

PENNSYLVANIA society of ANESTHESIOLOGISTS

WINTER 2021 NEWSLETTER

SENTINEL

Shailesh D. Patel, MD, FASA, MHA
PSA PRESIDENT

President's Message

First, I want to thank my distinguished predecessor, Richard Month, MD, FASA, for all his hard work and dedication in leading the Pennsylvania Society of Anesthesiologists during the previous two years.

As I begin my two years as the President of the PSA, I want to contribute to shape the future of our specialty. We, the PSA, are here for you, our members, to address your needs as an anesthesiologist, and make your membership valuable. My objective is to assure that we carry out activities that our members desire. First, to improve membership engagement, the Board recently approved the Member Development Fund. To further membership inclusion in such a process, we will solicit member input via responses to a survey for potential improvements. To date, suggestions include improvement of the PSA website, addressing members' licensing and practice management needs, MOCA support, and scientific education. Other recommendations include free or reduced fee Continuing Medical Education content, a webinar platform, and further development of scientific meetings. We want you, the members, to be involved and help chart the course for the future of the PSA.

The next two years will be challenging as we have many uphill battles ahead of us at the governmental level. Last fall, the Governor's office released a Regulatory Agenda with a concerning regulation regarding reimbursement. The proposed regulation would provide for direct payment for anesthesia to the administering CRNA rather than to the supervising physician. I suspect that the new regulation will not be favorable to us. Once we have more details, we will form a strategy and will keep the members abreast of the development.

"I want to contribute to shape the future of our specialty..."

Meanwhile, PANA has reintroduced their bill calling for legal recognition of CRNAs, allowing them to be one step closer to practice independently. We will, of course, work tirelessly to defeat this. Additionally, the PSA will continue to fight for physician-led anesthesia care and will continue to work hard to codify the current DOH regulations requiring physician supervision to administer anesthesia.

At the grassroot level, I want to work on improving our relationship with our state and federal legislators by having board members, as well as PSA members, speak to legislators directly or by reaching out to them through a virtual meeting.

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PENNSYLVANIA *society of* ANESTHESIOLOGISTS

SENTINEL *NEWSLETTER*

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President's Message

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A simple list with pertinent talking points is being developed. We are also working on establishing a list of PSA members by their legislative districts to help coordinate personal delivery of ZPAC donations to a legislator by a member of his or her respective district.

Logistic challenges of the pandemic in 2020 delayed the Ultrasound Workshop, as well as the first two-day statewide PSA Annual Meeting which was to include workshops, poster presentations, and lectures. We are planning on having these meetings in 2022, bringing CME and added value to Society membership.

The Pennsylvania Society of Anesthesiologists is here to serve you, our members. To do that, we need to know what we can do better and what you would like to see the PSA do to serve you better. Please contact us via our website, www.psanes.org, with suggestions. The PSA wants to be a resource for our members to take the best care of patients. It's the reason why we go to work every day.

NEW PSA MEMBERS!

Muhammad, Ajmal, MD
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Wing Fei Wong

EDITORIAL

Looking Ahead

Richard O'Flynn, MD, FASA
Editor

As we enter the winter season many things remain unsettled due to the COVID pandemic. I'm sure that most hospital operating rooms and surgical centers are almost back to full or at least near full capacity. It is important that patients not delay needed procedures, and with the appropriate safeguards in place, many procedures have been safely accomplished.

The vaccine rollout is proceeding and most front-line workers who desired it, have received at least the first injection. It remains to be seen whether this will allow loosening of restrictions as the general population joins the vaccinated ranks.

While the healthcare industry has been able to resume near normal operations, the same cannot be said for most restaurants, schools, places of worship, sporting arenas etc. The disparities seen between state regulations and even community reactions to regulations is hard to comprehend. Hopefully as we enter 2021 life will start to return to the old normal, although there will definitely be modifications. The vaccine rollout gives some hope that things will improve this year.

For members who look forward to the annual ASA meeting, 2020 represented a big change—a virtual ASA meeting! Many of us use the ASA meeting not only to attend CME lectures and examine new medications, machines, products but also as a way to reconnect with old colleagues. Unfortunately, that experience was limited in 2020.

The question is what becomes of future meetings? Already the 2021 ASA Practice Management meeting has been completed virtually and spring meetings will also be virtual. The format of the 2021 Annual meeting remains unknown. The question remains...how long can professional societies exist with purely virtual meetings?

In this issue of the Sentinel we welcome Dr. Shailesh Patel as the new Society President. Dr. Patel will guide our Society for the next two years. His article lays out his plans for the Society.

As the PA Legislation begins the new two-year term, there is much on the horizon. Our Legislative Counsel, Andy Goodman, breaks down the most recent election results in the House and Senate along with the Representatives in leadership positions. He also provides a list of anticipated legislation for this session.

Other articles of interest:

Dr. Answine shares his experience with a young patient with ARVD. While this is a relatively rare disease, his experience highlights the necessity of a thorough preoperative evaluation and investigation into any disease process that is unfamiliar to you.

Dr. Park comments on safety in the operating room and the importance of communication among the OR team, which is especially important at this time.

We welcome back Mark Weiss with important articles on anesthesia practice management and Charles Artz with his legal updates concerning anesthesia practice.

We hope that you find this to be a valuable resource and welcome your feedback and suggestions for future articles. The Sentinel is your journal. We encourage submissions, suggestions or comments. Write to us at psasentineleditor@gmail.com.

LEGAL UPDATE

Commonwealth of Pennsylvania again denied access funds from malpractive insurer

Charles I. Artz, Esq.
PSA General Counsel

In an update to a case we previously reported on, Pennsylvania Professional Liability Joint Underwriting Association v. Wolf, 2020 WL 7629243 (M.D. Pa. 2020), the federal court for the Middle District of Pennsylvania prevented, at least in part, Pennsylvania's latest attempt to exercise control over the Pennsylvania Professional Liability Joint Underwriting Association and its nearly $300 Million budget surplus. Pennsylvania has tried to exercise control over the Association three times before and has been rebuffed by the federal court each time.

In the most recent attempt, Pennsylvania attempted to pass legislation giving the Association access to state funding in exchange for government oversight and transparency. The Association sued the state.

The court granted the Association's motion as to the funding provision of the law and the law's requirement that the Association use an attorney employed by the Commonwealth. The court held that the state funding provision was a "gift horse to be of the Trojan variety" and effectively prohibited the Association from spending its own private funds, including the $300 Million surplus. The court reasoned as follows:

> The General Assembly made a choice when it created the Association in 1975, and its choice has present-day constitutional consequences. When it chose to meet its public-health objectives through a private, non-profit association in which the state is not alone or, indeed, at all interested, and over which the state retains virtually no control, the General Assembly relinquished any sovereign claim to the Association or its assets. The consequence of that choice is that the General Assembly may not interfere with the Association control of its private funds, and Act 15's attempt to do so is an unconstitutional regulatory taking [in violation of the Fifth Amendment to the U.S. Constitution].

This case is important because the Professional Liability Joint Underwriting Association has operated as a private entity since its creation. The Association is apparently being well managed as it has amassed a $300 Million surplus while it continues to provide access to medical malpractice insurance for certain health care providers in the Commonwealth.

The state filed an appeal to the Third Circuit U.S. Court of Appeals on January 20, 2021. The case will be monitored and a subsequent report presented after the Court of Appeals publishes its decision.

