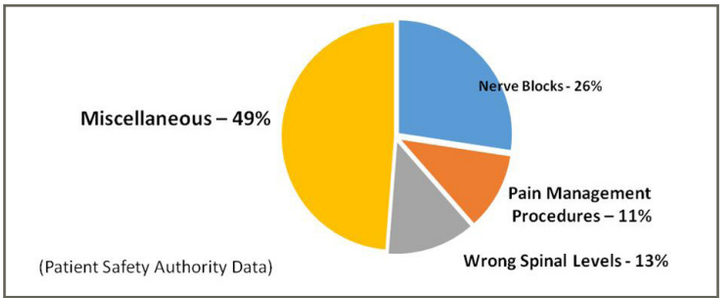
The Pennsylvania Patient Safety Authority (Authority), began a concentrated effort to combat wrong site procedures in 2007. The total number of wrong site reports to the Authority slowly but steadily declined from 2007 to 2014. However, it increased again in 2015.



Number of Wrong Site Surgeries Reported in Pennsylvania by Academic Year

http://patientsafety.pa.gov/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx#articles

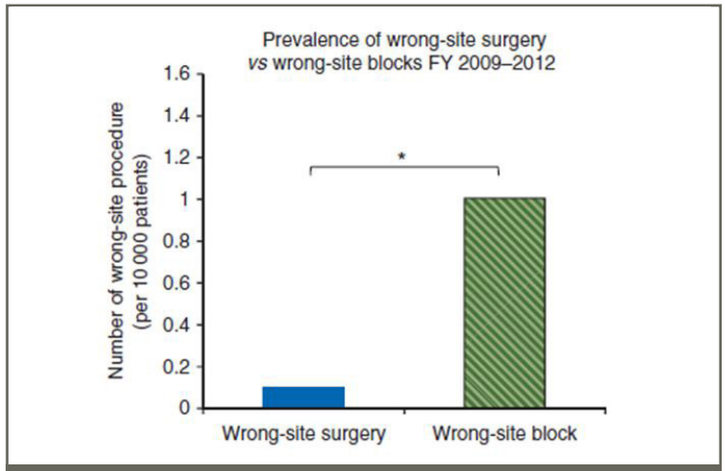
In Pennsylvania, wrong site procedures are not only a surgeon's problem. Since 2004, nerve blocks performed by anesthesiologists or surgeons made up 26% of all wrong site procedures in the Authority's database, and another 11% were chronic pain procedures. **Therefore almost 40% of all wrong site procedures may have involved nerve blocks.**



Types of Wrong Site Reports to the Pennsylvania Patient Safety Authority, July 2004 through September 2016

http://patientsafety.pa.gov/ADVISORIES/Pages/201612_160.aspx

Perhaps even more striking, Hudson, Chelly, and Lichter reported in the British Journal of Anaesthesia in 2015 that the prevalence of wrong site nerve blocks at the University of Pittsburgh between 2003 and 2012 was 1.28 / 10,000 procedures for patients receiving unilateral blocks, ten times higher than the prevalence of wrong site surgery. (Hudson ME, Chelly JE, Lichter JR: Wrong-Site Nerve Blocks: 10-Year Experience in a Large Multi-Hospital Health Care System. Br. J Anaesth 2015; 114:818-824). One reason for this difference may be that best practices designed to prevent wrong site surgery were implemented in the operating room, but not in nerve block or acute pain service areas.



Relative Prevalence – Wrong Site Surgery and Nerve Blocks

Hudson ME, Chelly JE, Lichter JR: Wrong-Site Nerve Blocks: 10-Year Experience in a Large Multi-Hospital Health Care System. Br. J Anaesth 2015; 114:818-824)

To address the ongoing reports of wrong-site nerve blocks, the Pennsylvania Society of Anesthesiologists and Pennsylvania Patient Safety Authority joined forces in 2015 to develop a set of principles to help standardize the nerve block process. The following ***Principles for the Reliable Performance of Correct-Site Nerve Blocks*** were developed by an Expert Task Force made up of Pennsylvania anesthesiologists, surgeons, pain service nurses, and patient representatives and are designed to help Pennsylvania physicians, acute healthcare facilities, and ambulatory surgical facilities take a new and broader approach to preventing wrong site nerve blocks.

Principles for Reliable Performance of Correct-Site Nerve Blocks

I. Process of Care

Preoperative Verification

1. Confirm patient identity using at least two forms of patient identification.
2. Reconcile and verify the exact site and laterality of the surgical procedure and the perioperative nerve block site using all forms of available primary and confirmatory patient sources including:
    a. Primary: Surgical consent
    b. Primary: Patient and/or representative
    c. Primary: Surgeon's notes (if available)
    d. Confirmatory: Operating room schedule
    e. Confirmatory: History & physical
3. If any of these sources differ, the process stops and a member of the anesthesia block team alerts the surgeon to resolve the disagreement.

Anesthesia Site Marking

1. After confirming the information in "Preoperative Verification" the responsible attending anesthesiologist (not a trainee) will use a standardized, institutionally-approved mark that is distinct from the one used for the surgical site to mark the perioperative nerve block site.
2. Place the mark close to the injection site to ensure it is visible in the prepped and draped field.
3. Repeat the marking process when there are multiple injection sites.

Time-out

1. Secure a block team consisting of at least two people with independent roles (e.g., responsible attending anesthesiologist and pre-operative or holding area nurse or circulating nurse)
    - Engage the responsible attending anesthesiologist to INITIATE or ask for the time-out.
    - Require that the responsible attending anesthesiologist be present during the time-out and nerve block
2. Conduct a time-out before:
    - Sedating the patient, when possible.
    - Inserting the needle or as close to the procedure as possible.
    - Each nerve block
3. Minimize distractions and stop unrelated activity before conducting the time-out.
4. Both the responsible attending anesthesiologist and block team member verify the procedure that is documented on the surgical consent (and anesthesia consent, if used).
5. Locate and verbalize the visible anesthesia site mark during the time-out.
6. Repeat the time-out process when there are changes to:
    - Block team
    - Patient location within the perioperative area
    - Patient positioning
    - Planned nerve block site

II. Healthcare Facility Structure and Culture of Safety

- Develop and maintain a single, consistent system-wide perioperative nerve block process similar to that implemented by other services to prevent wrong-site procedures (e.g., surgery, radiology).
- Engage a multidisciplinary stakeholder team to develop the nerve block process.
- Educate and train anesthesia, pain service teams, and preoperative nursing staff about the perioperative nerve block process (e.g., simulation).
- Use checklists, posters, stickers or other cognitive aids in the block area to encourage sustainability of the nerve block process for clinicians and patients.
- Designate a department leader or administrator (e.g., a liaison to administration and physicians) to support block team staff and to address non-compliance for the nerve block process.
- Empower all members of the block team to speak up if there is a safety concern.
- Engage the patient and their representative as active participants in the pre-nerve block process.
- Implement audit processes to promote enhancement of the nerve block process at regular intervals (e.g., monthly, quarterly).
- Obtain ongoing evaluation and feedback from anesthesia, pain services, and perioperative nursing staff to ensure process is consistent and maintains provider engagement.

