

(Don't) Let the Air Out



Litigation in the Era of COVID-19
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OCTOBER 2020

Volume 39 Number 10





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# Safe Elections During COVID-19

The role of emergency medicine physicians and public health

by KRUTIKA KUPPALLI, MD; MADELINE GRADE, MD, MPH; AND MARY MERCER, MD, MPH

he COVID-19 pandemic has had downstream effects on global elections as governments are forced to balance health and safety concerns of the public against the need for maintaining a democratic process. To optimize the chance of a safe election from a public health perspective, all citizens must play a role in reducing community transmission.

#### **Before Election Day**

A low community transmission rate on election day will minimize the chance of exposure and infec-

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**ELECTION 2020** 

People line up in Arlington, Virginia, during first day of early voting, 2020 presidential election.

#### 5 Emergency Physicians Vying for Congress

Meet your colleagues who are running for federal office this fall

by L. ANTHONY CIRILLO, MD, FACEP

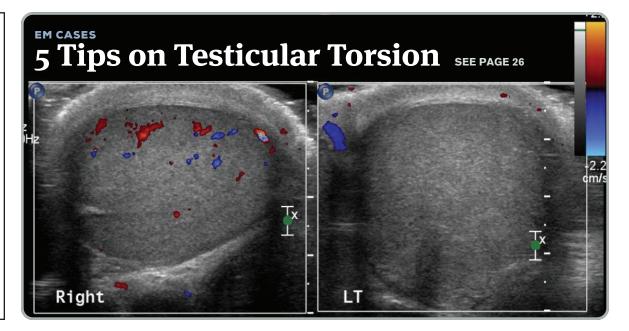
Nov. 3, 2020, a record number of emergency physicians will be on the ballot for election to the U.S. House of Representatives. Incumbents Mark Green, MD, and Raul Ruiz, MD, MPH, MPP, will be seeking reelection, while Ronny Jackson, MD; Rich McCormick, MD, MBA; and Hiral Tipirneni, MD, are seeking to increase the ranks of emergency physicians elected to federal office. Each of the emergency physicians running took some time to discuss their personal stories with me and answer a few questions to provide you with a sense of what they view as impor-

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#### **NEWS FROM THE COLLEGE**

**UPDATES AND ALERTS FROM ACEP** 

#### **Final Countdown to ACEP Scientific Assembly Is On**

WHO: Emergency physicians and other emergency care professionals from across the globe! It's easier than ever for our international audience to participate—no travel expenses, no hotels, no additional costs-so this is the year to give ACEP a try. And at a time when finances are tight for everyone, the value is there—just \$1.80 per CME credit hour for ACEP members.

WHAT: ACEP20 promises an unconventional (BETTER!) experience, way beyond your customary Zoom calls. The lineup features special guests like Anthony Fauci, MD; Ibram X. Kendi, PhD; and Laurie Santos, PhD, plus EM experts including Amal Mattu, MD, FACEP; Michael Winters, MD, FACEP; Marianne Gausche-Hill, MD, FACEP; and more. Learn from more than 250 live and on-demand courses in 28 different clinical and practice tracks. Take home pearls that you can use in your practice on your next shift. Plus, attend social events to stay connected, from distance dining with EM luminaries to battling your peers in Fortnite and swapping stories over s'mores. Popular regular features will be available, too, including career assistance, an interactive exhibit hall, and more.

WHEN: Oct. 26-29, with access to the courses for three years. The 22 hours of live content CME can be claimed immediately following the conclusion of the event, commensurate with your participation. The 250-plus hours of on-demand content will also be available starting Oct. 26.

WHERE: If you've been wondering what the ACEP20: Unconventional experience will look like, the preview at www.acep.org/sa/ education/videos provides a sneak peek at the many ways you'll be able to learn, connect, and have fun with your tight-knit EM community.

WHY: Because without you, ACEP just wouldn't be the same. Your voices and participation keep the specialty moving forwarddon't be left behind. Go for the education, the community, the career advancement opportunities. Or for the chance to break from the daily grind and treat yourself to some "me time." Whatever your reason, we hope you'll join us. Register today at www.acep.org/acep2o.

#### **Virtual Grand Rounds Continue with Neurology Topics in November**

ACEP's Academic Affairs and Education Committee created the monthly Virtual Grand Rounds program in April as a way to provide free education for emergency physicians and residency programs during this time of social distancing. It allows you to track learner participation while engaging in Q&As with course faculty on different monthly topics. Once the sessions are complete, they are posted in the ACEP eCME catalog for online learning. Topics previously covered include COVID-19, physician wellness, airway, ultrasound, pediatrics, and international perspectives on COVID-19. Register at www.acep.org/ virtualgrandrounds.

• Nov. 18: Neurology

• Dec. 16: Cardiology

- Jan. 27: Vulnerable Populations/Social Determinants of Health
- Feb. 24: Simulation: OB Emergencies with

#### **ACEP Introduces Peer Support Project**

ACEP recently introduced a new initiative, the ACEP Peer Support Project, designed to grow a network of peer supporters within emergency medicine while helping institutions break down barriers to care. Visit www.acep. org/peer-support-project to access new peer support resources and join the SupportER list.

#### **Navigate Election Season** Through the ACEP 2020 Voter **Resource Center**

ACEP created a special tool to help you engage in the 2020 elections and beyond. Check out the 2020 Voter Resources for nonpartisan information where you can easily check if you are registered to vote, see how to vote early, or request an absentee ballot. You can also share with colleagues, family, and friends. ACEP members can link to information about the influence and activities of the National Emergency Medicine PAC, ACEP's political action committee. See page 1 for more 2020 election updates.

#### **Get Your X-Waiver Training on**

ACEP, in partnership with Providers Clinical Support System, is hosting Medications for Addiction Treatment (MAT) X-Waiver (DEA DATA 2000) trainings this fall and in early 2021. These are free virtual live trainings done through the Zoom platform. Attendees who sign up for this training will attend a live fourhour webinar taught by clinical experts. Once the live session is completed, participants will receive the second half of the course, a fourhour online self-study portion. Participants are required to pass an exam to complete the training, and the course completion certificate does not expire. Sign up at www.acep.org/ ed-x-waiver. See page 16 for more information on MAT X-Waiver trainings.

#### Improve Your ED's Pain and Addiction Care

We may be in the midst of a global pandemic, but the opioid epidemic isn't going away. ACEP's newest accreditation program, Pain and Addiction Care in the ED (PACED), is the nation's only specialty-specific program that allows emergency departments to improve pain and addiction care. Elevate the quality of patient care with innovative treatments, alternative modalities, and impactful risk reduction strategies in a collaborative team setting, resulting in positive outcomes for your patients, families, health care workers, and communities. Learn more at www.acep.org/ paced. •

# **ACEP Surveys Members About COVID-19**

Emergency physicians speak out on how the pandemic has changed their work environment

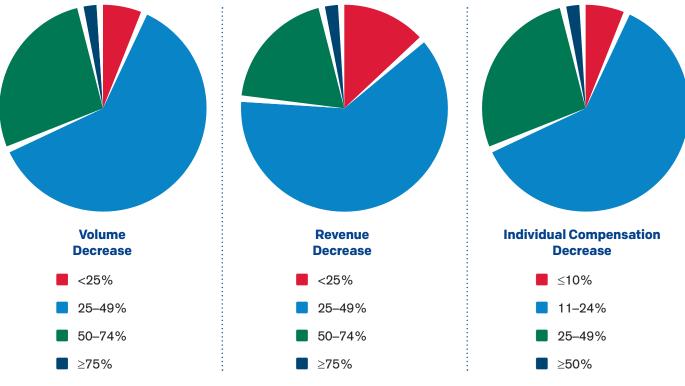
physicians on the front lines who are risking their own lives to combat the disease. ACEP has been actively advocating on your behalf to provide you with the tools and resources you need to safely do your job during the COV-ID-19 public health emergency. As part of that effort, ACEP staff, in conjunction with a subgroup of the ACEP Reimbursement Committee, designed a survey to help inform our advocacy strategy. The survey included 24 questions about the financial impact that COVID-19 has had on emergency medicine group practices and individual emergency physicians.