BLUE CROSS BLUE SHIELD OF MICHIGAN SUED OVER ANESTHESIOLOGY RATES

Anesthesia Associates of Ann Arbor, PLLC ("A4"), brought an antitrust suit against Blue Cross Blue Shield of Michigan ("BCBSM") alleging that BCBSM is using its 67% share of Michigan's health insurance market to coerce hospitals into boycotting anesthesia practices that do not participate with BCBSM. The case is Anesthesia Associates of Ann Arbor, PLLC v. Blue Cross Blue Shield of Michigan, No. 2:20-cv-12916-TGB-APP (E.D. Mich. 2020).

Before filing the lawsuit, A4 attempted to withdraw from its Provider Agreement with BCBSM. When A4 notified

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BCBSM that it was terminating the Agreement, Trinity Health Corporation terminated its relationship with A4. A4 did a substantial amount of its work with the Trinity Health Corporation. Trinity then began to recruit A4 physicians to come and work directly for their hospitals offering to indemnify them in any legal action related to their noncompete agreements. The CEO of Trinity Health is also alleged to have been a board member of BCBSM.

The case was filed in November of 2020. BCBSM filed a motion to dismiss in January 2021. In its motion, BCBSM argues:

- A4 failed to plead an antitrust violation because there was no illegal price effect, no reduction in output and no reduction in the quality of services in the marketplace;
- A4 failed to plead unlawful restraint, and failed to plead actual or attempted monopolization stating that lower prices are not in and of themselves anticompetitive;
- BCBSM can make its own terms and conditions in its agreements; and
- An antitrust cause of action needs to negatively affect the entire marketplace, not just one provider in it.

The hearing on the motion to dismiss is scheduled for May 26, 2021. A decision is expected within a few months after the hearing.

This is an important case because it affects independent anesthesiology practices in a number of ways:

- It will determine if it is proper for a health system to require anesthesia practices to participate with specific insurers through their agreements;
- It will evaluate the validity of noncompete agreements and whether or not a hospital can indemnify an anesthesiologist who chooses to leave a private practice to work for the hospital; and
- It will determine if BCBSM is engaged in improper conduct with respect to coercing health systems to honor low rates and colluding with the hospitals to enforce those rates.

TEXAS ANESTHESIOLOGIST FAILS IN ANTITRUST APPEAL

In Shah v. VHS San Antonio Partners, L.L.C., ___ F.3d ___ (5th Cir. 2021) (2021 WL 118627), Dr. Jaydeep Shah attempted to sue Baptist Health System for antitrust violations after his firing from the only medical practice that provides pediatric anesthesiology services to the hospital chain.

Dr. Shah was terminated by Star Anesthesia, P.A. for allegedly making false statements to other physicians about changes to its exclusive agreement with Baptist that would have reduced his income. An arbitrator and two different state courts rejected Shah's fraud and breach of contract claims against the anesthesiology provider. He sued Baptist and three of its executives alleging antitrust violations.

The court granted summary judgment for Baptist holding Dr. Shah failed in every conceivable way to make his case. The court concluded that Dr. Shah failed to show harm to competition in the marketplace rather than just harm to himself. Dr. Shah also failed to demonstrate the sorts of market effects that are traditionally used to measure competitive impact in antitrust cases the court concluded. The U.S. Court of Appeals upheld the dismissal.

The case demonstrates that a properly terminated physician cannot use the antitrust laws to reverse that termination.

STOLEN LAPTOP/LOST THUMB DRIVES GOVERNMENT $4.4 MILLION FINES REVERSED

A new U.S. Court of Appeals decision has invalidated and eliminated the federal government's draconian $4,348,000 fine imposed against a health care provider whose employed physician was victimized by a thief who stole his laptop, and two staff members who each lost one thumb drive containing electronic protected health information ("ePHI"), despite the provider's best efforts to comply with the HIPAA Privacy and Security regulations. This important decision may bring more reasonableness to the sanctions imposed by the Office for Civil Rights ("OCR") as a result of third party criminal misconduct and honest mistakes.

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In University of Texas M.D. Anderson Cancer Center v. U.S. Department of Health and Human Services, ___ F.3d ___ (5th Cir. 2021) (2021 WL 127819), a provider faculty member's laptop was stolen. It was not encrypted or password protected but contained ePHI of 29,021 individuals. Two other employees lost unencrypted USB thumb drives containing the ePHI of about 5,600 patients. The provider litigated the case, and the Administrative Law Judge ("ALJ") imposed an incredible fine of $4,348,000. The provider appealed to the U.S. Court of Appeals, which reversed the ALJ's decision, vacated (i.e. eliminated) the penalty, and found OCR's position to be arbitrary, capricious and unlawful. The U.S. Court of Appeals reversed on four separate grounds.

Each will be summarized briefly.

Some of the U.S. Court of Appeals' critical legal holdings include the following:

1. The Court of Appeals held "it is **plainly irrational to say [the provider's] desire to do more in the future means that in the past it failed to encrypt patient data on portable media at all**."

2. It was undisputed that the stolen laptop and two lost USB drives were not encrypted. But that does not mean the provider failed to implement a mechanism to encrypt ePHI. It only means that three **employees failed to comply with the encryption mechanism** or the provider did not enforce the mechanism rigorously enough.

3. The government argued and the Administrative Law Judge took the position that the Encryption Rule requires covered entities to **assure that all systems containing ePHI to be inaccessible to unauthorized users** with no exceptions.

4. In response, the Court stated: "But that is not the regulation HHS wrote. The regulation only requires a mechanism for encryption. **It does not require a covered entity to warrant [or guarantee] that its mechanism provides bullet-proof protection of all systems containing ePHI.** Nor does it require covered entities to warrant that all PHI is always and everywhere inaccessible to unauthorized users. Nor does the regulation prohibit a covered entity from creating a mechanism by directing its employees to sign an agreement that requires encryption of portable devices. Nor does it say that providing employees an encryption key is insufficient to create a compliant mechanism. Nor does it say anything about how effective a mechanism must be, how universally it must be enforced, or how impervious to human error or hacker malfeasance it must be."

5. The government's interpretation of the rule prohibiting health care provider from "disclosing" ePHI was improper for at least the following three reasons:

- Each verb HHS used to define "disclosure" – release, transfer, provide and divulge – suggests an affirmative act of disclosure, not a passive loss of information.

- The term "release" means the act of setting something free, not any loss of ePHI if the provider did not act to set free anything.

- The court stated: "It defies reason to say that an entity affirmatively acts to disclose information when someone steals it. That is not how HHS defined 'disclosure' in the regulation. So HHS may not define it that way in an adjudication."

6. The regulation defines "disclosure" as making information known to someone. A person cannot disclose a secret without actually taking affirmative action making it known to someone.

7. The court held: "We therefore refuse to interpret §160.103 to mean that HHS can prove [the provider] disclosed ePHI without proving that someone outside the entity received it. And the government concedes it cannot meet that standard."

8. The provider submitted evidence that other providers violated the Encryption Rule and faced zero financial penalties. One provider lost an unencrypted laptop containing ePHI for more than 33,000 patients in a burglary and HHS imposed no penalty at all.

9. Where, as here, a party makes a significant showing that analogous cases have been decided differently,

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the agency must do more than simply ignore the argument. Were it otherwise, an agency could give free passes to its friends and hammer its enemies—while also maintaining that its decisions are judicially unreviewable because each case is unique. The law prohibits that approach.

10. The government's application of the regulations establishing the fines was arbitrary, capricious and contrary to law.

11. Congress specified that the per year cap for all reasonable-cause violations is $100,000, not $1,500,000.

12. Two months after the ALJ decision, HHS conceded it misinterpreted the statutory caps and published a notice to explain its mea culpa, promising to exercise enforcement discretion to follow the statutory caps.

