Sentinel
Pennsylvania
Society of Anesthesiologists
Newsletter

Spring 2015

PRESIDENT'S MESSAGE

Emerging from Behind the Ether Screen

by Robert Campbell, M.D

This year is a time of great transformations and even greater aspirations for the Pennsylvania Society of Anesthesiologists. We have a new lobbying firm in Harrisburg, Quantum Communications, committed to helping us in the Pennsylvania Legislature. Our goal in 2015 is to educate lawmakers about who we are and what we do, and to encourage them to support good legislation.

We made progress in the last session with House Bill 1603. HB 1603, introduced by Rep. Jim Christiana, passed the Pennsylvania House of Representatives by an overwhelming, bipartisan vote, 131-67, on Nov. 20, 2013. The bill went to the Pennsylvania Senate on Dec. 5 and was referred to the Senate Public Health and Welfare Committee, an unusual referral. It was not reported out of committee before the end of the 2013-2014 legislative session.

This year we will be leveraging the "when seconds count" campaign and other media to deliver our message. Using the most advanced methods available in the information age, we will be delivering a very simple message: Patients want and need a physician in charge of anesthesia when seconds count. Citizens of the Commonwealth prefer, deserve, and expect anesthesiologists to be there during their most vulnerable encounters with health care.

PSA conducted a public opinion survey last year. The vast majority of Pennsylvanians (nearly 90 percent) want a physician to administer anesthesia or respond to anesthesia emergencies. This finding was featured in press releases, print and broadcast ads in key media markets, a story in *Capital Watch* (a publication widely read in the state Capitol) and in the *Harrisburg Patriot-News*. Op-eds were published in the *Altoona Mirror*, the *Allentown Morning Call* and the *Harrisburg Sunday Patriot-News*, among others.

One problem anesthesiologists have is this: We toil behind the ether screen, and if we do our jobs correctly, our patients are not

continued on page 3

Spring 2015

Contents

PENNSYLVANIA *society of* ANESTHESIOLOGISTS

Sentinel
Pennsylvania Society of Anesthesiologists Newsletter

Editor
Richard P. O'Flynn, M.D.

President
Robert Campbell, M.D.

Association Director
Susie Wilson

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:

PSA Newsletter
777 East Park Drive,
P.O. Box 8820
Harrisburg, PA 17105-8820
717/558-7750 ext. 1596
www.psanes.org

2014–2015 Officers

President
Robert Campbell, M.D.

President-Elect
Andrew Herlich, M.D.

Vice President
Bhaskar Deb, M.D.

Past President
Richard P. O'Flynn, M.D.

Secretary-Treasurer
Patrick J. Vlahos, D.O.

Asst. Secretary/Treasurer
Margaret M. Tarpey, M.D.

District Director
Erin A. Sullivan, M.D.

Alt District Director
Joseph F. Answine, M.D.

Delegates to the ASA House of Delegates
Joseph F. Answine, M.D.
Joshua H. Atkins, M.D., Ph.D.
James G. Cain, M.D.
Robert Campbell, M.D.
Bhaskar Deb, M.D.
Edward H. Dench, M.D.
Michael H. Entrup, M.D.
Joseph W. Galassi, M.D.
David M. Gratch, D.O.
Andrew Herlich, M.D.
Richard C. Month, M.D.
Craig L. Muetterties, M.D.
Richard P. O'Flynn, M.D.
Margaret M. Tarpey, M.D.
Thomas A. Witkowski, MD.D

Alternate Delegates to the ASA House of Delegates
Albert A. Belardi, M.D.
John J. BianRosa, M.D., J.D.
Robert F. Early, Jr., M.D.
Lee A. Fleisher, M.D.
Randy E. Lamberg, MD.D
A. Joseph Layon, M.D.
Philip Mandato, D.O.
Donald E. Martin, M.D.
Kristin M. Ondecko-Ligda, M.D.
Shailesh Patel, M.D.
Mark J. Shulkosky, M.D.
Anthony T. Silipo, D.O.
Kevin F. Slenker, M.D.
Patrick J. Vlahos, D.O.

Delegate, Pennsylvania Medical Society House & Speciality Leadership Cabinet
Donald E. Martin, M.D.

Alternate
Kristin M. Ondecko-Ligda, M.D.

Carrier Advisory Representative
Donald E. Martin, M.D.

Legislative Update

by Charlie Gerow, Quantum Communications

With the new year, a two-year legislative session began in Harrisburg. There are some significant changes.

First, we have a new governor, a Democrat, with very different priorities than his predecessor. Gov. Tom Wolf's agenda is still being formed. It will become clearer as his newly formed administration moves quickly into its first round of budget presentations in the state legislature. The governor, who gets an extra month to prepare his first budget address, presented it before a joint session of the General Assembly on March 3.

Sparks may inevitably fly as a result of the second major change: the balance of power in Pennsylvania's House and Senate. Pennsylvania's legislature had a Republican majority in the last session. But as a result of the November elections, they have moved from control to dominance of both chambers. The House Republicans gained eight seats to give them a solid 119–84 base—the largest Republican House majority since the 1957–58 legislative session. In the Senate, the Republicans added three seats. They now have a 30–20 edge over Democrats.

Promoting Patient Safety

In this new mix, PSA will be working hard to promote measures that serve the interests and needs of its members and their patients. Protecting the safety of the patients cared for by PSA's members is Job One.

PSA will again be pushing for legislation to place into law a requirement that the administration of anesthesia in Pennsylvania be provided or supervised by a physician. Last session, the vehicle for this effort was House Bill 1603, which passed in the House and then languished in a Senate committee.

This bill moves language requiring physician supervision of the administration of anesthesia—which already exists in state Health Department regulations—into the Medical Practice Act. PSA believes that physician supervision protects patient safety by ensuring that the most highly trained medical professional is on hand, especially in the event of an emergency during surgery.

Rep. Jim Christiana, who introduced H.B. 1603, is already moving toward reintroduction in this session, circulating a co-sponsor memo requesting that colleagues join him in sponsoring the bill. We anticipate similar activity soon in the Senate.

Your Support Required

Make no mistake, there will be strong opposition from organizations supporting certified registered nurse anesthetists (CRNAs). The fight will require the support of every member of PSA. Members of PSA must be prepared to again step up to the plate and visit with their legislators as well as make phone calls and other contacts with key legislators. Leading up to critical votes in the legislature, PSA will ask you to make these contacts. It is important that you do so. Legislators who hear nothing from the principal proponents of legislation will see no reason to act on their own. But working together, we will be successful in advancing this vital piece of patient safety legislation.

PRESIDENT'S MESSAGE

continued from page 1

aware of all we do. We must raise awareness among lawmakers and the general public about who we are and what we do. It is possible to be multi-dimensional with all our messaging—and that is what we intend to be.

The 2014 elections brought Pennsylvania an even more dramatically conservative House and Senate. The same election has produced a dramatically more liberal governor. At PSA we prefer to bring political parties together. In spite of partisan divides that can exist, it is reassuring to know that House Bill 1603 is one thing we all support. But we must demonstrate our support to lawmakers.

Expect to hear from PSA via the *Sentinel*, Twitter, Facebook, the PSA web page, LinkedIn, and e-mail. We will be asking you to visit your local legislators' offices and to call them to voice your support. We must be more visible. We cannot remain hidden comfortably behind the ether screen. Be ready to act.

VHA Nursing Handbook Would Affect Patient Safety

by Erin A. Sullivan, M.D., ASA District Director, Pennsylvania

The U.S. Department of Veterans Affairs (VA) is advancing an unprecedented policy change that will dangerously impact surgical anesthesia care available to our nation's veterans in the Veterans Health Administration (VHA). The new policy, which is included in the "VHA Nursing Handbook," would allow all advanced practice registered nurses (APRNs), which includes nurse anesthetists in the VA System, to practice independently in all VA facilities, in all states, regardless of their licensure.

This policy fundamentally changes how care is delivered in VA hospitals, effectively eliminating the longstanding "Anesthesia Service Handbook" which provides for physician-led, team-based anesthesia care.

The VA's "Nursing Handbook" was written by VA's Office of Nursing Services with no consultation or input from the VA's internal experts in anesthesiology—the VA chiefs of anesthesiology. Sixty-seven of these chiefs have come together and invoked VA's own patient safety and quality alert program, known as "Stop the Line," to express concern about the patient safety implications of the new policy. Prominent national Veterans Organizations—AMVETs and the Association of the U.S. Navy—have also raised concerns about the application of the "Nursing Handbook" to the surgical setting and anesthesia. More than 60 physician organizations and a bipartisan group of members of Congress have also expressed concern about abandoning team-based care for VA patients.

This new policy is untested and ill-advised for the veterans' population. VA patients are some of the sickest patients with complex medical needs. Physician involvement in veterans' anesthesia is imperative to patient safety.