These principles incorporate portions of prior guidelines from other organizations, but bring several additional concepts as well. The Clinical Principles:

- Focus entirely on performing the correct site procedure
- Relate specifically to perioperative nerve blocks, as do the ASRA guidelines
- Identify additional sources of information regarding the correct block site, but also maintain the simplicity of the process by distinguishing between primary and confirmatory sources based on their reliability
- Emphasize the elements of site marking and the "time out" that have most practical importance
- Perhaps the key difference from most current guidelines, however, is emphasis on the environment of care from beginning to end, including:
- A consistent process within each health system which fits within that system's work flow
- Clear administrative responsibility
- An ongoing audit and feedback process

The Authority / PSA project consisted of two parts. The first was a systematic review of the English language world literature regarding wrong site nerve blocks, led by Ellen Deutsch, MD, and assisted by the Project Management Team. A manuscript summarizing this systematic review has been submitted for publication.

The second part of the project was the development of the actual consensus-based set of clinical, organizational, and cultural Principles for the ***Reliable Performance of Correct-Site Nerve Blocks***. These principles were based on the literature review but resulted from collaboration between members of the Expert Task Force.

The members of the Task Force included the following experts:

Physician Anesthesiologists
- Nabil Elkassabany, M.D., University of Pennsylvania
- Michael Entrup, M.D., Geisinger Medical Center
- Joseph Galassi, M.D., Lehigh Valley Health System
- Arjunan Ganesh, M.B.B.S. F.R.C.S., Children's Hospital of Philadelphia and University of Pennsylvania
- Mark Hudson, M.D., University of Pittsburgh
- Kristin Ondecko-Ligda, M.D., University of Pittsburgh
- Brian Matusic, D.O., Advanced Surgical Hospital, Washington, Pennsylvania
- Laura Schleelein, M.D., Children's Hospital of Philadelphia and University of Pennsylvania
- Mark Taylor, M.D., Allegheny Health System

Pain Service Nurses
- Debbie Brickley, RN – Acute Pain Service Nurse, UPMC Mercy
- Beverly Kantz, RN – Director of Perioperative Care and Pain Management, Meadville Medical Center
- Christine Kreider, RN – Acute Pain Service Nurse, Penn State Health

Patient Representatives
- Dwight McKay – Lancaster, Pennsylvania
- Mary Ellen Mannix – Philadelphia, Pennsylvania

Consultants to the Task Force included:

Anesthesiologists with Expertise in Chronic Pain
- Vitaly Gordin, M.D., Director of the Pain Management Service, Penn State Health
- Kiernan Slevin, M.D., Private Practice Pain Management specialist affiliated with the University of Pennsylvania

Surgeons
- April Armstrong, M.D., Orthopaedic Surgeon, Penn State Health
- Randy Hauck, M.D., Plastic Surgeon, Penn State Health
- John Potochney, M.D., Plastic Surgeon, Penn State Health
- Douglas Wisner, M.D. Ophthalmologist, Will's Eye Hospital, Philadelphia

The project was initiated and led by a Project Management Team including Theresa Arnold, DPM, Manager of Clinical Analysis, Ellen Deutsch, M.D., MS, FACS, FAAP, Medical Director; Christina Hunt, MBA, RN, Director of Collaborative Programs; and Bob Yonash, RN, Patient Safety Liaison from the Authority. Joshua Atkins M.D. PhD., from the University of Pennsylvania, and Don Martin, M.D., from Penn State University represented the Pennsylvania Society of Anesthesiologists Board. ■

Anesthesia False Claims Decision Medical Direction/Medical Supervision

Charles I. Artz, Esq. | PSA GENERAL COUNSEL

A new Pennsylvania federal court decision involving a whistleblower alleging an anesthesiology company engaged in a scheme to defraud Medicare to receive higher reimbursement by knowingly and falsely billing Medicare for anesthesiology services provided as "medical direction" services when they should have been properly billed as "medical supervision" services is important to consider.

In U.S. ex rel. Lord v. NAPA Management Services Corporation, North American Partners and Anesthesia PA, LLC, ___ Supp.3d ___ (M.D. PA 2017) (2017 WL 5450757), the whistleblower alleged that the NAPA Break Model violated the law because it did not provide for continued immediate availability of medically directing anesthesiologists during CRNA breaks and, consequently, there was routinely no available replacement or any second anesthesiologists of record who assumed (and documented) the responsibility for meeting the Medicare requirement of immediate availability when the attending anesthesiologist of record was not available while providing CRNA break relief. The whistleblower also alleged the defendant anesthesiologist and NAPA pre-signed required attestations regarding their involvement in anesthesia cases before the cases started, and falsely stated they were immediately available. The whistleblower alleged these practices constituted fraud and false records in violation of the federal civil False Claims Act ("FCA").

The NAPA defendants filed a motion to dismiss the case. The federal court refused to dismiss the case, and will require the NAPA defendants to defend the case at least through discovery and perhaps trial (pending additional motions and decisions).

The federal court's important holdings and rationale include the following:

1. Medicare regulations authorizing anesthesiologists to bill Medically Directed care requires the anesthesiologist to remain physically present and available for immediate diagnosis and treatment of emergencies. 42 C.F.R. §410.110(a)(1)(iv).
2. The anesthesiologists routinely provided CRNAs multiple breaks, while medically directing other concurrent cases. When personally treating patients while a CRNA is on a break, the anesthesiologist cannot leave the patient's side and therefore is not "immediately available" to the other patients in his other concurrent cases.
3. The "immediate availability" requirement can be met by:
   - A second anesthesiologist assuming temporary medical direction responsibility for the anesthesiologist providing temporary relief to the CRNA;
   - The relieved CRNA remaining in the immediate area so he can return immediately to the procedure; or
   - A specified anesthesiologist remaining available to provide substitute medical direction services for the anesthesiologist providing temporary relief.
4. The NAPA defendants billed Medicare for anesthesia services involving CRNAs as if the anesthesiologist had "medically directed" the services in multiple cases contemporaneously, when in fact the physician had only "medically supervised" these concurrent cases.
5. When an anesthesiologist who billed for medically directing concurrent cases would fill in for a CRNA to give the CRNA a break, this rendered the physician ineligible to bill for medically directing other cases because he was not immediately available to assist in the other cases. The anesthesiologists who provided break relief did not arrange adequate medical direction coverage in their absence.
6. The allegations were sufficient to establish the anesthesiologists were not immediately available which, if proven, constitute fraud enforceable under the FCA.
7. The anesthesiologists would sign required attestations regarding their involvement in anesthesia cases before the cases started. The pre-signed attestations placed in the patient medical records by the anesthesiologists stated they were present for induction, the key portions of the procedure and emergence; and immediately available throughout. The pre-signed attestations were false because the immediate availability requirement was not met.
8. The anesthesiologist's pre-signing the attestations containing a false statement that they were immediately available throughout the procedure alleged sufficient facts to establish a false record that could violate the FCA.
9. The whistleblower's allegation that the anesthesiologist did not conduct an adequate evaluation (as opposed to conducting no evaluation) does not violate the Medicare regulations or the FCA.
10. The anesthesiologists' failure to obtain adequate informed consent from a dementia patient is not one of the Medicare regulatory requirements and does not violate the False Claims Act.
11. Non-compliance with the immediate availability requirement under the Medicare regulations is "material" pursuant to the U.S. Supreme Court's recent decision requiring materiality to be established in FCA cases.