13. HHS' own regulations require consideration of the following factors in assessing a penalty:

- Whether the violation caused physical harm;
- Whether the violation resulted in financial harm;
- Whether the violation resulted in harm to an individual's reputation; and
- Whether the violation hindered an individual's ability to obtain health care. 45 C.F.R. §160.408(b).

14. The government failed to prove all of these requirements.

The court concluded its opinion by holding that the government has offered no lawful basis for its civil money penalties against the provider, vacated the civil money penalty order and remanded the case.

The University of Texas decision is by far the most reasonable decision interpreting the HITECH Act and OCR Privacy and Security regulations in the 20-plus year history of HIPAA. Useful compliance points include the following:

1. Anesthesiologists do not have to warrant that their encryption mechanisms provide bullet-proof protection of all systems containing ePHI. The encryption regulations must be followed, but anesthesiologists do not have to make guarantees.

2. It does not appear that anesthesiologists can be sanctioned for third party criminal misconduct if reasonable efforts were made to comply with the HIPAA Privacy and Security regulations, including the encryption requirements, and the anesthesiologist adopts policies and implements training.

3. Passive loss is not equivalent to "disclosure" or "release."

4. Theft of a device containing ePHI does not appear to constitute a "release" or "disclosure" of ePHI.

5. If ePHI is lost or stolen and there is evidence that someone else accessed the ePHI, any Breach Notification filed with the OCR should include the following mitigation arguments:

- Whether there is any evidence that the release caused physical harm;
- Whether there is any evidence that the release resulted in financial harm;
- Whether there is any evidence that the release resulted in harm to any individual's reputation; and
- Whether there is any evidence that the release hindered an individual's ability to obtain health care.

6. All mobile devices containing ePHI should be encrypted. Implement policies and procedures explaining the encryption requirements. Provide encryption keys to all physicians and employees. Train new employees promptly and existing employees at least annually about the Privacy and Security Rules.

Z-PAC Update

No Time for Complacency

Richard O'Flynn, MD, FASA
Chairman of ZPAC

The new legislative session is underway in Harrisburg. Very soon, lawmakers will make important decisions affecting your practice of medicine. The success of our specialty in Pennsylvania is a direct result of the success of our advocacy efforts in Harrisburg. PSA works closely with Z- PAC, your registered political action committee.

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

Our profession, your livelihood, faces coordinated attacks by various parties who wish to promote the expansion of the scope of practice of nurses. They've been emboldened by the Federal and State government and are well-funded and organized.

Z-PAC is your voice in Harrisburg. The 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.

We need to accept zero tolerance for lack of support for physician advocacy efforts and zero tolerance for complacency. Too many of our colleagues are content to sit back and let a few motivated souls fight the fight. 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.

Your support is vital to our success. Do this today. You can make your donation to Z-PAC online at

www.psanes.org

or, better yet, take out your phone and scan the QR code to be taken to the Z-PAC page to contribute.

Working together, we will make a difference—a BIG difference for our patients and for our practices.

LEGISLATIVE UPDATE

HARRISBURG OVERVIEW:

Happy 2021! As you may have heard, the Pennsylvania General Assembly recently held swearing-in ceremonies to kick off the new legislative session (2021-2022) and committees have been officially organized. Legislators are off and running. Co-sponsorship memos have started circulating and bills are starting to be introduced and referred to their prospective committees.

Both the House and Senate are scheduled to be in session in February and March. The budget and its negotiations will be the primary and most difficult task ahead for the General Assembly. Governor Wolf gave his annual budget address on Tuesday, February 2nd. Typically, the House and Senate Appropriations Committees hold budget hearings with all relevant state agencies for several weeks after the budget address to discuss the Administration's plan in greater detail. However, due to COVID, the Senate has already postponed these hearings with the goal of holding in-person hearings later on. The House hasn't announced their plans for the hearings yet, but we will keep you updated as we learn more.

As far as the election outcomes, Republicans still hold a majority in both the House (112-90) and the Senate (28-21). And there were some notable internal leadership elections as well:

House leadership in 2021 is comprised of some of the following team members:

Republicans:

- Representative Bryan Cutler (R-Lancaster) will continue as Speaker of the House.
- Representative Kerry Benninghoff (R-Centre) will continue as the Majority Leader.
- Representative Stan Saylor (R-York) will continue as the Majority Appropriations Chairman.

Democrats:

- Representative Joanna McClinton (D-Philadelphia) became the first female and first African American Democratic Leader of the House.
- Representative Matt Bradford (D-Montgomery) will continue as the Democratic Appropriations Chairman.

Senate leadership in 2021 is comprised of some of the following team members:

Republicans:

- Senator Jake Corman (R-Centre) will serve as the new Senate President Pro Tempore (Joe Scarnati retired).
- Senator Kim Ward (R-Westmoreland) will be the first female Majority leader in the Senate.
- Senator Pat Browne (R-Lehigh) will continue as the Majority Appropriations Chairman.

Democrats:

- Senator Jay Costa (D-Allegheny) will continue as the Democratic Leader of the Senate.
- Senator Vincent Hughes (D-Philadelphia) will continue as the Democratic Appropriations Chairman.

Health Committee Chairmanships (No Changes):

The House Health Committee will continue to be led by Majority Chair Kathy Rapp (R-Warren) and Minority Chair Dan Frankel (D-Allegheny).

The Senate Health and Human Services Committee will continue to be led by Majority Chair Michele Brooks (R-Mercer) and Minority Chair Art Haywood (D-Montgomery).

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LEGISLATION:

Our team is anticipating another very active upcoming legislative session for the PSA. Remember it's a two-year cycle, so any bills introduced now, have until the end of November 2022 to be signed into law.

Below are some of the issues on our legislative and policy agenda.

PSA Supervision Legislation:
Last session, Representative Steve Mentzer (R-Lancaster) and Senator Tom Killion (R-Delaware) both introduced companion bills that would require physician supervision of the administration of anesthesia. We will be advocating for similar proposals again this session.

Anesthesiologists Assistants Legislation:
We plan to work with their professional organization on legislation that would license anesthesiologist assistants, under the medical direction of a physician, in Pennsylvania. More details to come.

PANA Title Legislation:
Last session, Representative Tarah Toohill (R-Luzerne) and Senator John Gordner (R-Columbia) both introduced companion bills that would define and recognize "Certified Registered Nurse Anesthetists" under the Professional Nursing Law. Both proposals failed to cross the legislative finish line, so we are anticipating that similar proposals will be introduced again this session. Representative Toohil already circulated her new "CRNA Designation" co-sponsorship memo. We will continue to keep you updated as we learn more.

CRNP Independence Practice Legislation:
Last session, Representative Jesse Topper (R-Bedford) and Senator Camera Bartolotta (R-Washington) introduced companion bills that would allow Certified Registered Nurse Practitioners to practice more independently from physicians. Both bills failed to get through the legislative process, so we are expecting that they will be reintroduced again.

Hospital Regulations:
At the time of this writing, the hospital regulations have not been made public and we anticipate further delay due to the COVID-19 response. The proposed draft regulations will be made public once they are published in the Pennsylvania Bulletin. At that time, the clock starts on a 30-day public comment period. The proposed draft regulations are over 500 pages, including preamble, proposed changes, and analysis. Once released, we will be reviewing these regulations and PSA will be commenting on any proposed changes that would negatively impact the quality and safety of anesthesia care provided to our patients.

Prior Authorization:
Last session, Representative Steven Mentzer and Senator Kristin Phillips-Hill (R-York) introduced companion bills that would address prior authorization and step therapy to help physicians and other healthcare providers deliver better and more appropriate care to their patients. Both legislators plan to reintroduce similar legislation this session and have circulated their co-sponsorship memos.