The next step in the process is for the release of the "Nursing Handbook" in the *Federal Register.* ASA had heard that the Department of Veterans Affairs may release the handbook in the first quarter of 2015. Other information suggests the release of the Nursing Handbook may be later; however, no specific date has been determined as of this writing. The ASA Committee on Communications is prepared to respond with a public relations plan to be enacted upon its release. Meanwhile, ASA plans to continue to engage the veterans' community.

Please support ASA's efforts to preserve patient safety standards by retaining current anesthesia policies within the VA. Email your local member of Congress and request a meeting to discuss the need for the VA to retain team-based care as described in the VA's "Anesthesia Service Handbook", the standard for patient safety for our nation's veterans receiving anesthesia care in the VA.

What Is the Cause of Drug Shortages? The Answer is Simpler Than You Think

by Robert Campbell, M.D.

As a practicing physician in Pennsylvania, I have become simultaneously intrigued and disturbed by the ever increasing drug shortages I have experienced in my practice. As an anesthesiologist, I am perhaps disproportionately affected as most of the drugs in short supply are generic injectables.

I am not alone as oncologists and emergency physicians have experienced dramatic shortages in their practices as well.

As I began investigating the shortages, I found the medical experts and their summits never really provided an answer that made sense. The question, of course, is why do we have so many shortages?

They began in 2006 and have only escalated over time. This is in spite of multiple drug summits, a Presidential Executive Order, and numerous remediation strategies by the FDA. The root cause, according to the smartest medical minds in the room, is that it is multifactorial and complex. In fact it is so much so that we must simply learn to ration and make do with the scarce resources available at any given time.

I have chosen to look for answers beyond the medical establishment. This has turned out to be very valuable in understanding drug shortages. I suggest other doctors do the same.

I made inquiries with attorneys, marketplace historians, economists, journalists, and supply chain specialists. What I discovered is that all these parties describe the condition as a marketplace failure. While the FDA repeats the mantra it is "beyond the purview of the FDA to consider economic causations," those outside of medicine say it is a simple economic marketplace failure.

There are multiple articles in law review journals, supply chain management textbooks, health policy and law publications, and a white paper published by the American Antitrust Institute. Every resource says the same thing. And the explanation in no way resembles the explanations emanating from the political and medical spheres.

So what is the real root cause of drug shortages? It must be whatever has caused the marketplace failure. There are only two causes for marketplace failures: government price fixing or anti-competitive market behavior.

The most common form of anti-competitive market activity is a monopoly. It turns out there is a monopoly in the supply chain. But this monopoly is not a run-of-the-mill monopoly like say AT&T, Standard Oil, Microsoft, or Google. Those are all vendor or supply-side monopolies.

It turns out the health care supply chain is subject to a very rare kind of monopoly. It even has its own name and one that I have never heard before, and I am willing to guess you have never heard this word before.

It is called a monopsony. What is that? It is a middle man monopoly also known as a buyers' monopoly. It is exceedingly rare in marketplaces. Because of its rarity, this health care monopsony has been studiously observed, characterized, and written about by many authorities. It turns out it just is not written about in medical

circles. Drug shortage experts in health care circles only reticently refer to this monopsony, if ever.

Economists will argue whether the market failure here is due to price controls or a middle man monopoly. No one endorses the multifactorial and complex hypothesis we read about in the medical literature all the time. This is good. I would rather it be a simple problem (a failed marketplace) with a simple solution.

Nothing complex for me please. Well it is a little complex but not so hard to understand.

Some economic marketplace scholars will argue the ASP+6% rule placed on the marketplace by the government is a price control. This is a little bit policy wonk talk

continued on page 6

continued from page 5

but this is a 6 percent cap above average wholesale price that providers can charge to insurance companies and other payers. Others argue it is not.

I have studied this and there are very convincing arguments this is not a price control. In fact it was created in such a way with the intent to prevent price gouging without being a price control. Economists know that price controls destroy markets. I do not think the ASP+6% rule is a price control but some people do.

Some say the presence of the GPO middleman cartel is the only market force powerful enough to cause this unprecedented marketplace failure. Yes that is unprecedented. You see prior marketplace failures have been of limited duration and not across an entire spectrum of marketplace products.

Yes this is the biggest market failure ever. Not the biggest medical marketplace failure but the biggest marketplace failure ever.

The middle man here is the group purchasing organizations (GPOs). Rather than explain everything here there are plenty of great articles written in lots of media outlets about GPOs. The most recent ones are two articles in *Fortune* magazine. They describe the state of affairs pretty well. Plus, my intent here is not to tell you my opinion:

- How to stop generic drug shortages: End hospital group purchasing kickbacks at http://t.co/dJLMpXW0T2
- There's a national shortage of saline solution. Yeah, we're talking salt water. Huh? at http://t.co/gvS7lvRm4X

So What Should Doctors Do?

Put on your critical thinking cap and read some articles yourself. There are plenty of links at http://www.physiciansagainstdrugshortages.com. Once you have done this, something funny will happen. When you hear complex and multifactorial, you will instinctively stop listening. Either your source is conflicted or uninformed. If you hear a marketplace failure with a simple solution, then you are onto a good source. Keep listening or reading to those sources.

Physcians Against Drug Shortages has a web page and anyone can join. No membership fees and you do not have to be a doctor to join. There will come a time when some powerful stakeholders will step forward and take action to end the shortages. If it is a price control then repeal the ASP+6% rule. If it is a middleman cartel then bust up the cartel. These arrangements usually are very profitable for the cartel participants and obliging politicians. That is why the shortages have persisted.

It may be that the only way to end the shortages is for enough individuals to understand that a middleman cartel enabled by government crony capitalists is responsible for all the shortages. Yes it is simple.

The opposite of complex and multi-factorial. A handful of shrewd people are making a lot of money from this masterpiece of crony capitalism. As long as there is no public outcry over shortages, it will persist.

The public, it turns out, is not aware we have drug shortages. Doctors, nurses, and pharmacists are all so busy with their jobs and even more so now that we have to manage the shortages that we have not taken the time to really use our critical thinking skills and read the proper literature on this problem.

We must take that step. This is the greatest threat to patient care in my career. In the name of quality care and saving precious health care dollars, we need to first understand the problem.

Only then can a group like Physicians Against Drug Shortages end the shortages.

If you would like to learn more about what physicians can do to end drug shortages, contact Dr. Campbell at rcampbellmd@comcast.net.

This article is reprinted with permission from the Pennsylvania Medical Society's Quality & Value Blog.

COMMENTARY

Just "Going to Sleep"

by Richard O'Flynn, M.D., *Sentinel* Editor

The other night as I drove home from a long day in the operating room, I listened to a local talk radio show. The topic that hour was awareness under anesthesia. The moderators quoted a study about the reported incidence of awareness in the United States and a few European countries. The host discussed the disparity in the reported incidence and then opened the lines for comment.

As I listened with interest, it soon became apparent that the callers were, without exception, reporting "awareness under anesthesia" during sedation cases. The typical call went like this, "I had the described procedure, I remember hearing people talk, and, while nothing hurt, I remember the conversations." Without exception each person described a minor surgical procedure such as cataract extraction, carpal tunnel release, or minor podiatry cases. Their understanding was that since they were "asleep" their expectation was to have complete amnesia and therefore any recollection during the procedure was "awareness."

I see this as a failure on our (anesthesiologists and CRNAs) part. We routinely describe the anesthesia experience as "being asleep." There are probably multiple reasons for this: we want to explain anesthesia in simple terms that the patient can relate to; we think that describing it as being asleep will put their minds at ease; or we are rushed in order to maintain operating room efficiency so we simply describe the anesthetic experience as being "asleep."

In my opinion, this has two negative repercussions for our profession. The first is obvious; patients expect to have no recall of anything that occurs in the operating room. Why would they remember anything if they were asleep? It is incumbent on all of us to fully explain what the patient can expect or experience. Sedation is just that, supplementation to either local anesthesia or conduction block. By giving a better explanation of what the patient can expect and experience, hopefully we will not have disappointed patients who felt that they "woke up during surgery."

The second and more problematic issue is that anesthesia is being looked at by the general public, and by extension, policymakers, as being something very simple—just going to sleep. We know it is more complicated; we are fully aware of the potential risks and possible complications. It is what anesthesiologists and CRNAs are trained for. It is more than simply going to sleep.

How can a machine or a non-anesthesia trained physician or nurse replace the skill and knowledge gained in an anesthesia residency or CRNA training program? We are the product of our own success. In the 1800s, when the first anesthetic was performed, surgery was a desperate and last attempt. Now it seems that no one is too sick for most procedures.

We should be proud of our safety record but not let that record lull the public, surgeons, lawmakers, or insurance executives into thinking that it is "just going to sleep." Patient safety requires trained anesthesia providers. Take your time the next time you discuss the anesthetic plan with your patient. Be an advocate for your profession and explain your role during the procedure. We need to come out from behind the mask.

The Power of the Nutraceutical

by Joseph F. Answine, M.D.