This is the first Pennsylvania federal court decision that I have seen involving False Claims Act allegations against anesthesiologists relating to providing CRNA breaks and billing for medical direction when medical supervision allegedly should have been billed.

Developments in this important case will continue to be monitored and any important additional decisions or the resolution of the case will be reported. ■

LEGISTLATIVE UPDATE

Kevin Harley
QUANTUM
COMMUNICATIONS

As the calendar turned to 2018 — an election year — "change" is the operative word in the state Capitol. The biggest change is the wave of legislators who have either announced their retirements or that they are candidates for other seats. Eighteen members of the House and Senate announced they are not running again; another nine members are running for other offices.

Among the biggest names not seeking re-election in the House are Republican House Majority Leader Dave Reed, Democratic Minority Whip Mike Hanna, Democratic House Appropriations Chairman Joe Markosek, Professional Licensure Committee Republican Chairman Mark Mustio and Health Committee Republican Chairman Matt Baker.

Professional Licensure Committee Republican Chairman Mark Mustio

In the Senate, where half the body is up for reelection this year, there are only four senators not seeking reelection. Two senators are running for higher office: Scott Wagner for governor and John Eichelberger for a seat in Congress.

Also on the minds of many legislators is congressional reapportionment. The Pennsylvania Supreme Court ruled the current congressional maps unconstitutional and directed the legislature to redraw the maps. Governor Wolf rejected a new map proffered by the Senate and House Republican leadership, and the State Supreme Court took it upon itself to draw its own map.

The Republicans, claiming the state Supreme Court doesn't have the constitutional authority to draw a map, are challenging the state court's ruling in the U.S. Supreme Court. There is also a challenge pending in the federal district court brought by current members of the Republican congressional delegation.

The congressional reapportionment ruling created turmoil and has dominated the political discussion in the Capitol. The uncertainty will remain until the court cases are decided.

BUDGET

Governor Wolf presented his budget to a joint session of the legislature in February. His address was a mere 19 minutes long and can accurately be described as an "election year" budget. Unlike his past budgets, the governor is not calling for an increase in the income or sales tax, although he did renew his demand for a severance tax on natural gas production. Gov. Wolf is asking the legislature to approve a $33 billion spending plan. That is an increase of $1billion, or three percent more than last's year budget.

Because this is an election year for Gov. Wolf, many Capitol insiders believe that this year's budget may be the first on-time budget in Wolf's tenure.

This year the governor is again calling for the merger of some cabinet-level departments, including combining the Department of Health with the Department of Human Services.

BALANCE BILLING

Balance billing has been an extremely active issue, with PSA as a key player in a coalition made up of hospital specialists and the Pennsylvania Medical Society

(PAMED). This group, the Pennsylvania Coalition of Out-of-Network Services, has agreed to language to improve the current house bill for providers and patients.

Specifically, the coalition proposed changes that would establish an equitable payment process for providers. The coalition proposed using the 80th percentile of charges from a non-profit, third-party benchmarking claims database — such as Fair Health — to determine the payment for an out-of-network provider. It also proposed a streamlined and impartial dispute resolution process.

The prime sponsor of the balance billing legislation in the House, Rep. Matt Baker, who chaired the House Health Committee, recently shocked his colleagues by announcing his resignation from the House to take a position in the Trump Administration. Baker, a 25-year veteran of the House, was the main driver of the legislation. His departure has created a level of uncertainty in the legislative landscape.

It is expected that the new chair of the House Health Committee will be Rep. Kathy Rapp of Warren County. Rapp is not a co-sponsor of this legislation.

To date, the Senate has not moved on the legislation. We are communicating with Sen. Don White, the prime sponsor of the Senate balance billing legislation, and other members of the Senate Banking & Insurance Committee.

SUPERVISION

We anticipate legislative activity in the next few months on the supervision bill in the House. Legislation (HB 789) introduced by Rep. Jim Christiana and supported by PSA places into the Medical Practice Act current Department of Health Regulations that require a physician to supervise the administration of anesthesia in a hospital.

Rep. Mark Mustio, chairman of the Professional Licensure Committee, is committed to the legislation. We are working closely with him to move the bill.

In the Senate, companion legislation (SB 960), was introduced by Sen. Tom Killion. We continue to gain additional co-sponsors in the Senate as we work to educate the members the on the importance of patent safety.

FENTANYL RESTICTIONS

Rep. Bryan Barbin has introduced a bill (HB1987) that would restrict the use of fentanyl to surgery and hospice centers. Rep. Barbin introduced the bill in an effort to curb fentanyl overdoses. We have met with Rep. Barbin to express concerns that the language may too restrictive. He is willing to work with PSA and the PAMED to improve the bill to provide adequate protection for patients who need the drug.

ADVOCACY

The next few months will be very busy as supervision and balance billing activity heats up in the legislature. We need your help. Our success depends on members of the General Assembly hearing from you. As a PSA member, you are the strongest lobbying voice we have.

Please make an effort to get to know and talk with your state senator and representative. ■

If you would like Quantum to help arrange a visit with your senator or representative, please contact us 717-213-4955.

CMS UPDATES

Donna Kucharski, MD | ANESTHESIA QUALITY COMMITTEE, CHAIRWOMAN
CLINICAL ASSOCIATE PROFESSOR OF ANESTHESIOLOGY | LEWIS KATZ SCHOOL OF MEDICINE, TEMPLE UNIVERSITY

The New Year has arrived with some good news for the practice of medicine and anesthesia. CMS has officially cancelled the Episode Payment Model (EPM) for CABG and AMI originally scheduled to go into effect in July 2017. The Care for Joint Replacement (CJR) mandatory bundling for hip and knee replacements has been scaled back in 67 markets and made voluntary in 33 markets.