We look forward to continuing to work with you and your team this session.
Please let us know if you have any questions or concerns.

Pressure, Transducers, and Manometers – a basic review

Jonathan Roth, MD

Background:

Transducers and manometers are devices for measuring pressure. Pressure is the sum of all the forces of a fluid (gas or liquid) applied against a surface divided by the area of the applied force (P = F / A).

Absolute pressure is zero-referenced against a perfect vacuum. An example would be atmospheric pressure as used by meteorologists. Just as there is no such thing as a negative absolute temperature, there is no such thing as a negative absolute pressure. Pressure is the result of the sum of all the impacts of a fluid (resulting in a force) divided by the area of impacts. The lowest possible value is 0, i.e., no impacts. In common usage, the term "**negative pressure**" means sub-atmospheric pressure.

Gauge pressure is zero-referenced against ambient air pressure (i.e., atmospheric pressure). Examples include blood pressure, tire pressure, or pressure in a gas cylinder. When the cylinder pressure gauge reads "0", there is still gas in the cylinder that is at atmospheric pressure. That gas is not accessible because there is no pressure gradient that would expel the remaining gas in the cylinder.

Thus:

Absolute pressure = Atmospheric pressure + Gauge pressure

Example of a pressure above atmospheric pressure:

If the systolic pressure is 130 mm Hg and atmospheric pressure is 760 mm Hg, the absolute systolic blood pressure is 890 mm Hg. By convention, we measure blood pressure as a gauge pressure, i.e., the pressure difference above atmospheric pressure.

Example of a pressure below atmospheric pressure:

When a blood vessel is opened to the environment, if the pressure in the blood pressure is greater than atmospheric, it will bleed. If the pressure in the vessel is less than atmospheric, air will tend to enter the blood vessel. Fluids always flow from high pressure to low pressure. During spontaneous ventilation, the central venous pressure becomes sub-atmospheric (e.g., -5 mm Hg). If a central venous catheter is then open to the air, air will enter the circulation. Common usage says air is "sucked" in, which is technically not correct. "Vacuum" and "suction" refer to an area of lower pressure. More correctly, air is pushed into the circulation from the higher atmospheric pressure (760 mm Hg absolute or 0 mm Hg gauge) to the lower central venous pressure (755 mm Hg absolute or –5 mm Hg gauge). Air is not pulled, or sucked, by the source of lower pressure.

Converting from one unit of pressure measurement to another:

There are multiple units of pressure measurement commonly used:

1 atmosphere = 760 mm Hg = 760 Torr = 14.7 psi (pounds per square inch) = 1,000 millibar = 1 Bar = 101.3 kPa (kilopascal) = 101,325 Pa (pascals) = 100% = 34 feet fresh water = 33 feet salt water.

To convert from one unit of measurement to another measuring the same quantity, we employ the technique of unit conversion. This utilizes the multiplicative identity that if you multiply any quantity by 1, the value does not change.

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Example: Change 800 Torr to atmospheres
Since 1 atmosphere = 760 Torr, this relationship can be expressed as:

1 atm/760 Torr = 1 or 760 Torr/ 1 atm = 1.

We then choose the appropriate conversion factor according to the units so that the starting unit is canceled out and the remaining unit is the unit we are converting to:

800 Torr x (1 atm/760 Torr) = 1.05 atm.

One relationship of note is between mm mercury and cm water. Mercury has a density of 13.6 grams/mL compared to 1 gram/mL for water. This means that a 13.6 mm fluid column of water will provide the same hydrostatic pressure as 1 mm fluid column or mercury. Since 10 mm = 1 cm, 1 mm Hg = 1.36 cm H20. Thus, mm Hg and cm H20 are commonly used to measure the same quantity as they are close in magnitude to each other.

Manometry

In medical usage, a fluid column is used as a manometer. Common examples would be measuring vascular pressures and opening pressure during a diagnostic lumbar puncture. The height of the column in centimeters estimates the fluid pressure.

In a hydrostatic column of fluid, the gauge pressure at any depth results from the pressure from the weight of fluid above it. Thus, as one descends into the fluid, pressure increases and as one ascends, pressure decreases until it reaches atmospheric pressure (gauge pressure = 0) at the surface. So, in the example of a central venous pressure of 10 cm H2O, a manometer will rise to a height of 10 cm. If the height of the fluid column is less than 10 cm, the pressure at the column surface will always be greater than atmospheric. With unequal pressures, the column will continue to rise. Similarly, if the fluid column is filled above 10 cm, the pressure at the surface of the column will be sub-atmospheric and the column will continue to fall. It is only when the hydrostatic pressure at the top of the column equals the atmospheric pressure will there be a steady state and the column will remain at that height.

One of the ways in which to verify that the vascular puncture is venous (e.g., internal jugular vein) and not arterial (e.g., carotid artery) is by manometry. The fluid column should rise to a height consistent to a venous and not arterial pressure. However, it is essential to overfill the tubing and see the blood level decrease to a height consistent with a venous pressure. If it does not fall or continues to rise, it suggests arterial puncture. The lack of rise is not sufficient. It is possible that it is an arterial cannulation, but the column height happens to stop at a height consistent with a venous pressure because of a technical issue (e.g., catheter against the vessel wall, kinking, plugging…). If it is an arterial cannulation, the fluid column will not fall even if it does not continue to increase in height.

Transducers:

In order to get an accurate measurement, two relationships must be established.

First, the variation in atmospheric pressure must be accounted for. This is accomplished by opening the transducer to air and "zeroing". This tells the transducer system that the atmospheric pressure, whatever it is, will have the value of "0". This pressure will be subtracted from the absolute pressure so the pressure readout will be the "gauge" pressure.

Second, the transducer needs to be on the same horizontal plane as the conventional bodily reference point. For supine patients, this is typically the midaxillary line. If the transducer is lower than this, the transducer will provide a falsely high value and if the transducer is higher than this, it will provide a falsely low value. The magnitude of the error is approximately 2 mm Hg for every inch of height difference.

[Even though the density of blood is 1.06 g/cm3 (1 cm3 = mL) compared to 1.0 g/cm3 for water, for simplicity and ease of calculation we are approximating the density of blood to that of water. The 6% error is clinically insignificant. Recalling that 1 mm Hg = 13.6 cm water and that 2.54 cm = 1 inch, we use unit conversion to get 1 inch water (i.e., blood) height x (2.54 cm/inch) x (1 mm Hg/1.36 cm water) = 1.87 mm Hg. This is commonly estimated as 2 mm Hg for every inch of height variation, or 0.75 mm Hg for every cm of height.]

Errors can occur and are more meaningful in low pressure systems (e.g., venous, portal) than in high pressure systems (arterial). The difference between a pulmonary capillary wedge pressure of 12 vs 18 is clinically more significant than a difference between a systolic blood pressure of 130 vs 124.

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In a transducer of common design, the stopcock, which gets opened to air, may be at a vertical height above where the pressure sensor is located. It is the stopcock, not the pressure sensor, that should be on the reference horizontal plane. Thus, in a vertically oriented transducer where the stopcock is 1 inch higher than the pressure sensor, when the transducer is opened to air, the pressure at the stopcock is atmospheric ("0" gauge), but the height of the fluid column makes the pressure at the sensor = Atmosphere + 2. Thus, at the pressure sensor, the zero reference is pressure = atmospheric pressure + 2. With the stopcock still open, if the transducer is inverted 180 degrees, the sensor will measure atmospheric pressure - 2, and the pressure of - 4, not 0, will be displayed. After the zeroing process and the stopcock is closed, a change in the vertical orientation of the transducer will affect the measurement, which may be significant in low pressure systems. It does not matter what orientation the transducer is in when zeroed. It just needs to stay in that orientation after it is zeroed. In the situation where the transducer is attached to the patient, the transducer should be zeroed after attachment when the orientation will not change.