I listened during the early morning hours (when of course I should have been sleeping) to a radio broadcast for a supplement to lower cholesterol. A board-certified physician on the broadcast made a statement that led me to pick up the phone and dial the station. I wasn't put through and that was probably a good thing. What did he say? He questioned why a patient would take a statin with all of its side effects when their product has no side effects. A product with no side effects! Even a sugar pill can cause hyperglycemia. A medical professional knows that we have not reached that pinnacle of drug therapy where we are able to achieve an effect without causing a side effect or a few.

Let's not dwell on the "unethical" nature of the statement and talk about the legality of it. It's legal I would think. He may be right if he is stating that there are no "published" side effects for the product. This product would fall under the category of a nutraceutical. A nutraceutical (or dietary supplement) is defined as a food, food derivative, or food product, usually in extracted form, that is reported to provide health or medical benefits, including the prevention and treatment of disease. This includes isolated nutrients, herbal products, and certain diets, as well as genetically engineered foods and processed or supplemented "functional" foods such as cereals, soups, and beverages. Furthermore, vitamins, minerals, herbs, botanicals, amino acids, fatty acids, and probiotics are included. (By the way, my wife accuses me of eating mostly "dysfunctional" foods.)

As per the US Food and Drug Administration (FDA) website, a dietary supplement is considered a "food" and not a "drug." Therefore, a dietary supplement does not have to be approved by the FDA, thanks to the Dietary Supplement Health and Education Act of 1994 (DSHEA) which diminished the power of the FDA over herbal remedies. The DSHEA was championed by Senators Tom Harkin (IA) and Orrin Hatch (UT), both from states where a significant amount of money has been made due to dietary supplements. At the time of the Act's passage, here is a statement as to its benefits: "The importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies; healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty…" But, this statement seems more straightforward: "The nutritional supplement industry is an integral part of the economy of the United States…"

As quoted from the FDA website, "dietary supplement manufacturers and distributors are not required to obtain approval from FDA before marketing dietary supplements. Before a firm markets a dietary supplement, the firm is responsible for ensuring that

- the products it manufactures or distributes are safe
- any claims made about the products are not false or misleading

- the products comply with the Federal Food, Drug, and Cosmetic Act and FDA regulations in all other respects."

The FDA's oversight for a new "drug" is more stringent as described on the FDA website:

> Drug companies seeking FDA approval to sell a new prescription drug in the United States must test it in various ways. First are laboratory and animal tests. Next are tests in humans to see if the drug is safe and effective when used to treat or diagnose a disease.
>
> After testing the drug, the company then sends FDA an application called a New Drug Application (NDA). Some drugs are made out of biologic materials. Instead of an NDA, new biologic drugs are approved using a Biologics License Application (BLA). Whether an NDA or a BLA, the application includes
>
> - the drug's test results
> - manufacturing information to demonstrate the company can properly manufacture the drug
> - the company's proposed label for the drug. The label provides necessary information about the drug, including uses for which it has been shown to be effective, possible risks, and how to use it.
>
> If a review by FDA physicians and scientists shows the drug's benefits outweigh its known risks and the drug can be manufactured in a way that ensures a quality product, the drug is approved and can be marketed in the United States.

Wow, from being able to police yourself to levels upon levels and layers upon layers of scrutiny.

For a nutraceutical, the FDA can step in when there appears to be problems with the manufacturing process, assuming that such problems are reported, or if a trail of bodies are found with a clear link to the product. That is a major difference in time and money alone, between what a "drug" has to go through as opposed to a "dietary supplement" before a bottle is in your hands. The money earned by the nutraceutical industry is now in the hundreds of billions of dollars. Why would you want to bang your head against the wall working a drug through the regulatory process (which has a high likelihood of failing) when a super food can be manufactured and sold with little oversight as long as the production process is clean and the ingredients are not known to be harmful in the doses used (assuming they are accurate) regardless of if the claims of any beneficial effects have ever been scientifically proven in any way shape or form? And why would people buy it? For one reason, doctor visits are now not "free" with insurance and pharmaceutical plans being a thing of the past. The Internet has replaced your physician, and "Bob" at the supplement store has replaced the pharmacist. "Bob" is probably also your barista on weekends.

Only recently have we in the peri-operative world been successful in convincing others of the importance of understanding the effects of the patient's super foods on their anesthetic and surgical care. Potential reactions can include bleeding, induction of the cytochrome p450 enzymes altering drug metabolism, interfering with immuno-suppressive agents used during transplant surgery, inducing serotonin syndrome, causing a hypertensive crisis when sympathomimetics are used intra-operatively, and promoting anxiety/agitation in the pre-operative period. This is far from a complete list as newer and stranger agents continue to appear.

This rant of mine occurred because I took note, during my morning coffee and blood pressure medications, that again when we as physicians have a chance to make a difference, to demonstrate our science-based education and care which sets us apart from all others, some choose to sell snake oil from the back of a wagon.

In the interest of full disclosure, my wife and I have been taking a vitamin with antioxidants for years. This is a "pill" that she "read about" that is so effective against the aging process that its users do not go grey. Recently my dark-haired wife stared at my mostly grey head of hair and said without missing a beat: "I guess nothing is 100%."

Mcare and Medical Marijuana

by Robert B. Hoffman, Eckert Seamans Cherin & Mellott, LLC

Mcare and medical marijuana will likely both be in the news as this edition of the *Sentinel* reaches you. This article discusses both.

Four times, from the *Sentinel* issue of Summer 2010 to that of Winter 2013, I've written about the developments, usually successes, in two major and longstanding lawsuits by physicians and hospitals against Mcare. Finally, I write about the settlement agreement, reached in early October 2014, that brought the lawsuits to a successful end, at least from the viewpoint of physicians. *Disclosure:* I was one of the attorneys who represented the Pennsylvania Medical Society (PAMED) in the two *Mcare Cases*, including in their settlement.

The Mcare Cases

The first lawsuit, commonly referred as the Mcare Assessment Case, began in 2008 (!). It challenged the manner in which Mcare calculated its yearly assessments, in particular Mcare's decision to raise money for its next claims year without considering the substantial reserves it had on hand. The result was higher than necessary assessments and a large pile of money sitting there unused, awaiting mischief—which took place. The Insurance Commissioner, in May 2011, upheld Mcare's way of calculating the assessment, but Commonwealth Court disagreed in August 2013, siding instead with PAMED and the Hospital and HealthSystem Association of Pennsylvania (HAP). The Commissioner asked the Pennsylvania Supreme Court to review the case and it agreed to do so. Oral argument was set for October 7, 2014.

The second case, known as the Mcare Fund Transfer Case, challenged the "mischief" referenced in the paragraph above—the transfer of $100 million to the general fund from Mcare in 2009. Commonwealth Court again ruled in favor of the physicians and hospitals, and the Supreme Court, in September 2013, did so as well in large part. But rather than deciding the case *in toto*, the Supreme Court sent the case back to Commonwealth Court to decide whether the transferred funds were "surplus funds," i.e., that the purpose(s) for which the funds had been collected remained. Commonwealth Court had not decided that question when the case settled.

The Settlement

The settlement agreement provides for the return of $200 million to physicians, hospitals, and other health care providers who paid assessments into the fund. Of that amount, $139 million will take the form of refunds for prior assessment overpayments and $61 million has already been used to reduce the amount of the Mcare assessment for 2015. The Commonwealth also agreed to calculate the Mcare assessments, beginning with the 2015 assessment, by using its excess funds to reduce the amount it needed to collect, just as PAMED had argued it had to do. As an example, Mcare's use of $61 million of surplus funds reduced the 2015 assessments by almost exactly one-third, from about 18% to 12% of the prevailing primary premium (which is the base used to calculate individual assessment amounts).

The agreement established a slightly complicated formula to determine how to divvy up the $139 million in refunds. The intent is to return that money, on a proportionate basis, to those who paid the assessment in the years 2009-12 and 2014. (There is no refund for 2013 because Mcare generated no surplus

funds that year). Because the overpayments were the greatest in 2010 and 2011, the refunds will be weighted to assessments paid in those years. The amounts to be refunded will also vary by specialty, location of practice, and the number of years the physician participated in Mcare during this period.

The agreement requires Mcare to pay the refunds "as soon as practicable" with an outside date of an initial mailing by March 2016 (18 months after the agreement). As many as 50,000 physicians and other providers will receive refunds, and a number of nuances remain to be resolved as of this writing. Mcare will be sending a notice, setting forth the details on how to receive a refund. For updates and another take on those details, go to the PAMED website, http://www.pamedsoc.org/. The next issue of the *Sentinel* may also outline and discuss some aspects of the process that are most pertinent to anesthesiologists.

To be sure, the settlement is not perfect. It is, as most settlements are, a compromise. It does not return to Mcare the $100 million that was spirited away. Mcare was allowed to keep $30 million of accumulated funds, as a one-time reserve fund, but it can only be used for legitimate and identified Mcare purposes. On the positive side, the settlement has made certain that Mcare will never again calculate its assessments so as to garner more money than it needs, as it had done for years. And it makes certain that no pot of gold, attractive to budget balancers, will build up in Mcare's coffers. The 2009 fund diversion will never recur.