The House of Medicine has received help on the Hill through a statement from the Republican Lawmakers to the CMS in September of 2016. The GOP opposed the CMS mandatory models and stated "the Center for Medicare & Medicaid Innovation (CMMI) has overstepped its authority and there are real-life implications - both medical and constitutional. That's why we're demanding CMMI cease all current and future mandatory models."

The most recent ASAPAC publication Vital Signs notes the tax reform bill passed in January 2018 included language which dissolved the Independent Payment Advisory Board (IPAC) largely opposed by medicine as it had no physician membership. Also reported is the "elimination of improvement scoring for the MIPS cost performance category for the third through fifth years of Merit-based Incentive Payment System (MIPS), and granting of new flexibility to CMS to reweight the cost performance category. These changes address ongoing challenges faced by CMS in accurately measuring physician performance in the MIPS cost category."

As the House of Medicine continues to work with lawmakers to refine and define the payment and quality programs physicians need to push forward to meet the demands of delivering and reporting quality care as we have entered MIPS Year 2. All anesthesiologists will be subject to performance improvement needs as a group subject to MIPS reporting or as part of a larger entity reporting broader indicators. Everyone must continue to develop best practices as most patients we see will be part of one or more metrics of interest. Best practices from hand washing, central line insertion practice, beta blocker and proper antibiotic usage, to best use of blood products, glucose control, pain management, as well as excellent operational practices for time management of the OR resources, reflect on the overall quality of the organization you contract with or in which you are employed.

Dialogue with the administration of your organization should give you insight into the areas of most demand or importance to your hospital. Discussion within your group to establish protocols and standards of care will become the norm. "How I do it" must now grow into "Our best practice". ■

Resident Well Being

Connie Bruno, M.D. | SECRETARY, PSA RESIDENT COMPONENT

Those of us who chose careers in medicine are champions in delayed gratification. We waited time and time again until the exam period was over, or for when that rough rotation would end. When Australian millionaire Tim Gurner suggested millennials are wasting their first-home funds on buying smashed avocados, it made me wonder if there is an appropriate amount of avocado toast.

The ACGME symposium on physician well-being resulted in revisions to the ACGME common program requirements, effective July 2017. The updated requirements are designed to foster resident development of their skills in self-care. This attention to physician well-being encourages residents to take command of their mental health, physical welfare, and professional relationships.

Improving self-care skills begins with self-awareness, so it is imperative to recognize that residents are undeniably and rightfully tired. Fatigue is unavoidable for an anesthesia resident despite mandatory duty hour restrictions. We have daily clinical duties, multiple call shifts per month, and a duty to study, in addition to everyday commitments from our home lives and social circles.

Hence the avocado toast. Resident physicians who are living entirely for their future selves may feel like they are constantly depriving themselves for a far too distant goal. The marathon to become an anesthesiologist requires exceptional endurance for more than a decade. So, plan for tomorrow but live for today. An avocado toast on occasion during medical school and residency may be an appropriate amount; it is a nice reprieve that can nourish a resilient trainee. Self-care must not be delayed until we are attending physicians, it should start now.

Here are some simple options for improving your well-being.

1. Decide to make your present-day self a priority.
2. Your sleep may be challenged by extended work shifts, work communications, and stress. Stop drinking coffee after lunch. Consider blackout blinds or a sleep mask to darken the room when you are sleeping post-call. If possible, keep your study materials out of the bedroom, and silence your phone overnight.
3. Mindfulness and meditation may help focus your energy. Close your eyes, concentrate on your breathing, and imagine yourself on a beach. There are many videos on YouTube that can guide your thoughts; alternatively, there are videos of nature sounds that can help you relax. Think about a patient who you have helped.
4. Eat healthy and stay hydrated.
5. Choose an exercise and do it regularly. Find an exercise partner and motivate each other. Otherwise, yoga, tai chi, or calisthenics may be enjoyed in the comfort of your own home.
6. It's okay to ask for help. Surround yourself with supportive friends and family. If you are not feeling like yourself, please recognize that you are not alone — 28% of residents experience a major depressive episode during their training. Reach out to a mental health provider now.

Promotion of resident well-being and fatigue mitigation techniques are clearly important on an individual basis but they are also relevant in the context of patient safety. Acute continuous and chronic partial sleeplessness have been shown to impair cognitive functions and motor skills. In fact, the ACGME duty hour requirements established in 2003 are attributed to a comparison made between reduced clinical performance under sleep deprivation to the effects of alcohol intoxication. As Timothy P. Brigham, MDiv, PhD, the Senior Vice President of Education at the ACGME stated, "We need to protect the workforce that protects our patients."

Our generation of resident physicians are already benefitting from these top-down efforts to create a culture of safety and to improve trainee work standards.

If you are interested in representing anesthesia resident interests on a state level, attend a PSA Board of Directors meeting, they are open to all members. If you are interested in attending the ASA Legislative Conference May 14-16, 2018 in Washington, D.C., please speak to your program director and notify us at psa.residents@gmail.com as there is funding for travel and lodging available through the PSA. ■

Volunteer Anesthesiologist

Craig Muetterties, M.D.

I don't know what possessed me to go out into a winter storm and shop for computers that January in 1984, but out I went. I was sure no one would be in line at the computer store, but I ran into an acquaintance who was also waiting in line. He just happened to be an anesthesiologist who had been contacted by an organization that was seeking volunteers to go into the island of Grenada after the "intervention" which was the term used by the islanders to describe the Grenada War. He told me that they had one previous volunteer who left the island after he saw the conditions in the operating room. The thought of going into a strange place and practicing my skills interested me and I applied to and was accepted by Project Hope, the organization that was supplying care on the island.

I brought my wife, Bonnie who was six months pregnant at the time along with our two children, ages five and three. We were given a small home in a cluster of cottages on the east end of the island where we lived with other volunteers.

The conditions in the OR were fascinating. There was an open window in the operating room and intravenous lines were only given to patients who were having larger procedures. Simple hysterectomies did not receive that same care. Surgical gloves were reused, needles were re-sterilized and an anesthetic induction consisted of a steel needle in a vein held by a hemostat so that syringes could be exchanged followed by management of the airway once the patient was asleep. A van would round up the OR crew for emergencies at night by going from cottage to cottage with its horn beeping. I did come to understand why my predecessor left so quickly, after I did my first machine check. There were so many leaks it sounded like a bagpipe.

The month that we spent on the island was unforgettable for us as a family and life-changing for me. As such, I proceeded to volunteer as a physician (not giving anesthetics) for numerous humanitarian trips into remote areas. Over the years, I have volunteered as a general medical doctor in remote areas of East Africa, South

America, the Dominican Republic and have even spent an unforgettable time in Timbuktu.