If a patient is lateral, a blood pressure cuff measures the pressure at the site of measurement. Thus, the measurement on an arm above the heart will be lower and a measurement on an arm below the heart will be higher. In contrast, blood pressure measured by an arterial line is not affected by which arm the arterial line is in but will depend upon the height of the transducer. For example, assuming the transducer is at the level of the heart, even though the pressure in the arm above the heart is less than the pressure at the level of the heart (the pressure will be reduced by the distance from the heart to the site of the catheter), it will be increased by an equal amount because of the height of the fluid column from the catheter site down to the transducer. Similarly, even though the pressure in the arm below the heart will be increased by the distance from the heart to the site of the catheter, it will be decreased by an equal amount because of the height of the fluid column from the catheter site up to the transducer.

With patients in the beach chair position (e.g., shoulder surgery), the brain is significantly higher than where the blood pressure cuff is. A normal cuff blood pressure may result in a dangerously low blood pressure perfusing the brain. Patients have suffered neurologic damage because this was not appreciated and accounted for. In these patients, you may need to keep the cuff blood pressure significantly higher in order to have a normal blood pressure for the brain. This also applies to any situation where the back of the patient is elevated (e.g., thyroid surgery, but to a lesser degree). If using an arterial line and the transducer is on the same horizontal plane as the circle of Willis, no pressure adjustment is necessary regardless of the insertion site of the arterial line.

A related but unanswered question is whether taller individuals should have a higher blood pressure as their normal.[1] Since blood pressure is measured at the level of the heart, it will require a higher blood pressure at the level of the heart to achieve the same cerebral perfusion pressure in a taller patient. The implication is that aggressive antihypertensive therapy may put taller patients at risk for syncope. It follows that tall patients when supine would require the same blood pressure as shorter patients. As an example, from another animal, the blood pressure of a giraffe is 280 / 180 mm Hg. If one corrects for the elevation of the head, the cerebral perfusion pressure of a giraffe is similar to that of a human.

1) Roth JV: Taller people should have higher BMI's and blood pressure measurements as their normal. Biomedical Journal of Scientific and Technical Research, 2018; 6(4): 5396-7.

Congratulations to PSA Member,
Francisco Felipe Suero, MD, FASA,
for being our newest member to become a Fellow of the American Society of Anesthesiologists®!

Safety in the OR, protecting our colleagues.

Benjamin Park D.O. D.ABA

As an anesthesia provider it is my responsibility to protect my patients, and as I often tell them "I will do my best to keep you comfortable and safe." In addition to protecting our patients, we also have a duty to protect our colleagues in the operating room. The past year, has been a time of adaptation and constant changes. One thing that I have noticed is that more anesthesia providers are cognizant of our colleagues in the operating room and concerned with their safety. People seem to recognize and care about risks to our fellow surgeons, circulators, and technicians, now more than ever. Many of these risks have always been present, but with the additional risk of COVID-19, we notice our colleagues' risks more. Who would have thought 5 years ago that many of us would now know the air-turnover averages of our operating rooms?

One of the most common risks to providers in the operating room is exposure to anesthetic gases. In the United States, the National Institute of Occupational Safety and Health (NIOSH) recommends that the exposure should be less than 2 ppm of a volatile anesthetic as a time weighted average of the anesthetic, and no more than 25 ppm of nitrous oxide. These time weighted averages were introduced in 1977 and are significantly lower than in many other countries. Nitrous oxide is not associated with genetic mutations in vitro, but it has been implicated in reduced fertility in exposed dental hygienists (Rowland). The highest exposure to nitrous oxide often occurs with the inhalational induction of children. Other exposures occur during anesthesia circuit disconnects or from the mechanical complications that occur via gas scavenging. When nitrous oxide is used, room contamination occurs at least 25% of the time (Kanmura). Halogenated volatile anesthetics that are currently in use have demonstrated some teratogenic effects in animal studies, at high doses 7+ppm (DOL). Retrospective studies suggest increased rates of spontaneous abortions in providers who are exposed to volatile anesthetics; however, some studies have also suggested no differences. While some providers dismiss these risks associated with occupational exposure to anesthetic gasses, it should be noted that we have a duty to protect our coworkers, and stress itself can be harmful to our colleagues. Simple communication is often the easiest way to protect our coworkers. It is easy to ask if people are comfortable with us turning on volatile anesthetic agents when masking a patient. If they feel uncomfortable or it is absolutely necessary, then we can ask politely for them to stand back to decrease their exposure level.

Another common hazard in the operating room is radiation exposure. Fluoroscopy, c-arms, and x-rays are just some of the sources of radiation. Many times, the surgeon, along with a radiology technician, is primarily responsible for protecting our coworkers from this exposure. However, we, as anesthesia professionals and good stewards of the operating room, should also take responsibility for our coworkers. The goal of radiation safety is to achieve as low as reasonably achievable (ALARA) with regards to radiation exposure. The current recommendations warrant exposure of less than 20mSv per year over 5 years, and no greater than 50mSv in any one year. We often recognize radiation risks to ourselves, but we must also recognize risks to operating room staff. It is important to remember that not all lead gowns surround 360 degrees, and therefore when facing away from the radiation source a person will be left exposed. Sometimes we need to be reminded that we have inadvertently put ourselves at risk because of our body position. Communication is paramount to radiation safety in the operating room. By communicating clearly and politely we can guide our colleagues to increase their distance from the radiation source, which happens to decrease exposure the most (doubling distance decreases radiation by 4-fold). We can guide people to remain shielded and limit personnel in the room during long runs of fluoroscopy. We can remind surgeons that people in the room have taken off lead and need time to replace it. It should be noted that in a 2014 study over ½ of orthopedic residents did not recognize that pregnant providers needed additional protection. Unfortunately, many internal audits at facilities reveal that often providers do not wear thyroid shielding as they should (Whittaker). This is important because the thyroid is one of the most sensitive organs to radiation damage.

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Safety in the OR, protecting our colleagues.

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The newest risk to the operating room and operating room safety is the novel coronavirus (COVID-19). We have learned a lot about this virus over the course of the last year. There has been a lot of information learned about droplet exposure, operating room airflow turnover, and video laryngoscopy. Initially many providers were recommending additional barriers be erected during intubation, which have been shown to reduce aerosol exposure (Fidler). Early intubation was initially recommended in the hopes of limiting viral spread but now intubation is delayed or avoided completely if possible (Cook). In addition, it is recommended that only essential providers be near the manipulated airway, and this works well to protect our colleagues. Many providers have developed methods of extubation to avoid or reduce exposure. Some use a cloth to cover the patient's mouth, others extubate to a facemask, and still others extubate to a protective barrier device. Whatever the decision, it shows a conscious decision to protect our colleagues in the operating room. Awareness of appropriate mask and eye precautions increased as well.

A gentle nudge or reminder is all most of us need to be compliant, and it can be easy for any of us to forget. Of all the examples mentioned, one thing that stands out in improving the safety of people in the operating room is improved communication. Even though times are stressful and communication is made more difficult during times of stress, I believe that I have seen improved communication in most operating rooms. It continues to instill me with pride that anesthesiologists lead in patient safety. And now, we may be able to claim that we are leaders in hospital and operating room safety as well.

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Why the hospitals idea of physician leader means follower

Mark Weiss, MD, FASA

It was the time that I almost died. The car was out of control and I was headed for a cliff. Then I awoke from the dream in a sweat. The smell of pancakes wafted in from the kitchen. I recently read an article about hospitals training physicians for "leadership" roles.