We received 197 responses, representing all emergency medicine group practice structures, group sizes, and historic volumes from across the country. The data confirmed anecdotal stories of the impacts on emergency medicine group practices, with almost all respondents reporting issues with the lack of reliable personal protective equipment and decreased volume and revenue.

Key findings on ED volumes and revenue are shown at right.

Visit ACEPNow.com to see more results from the survey. •





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#### **TOXICOLOGY Q&A**



# Plants Don't Growl But You Wish They Did

by JASON HACK, MD, FACEP, FACMT

Question: What toxin makes this pretty plant one to watch for—and avoid?

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- LPs in Febrile Infants 29-60 Days Old?
- Suicidal Risk: Assessment and Intervention
- Cardiovascular Pearls, 2019
- **DKA and Hyperglycemia Update**
- Sore Throat: Still Trying to Get It Right
- Sexual/Racial/Ethnic Disparities in the ED
- ACS & PE ACEP 2019 Guidelines
- Psychiatric Patients: Medical Evaluation
- Sepsis 2019: Hot Off the Press
- Challenges of Atrial Fibrillation Part 1
- Challenges of Atrial Fibrillation Part 2
- Otitis Media Doesn't Cause Fever
- Pearls from ED Leadership Monthly
- Pearls from Risk Management Monthly
- **Urologic Imaging Guidelines**
- Pediatric Vomiting and Diarrhea
- Trauma 2019: Hot Off the Press Myths in Emergency Medicine
- Myths in EMS Care
- ATS/IDSA Updated Pneumonia Guidelines
- Visual Diagnosis Challenges Part 1
- Visual Diagnosis Challenges Part 2
- Important Recent EM Literature Part 1\*
- Important Recent EM Literature Part 2\*

Topics listed with an asterisk (\*) are 90-minute faculty panel discussions all other topics are 30 minutes.











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# **ABEM's New President** on MyEMCert and More

Dr. Mary Nan S. Mallory tackles critical EM certification issues for ACEP Now





The American Board of Emergency Medicine (ABEM) has been transforming its approach to certification, a process that will culminate with the launch of MyEMCert next year. Mary Nan S. Mallory, MD, MBA, the new ABEM President, who was elected in August and serving for the 2020-2021 term, will be taking this multiyear process across the finish line.

Currently vice dean for clinical affairs and professor of emergency medicine for the department of emergency medicine at University of Louisville School of Medicine as well as an attending physician at the University of Louisville Hospital in Louisville, Kentucky, Dr. Mallory has been a member of the ABEM Board of Directors since July 2012 and ᠄ was elected to the Executive Committee in 2019.

Dr. Mallory recently responded in writing to ACEP Now's questions about her goals as ABEM President and the future of certification.

#### What are the priorities for ABEM this year?

Our number-one priority is to help physicians transition to a more continuous and lower-risk certification process. We will be continuing our conversations with physicians about changes to our certification process, such as online ConCert, the implementation of MyEMCert, and a virtual oral exam. We've designed these transitions based on what we've heard from physicians.

#### Why did ABEM go to a five-year certification cycle?

A number of factors contributed to the decision to change the certification cycle. It became apparent that smoothing out the costs of certification, launching MyEMCert, and shortening the 10-year certification cycle were all likely to occur very soon. The best way to accommodate these changes was to introduce the five-year certification cycle as soon as possible. Spacing out anticipated changes, such as an annual fee, MyEMCert, and a shorter cycle, would have created even greater complexity, which would have been difficult for physicians to navigate. In addition, if ABEM certification is going to remain a strong credential, we've got to reduce the time during which a certified physician could be not completing any certification activities. The five-year certification cycle creates a process that encourages ongoing engagement to keeping up with key advances in the specialty.

By instituting the five-year cycle with the launch of MyEMCert in 2021 and by going to an annual fee, the number of times physicians have to adjust to change will be minimized. It also simplifies the continuing certification process and reduces the total number of requirements. The move from 10-year to five-year certification—while simultaneously moving to an annual fee structure—does not come with any increased activity or additional costs.

Another factor ABEM took into account was the American Board of Medical Specialties Vision Initiative report that recommends certifying boards create a continuing certification process. A five-year cycle promotes more regular engagement in the process.

Finally, changing to a five-year cycle now allows physicians with certifications expiring in 2021 to recertify using MyEMCert. That gives nearly 3,000 physicians an opportunity they would not have had without going to a five-year certification cycle.

#### Also, why did ABEM choose to change to an annual fee?

The switch will allow physicians to avoid paying a one-time, large lump sum fee for the recertification exam (ConCert), which was \$1,950. Instead, physicians will pay an annual fee that will approximate the same amount as physicians are now paying for continuing certification. And any physician who has paid more than \$1,400 toward continuing certification activities will receive a check for the difference. (Refunds apply only to fees paid for successful completion of the ConCert Exam and Lifelong Learning and Self-Assessment tests; they will not apply to fees paid for retaking exams or for late fees.) None of these changes will result in increased revenue for ABEM. In fact, the five-year certification cycle will result in considerably less continuing certification revenue over the next decade.

Increasingly, ABEM directors heard from physicians that they wanted an annual fee structure. Physicians are then able to budget a lesser amount on an annual basis in their continuing professional development allocations instead of a large amount at one time when taking

#### What is the latest news on MyEMCert?

MyEMCert development continues at a rapid pace. Participants for the pilot have been selected, and the pilot begins this fall.

ABEM recently posted MyEMCert presentation scenarios—the core content for the specialty—on our website. We've also been developing key advances, areas in which there has been incomplete adoption of certain practices into emergency care. One example is the selection of acute ischemic stroke patients for potential endovascular reperfusion therapy. Some key advances are fairly recent, some less so, but the unifying theme is that we need to integrate these evolving practices into clinical care.

#### What new technology or apps are being developed or considered by ABEM to allow continuous interaction with the ABEM certification process from mobile devices?

The ABEM public website was redesigned a couple of years ago and is fully responsive, so it can be viewed on a mobile device. The new ✓ ABEM Reqs tool on the public website has been added so that you can check your requirements based on the year your certification expires. Although several app ideas have been explored, right now our resources are focused on the development of the MyEMCert platform. We hope to look into those ideas again after MyEMCert has launched and been fine-tuned. ABEM is also developing a virtual oral exam to accommodate physicians who were scheduled to take the exam in 2020.

#### What is ABEM doing to support physicians and destigmatize mental health challenges?

ABEM works with physicians who have had medical license issues as a result of mental health or substance disorders so that they don't lose their certification. We supported 2019 Council Resolutions that addressed these concerns. We work with physicians in recovery programs to help them maintain their certification. ABEM believes that seeking assistance for mental health challenges is a sign of medical professionalism. Physicians are encouraged to contact ABEM prior to surrendering any state medical license to understand potential implications to their ABEM certification.

#### What is ABEM doing about the issues of advanced practice providers?

ABEM recently issued a statement and press release stating that the delivery of emergency care is best led by ABEM-certified physicians. While ABEM honors the contributions to emergency care by other providers, the path to become a nurse practitioner or physician assistant is not equivalent to the complex training required to become an ABEMcertified physician. ABEM-certified physicians should be leading teambased care in the emergency department.