I was, at first, somewhat hesitant to volunteer as a general physician since I was trained to practice as an anesthesiologist for my entire career. I came to realize that anesthesiologists have an excellent knowledge of general medical conditions, and actually function very well in this capacity.

It was, however, somewhat frustrating that there was no long-term medical care in the areas I served. My wife Bonnie and I became supporters of clean water projects that made a big difference to the people they served.

The Mercy Ship

A few years ago, a friend of mine became interested in volunteering as a pharmacist on the Mercy Ship. His description of the mission interested me. Mercy Ships are described as "... the world's largest civilian hospital ship providing state-of-the-art care to those in desperate need—free of charge.". An excellent video done by the CBS 60 Minutes program can be viewed at https://www.youtube.com/watch?v=H4rmbcU9Jxo. The charity has a 4-star rating from Charity Navigator, an independent evaluating organization of charities.

BEFORE

AFTER

The ship Africa Mercy is a 500-foot-long vessel that has eight decks and a crew of 450 volunteers — approximately 15 of whom are physicians. There are 90 nurses serving in the operating room, the inpatient wards and ICU. There are four well-equipped ORs staffed by teams from around the world who practice excellent 21st century medicine on the ship. Anesthesiologists from different countries (and anesthetic cultures) serve onboard for stints of two to four weeks. My wife, Bonnie also practiced as a nurse anesthetist with the crew. The Chief of Anesthesiology, Brian Barki, MD, a physician from Tulsa, Oklahoma lived with his wife and three children on the ship for the last three years.

The ship docks from late August until the first week of June in each country where it serves. When the ship arrives in August, teams have already been in the country for at least a year looking for candidates who can perform complex surgical procedures that will change patient's lives — patients who have the least hope for surgical care.

Chief Surgeon, Dr. Gary Parker, is a world famous maxillofacial reconstructive surgeon who works on the Mercy Ship. Surgeons come from around the world to work with him for some of these cases. Some procedures require neurosurgeon, plastic and maxillofacial surgeons working together. The camaraderie between the entire surgical staff is excellent. A long day in the OR is frequently followed by a visit to a local restaurant with the entire OR team.

As I was preparing this article, I was introduced to Dr. Verghese Cherian from Penn State Hershey who has also served on the ship in Cameroon and Benin. He was impressed with the tremendous learning experience serving on the ship is for all its volunteers. He will again serve on the ship in September when the Africa Mercy will be in Guinea.

Dr. Verghese Cherian

Each day that I have served on the Mercy ship has provided me with at least one unforgettable patient. I will never forget the 18-year-old man in Madagascar who presented for repair of a bilateral complete cleft lip and palate. His condition was so severe that he was unable to phonate well enough to be understood by my translator.

I was working that day with Dr. David Chong from Australia. He had to remove the tooth that was protruding forward from the cleft and then repair the defect. Photographs of this gentleman would be taken after his repair and compared to preop photos. As he emerged from the anesthetic his transformation was so dramatic that I took my cell phone out and used its mirror function to show him the miracle that had just occurred. He stared intently at his image on my phone and looked at me and wept. He pointed at me and then at himself and pounded his chest with his right fist. The translators later told me that he was indicating that we would be friends forever. Of course, the true worker of the miracle was David, but being a part of this is something I will never forget. Our patient stayed on the ship for a day or so and was given a mirror so he could acquaint himself with the new person he had become (all maxillofacial patients are given mirrors).

I also was transformed by this, and many other experiences I have had on the Africa Mercy. Each year I return with new skills and renewed enthusiasm for my "day job" at home.

You can find more information about Mercy Ships at https://www.mercyships.org or contact me at cmuetterties@mac.com. ■

Production of PHI in Response to Subpoena Breach of Confidentiality

Charles I. Artz, Esq. | PSA GENERAL COUNSEL

A new Supreme Court decision allowing a patient's breach of confidentiality claim against a health care provider for disclosing protected health information ("PHI") in response to a Subpoena provides additional guidance regarding the complicated analysis and tension between the federal HIPAA Privacy regulations and state confidentiality laws that may be more stringent than the HIPAA Privacy regulations.

In Byrne v. Avery Center for Obstetrics and Gynecology, P.C., ___ A.3d ___ (2018), the patient sued the health care provider for improperly breaching the confidentiality of her medical records, and asserted several claims under state law for breach of confidentiality and negligence. The trial court dismissed the complaint, holding the provider properly disclosed PHI in response to a subpoena in a civil court litigation matter. The state Supreme Court reversed the dismissal and will require the trial court, on remand, to determine if the proper subpoena procedures were followed under the HIPAA Privacy regulations.

Here are the important facts. The patient instructed the provider not to release her medical records to an individual with whom she had a previous personal relationship. That person filed a paternity action against the patient in state court. In that litigation, the provider was served with a subpoena requesting production of medical records. **The health care provider did not alert the patient of the subpoena; did not file a motion in court to have the subpoena stopped; did not appear in court; and did not receive satisfactory assurances that the patient was given prior notice of the subpoena and an opportunity to object.** Instead, the provider produced the medical records. The patient then sued the provider for breach of confidentiality, i.e. negligently failing to use proper and reasonable care in protecting her medical file, including disclosing it without authorization and without following the HIPAA subpoena response protocol.

The Supreme Court's important legal holdings include the following:

1. The HIPAA Privacy regulations do not preempt state breach of confidentiality legal claims. In other words, **a patient can sue a health care provider in state court for damages under a breach of confidentiality legal theory, and the HIPAA Privacy regulations do not prevent that.**
2. The health care provider's **failure to follow the HIPAA Privacy subpoena "satisfactory assurance" requirements** and production of medical records in response to a subpoena can create **breach of confidentiality claims and damages** exposure in state court.
3. The HIPAA Privacy regulations do not allow patients to sue health care providers, i.e. there is no "private right of action" in court to enforce violation of the HIPAA Privacy regulations. The only remedy as it relates to the HIPAA Privacy regulations themselves is for the offended person to file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights.
4. Despite the fact that there is no private right of action in federal or state court to enforce a violation of the HIPAA Privacy regulations, **a patient can still sue the provider for breach of confidentiality in state court and use the HIPAA Privacy regulations as the theoretical basis to establish the required standard of care, the required duty, and violation of those duties**. If that seems counterintuitive to point #3 above, it probably is. In fact, another federal court decision that was published at the same time in Haywood v. Novartis Pharmaceuticals, 2018 WL 437562 (N.D. Ind. 2018) specifically held the opposite, i.e. the plaintiff cannot use the HIPAA Privacy regulations as the basis for establishing negligence because to do so would circumvent HIPAA's enforcement mechanisms. The courts throughout the United States are split on this issue. Many state courts, however, continue to allow patients to exploit a loophole to **sue for breach of confidentiality using the standards set forth in the HIPAA Privacy regulations as the legal basis for a state law breach of confidentiality claim**.
5. The HIPAA Privacy regulations allow PHI to be produced in response to either a Court Order or a subpoena if the provider receives **satisfactory assurance** from the party seeking the information that **reasonable efforts have been made by that party to ensure that the individual who is the subject of the PHI that has been requested has been given notice of the request**; or they have secured a qualified protective order. Receiving **satisfactory assurances** from the party seeking the PHI constitutes a written statement and accompanying documentation demonstrating that:
   - The party asking for the PHI made a **good faith attempt to provide written notice** to the individual (patient);