Medical Marijuana

More than 20 states have legalized the use of marijuana for medical purposes. Pennsylvania seems likely to join the list. Pain management specialists need to be ready to answer patient questions, both now and upon passage.

The reason the prospects are good is that a medical marijuana bill passed the Pennsylvania Senate, with broad bipartisan support, in the fall of 2014. The bill ran into some opposition in the House of Representatives, but ultimately the House adjourned for the year without voting on it. Then-Governor Corbett was an opponent and had announced he would veto any bill the legislature enacted.

The bill has been reintroduced into the Senate, as Senate Bill 3, and Gov. Wolf has declared himself as a supporter who, as governor, will happily sign the bill. The prospects in the House of Representatives are at least decent. The House's newly elected majority leader, David Hess, was a supporter in the House in 2014 and has announced himself a supporter in 2015. A majority leader's support doesn't guarantee passage, but it is a very handy thing to have.

If the bill passes, it will likely do so without substantial physician support. PAMED, for example, stresses the need for more research on the use of cannabidiol, to treat children with seizure disorders and for other conditions, before there is broad usage. There is no doubt that the legalization of medical marijuana has followed a process quite different than that used by the FDA to approve new drugs, owing no doubt to its status as a Class I controlled substance. Reports of clinical success in the United States are just that: reports of clinical results, usually one at a time, rather than the results of extensive and randomized clinical trials. Nonetheless, momentum for passage seems strong and those reservations seem unlikely to block passage.

Senate Bill 3 would set up a state agency to license growers, processors, and dispensers of medical marijuana, somewhat akin to the way the state regulates liquor and gaming. That state agency would also issue medical cannabis access cards that would allow patients, with a qualifying medical condition, to receive medical cannabis on a physician's prescription. Currently, the qualifying medical conditions are: cancer (presumably cancer pain), epilepsy and seizures, amyotrophic lateral sclerosis, cachexia/wasting syndrome, Parkinson's disease, traumatic brain injury and postconcussion syndrome, multiple sclerosis, spinocerebellara ataxia, posttraumatic stress disorder, and severe fibromyalgia. That list may expand as the bill progresses – severe pain would appear to be one likely addition — and there is a process in the bill for the state agency to add medical conditions.

SB 3 is not a decriminalization bill and it would not legalize marijuana usage outside the medical arena. A number of provisions are intended to ensure that prescriptions for marijuana are legitimate and not for a disguised recreational use. For example, a prescription can only be lawfully written for an individual who has "an established practitioner-patient relationship and has been diagnosed with a qualified medical condition." A physician prescribing medical marijuana must first have assessed the patient's medical history and current condition and conducted a personal examination. Much like a traditional prescription, a physician must specify the strain, dosage, and amount of medical cannabis to be taken.

The bill may change, even substantially, as it progresses through the legislature. Stay tuned.

Bungling Bundled Billing?

by Mark F. Weiss, J.D.

Bundled billing: the combination of multiple entities' fees into a single price. What could be wrong with it? A lot, depending on who is doing the bundling. And, in some cases, depending on *why* they're doing it.

History

The concept of bundled billing came out of the hospital world: In order to market for a discrete service, for example, a certain surgical procedure, the hospital sought to have all, or at least some, of the physician providers involved in that procedure agree with the hospital on a fixed price for their services. Those prices were then added, together with the hospital's fixed price for its fee, into the bundle. The idea was to present a coordinated, discounted, competitive price for the bundled procedure or service.

As the hospital-based providers most certainly involved in all surgical procedures, the anesthesia group's fees were, and are, a key component in hospital centered bundled billing.

Metastatic Change

While that hospital centered business practice has continued, and although even in the hospital context bundling poses significant compliance questions, the original notion of bundled billing, a competitive edge passed through to the customer, has metastasized into a tool used by surgeons and other referring physicians outside of the hospital setting to extract kickbacks from anesthesia providers.

This type of metastasized bundling appears to be on the rise as an alternative to the "company model" set up that's attracted regulatory notoriety. (See, for example, my articles "The Company Model: Is Taking Less Money to Work at a Surgicenter Worth Jail Time?", *Anesthesiology News*, January 2011, and "OIG Opinion Adds Clarity to Illegality of Company Model," *Anesthesiology News*, February 2014.)

As a quick refresher, in the company model arrangement, either the ASC controlled by referring physicians or the referring physicians themselves set up a separate anesthesia company to employ the anesthesiologists and nurse anesthetists working at the facility. The owners extract a portion of the anesthesia service profits.

In the bundled billing scenario, instead of forcing the anesthesia providers into an employment or subcontract relationship via a company model entity, those with control of the referrals demand that the anesthesia providers enter into what they'll call a "bundled billing" arrangement with the referral source.

This sort of bundling can be misused to shift a portion of the anesthesia fee into the pocket of the bundler:

- The bundler collects a larger anesthesia fee from the payor or patient and retains the difference after paying you your agreed-to discounted amount; or
- The bundler uses the discounted anesthesia fee to enable it to collect its full, or less-discounted, facility fee, professional fee, or both.

Either way, you've allowed the bundler to achieve an economic advantage at your expense.

For example, a plastic surgeon providing purely cosmetic procedures at her solely owned surgery center demands that you "bundle" your fees, at a substantially reduced rate, with her fees and her facility's fees for purposes of providing all-inclusive pricing to patients. The plastic surgeon will collect the bundled, all-inclusive fee from her patients and pass along your discounted portion upon collection.

Compliance Quagmire

The federal Anti-Kickback Statute (AKS) is designed to prohibit payments to physicians and other providers that are made in order to induce the referral of patients whose care is paid for by federally funded health care programs.

The AKS is a criminal statute and intent is required, but that intent can be inferred from the circumstances and many seemingly appropriate arrangements are, upon examination, viewed by the enforcers, the OIG, as highly suspect.

States have AKS-counterpart statutes, some of which approach the issue from the same angle as the AKS but which may not make any distinction between the source of the patient's funding, and others of which approach the issue from the angle of "fee-splitting," the sharing of a physician's fee with certain third parties under certain circumstances.

A bundling arrangement that results in the transfer of the referral receiving physician's fee to the referral source may implicate the

AKS and similar state statutes. Additionally, even arrangements that involve no transfer of wealth from the receiving physician to the person or entity coordinating the bundling may trigger a state's fee-splitting prohibitions and its corporate practice of medicine prohibitions.

Depending on the nature of the services provided, it's possible that the arrangement violates the Stark law, the federal "self-referral" prohibition which applies to any physician who makes referrals to those with whom the physician has a direct or indirect ownership or investment interest, or a compensation arrangement. Stark is a "strict liability" statute that imposes civil, not criminal penalties, although the severity of the penalties makes it a distinction without much difference.

The states, too, have counterpart self-referral statutes that, depending again on the nature of the services involved, might be triggered.

And last, but by no means least, violations of Stark and of the AKS lead to federal False Claims Act liability (commonly spoken of as "whistleblower actions") in which violators stand liable to regurgitate reimbursement, plus treble damages, and up to $11,000 per claim.

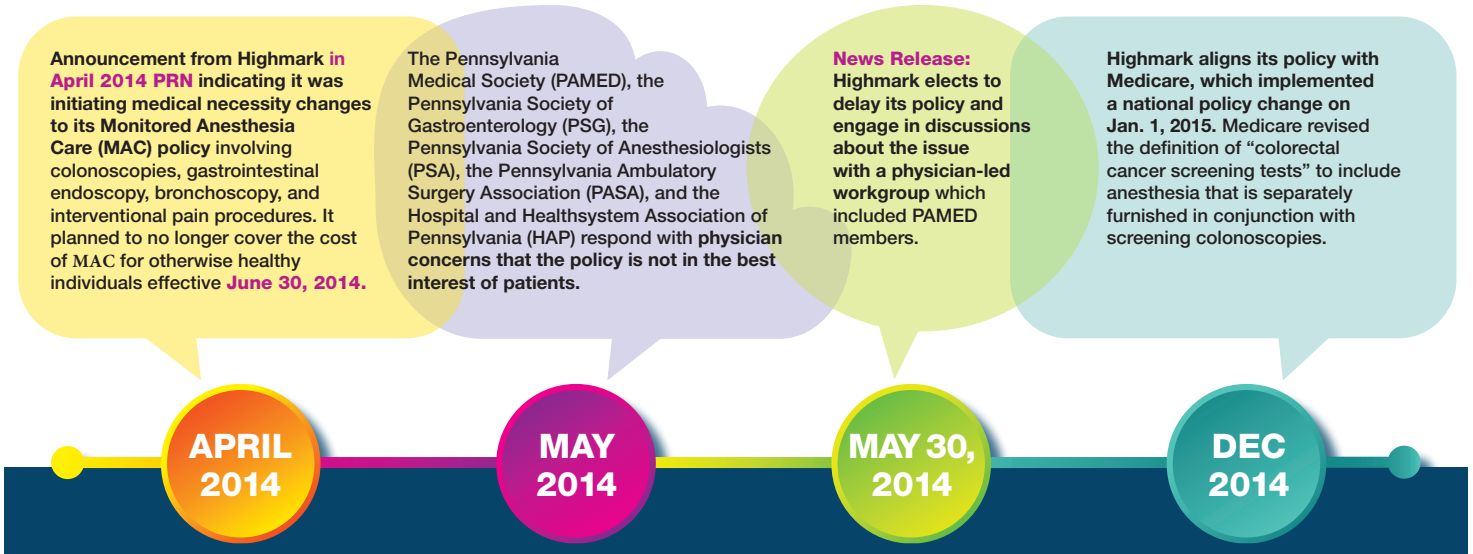
Conclusion

In terms of intent, all may be above board in connection with a bundling relationship. Or, it could be a poorly designed substitute for a direct kickback, or an alternative to a kickback-infested company model scheme. No matter which, innocent or deceitful, intent or no intent, bundling arrangements implicate a number of federal and state compliance laws.