#### Finally, what would you like ACEP members to know about you that they might not know?

While my vitae reads of an academic physician, it's my early career experiences in military medicine, as well as the years spent practicing emergency medicine in rural and community hospitals, that continue to inform and shape my service commitment to ABEM's mission of ensuring the highest standards across our specialty. But there's life and lifelong learning to be had outside of the professional classroom, too. My husband and I enjoy long weekends hiking, wading, and roll-casting in the Great Smoky Mountains, where we are awed by the natural beauty of its streams and continually humbled by the innate brilliance of its wild trout. •

#### EM CANDIDATE PROFILES | CONTINUED FROM PAGE 1

tant issues at this time. Here, presented alphabetically, is a brief profile of each candidate and their responses to the following questions:

- 1. What is the most important issue facing the nation today?
- 2. What is the campaign issue that are you most passionate
- 3. In the midst of the pandemic, health care insurers are making record profits while emergency physician practices are challenged by significant decreases in emergency department volumes. What can Congress do to ensure that health care insurers spend more on patient care and less on profits for shareholders?



#### Rep. Mark Green, MD (R, incumbent TN-7)

Following his graduation from West Point, Dr. Green was initially an infantry officer. He graduated from Boonshoft School of Medicine at Wright State University and became a flight surgeon, serving tours of duty in the Afghanistan War and Iraq War. He authored a book about his

experience in Operation Red Dawn, which saw the capture of Saddam Hussein. Following his military retirement in 2006, Dr. Green founded a hospital emergency department physician group in Tennessee as well as two free clinics.

Dr. Green first entered politics in 2012 by defeating Democratic incumbent Tim Barnes for a seat in the Tennessee State Senate. When Rep. Marsha Blackburn announced her candidacy for the United States Senate in 2018, Dr. Green announced his campaign to succeed her and was sworn into his first term of office in January 2019 and currently serves on the Foreign Affairs, Homeland Security, and Oversight and Reform committees. Dr. Green has sponsored legislation important to emergency medicine, especially in the areas of rural health and access to care.

- 1. "In the near term, the most important issue is obviously the COVID-19 pandemic. As a nation, we need to stay focused on addressing the challenges created by COVID. We need to continue to find innovative ways to address those challenges, like the creation of Operation Airbridge to improve the availability of PPE [personal protective equipment] and Operation Warp Speed to speed the develop of vaccines. We need to make sure that we have vaccines that are safe and that everyone who's eligible gets vaccinated."
- 2. "For me, running here in the Tennessee 7th district, the issues that are most important to my constituents are safety and security. People are concerned about local safety with rioting and protests but also still concerned about the global threats of terrorism and what a Russia/China: alliance would mean to global security. The other issue that I am focusing on is how to improve our economy and reduce the national debt. [Also,] our fiscal House powers our national security, and we need to find ways to safely get our economy growing again."
- 3. "We have to defend the doctor-patient relationship. Insurers have put a wedge between doctors and patients. My role, as an emergency physician in Congress, is to

educate the Congressional leaders and my colleagues on how legislation that only helps insurance companies will have devastating downstream effects on the stability of our health care delivery system in this country. I need the help of every emergency physician to amplify that message by taking the time to educate their individual members of Congress."



**Rear Admiral** (Ret.) Ronny Jackson, MD (R, candidate **TX-13**)

Born and raised in the town of Levelland, Texas, Dr. Jackson graduated from Texas A&M University at Galveston and then attended medical school at the University of Texas Medical Branch. During his time in

medical school, he served in the Navy Reserves and immediately upon graduating in 1995 began his active-duty military career as an officer in the U.S. Navy. In 2001, after five years in the Navy Diving community, Dr. Jackson returned to the Naval Hospital in Portsmouth, Virginia, to complete his residency in emergency medicine.

In 2006, while serving in Iraq, Dr. Jackson was selected as a White House physician in the George W. Bush administration. Over the next 14 years, he served three administrations includ-



ing serving as the director of executive health care for the president's cabinet and senior staff, physician to the White House, and commanding officer of the White House medical unit. In January 2019, President Donald J. Trump appointed Dr. Jackson as assistant to the president and to the newly established role of chief medical advisor to the White House and the Executive Office of the President.

Dr. Jackson retired from the military as rear admiral on Dec. 1, 2019, with his last duty assignment at the White House.

- 1. "The most important issues facing the nation today are related to our safety and security, including our medical, economic, and physical safety. As a nation, we are being challenged by COVID-19 and its effect on all aspects of our daily life. We need to continue to rally all the resources at all disposal and work together to ensure that we get our country safely moving forward toward a return to normal."
- 2. "In my campaign I am most passionate and excited about the opportunity to be a voice in D.C. that truly represents the people and being a voice for doing the right thing. I am not afraid to challenge my Congressional colleagues on both sides of the aisle to focus on passing thoughtful and sensible legislation that reflects what is best for the entire nation."
- 3. "As a member of Congress, I will work to ensure that insurance companies, especially large, for-profit companies, do not get to use their size and large profits to take advantage of frontline physicians or small and rural hospitals. As physicians, we also need to educate and remind our patients that we are their advocates in the health care policy debate. I will push for insurance companies to be more transparent in how health care premium dollars are being

spent and how physicians are not the real problem in the increasing cost of health care in this country."



#### Rich McCormick, MD, MBA (R, candidate GA-7)

Dr. McCormick is a graduate of Morehouse School of Medicine in Atlanta, where he was also student body president. He completed a residency in emergency medicine through Emory while training at Grady Hospital in Atlanta. He received his MBA from National University in La Jolla, Califor-

nia. With over 20 years in the U.S. Marine Corps and Navy, Dr. McCormick served in combat zones in Africa, the Persian Gulf, and Afghanistan. As a Marine, he flew helicopters and taught at Georgia Tech and Morehouse College as the Marine officer instructor. In the Navy, Dr. McCormick earned the rank of commander and served as the department head for the emergency medicine department in Afghanistan. At the completion of his military medicine career, Dr. McCormick returned to private clinical practice and currently practices at Gwinnett Medical Center and Northside Hospital in Georgia.

1. "I believe that we have to stop the march toward thinking that government is the solution to our problems. We have been asking government to fix the problems that they created. Government may be well intentioned, but too much government regulation has reduced physician compensation and given physicians less control over the most important part of health care...the doctor-patient relationship."

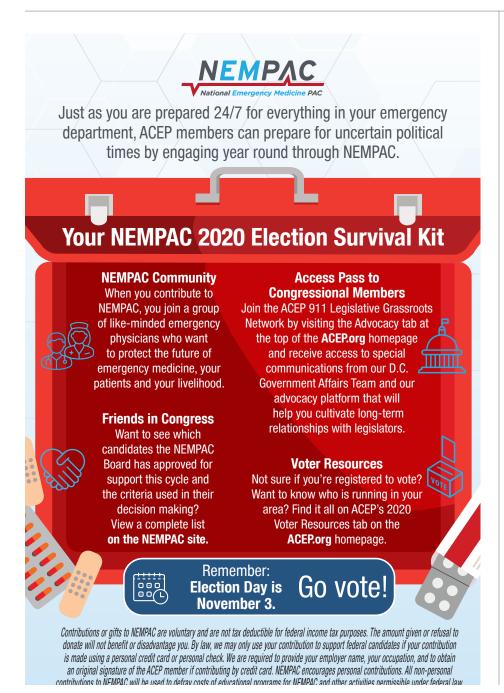
- 2. "We need to keep government 'right-sized' by reducing government expansion and by expanding the private-sector economy by deregulation. Only by growing the private-sector economy can the United States be a country that people will want to come to because of economic opportunity, freedom, and the potential for upward mobility."
- 3. "We must think outside the box and replace the antiquated system of health care insurance. The current system of health care insurance has no pricing transparency, limits flexibility, and creates no incentives for patient choice. By reducing government regulation, we can encourage more competition. We need to increase care delivery directly from physicians to patients, reducing the cost of intermediaries in health care delivery."