What those hospitals are really doing is training more physicians to become hospital-employed or hospital-controlled managers in order to monitor, cajole and threaten the members of the medical staff to follow mandated cost cutting measures. Oh, excuse me, they called them "quality goals."

Don't get me wrong, I'm all in favor of better quality. I am in favor of doing things the right way. But who should decide what the right way is for Ms. Betty Bobson, age 47, or Mr. Bob Beatty, age 74 — the hospital or that patient's physician? I've dealt with instances in which a surgeon's orders were changed, without consultation, by a hospitalist engaged by the hospital. When the surgeon complained, she found herself subject to a medical staff investigation. Oops! Just a coincidence!

So, if you're the hospital CEO, why not put that situation on steroids?

Instead of the sole hospitalist changing orders, the hospital can now instruct all of its employed or controlled physician "leaders" to enforce what the hospital deems to be evidence-based best practices or protocols or whatever the name of the week is for cookie cutter behavior or for using only those products or pharmaceuticals on which the hospital gets the best deal. But the bottom line is the same: Who is making the decision, Ms. Betty Bobson's physician or the system?

Don't get me wrong, I'm all in favor of physician leaders. In fact, I wonder if an all physician board and all physician top leadership should be requirements for a hospital's Medicare participation? Think about that for a while. But in the politically correct patois of Orwellian hospital double-speak, "leader" now means follower.

Is following orders best for patient care? Is it really best for your career? Your career is in a car and it's heading over a cliff. Ms. Betty Bobson or Mr. Bob Beatty is in the passenger seat. No, it's not a dream. No one is in the kitchen making pancakes. Grab the wheel and do something before it's too late.

How to prevent your Medical group from getting robbed of it's staff

Mark Weiss, MD, FASA

Ever watch those old black and white B-movie Westerns?

The bad guys would ride into town and rob the bank.

"Hands up! Give us all the money!" And then off they'd ride, carrying bags of cash.

What if the writers had put a different twist on how the bad guys robbed banks? Instead of grabbing all of the money and riding off with it, what if they just forced the banker out of the bank and took over the business? First Citizens Bank of Tumbleweed? No! First Bad Guys Bank of Tumbleweed? Yes!

Ha ha, someone is laughing. That's ridiculous, they say.

Unfortunately, it's not at all ridiculous. It happens all the time, except not at banks where it would be a crime but to medical groups, where it's just good business.

A hospital informs the emergency medicine group that's been providing services to it for the past 15 years pursuant to an exclusive contract that the contract won't be renewed next August. Instead, the group's physicians will be offered jobs with the hospital controlled medical group.

Or, a national group takes over the anesthesia contract at St. Mark's Community Memorial Hospital and tells the local group that it will employ all of its members, well, not exactly all, those who don't make the cut, like the local group's executive committee members, should start looking for jobs elsewhere.

Again, what's bank robbery in the Old West is "just business" at the hospital.

But that doesn't mean that you have to make it easy for someone to drop a neutron bomb on your medical group, mooting your business structure and "liberating" your employees.

BIO

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Know Your Equipment: Vaccines for COVID 19

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Introduction

Although physical distancing, facemasks and handwashing has helped in the fight against the COVID-19 pandemic, the greatest weapon we now have is the vaccine. The race to develop this vaccine started on January 11th, 2020, when the genetic code for SARS-CoV-2 was published. As of December 2020, the New York Times coronavirus vaccine tracker lists 63 vaccines in human trials. On December 11th, 2020, the U.S. Food and Drug Administration (FDA) issued an 'emergency use authorization' for Pfizer-Bio N-Tech COVID-19 Vaccine in individuals 16 years of age and older.[1, 2] Currently (January 2021), there are other vaccines for COVID-19 that have been or are soon to be approved, globally. [3] This article is an attempt to give a brief outline of such vaccines. I would like to start with a disclaimer that I am an ordinary, 'village' anesthesiologist and not an expert virologist.

SARS-CoV2 virus

SARS-CoV2 belongs to the same family of β-coronavirus that caused 'Severe Acute Respiratory Syndrome' (SARS) in 2002 and 'Middle Eastern Respiratory Syndrome' (MERS) in 2012. It is about 65–125 nm in size and contains a single strand of RNA as its genetic material. It has crown-like spikes on the surface which facilitates binding to the angiotensin-converting enzyme 2 receptor (ACE-2). SARS-CoV2 has four main structural proteins, namely spike (S) glycoprotein, small envelope (E) glycoprotein, membrane (M) glycoprotein, and the nucleocapsid (N) protein which has the RNA genome. The hemagglutinin esterase dimer serves as a receptor-destroying enzyme and facilitates the entry of the viral genome into the host cell. [4]

Figure 1

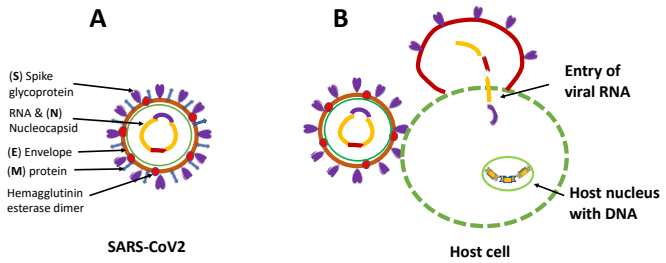

Figure 1: A schematic of the SARS-CoV2 virus (A). B shows the virus attaching to the host cell using the spike proteins, assisted by the hemagglutinin esterase to gain entry into the cell. The genome released into the cell would then generate viral proteins to propagate.

How do Vaccines work?

Even though the concept of immunization dates back many centuries when Buddhist monks drank snake venom to become immune to snake bites, the credit of creating the first vaccine goes to Edward Jenner, who inoculated a 13-year-old boy with vaccinia virus (cowpox) and demonstrated the child developing an immunity to smallpox.

The basic premise of a vaccine is to introduce a small quantity of a disabled microbe into a human body to produce a part of it to stimulate an immune response. Once in contact with microbial antigens, the dendritic cells mature and migrate to the draining lymph nodes and present the antigens to the naïve T-lymphocytes. An antigen-specific activation of the T-lymphocytes results in their transformation into killer T cells and the transformation of B lymphocytes into antibody-producing plasma cells. This adaptive immunity develops immunological memory, allowing the host to rapidly respond when exposed to the same pathogen again.

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Figure 2

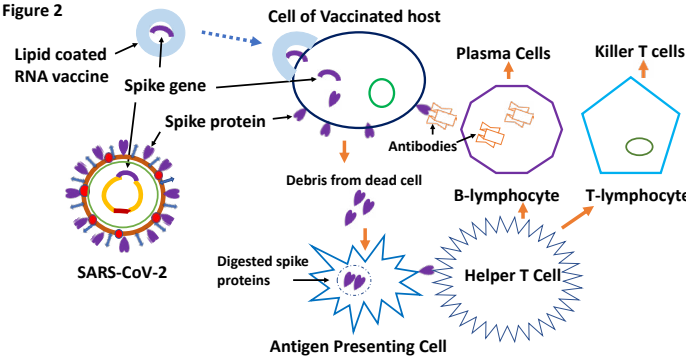

Figure 2: The mRNA vaccine has the genetic code for the spike protein and is swathed in a lipid layer to provide stability. When it enters the human cell, the ribosomes use this RNA to produce numerous copies of the spike protein. The spike protein is presented on the cell surface and when the cell dies, this antigen is engulfed by the dendritic cell, which presents it to the lymphocytes in the lymph node, leading to production of antibodies and killer T cells.

How is Vaccine Efficacy measured?