Tread carefully before entering into one of these questionable relationships. On the other hand, if you've already become involved in one without considering the risks, it's essential that you engage in a thorough evaluation immediately.

In the out-of-hospital context, bundled billing is often bungled billing.

A version of this article previously appeared in Anesthesiology News. Mark F. Weiss is an attorney who specializes in the business and legal issues affecting physicians and physician groups on a national basis. He served as a clinical assistant professor of anesthesiology at USC Keck School of Medicine and practices with The Mark F. Weiss Law Firm, a firm with offices in Dallas, Texas and Los Angeles and Santa Barbara, California, representing clients across the country. He can be reached by email at markweiss@advisorylawgroup.com. Complimentary resources are available at advisorylawgroup.com.



The Basis of Modern Anesthesia Practice

by Robert B. Hoffman and Donald E. Martin, M.D.

Editor's Note: A similarly titled article by these authors was published in the Summer 2012 *Sentinel*. At the editor's request, the authors have revised and updated it.

In the second half of the nineteenth century, surgeons trained operating room staff and then nurses to assist them in providing anesthesia for their procedures. Nurses soon became a common anesthesia provider in most US hospitals. Then physicians who were specially trained in anesthesia entered the operating theatre. They took over responsibility for anesthesia care, assuming the surgeon's role as the nurse's supervisor and leading to the creation of the anesthesia care team. Now and for at least several years, some CRNAs, nurses with anesthesia training, have chafed at the relationship, wanting the right to practice independently, i.e., without physician direction or supervision.

This article explores that issue. It does so by looking at the history of modern surgery and modern anesthesia care, an epoch we define as beginning in a Boston operating theatre, in 1846.

The Origin of Modern Surgery: Boston, 1846

Prior to the mid-1840s, elective surgery was an uncommon event. From 1821 to 1846, the annual reports of the Massachusetts General Hospital recorded only 333 surgeries, barely more than one per month (http://neurosurgery.mgh.harvard.edu/history/beforeth.htm). Surgery was a desperate and last resort, and understandably so, because the ability to do so safely and without subjecting the patient to great pain were both limited. As of 1846, opium and alcohol (or more probably an alcohol induced stupor) were the only agents generally regarded as having practical value in reducing surgical pain. An 1847 publication on *New Elements of Operative Surgery* listed opium, water of nightshade, hebane, lettuce, hypnosis, strapping, compression of nerve trunks and noise as anesthetics then in use.

The worlds of surgery and anesthesia changed together in 1846. The event was the surgery performed by William T. G. Morton, a Boston dentist, who used ether as he removed a tumor from a patient's jaw. Surgeons watched and saw that ether could anesthetize. Morton became widely recognized as the founder of anesthesia. Morton's use of ether was a substantial advance in both surgery and anesthesia, establishing beyond dispute the relationship between the two. As Beecher and Todd would write 100 years later: "Anesthesia … is not of itself the therapeutic act which makes possible the correction of deformity, the restoration to health, or the staying of death. *It merely makes possible the acts which can accomplish these things.*" (emphasis added)

Morton had no anesthesiologist at the patient's head or monitors of any kind. The physicians who first gained experience on the new subject of anesthesia were inevitably surgeons; there were no physicians specially trained to provide anesthesia. Someone needed to administer ether for the early surgeons and keep an eye on the patient's level of unconsciousness while the operation proceeded. The "someones" the surgeons turned to were their operating room staff. But it was undoubtedly Morton and his fellow surgeons who gave the orders, who decided how much ether to use, and who were the proverbial captains of the anesthesia ship.

Over the next several decades, the profession of nursing developed and grew, and a subset of nurses became knowledgeable in anesthesia. The AANA dates to 1887, at St. Vincent's Hospital in Erie, Pennsylvania, "the earliest existing records documenting the anesthetic care of patients by nurses." By the late 1800s, nurse anesthesia had become a recognized nursing specialty, and training, almost entirely empirically in the operating room, became available. Ultimately, the process gave rise to the certified registered nurse anesthetist.

At that time, the analogy between nurses administering medication bedside and administering anesthetics in the operating room was a fair one. In both settings, physicians issued orders, including those for medications, while nurses carried them out. Likewise, at that time, little specialized training was required to manage anesthesia

in healthy patients without great misadventure. Ether, the primary choice of anesthetic agent in the U.S. at that time, both supported respiration and was relatively well tolerated hemodynamically. With ether, reversing anesthesia generally meant terminating the inhalation and allowing the patient to awaken. The surgeon was close at hand and firmly in charge if needed. Elderly patients, or those with any serious medical problems, rarely if ever came to the operating room because they were considered too old or sick for surgery.

But other inhaled gas anesthetics began to be used—chloroform (including on Queen Victoria for childbirth in 1853, with later usage in the United States) cyclopropane (beginning in the mid 1930s), and halothane (first used clinically in 1956) —and the experience with them differed. These anesthetics depressed respiration and circulation, bringing with them potential problems for patients along with relief from pain. The death of a 15-year-old girl from chloroform was reported in 1848. The difference between an effective dose of chloroform and a dangerous dose took skill to identify. Patients died of unexpected cardiac arrest under chloroform, a result later understood to arise from an interaction between chloroform and catecholamines released during stress. A real understanding of the pharmacology of these anesthetics and more intensive medical monitoring was needed to administer these anesthetics safely.

It became apparent that anesthesia, for all of its benefits, brought significant new risks to the operating room, including asphyxia, aspiration of gastric contents, a drop in blood pressure, and cardiac arrhythmias, in some cases resulting in death. Anesthesia safety needed to be greatly improved if surgery was to proliferate and the promise of Morton was to be realized.

Even in that era, though, some thought medical personnel were the key to patient safety. In 1893, the *British Medical Journal* opined:

> Anaesthetics should be administered only by duly qualified medical men. There is no law upon the subject, but only those who are able to perform [a] tracheotomy in the event of asphyxia ought ever to administer nitrous oxide gas

The observation that "only those who are able to perform [a] tracheotomy in the event of asphyxia ought ever to administer nitrous oxide gas" reflects an important new insight: anesthetists needed to know how to rescue their patients, including performing surgery, when circumstances required.

Another dynamic was at work, both during this period and on an ongoing basis thereafter: steady change, both in surgery and anesthesia and, indeed, in the very role of the anesthetist. Although we discuss these as *independent* items, they are more properly viewed as interdependent, with advances in one necessitating, prompting or facilitating advances in the other. Surgeons sought to do more complex and lengthier operations, anesthetists tried to allow that to happen. Anesthetists, physiologists, pharmacologists, and engineers discovered better anesthetics or equipment; surgeons tried to take advantage of what those advances allowed.

The Origin of the Science of Anesthesia

Morton and his contemporaries used anesthetics but did not understand the science that underlay them. The scientific basis for anesthetic practice developed primarily during the 19th and early 20th centuries. In the late 18th and early 19th centuries, Joseph Priestley, who came to live in Northumberland County, Pennsylvania in 1794, discovered oxygen and carbon dioxide. John Haldane pioneered oxygen therapy for respiratory disease and blood gas analysis, beginning in the early 1890s. Scipione Riva-Rocci discovered the principles used in the blood pressure cuff in 1896, and in 1905 Nikolai Korotkov described the sounds produced as a cuff is deflated. In 1897, John J. Abel, one of the first American pharmacologists, discovered and named epinephrine and characterized the sympathetic nervous system. Theodore Tuffier, Gaston Labat, and others described the relationship between the sympathetic nervous system and anesthesia, and the use of ephedrine to treat anesthetic-induced hypotension, between 1900 and 1915. Finally, Moritz Schiff described the origin of pain perception in the nervous system and the ability to block pain transmission with the injection of cocaine in the early 20th century.