#### Rep. Raul Ruiz, MD, MPH, MPP (D, incumbent **CA-36**)

Dr. Ruiz grew up in the community of Coachella, California, where both of his parents were farmworkers.

Dr. Ruiz achieved his lifelong dream of becoming a physician through public education. After graduating from







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Coachella Valley High School, Dr. Ruiz graduated magna cum laude from UCLA in Los Angeles. He went on to Harvard University in Boston, where he earned his medical degree as well as a masters of public policy from the Kennedy School of Government and a masters of public health from the School of Public Health, becoming the first Latino to earn three graduate degrees from Harvard University. He completed his residency in emergency medicine at the University of Pittsburgh and a fellowship in international emergency medicine at Brigham and Women's Hospital in Boston.

Dr. Ruiz worked full-time as an emergency physician until he was elected to the U.S. House of Representatives, where he serves on the House Energy & Commerce Committee. Dr. Ruiz has sponsored many bills important to emergency medicine, including surprise medical billing, mental illness care, and veterans' care.

- 1. "The most important issue is our national and global response to the COVID-19 pandemic. Our goal as a nation must be to navigate through all of the challenges posed by the pandemic as quickly and safely as possible. We must rely on the evolving medical and public health science to guide our decisions and actions on the health care, public health, and economic arenas."
- 2. "Without a doubt, the issue that I am most passionate about is health care and health care system improvement. Our health care system still has too many people fall through gaps in care, is too difficult for patients to navigate, and too expensive for the nation. We have to protect people by increasing access to care, lowering the high costs of prescription drugs, and improving the quality of care we deliver."

of the economic programs that have been created or proposed to support physician practices during the pandemic, including the Provider Relief Fund, small business grants, and hazard pay for frontline health care providers. I also strongly believe that physicians deserve a fair legislative solution on the surprise medical billing issue and that this is definitely the wrong time for a 'bad' solution. This is also the time for insurance companies be held accountable to meet their required medical loss ratio requirements for spending on health care."



#### Hiral Tipirneni, MD (D, candidate AZ-6)

Dr. Tipirneni came to America from India with her family at the age of three. She was raised in a suburb of Cleveland.

Following a childhood illness, Dr. Tipirneni was inspired to learn more about medicine, and after graduating from public school, she

eventually earned her medical degree through an accelerated, competitive program at Northeast Ohio Medical University. After serving as chief resident of the University of Michigan's emergency medicine program, Dr. Tipirneni and her family moved to Arizona, where she worked in emergency depart-3. "From my position here in the Congress, I support many iments at the Maricopa County Medical Center, Banner Thun-

derbird, and Abrazo Arrowhead hospitals—all while raising three children in the Arrowhead community.

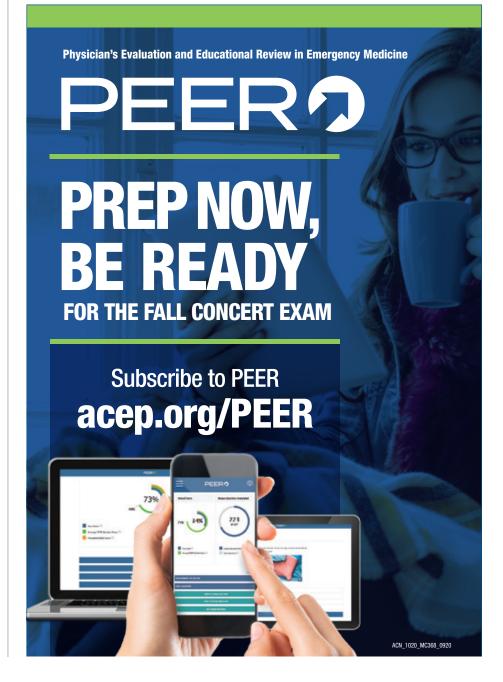
After losing her mother and nephew to cancer, Dr. Tipirneni directed her passion and problem-solving skills to evaluating and directing funding for cutting-edge cancer research. She now leads teams of researchers, clinicians, and patient advocates in the fight to treat and cure breast cancer, prostate cancer, and childhood leukemia.

- 1. "The loss of value and respect for science and data, because that affects how we address socioeconomic inequity and injustice. Science has become demonized and politicized, which has led to [us] poorly responding to the pandemic."
- 2. "No surprise...it's health care. We need to promote policies that create healthy families, healthy communities, and a healthy nation. Good public policies must address the social determinants of health including mental illness, addiction, housing, and food security."
- 3. "We need to rethink our reimbursement strategies to clinicians toward a system that is based more on value and less on volume of services and procedures performed. The federal government must enforce medical loss ratio requirements that insurers are required to meet." •



DR. CIRILLO serves on the ACEP Board of Directors and the NEMPAC Board of Directors. He still actively practices emergency medicine and serves as the director of government affairs for US Acute Care Solutions.





# Under Pressure

#### Abdominal compartment syndrome in the emergency department

Table 1: Grading of Intra-Abdominal Hypertension and Abdominal Compartment Syndrome

•	
IAH Grade	Intra-Abdominal Pressure
Grade I	12–15 mm Hg
Grade II	16–20 mm Hg
Grade III	21–25 mm Hg
Grade IV	>25 mm Hg
Abdominal compartment syndrome	Sustained IAP >20 mm Hg with new organ dysfunction

IAH, intra-abdominal hypertension; IAP, intra-abdominal pressure

#### **Table 2: Measuring IAP in Suspected ACS**

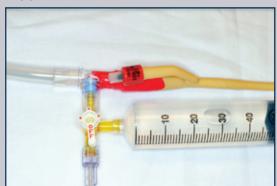
- 1. Gather the following supplies: Foley catheterization kit, sterile gloves, 60-mL syringe filled with 25 mL of saline, curved hemostat, 1-L bag of fluid, and arterial line tubing and transducer kit (see Figure 1A).
- 2. Insert Foley catheter to drain all urine.
- 3. Place the patient in the supine position and provide appropriate analgesia.
- 4. Set up an arterial line, and prime with a 1-L bag of fluid.
- 5. Attach the stopcock to a 60-mL syringe filled with saline at the end of the arterial line tubing.
- 6. Clean the access port with an alcohol swab, and attach a three-way stopcock to the catheter access port (see Figure 1B).
- 7. Zero the pressure transducer at the level of the bladder, located at the iliac crest in the midaxillary line.
- 8. Clamp the drainage bag of the Foley catheter just distal to the aspiration port.
- 9. Instill a maximum of 25 mL of warm sterile saline into the bladder (see Figure 1C).
- 10. Turn the stopcock so the off position is now directed toward the 60 mL syringe. The syringe may now be removed.
- 11. Unclamp the distal Foley catheter to allow air in the proximal tubing to pass into distal tubing. The tubing should then be clamped again.
- 12. Before obtaining the IAP value, at least 30 seconds should pass with fluid in the bladder to ensure the detrusor muscle relaxes.
- 13. After this period, obtain the bladder pressure at end-exhalation.
- 14. Once the IAP is obtained, unclamp the Foley catheter.

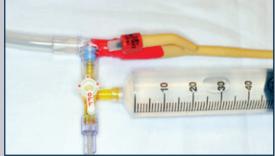
IAP, intra-abdominal pressure; ACS, abdominal compartment syndrome; Adapted from Gottlieb et al.5

#### FIGURE 1A

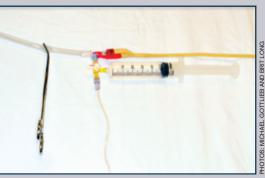


#### FIGURE 1B





#### FIGURE 1C



by MICHAEL GOTTLIEB, MD, FAAEM; AND BRIT LONG, MD, FACEP

62-year-old female patient presents with fever, cough, and an infiltrate on her chest radiograph. She receives intravenous fluids and antibiotics, but her symptoms worsen, eventually requiring intubation for respiratory decompensation and vasopressors for presumed septic shock. The intensive care unit is full, so the patient remains in the emergency department. During this time, her condition worsens, and she develops new renal and hepatic injury. You wonder if there is something you may be missing. Could this patient have abdominal compartment syndrome? If so, how do you test for it, and what are the next steps in management?