- The notice included **sufficient information about the litigation** or proceeding in which the PHI is requested to allow the patient to raise an objection in court; and
- The **time for the individual to raise objections has elapsed** and either no objections were filed or any objections have been resolved by the court.

6. In this case, **the provider should have contacted the patient, but did not, before any PHI was disclosed in response to the subpoena**.

The important compliance points include the following:

1. This case demonstrates the requirement to **check the patient's file to determine whether the patient has made any notification not to produce records when a subpoena is received, and honor the patient's directives**. It essentially means the patient can veto a subpoena. If the health care provider does not honor the "veto", the patient can sue the provider for breach of confidentiality.
2. The most prudent course of action when a subpoena is received is to do each of the following:
   - Contact the patient to determine whether the patient has any objections to production of the records;
   - Look in the file for any restrictions on production of PHI to any particular parties; and
   - Obtain the authorization from the patient or confirmation by the patient's attorney granting permission before producing the medical records.
3. If the patient has not asserted any specific objections to the production of PHI, make sure all of the "reasonable assurance" requirements stated above are followed before producing the PHI in response to the subpoena.
4. If an actual Court Order signed by a Judge exists, the Court Order trumps everything, and requires production of the PHI.

This continues to be a complicated and vexing legal and compliance issue. Careful review of the foregoing and conducting training of all providers and medical records staff on this issue to avoid the expense and distraction of breach of confidentiality litigation in state court is important. ■

PSA Resident Component Meeting in Boston, MA

Duration of Dual Antiplatelet Therapy in Coronary Artery Disease Patients With Perioperative Considerations: A Recent Update

Vendhan Ramanujam, M.D., Michael S. Green, D.O., M.B.A.

Coronary artery disease (CAD) is characterized by atherosclerosis of coronary arteries that progressively impairs blood flow to the myocardium either with symptomatic or asymptomatic manifestations. Platelet activation and subsequent aggregation plays a major role in the pathogenesis of CAD (1). Antiplatelet agents interfere with a number of platelet functions and are the key therapeutic medicaments used in the management of CAD (2). Aspirin blocks cyclooxygenase, preventing prostaglandin and thromboxane biosynthesis, thus platelet aggregation. P2Y12 receptor inhibitors (clopidogrel) block ADP binding to P2Y12 receptors, thereby inhibiting GP IIa/IIIb complex and platelet aggregation. Anti GP IIa/IIIb antibodies and antagonists inhibit cross bridging of platelets by fibrinogen. The following is a summary of the focused update on duration of dual antiplatelet therapy in patients with coronary artery disease.

Dual Antiplatelet Therapy

Dual antiplatelet therapy (DAPT) (aspirin and a P2Y12 receptor inhibitor) is an intensified antiplatelet therapy that reduces the risk of acute ischemic events and recurrent atherothrombotic events, including stent thrombosis. The recommendations are as follows (3). As a standard, a daily dose of aspirin 81 mg (range: 75-100 mg) is almost always continued indefinitely in patients with CAD (4).

Stable Ischemic Heart Disease Patients

Stable ischemic heart disease (SIHD) includes patients with stable angina pain syndromes and low risk unstable angina. After bare-metal stent (BMS) and drug-eluting stent (DES) placement, DAPT with clopidogrel should be given for a minimum of 1 and 6 months respectively (5,6). It may be reasonable to continue therapy further in those who are not at high bleeding risk and who have well tolerated without complication. In case of high bleeding risk and significant overt bleeding episodes in patients with DES, discontinuation of P2Y12 inhibitor therapy after 3 months may be reasonable. Following coronary artery bypass graft (CABG), DAPT with P2Y12 inhibitors could be continued for 12 months to improve vein graft patency. DAPT is not beneficial in patients with SIHD without prior history of acute coronary syndrome, coronary stent implantation, or recent (within 12 months) CABG.

Acute Coronary Syndrome (NSTE-ACS; STEMI)

In acute coronary syndrome (ACS) patients managed only with medical therapy that includes DAPT, P2Y12 inhibitors (clopidogrel or ticagrelor) should be continued for at least 12 months and could be continued longer if the therapy is well tolerated and without any bleeding risks. Following stent implantation, P2Y12 inhibitors (clopidogrel, prasugrel, or ticagrelor) are recommended for at least 12 months. In both scenarios ticagrelor is preferred over clopidogrel (7). It may be reasonable to continue them longer than 12 months in those who are not at high bleeding risk and have tolerated DAPT without bleeding. In such cases prasugrel is preferred over clopidogrel. If not, in DES implanted patient's discontinuation of P2Y12 inhibitor therapy after 6 months is recommended. Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack. Following CABG, P2Y12 inhibitor therapy should be resumed postoperatively and DAPT should be continued for 12 months (8).

STEMI in Conjunction With Fibrinolytic Therapy

P2Y12 inhibitor therapy (clopidogrel) should be continued for a minimum of 14 days and ideally at least for 12 months (9). It may be reasonable to continue DAPT for longer than 12 months if it is well tolerated without any bleeding risks.

Elective Noncardiac Surgery Following PCI

Elective noncardiac surgery should be delayed 30 days after BMS and optimally 6 months after DES implantation rather than 1 year since the newer-generation DES compared to first generation are associated with lower risk of stent thrombosis (10). The risk of stent thrombosis is the highest in the first 4-6 weeks and discontinuation of DAPT after stent implantation is one of the strongest risk factors for stent thrombosis. If the risk of further delay of noncardiac surgery is greater than the expected risks of stent thrombosis in DES implanted patients, the P2Y12 inhibitor therapy may be discontinued after 3 months to proceed with the surgery rather than the previously recommended 180 days. In emergent situations that mandate the discontinuation of P2Y12 inhibitor therapy, it is recommended to continue aspirin if possible and the P2Y12 inhibitors be restarted as soon as possible after surgery. Considering the complexity, a consensus among treating clinicians in regards to the relative risks of surgery and discontinuation or continuation of antiplatelet therapy can be useful. ■

		ASA	P2Y12 receptor inhibitors
Stable Ischemic Heart Disease	BMS	Continue	Continue 1 month minimum
	DES	Continue	Continue 6 month minimum
Acute Coronary Syndrome; Medical management or stent implantation		Continue	Continue 12 month minimum
ST Elevation MI w/ Fibrinolysis		Continue	Continue 14 day minimum, ideally continue for 12 months

		ASA	Delay for Elective Surgery; Continue P2Y12 Receptor inhibitors
Elective Surgery after PCI	BMS	Continue	30 days minimum
	DES	Continue	3 month minimum, ideally 6 months

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know your equipment...