These discoveries provided the scientific basis on which the medical practice of anesthesiology was founded. These advances, individually and even more so *in toto*, allowed anesthesia to become part of the modern practice of medicine. There was, of course, a great deal more to come, as throughout the 20th and now the 21st centuries, engineers, physiologists, pharmacologists, and anesthesiologists have expanded that understanding to produce 21st century anesthesia.

continued on page 16

continued from page 15

The Development of the Medical Speciality of Anesthesiology

The use of newer and more complex anesthetics, the potentially adverse consequences of their use, and their use on more fragile patients, led physicians to acquire special expertise in not only anesthetic administration – keeping the patient pain-free during surgery – but also in the medical management of surgical patients – keeping patients safe. The close analogy between nurse anesthetists and regular RNs, between administering medication bedside and doing so in the operating room, began to break down as the provision of anesthesia care began to require skills and actions more akin to those that physicians possessed and took elsewhere in the hospital. At the same time, surgical procedures became longer and more complex and patients themselves were sicker, trends that have persisted to this date. These various developments made the safety of patients during surgery a more pressing issue. Specialized medical management—and physicians who could quickly determine what was happening, why, and what to do about it—became increasingly necessary.

Surgeons themselves, fully occupied in performing this more complex surgery, could neither perform the task of medical management themselves nor even provide meaningful supervision to non-physician anesthetists. Issues requiring active medical management often arise together with complications in the surgery itself.

The result was that other physicians with expertise in anesthesia care, including the medical management of surgical patients, began to either administer anesthetics themselves or to supervise the non-physicians in doing so. From the early 1900s (the creation of the first physician anesthesia society, the Long Island Society of Anesthetists) to the 1940s (the American Board of Medical Specialties' recognition of anesthesia as a new medical specialty) anesthesiology grew into a recognized medical specialty, complete with residency programs, a national professional association, and Board Certification. Physician anesthesiologists came to the operating room.

But nurses with training and experience in anesthesia were already in place, and had been since the decades after Morton. As physician anesthetists appeared, it was inevitable that they would take charge. That was the relationship between physicians and nurses generally: physicians issued orders while nurses carried them out; nurses reported patient complaints or problems to the attending physician or resident who then gave new orders and/or went to see the patient.

That paradigm took root in the operating room, giving rise to the anesthesia care team, a hierarchical pairing of anesthesiologists and CRNAs, with the former squarely in charge. An anesthesiologist decided what to do (in today's lingo, developed an anesthesia care plan), a CRNA helped to implement it, the CRNA monitored the patient and brought problems to the anesthesiologist's attention, the anesthesiologist gave new orders and/or saw the patient. The traditional relationship between physicians and nurses was simply replicated in the more dangerous world of the operating room. Anesthesia care fit this model particularly well; post-induction care can involve long periods of uneventful monitoring interspersed with occasional periods in which prompt and skilled action is necessary to avoid serious injury or worse.

Aesthesia Care Advances in the Twentieth Century

Anesthesia care began to change in meaningful ways beginning in the 1930s and 1940s. The ability of anesthesiologists to monitor the patient's condition, and the resulting need to be able to respond to what that monitoring revealed, changed over time as well. EKG monitoring began in the 1950s and electronic arterial pressure monitoring in the 1970s. John Severinghaus, Leland Clark, and J.F. Bradley put the clinical blood gas analyzer into use in the late 1950s. Infrared absorption was first used to measure exhaled CO2 by K. Luft in 1943, was introduced into the clinical practice of anesthesiology in the 1950s, and became widely used in the 1980s. Glenn Milliken first described the ear oximeter in 1942, which was developed into the commercial Nellcor pulse oximeter, first marketed in 1982. Specially processed EEG measurements allowed better quantification of the depth of anesthesia. Each of these advances in patient monitoring, when incorporated into anesthetic practice, led to improvements in patient safety. Anesthesiologists could determine far more precisely how the patient was responding to the anesthesia and to the surgery as well as to the actions they had taken when problems had arisen.

But as anesthesiology care improved, the trend of surgical patients being ever sicker continued.

New types of surgery, such as open heart and organ transplantation, arose and then became commonplace. The serious health issues that these patients brought with them to the operating room were associated with greater risks from the surgery itself and from anesthesia.

As monitoring tools developed, the use of medication during anesthesia has mushroomed. While in the 1840s only a single drug, ether, was used for pain relief, anesthesiologists currently have available and use a wide array of drugs, many classified as controlled substances, for multiple purposes: benzodiazepines or other drugs as pre-surgical sedatives; a narcotic such as fentanyl and a hypnotic such as propofol for anesthesia induction; a neuromuscular blocker for intubation in general anesthesia; drugs for maintenance of anesthesia and drugs to facilitate emergence; and others throughout to treat side effects of general anesthetics or patient-specific conditions such as low blood pressure or arrhythmias.

At the same time, anesthesiologists more frequently perform medical procedures, such as administering spinal, epidural, and regional anesthetics; and placing arterial, central venous pressure, and pulmonary artery pressure catheters. Even more recently, diagnostic monitoring techniques developed and used first by cardiologists, neurologists, and internists—transthoracic and transesophageal echocardiography, evoked potentials, and ultrasound—have been adapted for use in the operating room, providing new and better tools for anesthesiologists to monitor the physiology of their patients.

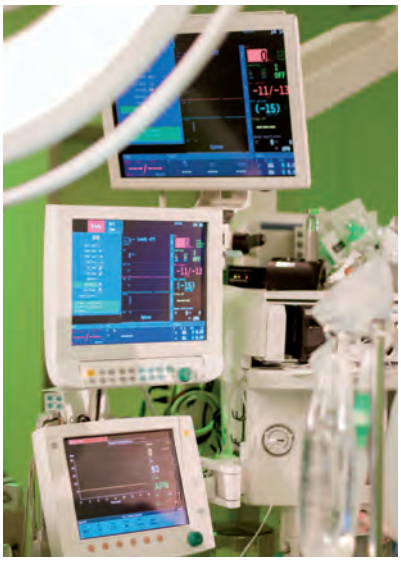
In the last 30 years, the anesthesiologists' responsibility for intraoperative medical management has expanded to the perioperative period. Reflecting this development, the American Board of Anesthesiology has established certified subspecialties in critical care medicine and chronic pain management. Anesthesiologists are providing relief of postoperative pain, both in the hospital and at home. Anesthesiologists are expanding their services as perioperative physicians in many hospitals from preoperative evaluation to pre *and* postoperative management of patients' medical problems.

Improving Anesthesia Safety

The safety of anesthesia, measured in mortality, is now an accepted fact. But the path to that point has been bumpy.

In 1954, the Annuals of Surgery, 140:2, July 1954, published a study by Beecher and Todd entitled *Deaths Associated With Anesthesia and Surgery*. The paper discussed outcome data from 600,000 surgical patients over five years, from 1948 to 1952, at ten university hospitals. The results were shocking: an overall anesthesia-related mortality rate of 6.40/10,000 (384 deaths, a ratio of one death out of every1,560 patients). Nearly one-fourth of all surgical deaths that were attributed to causes other than patients' own ailments were from anesthesia itself. Finally, men had a higher anesthesia mortality rate than women, most likely because they were sicker patients and/or undergoing more complex surgeries. The use of anesthesia, the authors declared, was a "public health problem." The data showed the presence of anesthesiologists, including anesthesia residents, in approximately one half of the cases, with surgeons and nurses each providing anesthesia in about 20% of the cases.

Later that same month, the Report went mainstream. Time Magazine published an article, *"Medicine: Pain & Patience-Killer"*



(July 26, 1954), that reported these findings and added context:

> Anesthesia has advanced far beyond the ether mask and morphine stage of 20 years ago. Today, during critical operations, *e.g.*, inside the heart, as many as eight different painkillers may be administered to ease the patient's lot and the surgeon's task. Even in minor surgery, drugs are used lavishly to prevent discomfort. But even the best of the new techniques carry their own hazard. Last week, two top Boston anesthesia experts, Henry K. Beecher and Donald Todd, laid down evidence that modern anesthesia is killing not only pain *but is still killing a shockingly high percentage of patients.*

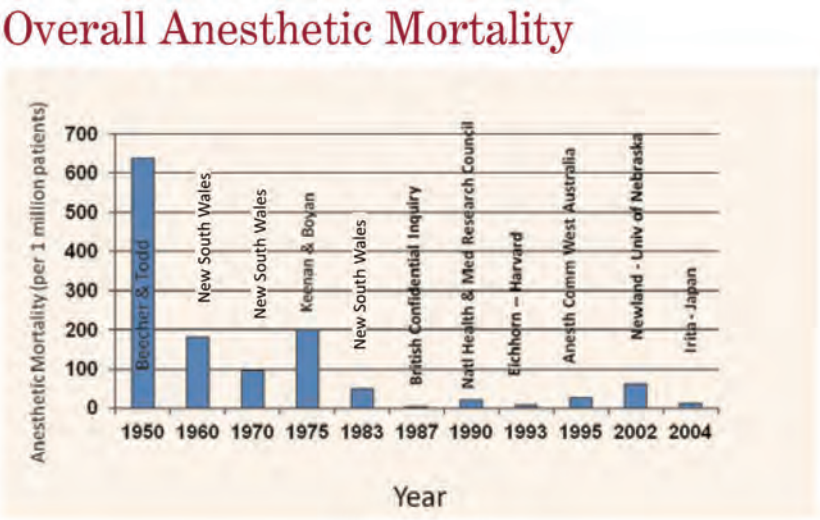
(emphasis added). The problem was not only in pain relief but in medical management of the surgical patient.