#### **Discussion**

Abdominal compartment syndrome (ACS) is a disease that can lead to significant morbidity and mortality.1-3 However, it is not often considered in the emergency department. With high rates of ED boarding in many areas, it is essential for the ED clinician to be aware of this disease and monitor for it.

ACS is similar to limb compartment syndrome in that there is excessive pressure within a closed space (ie, the abdominal



compartment), resulting in damage to the surrounding structures. This exists as part of a continuum beginning with elevated intra-abdominal pressure (IAP) and ending with organ dysfunction (see Table 1). There are numerous

causes of ACS, but they mainly fall into four general categories: reduced abdominal wall compliance (eg, abdominal surgery, obesity), increased abdominal contents (eg, large-volume ascites, hemoperitoneum), increased intraluminal contents (eg, ileus, gastroparesis), or capillary leak (eg, sepsis, pancreati-

Obtaining a relevant history may prove challenging because most patients with ACS are critically ill, and many are intubated. For patients who can provide a history, worsening abdominal pain, abdominal distension, or difficulty breathing (particularly when supine) may be reported. 6.7 The physical examination is also limited in these patients; studies demonstrate a sensitivity of 40-60 percent and a specificity of 80-94 percent for ACS diagnosis.8,9 Abdominal distension and the absence of bowel sounds are associated with ACS, but their absence cannot exclude it.5 Therefore, clinicians should remember this condition for critically ill patients with worsening or refractory hypotensio and those with new organ failure.

Laboratory studies may demonstrate evidence of severe organ dysfunction, including elevations in lactate, creatinine, and liver markers.10 If obtained, a computed tomography scan of the abdomen and pelvis may demonstrate an increased anteroposterior diameter, inferior vena cava collapse, diaphragm elevation, renal vessel compression, thickened bowel wall, pneumoperitoneum, or inguinal hernias bilaterally.11-13 However, neither the history and physical examination nor advanced imaging is sufficient to exclude the diagnosis. Therefore, clinicians who are concerned about ACS should measure the IAP (see Table 2).

Although multiple methods of IAP measurement have been proposed, intravesicular measurement generally preferred. As the name suggests, this measurement is obtained by placing a Foley catheter into the bladder. When measuring IAP, the patient should be supine and relaxed to avoid artificially increasing the IAP measurements.<sup>5,10</sup> Ensure the patient's pain is adequately controlled and measure the pressure at end-expiration.14 Clinicians should use warm saline to avoid detrusor muscle spasm, and no more than 25 mL of fluid should be

instilled to avoid false elevations of IAP.14 ACS is defined as an IAP >20 mm Hg with evidence of organ dysfunction.14

Treatment of ACS focuses on improving end-organ perfusion by reducing IAP. This includes four main steps: 1) evacuating intraluminal and intraperitoneal contents, 2) improving abdominal wall compliance, 3) optimizing intravascular fluid therapy, and 4) early surgical consultation for possible surgical decompression.

Ileus and luminal distension are common in patients with ACS. 15,16 Nasogastric or orogastric tubes can reduce gastric distension, while prokinetc agents (eg, metoclopramide, erythromycin) may help reduce intraluminal contents.14,17 Extraluminal pathologies (eg, ascites, hemoperitoneum, pneumoperitoneum) may also require drainage, which can be performed percutaneously or through operative drainage. 18-20

Adequate analgesia and sedation should be provided because pain and sedation can further increase IAP. If the patient is intubated, clinicians should aim for as low positive end-expiratory pressure and plateau pressures as the oxygen saturation allows. 10,16 Paralysis can also be used as a temporary bridge for refractory cases while awaiting surgical decompression.21-23

Clinicians should avoid excessive fluid administration because third spacing will worsen existing ACS. 10,16 If patients are hypotensive or septic, early vasopressor and inotropic therapy may be preferable in these patients; norepinephrine and dobutamine have the best literature support in treating ACS-associated hypotension.24-27

In cases that are refractory to the above interventions, surgical decompression may be warranted. Therefore, it is important to consult a surgeon early in the management of suspected ACS patients.

#### **Case Resolution**

You suspect ACS and assess the IAP using a Foley catheter. The IAP is 25 mm Hg, and a repeat creatinine level is significantly elevated. You place an orogastric tube, administer metoclopramide, ensure the patient is adequately sedated, and consult a surgeon for possible operative management. The patient is taken to the operating room for surgical decompression. •

#### **KEY POINTS**

- 1. Consider ACS in patients with risk factors who are persistently hypotensive or develop new organ injury.
- 2. Remember that the history and physical examination are unreliable. The preferred method for pre-operative diagnosis is to measure intra-abdominal pressure by using intra-vesicular pressure with a Foley catheter as a surrogate.
- 3. Management should include evacuating intraluminal and intraperitoneal contents, improving abdominal wall compliance, optimizing intravascular fluid therapy, and early surgical consultation for possible surgical decompression

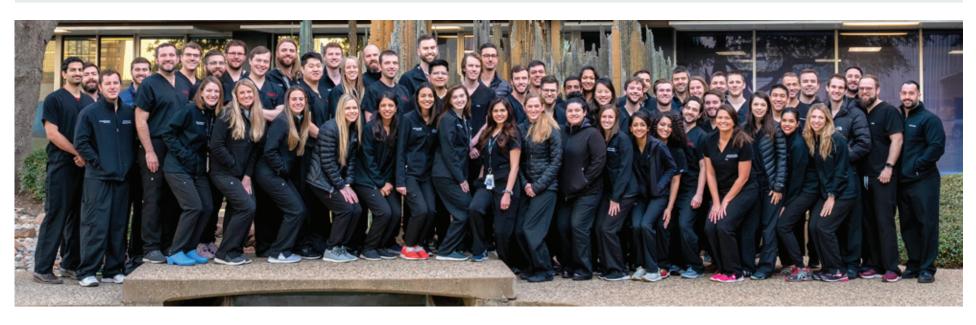
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#### UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER EMERGENCY MEDICINE RESIDENCY PROGRAM

Twitter: @dallasemed

Location: Dallas, Texas

Year founded: 1997

Program length: 3 years Current number of residents: 66

#### What sets your program apart?

Our "unicorn" program combines a lot of things: nty setting at Parkland Health & Hospital System, an academic setting at William P. Clements Jr. University Hospital, a pediatric hospital at Children's Medical Center Dallas, and several community rotations. From being in an ivorytower academic setting, to observing social determinants of health and population health in a county hospital with patients who are super-appreciative, to working in the community, we have it covered. A lot of our residents stay in the Texas area and end up taking care of patients in small towns in rural areas.

We also have lots of resources. Anything in emergency medicine, we probably have: toxicology, global health, simulation, ultrasound, research, addiction medicine, EMS. We're constantly adding opportunities for fellowships. This year, we started a medical education fellowship. Next year, we are planning an administrative fellowship.

#### What does the global health program involve?

For the past 14 years, we've had a standing two-month rotation for our senior residents at Hawke's Bay Hospital in New Zealand. New Zealand has an advanced health care system, but work in a different environment.

there is more autonomy and it's an opportunity to

#### wnat's so great about Dallas?

People think Texas is all country, but Dallas is very metropolitan. It's a great foodie city. Bon Appetit named it the 2019 Restaurant City of the Year. As far as entertainment, we have a symphony orchestra, world-renowned museums, a great opera house, and multiple Broadway shows that come to Dallas.