NEW SERIES!

PULSE OXIMETER

Dr. Verghese Cherian, B.S. M.B.
ASSOCIATE PROFESSOR OF ANESTHESIOLOGY | HERSHEY MEDICAL CENTER

This article has been edited for the newsletter. To see the full article, go to www.psanes.org.

As anesthesiologists we are surrounded by equipment which we use to administer anesthesia, monitor our patients and rely upon during an emergency situation. It is therefore crucial to have a good understanding of the physical principles of these tools and a working knowledge of its usefulness, limitations, source of errors and ways to trouble-shoot them. 'KNOW YOUR EQUIPMENT' series will be an attempt towards meeting this goal.

The cascade of oxygen from the atmosphere to the mitochondria passes through the lung and the arterial blood. Although measuring the PaO2 is the gold standard of assessing oxygenation, it requires a sample of arterial blood. Since the majority of oxygen carried in blood is combined with hemoglobin, measuring the percentage of hemoglobin saturated with oxygen is a surrogate measure of oxygenation and it can be done non-invasively and in real time, using a pulse oximeter.

Physiological Fundamentals

Uptake and delivery of oxygen is one of the primary roles of the cardio-respiratory system.

Some commonly (mis)used terminology about oxygen carriage:

Oxygen Content (CaO2) is the amount of oxygen carried by 100ml of blood; both combined with hemoglobin and dissolved in plasma, and it is expressed as 'ml in 100ml of blood'.

Oxygen Saturation (SaO2) is the percentage saturation of hemoglobin with oxygen as measured using an arterial blood sample, as opposed to SpO2 which is measured by a pulse oximeter.

Partial pressure of oxygen (PaO2) is the pressure of oxygen in the arterial blood and is normally close to 100mmHg when breathing room air.

Oxygen Delivery (DO2) is the amount of blood that exits the heart every minute and so is a product of arterial oxygen content and cardiac output.

Types of Hemoglobin

Hemoglobin A (Hb A) makes up about 95%-98% of hemoglobin found in adults and it contains two alpha (α) chains and two beta (β) protein chains.

Hemoglobin A2 (Hb A2) makes up about 2%-3% of hemoglobin found in adults and it has two alpha (α) and two delta (δ) protein chains.

Hemoglobin F (Hb F) or fetal hemoglobin makes up to 1%-2% of hemoglobin found in adults and it has two alpha (α) and two gamma (γ) protein chains. It is the primary hemoglobin produced by the fetus and its production usually falls shortly after birth and reaches adult level within 1-2 years.

Forms of Hemoglobin

Hemoglobin (Hb) occurs in various forms in human body

Oxy-hemoglobin (OHb) when combined with oxygen

Deoxy-hemoglobin (deOHb) when it gives off the oxygen

Carbamino-hemoglobin (CO2Hb) when it combines with CO2

Carboxy-hemoglobin (COHb) when it combines with carbon monoxide (normally <2%, but can increase to 2-4% in smokers)

Meth-hemoglobin (MetHb) when the iron in the heme group is in the Fe3+ (ferric) state instead of the normal, Fe2+ (ferrous) form. (Normal levels - 1-2%)

Components of a Pulse oximeter

The pulse oximeter probe consists of two light emitting diodes (LED) emitting two different wavelengths (660 nm & 940 nm) and a detector, located on the other side of the fingertip, which measures the amount of light transmitted through the tissue. The probe is connected to a processor and the monitor displays the pulse waveform, the pulse rate and the oxygen saturation which is denoted as 'SpO2'. The monitor also gives an audible beep with each pulse, the pitch of which changes with the value of oxygen saturation. The pitch drops as the saturation falls and rises as it recovers.

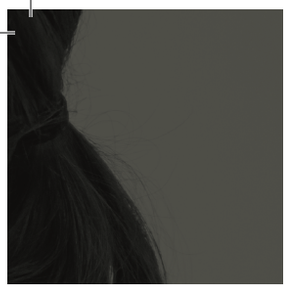
Physical Principles

Beer-Lambert Law

The pulse oximeter operates on the principle of absorption of light by the solutes in a solution. The Beer-Lambert law states that the amount of light absorbed by a solute is proportional to the concentration of the solute and the distance the light is transmitted through the solution.

Extinction coefficient

The extinction coefficients of the four forms of Hb, namely deOHb, OHb, COHb and MetHb, for a range of wavelengths of light, are shown in Figure 1. Since in normal individuals the amount of MetHb and COHb are negligible, the pulse oximeter has to differentiate between OHb and deOHb. The best separation of absorbance curves occurs at wavelengths 660 nm (red) and 940 nm (infrared).



The points at which two lines cross indicate the wavelength at which the absorbance is equal. This is known as the isobestic point, and for deOHb and OHb it occurs at 805nm and 590nm.

Pulsatility

The purpose of the pulse oximeter is to detect the amount of OHb in the arterial blood. When compared to measuring oxygen saturation in vitro from an arterial blood sample, the challenge in measuring it in vivo is to separate the light absorbance by the venous blood and the tissue proteins from that by the arterial blood.

The pulse oximeter uses technology that takes advantage of the pulsatility of arterial blood. (Figure 2) It emits and analyses light signals at a very rapid rate (400-600/s) and thus can detect the peaks and troughs of the arterial pulse wave. Since, with each pulse there is a surge of arterial blood across the measuring point and therefore an increase in distance of absorbance, the amount of light absorbed would increase, cyclically. Historically, the pulsatile component is referred to as AC and the non-pulsatile as DC. The ratio of the absorbance of the pulsatile (AC) to that of the non-pulsatile (DC) at both the wavelengths is calculated.

R = (AC660/DC660)/(AC940/DC940)

The ratio (R) of absorbance at 660 nm and 940 nm bear a linear relationship to oxygen saturation. (Figure 3) This calibration curve is created by having volunteers breathe hypoxic gas mixtures to measure R values over a range of SpO2 values between 100% and 70%. The accuracy of most pulse oximeter is ±2-3% over this range. At high O2 saturations, this ratio is less than one. At approximately 85% saturation this ratio is equal to one. The values for R for SpO2 below 70% are mathematically calculated and therefore are less accurate clinically.