The efficacy of a vaccine is a measure of the proportionate reduction in disease among those who are vaccinated or the risk reduction attributable to the vaccine. It can be expressed mathematically as:

$$\text{Efficacy} = \frac{\textit{(Risk among unvaccinated-Risk among vaccinated)}}{\textit{(Risk among unvaccinated)}}$$

However, there are two important aspects of efficacy. How much is acceptable and what risk does the vaccine reduce? The WHO, as a target profile for COVID-19 vaccines, has suggested that an acceptable vaccine should demonstrate an efficacy of above 50%-point estimate and that efficacy can be assessed against transmission, infection, severe disease, or death by COVID-19. Therefore, while assessing a vaccine, attention should be paid to what outcomes were measured during the study.

Platforms for vaccine generation

The mechanism of introducing the 'antigen' into the host varies with the type of vaccine. Here is an outline of the four types of platforms that are currently used to create vaccines, with examples of COVID-19 vaccines made using that technique.

Figure 3

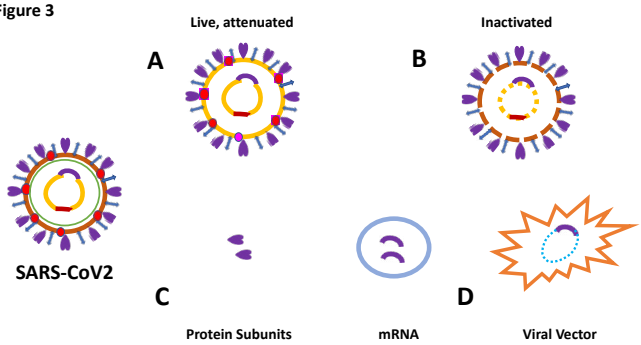

Figure 3: The four platforms that are used to make vaccines are the live- attenuated (A), the inactivated (B), the protein subunit (C) or the nucleic acid (D). The nucleic acid can be carried as such or attached to a viral vector. Please refer to the text for examples of each type.

Live, attenuated: It contains a living virus or bacteria that has been weakened so that it is unable to cause disease in people with a healthy immune system, but can stimulate the immune system. Children with weakened immune systems and those undergoing chemotherapy should not receive this type of vaccine. The MMR (measles, mumps, and rubella), Varivax (varicella-chickenpox), Influenza (nasal spray), Rotavirus, BCG (tuberculosis), yellow fever and the oral polio (OPV) are all attenuated, live vaccines. The FluMist Quadrivalent (AstraZeneca) contains live, attenuated influenza A virus and is delivered as a nasal spray.

> **Covi-Vac** (Codagenix) is a single-dose, intranasal, live-attenuated vaccine against COVID-19, generated using a proprietary deoptimization technology. It is designed to produce immunity against all SARS-CoV2 proteins and is associated with long lasting cellular immunity. These vaccines are ready for phase I clinical trials. Codagenix is partnered with the Serum Institute of India, the largest vaccine manufacturer in the world. [5, 6]

Inactivated: These vaccines are made by inactivating or killing the whole virion or bacteria and therefore cannot cause the disease, but the antigens can stimulate an immune response. The inactivated polio (IPV), hepatitis A, rabies and the commonly used vaccine for seasonal 'flu' contain inactivated virus.

> **Covaxin** (Bharat Biotech, India) is a whole-virion inactivated vaccine that has been approved for use in India. Clinical trials have shown that it can elicit IgG production against spike (S) protein and nucleocapsid (N) protein of SARS-CoV2 and stimulate a strong cellular immune response.

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Corona Vac (Sinovac) contains Coronavirus that is grown in monkey kidney cells and then inactivated with beta-propiolactone. [5] The inactivated viruses cannot replicate, but the spike proteins can stimulate an immune response.

Protein subunit: These vaccines contain parts or a specific protein of the microorganism. Since these contain only the antigen and not the whole pathogen, these are safer and easy to produce. However, these often require an adjuvant to enhance the immune response and may need booster shots to achieve ongoing protection against the disease. The acellular pertussis (whooping cough) component of the DTaP vaccine is a protein subunit. These subunits can be specific pieces of the micro-organism, such as its protein, sugar (polysaccharide) or capsid, and need special processing.

Conjugated: Certain vaccines that are based on the polysaccharides of the outer coating of the bacteria, are augmented by attachment (conjugation) to a protein antigen. Since the immune response in children to the original Haemophilus influenzae type b (Hib) was insufficient, this polysaccharide vaccine was conjugated to a protein antigen to offer improved immunogenicity

Recombinant: The protein subunit for the vaccine can be created via genetic engineering. The gene coding for a viral protein is inserted into another virus or into producer cells in a culture. When the carrier virus reproduces or when the producer cell metabolizes, the vaccine protein is created. Hepatitis B and shingles (Shingrix) vaccines are created by recombinant DNA technology.

Novavax (NVX-CoV2373) contains the spike protein of SARS-CoV2, made using the recombinant nanoparticle technology and a proprietary saponin-based Matrix-M™ adjuvant. The purified S protein is produced in insect cells. [5] This vaccine can neither cause COVID-19 nor can it replicate. It is stable at 2- 8°C and is shipped in a ready-to-use liquid formulation that permits distribution using existing vaccine supply chain channels. The first interim analysis of the Phase III study in UK, suggests a point estimate of vaccine efficacy of 89.3% (95% CI: 75.2 – 95.4). This was based on 62 cases of COVID-19, of which 56 cases were observed in the placebo group versus 6 cases in the NVX-CoV2373 group. Of the 62 cases, 61 were mild or moderate and 1 in the placebo group was severe.

Peptides: The protein fragment or subunit is synthetically produced. This methodology is new for human vaccines and is being used in the early stages of production for COVID-19 vaccines.

Toxoid: Certain bacterial infections are caused by the toxins that these bacteria produce. These vaccines contain inactivated forms of the toxins, which are called toxoids. The DTaP vaccine contains the toxoids of diphtheria and tetanus.

Nucleic Acid: A relatively recent technique of vaccination involves introducing into the recipient the genetic material that codes for the antigen against which an immune response is sought. The human cells use this genetic material to produce the antigens that then activates the immune system.

RNA vaccine: These vaccines are made of the messenger RNA (mRNA) that encodes a specific protein of the pathogen. When the mRNA enters a human cell, the machinery within the cell translates it into the encoded viral protein, which then activates the immune system. The mRNA is encapsulated inside a lipid membrane, which protects it when it first enters the body and also helps it to get entry into the cell by fusing with the cell membrane. Once the viral protein is generated, the mRNA is broken down by the cell. The RNA vaccines are not capable of combining with the DNA or the genetic code of the recipient cell.

BNT-162b2 (Pfizer BioNTech) contains the nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 and has been shown to have 95% (95% confidence interval - 90.3%–97.6%) efficacy in preventing symptomatic COVID-19. It must be stored and shipped at -70°C and the dose is administered as two intramuscular injections, 21 days apart.

mRNA-1273 (Moderna) vaccine contains the nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 and has been shown to be 94.1% (95% confidence interval - 89.3%–96.8%) efficacious in preventing symptomatic COVID-19. It must be stored and shipped at -20°C and administered as two IM injections 28 days apart.

Self-amplifying RNA (saRNA)- The unique feature of saRNA is that it produces more copies of the RNA, once it enters the host cell, resulting in higher protein expression. A saRNA vaccine that can be administered by inhalation is being developed by the Imperial College, London.

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DNA vaccines: These vaccines have the plasmid DNA that contains the code for the target protein. The genetic code is incorporated into the nucleus of the host cell before it can be translated to mRNA. The cellular ribosomes use this mRNA to produce the antigen protein which stimulates the immune response. DNA vaccines are more stable than the mRNA ones and are typically administered using a technique called electroporation, which uses low level electronic waves to allow the cells to take up the genetic material.