> -Dustin Williams, MD, residency program director



Parkland Health & Hospital System, our main training site, is one of the busiest EDs under a single roof in the United States, with an annual volume of more than 260,000 patients. And yes, the Parkland Formula for fluid resuscitation in burn management was developed here.

# Waiver the Residents!

We can improve opioid use disorder management by changing how we train residents

by RACHEL HAROZ, MD; ALEXIS LAPIETRA, DO, FACEP; STEPHEN HOLTSFORD, MD; AND REUBEN J. STRAYER, MD

he last decade has witnessed a brutal toll of opioid-related suffering and deaths. Opioid addiction has shifted from a perceived moral failing confined to urban slums to one of accepted neurobiological disease pathology observed across geographic, racial, and socioeconomic lines. Medication-based treatment of opioid addiction reduces mortality and improves lives. Buprenorphine is safe and effective and can be initiated in the emergency department for patients with opioid use disorder (OUD).¹ Significant barriers to treatment remain, however.

While buprenorphine can reduce mortality by two-thirds, only one out of three patients with OUD have access to this medication. Dioid use disorder has the highest short-term mortality of any acute disease we routinely treat in the emergency department, and it often occurs in young, otherwise healthy patients who, if moved to recovery, will go on to live long and productive lives. Due to stigma, however, addiction and addiction treatment have been siloed away from the rest of medicine. While we can have a substantial impact on our patients with OUD, we are much more comfortable treating heart disease, stroke, and sepsis. The work to bring OUD recognition and treatment into the purview of emergency medicine starts with the way we teach it to emergency medicine residents.



Residency training is structured to systematically address the pathology and treatment of disease encountered in the emergency department. Residents are trained to make lifesaving diagnoses and perform complex procedures. This training gives little consideration to where the resident will eventually practice; the prevailing paradigm is that all emergency department doctors should be able to treat all life-threatening diseases in any acute care setting.

As opioid deaths have skyrocketed over the last decade, emergency medicine residencies have largely continued to treat addiction according to the principles espoused since the specialty's inception: provide a referral to outpatient addiction services and discharge the patient with a slap on the back. The data supporting the initiation of buprenorphine in the emergency department are clear and compelling, but most current EM residents have not received training on its use. This omission is a disservice to residents, patients, and the community at large.

Changing established behavior in practicing physicians is harder than learning a new concept in an unchartered space. Residents do not harbor the accumulated negative experiences from patient interactions resulting from poor addiction treatment of years past and can approach these challenging and stigmatized patients more easily, focusing on the disease rather than the behaviors. Today's residents came of age during the opioid epidemic and are eager to be given the tools to manage it. They do not harbor the biases we developed and inherited from generations past and are less likely to develop stigmatized attitudes if trained to appropriately manage patients with substance use disorder.

#### We Can Make a Difference

Emergency physicians, by virtue of their daily interactions with the most vulnerable patients, are natural agents of social change. We bear witness to the daily



pain and suffering of marginalized and disenfranchised populations, the gaping holes in our social system, and the gross inequities of medical care and treatment. We understand the patients' inherent mistrust of the medical system fueled by addiction's underserved, stigmatized place as a failure of willpower rather than a disorder of brain chemistry. And yet, by failing to incorporate evidence-based addiction training as a skill firmly within an emergency medicine physician's scope of practice, we continue the sad tradition of inadequate access and perpetuate stigma. We convey the message that OUD as a disease is not worth our time or effort.

Addiction training should start with equipping all emergency department residents with a Drug Enforcement Administration (DEA) X-Waiver so they can prescribe buprenorphine, and this should be incorporated into the standard curriculum of emergency medicine residency training. This training can be easily incorporated into weekly didactics, and the certification never expires. Equipping our future emergency department physicians with the ability to treat the life-threatening disease of opioid use disorder is just good medicine. We must be part of the solution. •

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Brooklyn, New York.



## GET YOUR DEA X-WAIVER THROUGH ZOOM THIS FALL

ACEP, in partnership with Providers Clinical Support System, is hosting **Medications for Addiction Treatment** (MAT) X-Waiver (DEA DATA 2000) trainings this fall and in early 2021. These are free virtual live trainings done through the Zoom platform. Attendees who sign up for this training will attend a live fourhour webinar taught by clinical experts. Once completed, participants will receive the second half of the course, a four-hour online self-study portion. Participants are required to pass an exam to complete the training, and the course completion certificate does not expire. Sign up at www.acep.org/ed-x-waiver.



# By the Numbers **X-WAIVER**

**HEALTH CARE WORKERS** 

signed up for the largest ever remote DEA X-Waiver session



#### **3 STATES WITH UPCOMING GET WAIVERED** REMOTE **COURSES**

(California, Michigan, Ohio)

In just one May X-Waiver course,

**HEALTH CARE WORKERS** started the waiver process

THE GOAL:

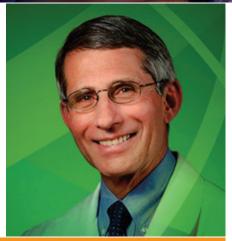
**WAIVERED BY 2022** 

Compiled by Shuhan He, MD, an emergency physician at the Center for Innovation in Digital HealthCare, and Alister Martin, MD, MPP, faculty at the Center for Social Justice and Health Equity at Massachusetts General Hospital in Boston. Visit ACEPNow.com for the sources of these statistics.

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**DR. ANTHONY FAUCI** 



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UNCONVENTIONAL 2020



# Bad news for SARS-CoV-2 and his pals.

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Right now, SARS-CoV-2 is everyone's top suspect, but respiratory bugs can cause similar, overlapping symptoms. Now you can test for 22 common respiratory pathogens, including SARS-CoV-2, with the BioFire® Respiratory 2.1 (RP2.1) Panel—now available under an FDA Emergency Use Authorization.<sup>1</sup>

Syndromic testing means all it takes is one test and just 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects. Rapid answers on a broad range of pathogens can inform patient management and alleviate patients and staff alike. What's your frontline solution into respiratory season and beyond?

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**Sample Type:** nasopharyngeal swab in 0.3 mL of transport medium

Overall 97.1% sensitivity and 99.3% specificity (prospective specimens)<sup>2</sup> SARS-CoV-2 98.0% sensitivity and 100% specificity (archived specimens)<sup>3</sup> SARS-CoV-2 100% PPA and 100% NPA (contrived specimens)<sup>4</sup>

#### **VIRUSES**

Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus 0C43
Coronavirus NL63
Severe Acute Respiratory Syndrome
Coronavirus 2 (SARS-CoV-2)

Human Rhinovirus/Enterovirus Influenza A

Human Metapneumovirus

Influenza A/H1
Influenza A/H3
Influenza A/H1-2009
Influenza B
Parainfluenza Virus 1
Parainfluenza Virus 2
Parainfluenza Virus 3

Parainfluenza Virus 4

Respiratory Syncytial Virus

#### **BACTERIA**

Bordetella parapertussis
Bordetella pertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

<sup>1.</sup> This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

2. Based on the prospective portion of the clinical study for the BioFire FilmArray Respiratory 2 (RP2) Panel.

3. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission.

tion in voters, poll workers, and election officials. Local public health departments are promoting this objective through three strategies: behavior modification, disease surveillance, and outbreak control.1

Behavior modification guidelines target preventing disease transmission and include recommendations for individuals and organizations. These include isolation and quarantine of people who have symptoms of COVID-19, vigilant surface cleaning, hand hygiene, respiratory etiquette (covering coughs or sneezes), masking while in public or when interacting with people outside of one's immediate household, and maintaining physical distancing of six feet or greater with others.

Disease surveillance requires a robust testing program with adequate supply of materials, efficient laboratory test turnaround times, and delivery of results to patients and health care workers. Stratification of data by demographic factors including age, race/ethnicity, and neighborhood will help communities respond to rises in disease transmission rates. Public health departments should partner with a variety of community stakeholders to promote active engagement in testing efforts.