Clinical Points

Pulse oximetry is an extremely useful tool to measure the percentage of oxygen saturation and has been part of the ASA minimum monitoring standard since 1986. The pulse oximeter is currently available in various shapes and sizes, from small portable devices to fully integrated monitors. It is extremely important to have a good understanding of its functioning, the interpretation of its display and its limitations.

Factors that affect the functioning of a pulse oximeter:

At low pulse amplitude, the SpO2 reads low relative to SaO2

Situations in which this commonly occurs: hypothermia, hypovolemia, hypotension,vasoconstriction, blood pressure cuff inflation, tourniquet, cardiac arrest, arrhythmia

Presence of COHb and MethHb affects pulse oximeter readings

The standard pulse oximeter with two wavelength of emitted light is suited to differentiate OHb from deOHb. Presence of MethHb or COHb can interfere with accurate measurement of OHb. COHb is interpreted by the pulse oximeter as a mixture of approximately 90% OHb and 10% deOHb. (Figure 1) Thus the pulse oximeter overestimates the true saturation. MethHb absorbs equal amounts of red and infrared light, resulting in an R ratio of 1, which is extrapolated as 85% saturation. Therefore, as MethHb increases the pulse oximeter approaches 85% irrespective of the true saturation.

To measure COHb and MetHb, a 'Co-oximeter' is used wherein a sample of blood is analyzed by 4 wavelengths of light.

Dyes and pigments

Serum bilirubin elevation does not affect the accuracy of pulse oximeter

Nail polish, especially black, dark blue and purple colors reduces the SpO2

Acrylic finger nails, if not dark colored, does not have significant effect

Dyes administered intravenously, such as 1% methylene blue, 0.25% indo-cyanine green and 0.8% indigo-carmine, transiently (1-2 minutes) decrease the SpO2 in about 30-45s after the injection

Ambient light does not affect the measured value significantly, as it is compensated for, in modern pulse oximeters

Physical movement of the finger as during peripheral nerve stimulation or shivering can create artifacts, as can electrosurgical cautery

Radiofrequency interference from a MRI magnet would generate heat from the current passing through the wires in the probe,and has been reported to cause burns under the probe. Therefore, the probes that are MRI compatible do not have any wires in them; instead the light is transmitted through fiberoptic cables. ■

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RFPs: Reality, Unicorns, and Cognitive Bias

Mark F. Weiss, J.D.

Think back in time to a job interview. You dressed for success and were on your best behavior.

In the advertising world, they call them "reviews." In healthcare, we call them RFPs. They're the same thing. If you're the incumbent medical group, the relationship or the contract is at risk. If you're an outside aspirant, there's an opportunity to expand your business to an additional location. Or, no matter who you are, maybe you're just being played.

As in the course of a job interview, in an RFP everyone is on their best behavior. On both sides.

The hospital is telling fibs about how great it will be to provide services at the facility, and how supportive the administrators will be. The outside aspirants are puffing about what great service they'll provide.

The incumbent medical group suffers from the fact that it is well known to the facility's administrators, warts and all.

Being not as well known, the aspirant medical groups are all rainbows and unicorns, sugar and spice, with a snuggly puppy or two tossed in for good measure.

Let's start with the truth: Professional services are not, and cannot, be a commodity. But it's also true that many have fooled themselves (or, more likely, others) into believing that they are. In fact, there's a healthcare RFP industry.

But, even if you're a true believer in the commodity theory of healthcare, an RFP process for anything other than fixed items (such as a screw meeting Mil-Spec MS51861-1C) is a ridiculous way to make a decision. A way that exists only in a world in which bureaucrats are rewarded by visible, yet lazy, action, situated in a universe devoid of the knowledge that not taking visible action can be action just the same. A way in which decisions are made based on the lies that they're told and the lies that they tell themselves.

Are these lies moral failings? Usually not. They're generally more akin to resume embellishments, nicely pressed suits and shiny shoes. But either way, they're a fiction, a fantasy, and perhaps even fraud.

So, what to do in the real world in which my thoughts about the craziness of the process have (unfortunately) little weight?

If you're the incumbent, you must have a strategy to avoid, deflect, and defeat an RFP. You must create an Experience Monopoly™*, not just perform in a service role. You must develop a propaganda strategy, deployed over time, to educate and sway the administrators and to continuously garner the support of key influencers.

Is that enough to guaranty there'll never be an RFP and if there were one, that you'd come out on top? No. There is no such guaranty anywhere. But that action is required just the same or you're wasting time and working against your own interests.

And, you must develop a true business that is broader than based simply on one hospital, so that you can negotiate from a place of strength. You must have taken action to secure the cohesiveness of the group. Optimally, you need to have the ability to walk away, to say, "No thanks, we won't be submitting a proposal. But hey, good luck with that unicorn!" Developing the required structure takes time. It takes playing the long game. If you haven't already started playing it, start today.

If you're a hospital administrator, remember what Richard Feynman, the famous physicist, said: people are easily fooled, and the easiest person to fool is yourself. Cognitive biases abound. And, that unicorn may just be an ass wearing a fake horn.

If you're on the outside looking at the opportunity that exists to expand your business to another facility, understand how to play to the administrators' cognitive biases. But be very careful about what you promise, because in the event that you "win," you'll actually have to deliver. It takes more effort to continue to play the unicorn after the audience knows it's a trick.

You can count on a honeymoon period, again cognitive bias (confirmation bias) on the part of the administration, but at some point your unicorn horn will fall off, you'll be seen in the light of reality, and, damn it, there's probably a wart or two where that horn used to be. Then, you'll need to be on the lookout for yet another cognitive bias, buyer's remorse. If it kicks in, know that the administrators are incapable of blaming themselves, so they'll naturally have to blame you. Your only hope is that there's some junior administrator to throw under the bus as a sacrifice to the hospital board. (In my experience, this is usually the CFO, but sometimes it's a vice-president).

Whether you're the incumbent or on the outside, if you "lose," then, if you've developed the larger business that I advise is required, it might turn out to have been a win in disguise, for winning the race to the bottom is like a participation trophy: it isn't a real win.

And, there's also always a chance (in many cases a very high chance) that you were defrauded in the course of the RFP, either by the facility or by the consultants brought in by the facility to stage the RFP. Depending on the facts, "bid rigging" inherent in a fake or fraudulent RFP can be charged criminally, both under state law and a host of federal laws. ■

**An Experience Monopoly™ is the overall combination of the way that your group delivers services and the experience that you provide to the facilities, to the other members of the medical staff, to their patients and to the community at large, that creates a benefit that competitors, even if they understood what was being provided, would not be able to duplicate it.*

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