Subsequent studies, from 1960 to 2004, have shown a dramatic improvement in these alarming figures. The anesthetic mortality rates reported in 11 studies, over the last 60 years, beginning with Beecher and Todd, are shown in the table on page 18.

As the Table shows, anesthetic mortality has decreased from approximately 640 per million anesthetics reported by Beecher and Todd in 1954 to

continued on page 18

continued from page 17



approximately 60 per million reported in 2002 (Newland MC, Ellis SJ, Lydiatt CA, Peters R, Tinker JH, Romberger DJ, Ullrich FA, Anderson JR: *Anesthetic-Related Cardiac Arrest and Its Mortality,* Anesthesiology 2002; 97:108-115) to 10 per million reported in 2004 (Irita K, Kawashima Y, Iwao Y, Seo N, Tsuzaki K, Morita K, Obara H: *Annual Mortality and Morbidity in Operating Rooms During 2002 and Summary of Morbidity and Mortality Between 1999 and 2002 in Japan, A Brief Review,* Masui 53:320, 2004).

The greatest portion of this decrease in anesthetic mortality occurred between 1950 and 1990, a period marked by an increased presence of physician anesthesiologists, improvements in technology and techniques resulting from medical research, as well as concerted patient safety programs. The Anesthesia Patient Safety Foundation, founded in 1985, has promoted patient safety by sponsoring research and advocacy for enhanced safety practices and has been widely recognized for its efforts.

This period also saw developments in nursing education and nursing scope of practice, in particular the development of training programs for advanced practice nurses – Certified Registered Nurse Practitioners (CRNPs) and Certified Nursing Specialists – who would assist in the delivery of primary care. In Pennsylvania, CRNPs received statutory recognition in 2002 and clinical nurse specialists in 2007. Regulations on CRNPs were first issued in 1977. While registered nurses executed orders from physicians, and could neither diagnose nor prescribe, CRNPs eventually were allowed to do both. They did not practice independently but generally under a form of physician oversight often referred to, albeit inaccurately, as "collaboration." A CRNP's practice is required to be governed by "collaborative agreements" with an individual physician, under which the physician retained involvement with the patient and exercised oversight of the CRNP. This same model governs the relationship between physicians and other midlevel professionals, such as nurse midwives and physician assistants. It is to be sure a modification of the traditional physician-nurse relationship, but it retains, in a looser fashion, the traditional hierarchal relationship.

Physicians and CRNAs in Pennsylvania and in many, but certainly not all, states have worked under an analogous relationship. In Pennsylvania, hospital licensing regulations require a physician, either an anesthesiologist or surgeon, to supervise a CRNA who is providing surgical anesthesia. Under "Medical Direction," a term embodied in Medicare regulations, anesthesiologists "personally participate in the most demanding procedures of the anesthesia plan" while supervising the CRNA's performance of other tasks, primarily intraoperative monitoring. Although Medical Direction is a payment rule, it describes a delineation of tasks within the anesthesia care team that makes good medical sense and is a common real-world model of care, allowing different levels of expertise to be brought to bear in different situations.

In Pennsylvania, nurse anesthetists have not become advanced practice nurses but have instead remained as RNs for legal purposes. Thus, CRNAs operate in Pennsylvania under a Nursing Board regulation, first issued in 1976, that declared that the "administration of anesthesia" was "a proper function of a registered nurse," provided the nurse had been accredited to do so. Originally, the regulation required the nurse to do so "under the direction of and in the presence of a licensed physician or dentist" but a 1982 amendment changed that to "administer[ing] anesthesia in cooperation with a surgeon or dentist." These regulations are of questionable legality. They also fundamentally mislead both in suggesting that the "administration of anesthesia" is the sum of what constitutes anesthesia care in 2015, or in 1976 and 1982 for that matter, and in equating the bedside administration of drugs on the hospital floor with the administration of anesthesia and

related drugs in the operating room. The sophistication and complexity of the use of drugs on surgical patients has made that an inappropriate comparison of quite dissimilar tasks. But these Nursing Board rules also have little practical significance because they are superseded by the more stringent licensing rules established by the Department of Health for hospitals and ambulatory surgical facilities.

Conclusions

The history of modern anesthesia over the past 160 years began with operating room staff and then nurses assisting surgeons in the use of ether. Anesthetics became increasingly more complex, from approximately the 1920s on. Surgical patients became sicker and surgery more complex and longer in duration. Surgeons had their hands more than full performing surgery. Anesthesia outcomes worsened. These trends led to the need for and development of specially trained physicians—anesthesiologists—who assumed, and have retained, responsibility for providing and directing anesthesia care, as well as for performing the increasingly complex medical procedures associated with the perioperative care of surgical patients. Medical management of surgical patients became as big, or bigger, a part of the job as making the patient insensate to pain.

Indisputably, the nature of anesthetic practice has changed tremendously since the 1840s, bringing dramatic changes in the necessary body of knowledge and skills. Medical training and medical research have transformed surgery and anesthesia into complex and inseparable medical disciplines. The body of knowledge and skills necessary to provide anesthesia care for patients has changed dramatically.

Fundamentally, anesthesia care has evolved to requiring *medical* decision-making regarding the management of the patient's surgery as well as the patient's co-existing *medical* diseases. Those judgments must, on occasion, be made and implemented rapidly and in circumstances in which an error can have immediate and profound consequences.

Medical decision-making requires having acquired both a substantial knowledge base on bodily systems, physiologic processes, and diseases, as well as the basic science underlying them, and extensive practical training in the application of that knowledge to individual patients. Anesthesiologists acquire that knowledge base and the mode of analysis that leads to its proper application initially in medical school and then put it into practice during residency. Medical decision-making includes the formation of a differential diagnosis; determination of a final diagnosis using physical signs, monitoring parameters, and laboratory tests; and prescribing medical therapy as indicated. It allows medical expertise and training to be brought to bear when and where needed.

The need for *medical* decision-making is, we believe, the central change in anesthesia care from the beginning of the modern era to the present. The trend lines that led to it—more complex and longer surgery, sicker patients, the use of multiple drugs before, during, and after surgery—are likely to continue. Anesthesia care will inevitably become still more complex. Although it may often seem so, the care will never be routine.

There is a push by advanced practice nurses in primary care to expand their scope of practice and to largely abandon physician oversight and discard the traditional physician-nurse model. At the same time, there is recognition of the merits of a physician-led team of mid-level professionals managing and providing care, primarily to chronic disease patients and in other care scenarios in which care can be divided into portions requiring differing levels of expertise.

Whatever the resolution of that debate, it seems to us that the operating room presents a very different dynamic. Simply put, the stakes are much greater. Many conditions seen in primary care allow diagnosis and treatment over time. Anesthesia care is commonly uneventful, although even that is misleading: it is uneventful because it is so well-provided rather than because it is simple. But when things go amiss in the operating room, the risks are high and the need is for quick and effective action. The operating room is the wrong place to abandon physician oversight.

As we have noted, anesthesia care is a mixture of simple and complex, of routine and life-threatening. It divides itself relatively clearly into those situations that require direct physician involvement and those that do not. The anesthesia care team model, and the concept of "medical direction" recognize this, allowing different levels of expertise to be brought to bear when and where needed. Not all medical care allows that division of labor. When it does, however, that division of labor should be embraced, not abandoned. The result of maintaining that model is quality care for patients provided in a manner that is efficient and economical.

Mr. Hoffman is an attorney with Eckert Seamans Cherin and Mellott, LLC, and serves as outside legal counsel to the Pennsylvania Society of Anesthesiologists. Dr. Martin is Professor of Anesthesiology at the Milton S. Hershey Medical Center, former president of the Pennsylvania Society of Anesthesiologists, and was a long-time delegate and District 6 Director to the American Society of Anesthesiologists.

Welcome New PSA Members

Effective November 1, 2014, to February 25, 2015

ACTIVE

Bilal Ahmad, M.D.
David Roger Bargainnier, D.O.
Karen Bender, M.D.
Mulki G. Bhat, M.D.
Ricardo Alberto Cardenas, M.D.
Ana J. Corcino, M.D.
Kunal Karamchandani, M.D.
Jhansi Lanka, M.D.
Marshall K. Lee, M.D.
Thomas Joseph Maliakal, M.D.
Mary J. McIlwain, M.D.
Michael D. Minton, M.D.
Bryan Paul Noorda, M.D.
Isoken Osunde, M.D.
Jessica Peretin, M.D.
Tricia Lee Pockey, M.D.
David Alexander Roberts, D.O.
Tanisha Orriana Robinson, M.D.
Max E. Rohrbaugh, M.D.
Steven S. Silvonek, M.D.
David J. Simons, D.O.
Shanthan Sunki, M.D.
Michael Tuan Tran, D.O.
Ajay Darsh Wasan, M.D.