When a case is identified through testing, successful outbreak control requires case investigation and contact tracing (CI/CT). Although time-intensive, effective CI/CT programs have been shown to reduce the reproductive rate of the virus (the R) from local values of more than 2.0 to 0.4 by offering two key interventions.<sup>2</sup> First, a case investigator should educate an infected individual on how to self-isolate for up to 14 days to decrease transmission to others. Successful isolation may require referrals to social services such as isolation and quarantine hotels, food delivery programs, or temporary income assistance. The second important step, contact tracing, involves determining who else in a patient's household, workplace, and community may have been a "close contact" (a person who was exposed to the person for greater than 15 minutes). Close contacts are contacted by the department of public health and are confidentially advised of an exposure; assessed for symptoms; and advised for quarantine, self-monitoring, or testing, depending on the time since exposure and symptoms.3

#### **Role of Emergency Physicians**

Emergency physicians can play a role in helping patients stay healthy and vote safely this November through both clinical care and communication. Most directly, our duty as frontline physicians involves ensuring that members of higher-risk groups (eg, older individuals, immunocompromised individuals, residents of group living facilities, and essential workers) are appropriately tested leading up to and following the election. This includes excellent history-taking around symptoms and potential exposures as well as identifying close contacts so cases can be identified early and spread of disease is mitigated.

Beyond history and workup, communication is crucial. According to a large, nationally representative survey released in April 2020, trust in hospitals and physicians during COVID-19 is high, particularly relative to other institutions and groups.<sup>4</sup> We are important sources of information and education regarding public health guidelines such as hand hygiene, face masks, and social/physical distancing. We can help patients understand what to expect if they undergo testing and link to appropriate resources so they can safely isolate.

As various state and local elections officials adapt their voting strategies this year, we can inform our patients about their local voting options. Not only are these discussions clinically relevant, they have legal and logistical precedent. The 1993 National Voter Registration Act allows any institution providing "public assistance," including hospitals, to participate in nonpartisan voter registration and information sharing. National organizations such as VotER and Community Health Vote empower thousands of health care workers to engage patients in conversations about voter registration and safe voting plans.<sup>6-8</sup>

#### **How to Have Safe In-Person Voting**

Healthy and safe elections are a priority for all Americans and our democracy. Clear, nonpartisan, and evidence-based recommendations are needed for public health and elections officials



In Arlington, Virginia , people line up and look at sample ballots during first day of early voting, 2020 presidential election.

#### **KEY POINTS**

- To optimize the chance of a safe election from a public health perspective, all citizens must play a role in reducing community transmission of COVID-19. This includes using hand hygiene, wearing face masks that cover the nose and mouth, and maintaining physical distance of at least six feet between individuals.
- To lower community transmission rates of COVID-19 in advance of election day, public health officials can promote behavior modification, disease surveillance, and control of COVID-19.
- By ensuring appropriate individuals are tested for COVID-19 and through the education of patients, emergency physicians play a key role in helping patients stay healthy so they can vote safely on election day.
- For safe in-person elections to occur, the number of polling locations should be increased to avoid overcrowding and polling locations should be relocated to large, wellventilated areas to allow for appropriate physical distancing.
- On election day, voters should arrive to the polling location alone, arrive early, and expect to wait.
- · Wide-scale campaigns to recruit extra poll workers from low-risk groups must be implemented and these individuals should be offered free testing for COVID-19 before and after their shifts at polling stations.

to follow as they develop policies and procedures in advance of election day.9

Early and mail-in voting can help reduce crowd volumes, reduce in-person contact, and ultimately reduce transmission risk. Some individuals will need to vote in person, and for these people, a uniform, evidence-based public health message about what to expect at polling sites is important. This messaging should include using hand hygiene, maintaining physical distance of at least six feet between individuals, and wearing face masks that cover the nose and mouth to prevent the transmission of COVID-19. For safe in-person elections to occur, elections officials should increase the number of polling locations to avoid overcrowding and relocate polling locations to large, well-ventilated areas to allow for appropriate physical distancing. Localities should aim to have polling locations in large, well-ventilated sites such as sports arenas, concert venues, convention centers,

school gymnasiums, or community recreation centers. For optimal infection control, voting locations should conduct checkin activities outdoors (weather permitting), establish separate points of entry and exit for voters, and have unidirectional flow of foot traffic. Additionally, ventilation should be optimized by avoiding recirculation of potentially contaminated air.

Polling locations should have adequate supplies to support healthy hygiene for voters, poll workers, and elections officials. This includes hand sanitizer with at least 60 percent alcohol, soap, paper towels, no-touch trash cans, disinfectant wipes, and face masks. Polling sites should be thoroughly cleaned with an Environmental Protection Agency-approved disinfectant prior to opening on election day, with special attention given to high-touch surfaces, such as poll worker stations and voting booths. These areas and any reusable items should be routinely disinfected throughout the day. Hand sanitizer should be available at entrances, exits, and each step of the voting process for voters and poll workers. Polling locations should have plexiglass barriers between workers and voters at registration tables.

In addition, voters should expect to arrive at polling locations early and expect to wait. They can minimize their time and risk of COVID-19 by filling out a sample ballot prior to election day to make in-person voting time-efficient, vote during an off-peak time, and come alone to the polling location.

Election day does not happen without poll workers, and wide-scale campaigns to recruit extra workers may reduce the burden of individual exposures to others. Poll workers should be trained in the appropriate use of personal protective equipment and offered free testing for COVID-19 before and after their shifts at the polls. Any individual concerned about their personal risk for COVID-19 as a poll worker should consult their physician.

COVID-19 is the greatest social, health, and economic threat of our generation. As we approach Nov. 3, it is critical that local communities, health care workers, and public health departments work together to minimize the risk of COVID-19. We have the knowledge and scientific evidence to have a safe election. Now is the time to implement policies and practices and keep our patients informed about them. No person should have to choose between the right to vote and the right to be healthy.

Disclosure: Dr. Kuppalli is a consultant for Galaxosmith Kline.

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DR. KUPPALLI (left)is a physician in the division of infectious diseases at the Medical University of South Carolina in Charleston. DR. GRADE and DR. MERCER are physicians in the department of emergency medicine at the University of California, San Francisco.

# 2020 ACEP Leadership **AWARD WINNERS**

Congratulations to the 2020 recipients of the College's most prestigious awards. These recipients will be recognized during ACEP20 Unconventional with video tributes and acceptance speeches.



John G. Wiegenstein **Leadership Award** 

David C. Seaberg, MD, CPE,

Dr. Seaberg graduated with a BA in chemistry from Washington University in St. Louis, attended the University of Minnesota School of Medicine, and completed his emergency medicine residency at the University of Pittsburgh.

His leadership roles include research director at the University of Pittsburgh, residency director at the University of Florida, Jacksonville, and chair of emergency medicine at the University of Florida, Gainesville. In 2017, he became the inaugural dean at the University of Tennessee College of Medicine Chattanooga, also serving as chair of emergency medicine and senior vice president of physician integration at the Erlanger Health System.

Dr. Seaberg was elected to the ACEP Board of Directors and became President in 2011 and Chair of the Board in 2012. He also helped US Acute Care Solutions reestablish the Summa Department of Emergency Medicine as chair and Executive Vice President.



James D. Mills **Outstanding Contribution to Emergency Medicine Award** 

John J. Rogers, MD, CPE, FACEP

Dr. Rogers graduated from Augustana College in Rock Island, Illinois, with a degree in biology and completed a surgical internship at the University of Iowa College of Medicine, and a surgical residency at the Medical Center of Central Georgia in Macon.

He began working in emergency departments in 1979 part-time and full-time in 1994.