INO-4800 (Inovio Pharmaceuticals) is a DNA vaccine for COVID-19 that is in the initial stages of development

Viral vector: These types of vaccines use an unrelated harmless virus (the viral vector) to deliver a section of the genetic material of the disease-causing virus. The human cells use the genetic material to produce the encoded viral protein, which is recognized by the immune system. The viral vector could be replicating and retain its ability to make new viral particles alongside delivering the viral antigen, or be non-replicating. Ervebo (rVSV-ZEBOV), a vaccine to prevent Ebola, uses a recombinant vesicular stomatitis virus as its vector.

Covi Shield AZD-1222 (AstraZeneca/Oxford University) uses a non-replicating, chimpanzee adenovirus (ChAdOx1) as the vector to carry the genetic code for the spike protein of SARS-CoV2. The efficacy of this vaccine has been shown to be 62%, although in a subset of patients who received a lower first dose, it was found to be 90% efficacious. This vaccine is approved for clinical use in the UK and India

Ad26.CoV2.S (Johnson & Johnson) uses a recombinant adenovirus, Ad26, to carry the code for the spike protein. This vaccine was 66% protective against moderate to severe Covid infections. This single-dose vaccine is estimated to remain stable for two years at -20°C (-4°F) and for three months at 2-8°C (36°F–46°F). This vaccine has the potential to be the next vaccine approved for clinical use in the USA.

Sputnik V or Gam-COVID-Vac Ad26, Ad5 (Gamaleya Research Institute, Moscow), contains two recombinant adenovirus (types 26 and 5) and was approved for clinical use in Russia in August 2020. The vaccine is administered (0·5 mL/dose) intramuscularly with a 21-day interval between the first dose (rAd26) and the second dose (rAd5). Both vectors carry the gene for the full-length SARS-CoV2 glycoprotein S. It has been shown to be safe and has an efficacy of 91.6%. [7] Recipients produced antibodies against the spike proteins and generated CD4+ and CD8+ responses.

The race for a vaccine to control this devastating pandemic has begun and the pace is unprecedented due to the pooling of global resources. The challenges ahead are many.

Creating one or more vaccines that is effective in controlling this virus including any mutant variant that it creates in the future.

Mass production of the appropriate vaccine to immunize the global population.

The logistics of vaccinating the population of the world or at least generating a 'herd immunity' to control the spread of this pandemic.

Till then, it is our moral obligation to maintain physical distancing, use facemasks and practice good hygiene.

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Anesthesia and Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C)

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I was recently surprised to be introduced to a young man in his 30s with an implantable defibrillator. He required general anesthesia for a relatively minor procedure. I asked him why he had the defibrillator and he stated that he had ARVD diagnosed after his father died suddenly a few years prior. I excused myself, walked around the corner and consulted Dr. GOOGLE.

ARVD or arrhythmogenic right ventricular dysplasia (sometimes also called arrhythmogenic right ventricular cardiomyopathy) is a progressive form of cardiomyopathy in which the heart muscle of the right ventricle is replaced by fat and fibrous tissue. The dysplasia usually leads to dilatations or aneurysms frequently leading to paradoxical systolic motion. Although usually spared, in more extensive cases, the left ventricle and septum may be involved. It occurs in one in 5000 individuals and males are affected more commonly in a 3:1 ratio. Thirty percent to fifty percent of the individuals with the disease have an associated family history demonstrating a genetic predisposition.

Over time, the right ventricle becomes dilated and contracts poorly leading to right heart failure. More importantly, patients with ARVD often have arrhythmias which can increase the risk of sudden cardiac arrest and death. It is usually diagnosed before the age of 40 and is a cause of sudden death in the young. This is a common first sequelae when a family history has not yet been identified and the family followed. Symptoms of ARVD are often nonspecific and include chest palpitations, dizziness, fainting and shortness of breath.

Researchers have found two patterns of inheritance for ARVD. Within the autosomal dominant inheritance pattern, the symptoms and age of onset may be different between family members. The autosomal recessive form is commonly associated with a syndrome called Naxos disease. Naxos disease is associated with thickening of the outer layer of skin on the palms of the hands and soles of the feet (hyperkeratosis) and thick, "wool-like" hair.

Fifty to ninety percent of persons with ARVD will have some characteristic findings on a resting electrocardiogram (ECG). These findings include T-wave inversion in the anterior precordial leads (V1 through V6), "epsilon waves" (small deflections just after the QRS complex best visualized in leads V1 through V3), and left bundle branch block reentrant ventricular tachycardia, although polymorphic and right bundle branch block patterns have also been reported. Any potential in leads V1 through V3 that exceeds the QRS duration in lead V6 by more than 25 milliseconds should be considered an epsilon wave.

Not all of the genetic mutations that cause ARVD have been identified and there are no specific genetic tests. The preferred method for making the diagnosis is based on histologic evidence of fibrofatty myocardium. Unfortunately, biopsy lacks sufficient sensitivity because of the segmental nature of the disease process. Therefore, the diagnosis is made with invasive and noninvasive modalities. Noninvasive testing includes Holter monitoring, exercise stress testing, chest radiography, and cardiac MRI. Invasive testing includes right ventricular angiography, contrast echocardiography, electrophysiologic studies, and endomyocardial biopsy as above.

Treatment involves antiarrhythmic medications. Intravenous amiodarone reportedly has been effective in terminating acute VT in patients with ARVD. Nor one drug or class of drugs has been shown to effectively abolish the arrhythmias so combinations of drugs of different classes are commonly used. Radiofrequency ablation is used in cases of drug refractory arrhythmias. Commonly, a series of ablations are required since numerous foci are involved. After successful ablation, "relapses" occur because of disease progression that creates a new reentrant circuit. AICD placement is performed to provide anti-tachycardia pacing and defibrillation shocks as needed when arrhythmias occur. Timing of AICD placement is debatable because no reliable risk stratification exists for patients with ARVD. In general, placement of an AICD should be strongly considered in patients with drug-refractory arrhythmias.

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Other indications for an AICD include younger age at onset, cardiac arrest, and left ventricular involvement. (1)

So, how does this affect anesthesia management? In an article from 2000 entitled "Unsuspected cardiac lesions associated with sudden unexpected perioperative death", the authors examined 1700 forensic autopsy reports and found 50 cases of death under anesthesia performed on presumed young ASA 1 patients. Forty seven had cardiac lesions of which 18 had the pathologic diagnosis of ARVD. Cardiac arrest took place upon induction of anaesthesia in 16 percent of cases, during surgery in 64 percent and at the end of surgery in 20 percent. (2)

Maintaining a hemodynamic state near normal physiological conditions for the patient is vital for arrhythmia protection. Along with routine monitoring, an arterial line should be strongly considered regardless of the invasiveness or length of the procedure since a significant portion of the deaths are on induction and emergence. For more invasive procedures, monitoring central venous pressure could be beneficial to provide information about right heart function and filling status. Intraoperative transesophageal echocardiography would be extremely beneficial and avoids the risks of arrhythmia from a central line and/or pulmonary artery catheter. Non-invasive forms of continuous cardiac output monitoring allow assessment of contractility and ventricular filling.

All anesthetics can lead to changes in hemodynamics, therefore, to suggest one agent or method (general versus regional for example) is not as important as being vigilant with hemodynamic control, avoiding hypoxemia and hypercarbia and keeping serum electrolytes within a normal range. Considering some intensive care time after anesthesia would not be overkill with this disease. (3)

My patient did well, but I had episodes of palpitations during his care.

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