AFFILIATE

Demet S. Sulemanji, M.D.
Marc C. Torjman, Ph.D.

RESIDENT

Adam Craig Adler, M.D.
Jessica Rose Black, M.D.
Shawn Marten Falitz, M.D.
Sankalp Sehgal, M.D.
Julia Frances Serber, M.D.

PSA Board members Joseph Galassi, M.D. (left) and Joseph Answine, M.D. (right) meet with PA Senator Patrick Toomey.

Anesthesiologist and PSA Board Member Philip Mandato, D.O., at left, with newly elected Congressman Ryan Costello, who represents the 6th PA Congressional District consisting of parts of Chester, Montgomery, Berks and Lebanon counties. Representative Costello replaces Jim Gerlach who retired. Representative Costello was supported by ASAPAC and individual members of the PSA.

In Memoriam

John R. Quinn, M.D.

Dr. John R. "Jack" Quinn, 87, died Oct. 21, 2014, surrounded by love with family. Dr. Quinn served as president of PSA in 1993-94 and as long-time secretary and treasurer. He practiced as a family doctor in Johnstown before specializing in anesthesia, serving his internship and residency at Conemaugh Valley Memorial Hospital in Johnstown. Dr. Quinn held a number of posts spanning his 40-year career, including serving as director of the anesthesia department for Eye and Ear Hospital in Pittsburgh. At Lee Hospital in Johnstown, he was director of the department of anesthesiology, founder and director of Lee Hospital/UPJ School of Anesthesia for Nurses, president of Lee Hospital medical staff, and medical director of Lee's Department of Anesthesiology and Recovery Room for 20 years. Dr. Quinn gained deep satisfaction in mentoring others to reach their full potential. An eternal optimist, he will be especially remembered for his life philosophies to "make it happen!" and "if it's worth doing, it's worth doing right" that were demonstrated by example daily.

Help Z-PAC Gives Anesthesiologists a Unified Voice in the Capitol

The new legislative session is underway in Harrisburg. Very soon lawmakers will be making important decisions affecting your practice of medicine. The Pennsylvania Society of Anesthesiologists is your voice in the Capitol.

PSA works closely with Z- PAC, your registered political action committee. Z-PAC exists to support those members of the General Assembly who believe in what you do and who work to advance PSA's views on important patient safety and medical practice issues.

In 2013-14, we had a huge victory in the Pennsylvania House with a bipartisan 131-67 vote on House Bill 1603, which would have made physician supervision of anesthesia care the law in Pennsylvania. However, the bill was held up in the Senate. For the sake of our patients and the health of the Commonwealth, we intend to renew this fight in this new legislative session.

On another front, PSA and Z-PAC continue to fight for you when medical insurers implement bad policy. We vehemently fought proposed policies from Highmark and Novitas, successfully defending the medical necessity of anesthesia for colonoscopy, bronchoscopy, EGD, and pain management procedures.

Our profession repeatedly faces coordinated attacks by various parties who wish to promote the expansion of the scope of practice of nurses and other physician extenders. They've been emboldened by the federal government and the Affordable Care Act.

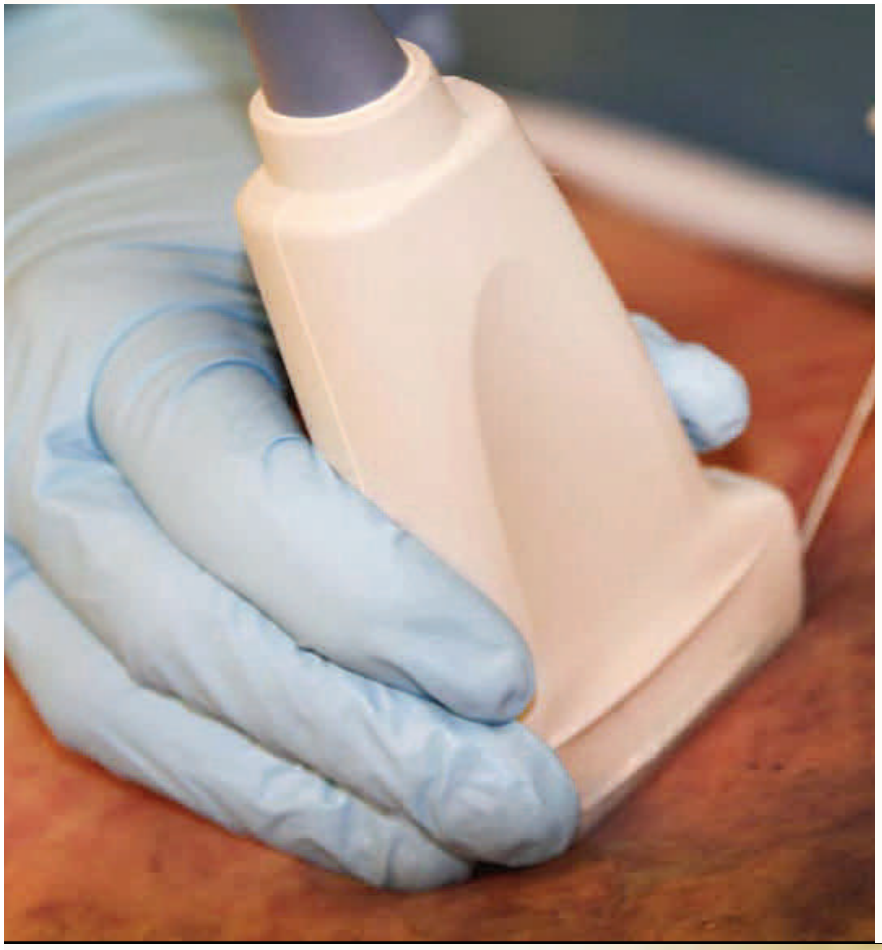
"I know you care about these issues. I know that you are aware that too many of our colleagues are content to sit back and let a few motivated souls fight the fight," says Z-PAC Treasurer Richard O'Flynn, M.D. "We need to accept zero tolerance for not supporting physician advocacy efforts, zero tolerance for complacency. A few voices cannot have the impact that all of us will have speaking out together. Z-PAC gives us a unified voice on our issues and concerns."

Political action means seeking out legislators who understand what physician anesthesiologists do and, who are willing to listen to the needs and opinions we hold. Through Z-PAC, PSA members support lawmakers who will make a difference on our issues—issues like ensuring that Pennsylvania retains physician oversight of the administration of anesthesia.

You can help make a difference for your patients and practices by sending your maximum personal contribution to Z-PAC. You can make your donation to Z-PAC online at www.psanes.org or simply scan the QR code in this article to make an online contribution. It's time for you to get involved.

| Fifth Annual |

Ultrasound–Guided / Cadaver Course *in* Regional Anesthesia *and* Central Vascular Access



Best value for your CME dollars..

REGISTER TODAY!

May 30-31, 2015

An exciting opportunity to acquire hands-on experience with:

- Cadavers
- Phantoms
- Volunteers

- Reduced registration fee of $750 for PSA members!
- Go to http://www.psanes.org — ”Anesthesiologists” - “Meetings” for more information.
- For registration go to http:// www.PennStateHershey.org/ce . -”Our Programs” - “Conferences”

MOCA®

ASRA Regional Anesthesia Portfolio

A continuing education service of Penn State College of Medicine and the Department of Anesthesiology

Jointly sponsored by the Pennsylvania Society of Anesthesiologists

PENNSYLVANIA society of ANESTHESIOLOGISTS

PENNSTATE HERSHEY College of Medicine 1855

The Julien F. Biebuyck

Faculty and Alumni Library

Room C 2860

Biomedical Research Building

Penn State Milton S. Hershey

Medical Center, Hershey, PA

PENNSYLVANIA
society of
ANESTHESIOLOGISTS

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820

Follow PSA on Facebook

To sign up for a new account, enter your name, birthday, gender and email address into the form at https://www.facebook.com. Then pick a password.

After you complete the sign up form, Facebook will send an email to the address you provided. Just click the confirmation link to complete the sign up process.

How do I follow PSA on Facebook?

First, sign in to your Facebook account. At the top of the screen, in the "Search for people, places, and things" box, type "**PA Society of Anesthesiologists**" and press "Enter." This will take you to the PSA Facebook page.

On the PSA Facebook page, click "Like" under the cover photo. Doing this will add you to the list of PSA followers, so to speak, and through your Facebook account, you will be alerted about any activity or updates made to the PSA Facebook page.

Follow PSA on Twitter

Visit https://twitter.com/signup to create a Twitter account.

Twitter will send a confirmation email to the address you entered on sign up. Click the link in that email to confirm your email address and account.

How do I follow PSA on Twitter?

First, sign in to your Twitter account. At the top of the screen, in the "Search" tab, type "**@PSAnesth**" and press "Enter." This will take you to the PSA Twitter page.

On the PSA Twitter page, click "Follow" under the cover photo. Doing this will add you to the list of PSA followers, so to speak, and through your Twitter account, you will see all of the new items posted by PSA.