Dr. Rogers is Vice President and a member of the Board of Directors of the Bibb County Medical Society. He is a member of the Medical Association of Georgia's Council on Legislation and a delegate to the Medical Association of Georgia House of Delegates. He is ED medical director at Coliseum Northside in Macon.

Dr. Rogers held several leadership roles in the Georgia Chapter of ACEP, including chapter President, and remains on the Board of Directors. He has served on several ACEP committees, chaired the Rural and Workforce Sections, and founded the Telemedicine Section. He was elected to the ACEP Board of Directors in 2011 and served two terms.



John A. Rupke **Legacy Award** Peter M. Fahrney, MD, FACEP(E)

Dr. Fahrney was a Seabee medical officer in

Vietnam, working as a volunteer in the 3rd Marine Division MASH unit, and later was appointed command medical officer for the 12 battalions of Seabees that made up the Atlantic Command (COMCBLANT).

Dr. Fahrney took a position at Suburban

Hospital in Bethesda, Maryland, where he: remained for his 32-year career. He attended meetings in Arlington and Alexandria, Virginia, with the "founding fathers" of emergency : medicine. Soon, ACEP was established.

He joined ACEP in 1969, serving in many

capacities. At the first meeting of the Council in Washington, D.C., in 1973, Dr. Fahrney was elected as the first Speaker of the Council and presided over its tumultuous first meeting. He was also elected that year to the Board of Di-

**CONTINUED** on page 18



#### INDICATIONS AND USAGE

NUZYRA® is a tetracycline-class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

Community-Acquired Bacterial Pneumonia (CABP) caused by the following: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila

Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused **by the following:** Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria

#### IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline class antibacterial drugs, or to any of the excipients.

#### WARNINGS AND PRECAUTIONS

Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients > 65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality

The use of NUZYRA during tooth development (last half of permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth.

Hypersensitivity reactions have been reported with NUZYRA. Lifethreatening hypersensitivity (anaphylactic) reactions have bee reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs. NUZYRA is structurally similar to tetracycline-class of antibacterial

drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests), have been reported for other tetracycline-class antibacterial drugs and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

Prescribing NUZYRA in the absence of a proven or strongly suspected  $% \left( 1\right) =\left( 1\right) \left( 1\right)$ bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

#### ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and

#### DRUG INTERACTIONS

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA. Absorption of tetracyclines, including NUZYRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

#### **USE IN SPECIFIC POPULATIONS**

Lactation: Breastfeeding is not recommended during treatment with NUZYRA.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary of Full Prescribing Information on the



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rectors, where he served two terms. During his membership, he has served on many committees and assisted in getting the acceptance of the specialty of emergency medicine within the American Medical Association (AMA).



Colin C. Rorrie, Jr, PhD Award for **Excellence in Health Policy** 

Steven J. Stack, MD, MBA, **FACEP** 

Dr. Stack spent seven years at The Ohio State University in medical school and emergency :

medicine residency. Early on, he became involved in the American Medical Association. In 2006, he became the first board-certified emergency physician ever elected to the AMA board of trustees and served in 2015-2016 as the AMA's youngest president since 1854.

In 2017, he completed an MBA program at The University of Tennessee and became an adjunct professor teaching health policy and advocacy. He was appointed commissioner of the Kentucky Department of Public Health in February 2020, just weeks before the COVID-19 pandemic swept across the nation. Dr. Stack's life journey, though, has prepared him well for today's challenges.



#### Pamela P. Bensen **Trailblazer Award**

Sharon E. Mace, MD, FACEP

Dr. Mace attended Syracuse University, majoring in

chemistry, attended medical school at Upstate Medical Center in Syracuse, New York, and did a pediatric residency at Rainbow Babies & Children's Hospital in Cleveland.

During her time in Ohio, Dr. Mace served on the Ohio ACEP Board of Directors and chaired the Education Committee.

She returned to New York and worked in various positions including ED director at : Saratoga Springs, ED director of St. Mary's :

Hospital, and pediatrician and chair of the emergency department at St. Elizabeth Hospital. She started the 911 dispatch for Monroe County, was EMS medical director for Monroe and Saratoga Springs Ambulance Services, and worked with Monroe Community College to establish an EMT/paramedic training program. She was elected to the NY ACEP Board of Directors.

After about a decade, Dr. Mace became director of pediatric education and quality improvement and director of the observation unit at the Cleveland Clinic. She is currently director of research and assistant director of

#### NUZYRA® (omadacycline) injection for intravenous use NUZYRA® (omadacycline) tablets, for oral use

#### **BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION**

For complete details, please see Full Prescribing Information

#### INDICATIONS AND USAGE

**Community-Acquired Bacterial Pneumonia (CABP)**NUZYRA is indicated for the treatment of adult patients with community acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus Maccinisiiii ausseptible Isaades, rideriingiiiiia iiiineriize, roparainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

#### Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

NUZYRA is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the  $\,$ following susceptible microorganisms: Staphylococcus aureus (methicillin susceptible and -resistant isolates), Staphylococcus lugdunensis Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae

**USAGE:** To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs NUZYRA should be used only to treat or prevent infections that are prover or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such 

CONTRAINDICATIONS: NUZYRA is contraindicated in patients with nown hypersensitivity to omadacycline or tetracycline-class antibacterial drugs, or to any of the excipients.

#### WARNINGS AND PRECAUTIONS

Mortality Imbalance in Patients with Community-Acquired Bacterial

Pneumonia - Mortality imbalance was observed in the CABP trial with eight deaths (2%) occurring in patients treated with NUZYRA ompared to four deaths (1%) in patients treated with moxific The cause of the mortality imbalance has not been established.

All deaths, in both treatment arms, occurred in patients >65 years of age most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients particularly in those at higher risk for mortality.

Tooth Discoloration and Enamel Hypoplasia-The use of NUZYRA during both development (last half of pregnancy, infancy, and childh to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during longterm use of the tetracycline-class drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported with tetracycline-class drugs. Advise the patient of the potential risk to the fetus if NUZYRA is used during the second or third trimester of pregnan

 $\textbf{Inhibition of Bone Growth}\text{-} \textbf{The use of NUZYRA} \ \textbf{during the second and}$ third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was show to be reversible when the drug was discontinued. Advise the patient of the potential risk to the fetus if NUZYRA is used during the second or third trimester of pregnancy

**Hypersensitivity Reactions**-Hypersensitivity reactions have been reported

Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic read

Clostridium difficile-Associated Diarrhea-Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use.

Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated

Tetracycline-Class Effects-NUZYRA is structurally similar to tetracyclineclass of antibacterial drugs and may have similar adverse reactions Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acido: hyperphosphatemia, pancreatitis, and abnormal liver function tests), have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse

Development of Drug-Resistant Bacteria: Prescribing NUZYRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS: The following clinically significant adverse reactions are described in greater detail in the Warnings and Precautions section of the labeling:

- · Mortality Imbalance in Patients with Community-Acquired Bacterial Pneumonia
- · Tooth Development and Enamel Hypoplasia
- · Inhibition of Bone Growth
- · Hypersensitivity Reactions
- · Tetracycline-Class Effects

Clinical Trials Experience-Because clinical trials are conducted under videly varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Overview of the Safety Evaluation of NUZYRA: NUZYRA was evaluated in three Phase 3 clinical trials (Trial 1, Trial 2 and Trial 3). These trials included a single Phase 3 trial in CABP patients (Trial 1) and two Phase 3 trials in ABSSSI patients (Trial 2 and Trial 3). Across all Phase 3 trials, a total of 1073 patients were treated with NUZYRA (382 patients in Trial 1 and 691 in Trials 2 and 3) of which 368 patients were treated with only oral NUZYRA Imbalance in Mortality: In Trial 1, eight deaths (2%) occurred in 382

patients treated with NUZYRA as compared to four deaths (1%) in 388 patients treated with moxifloxacin. All deaths, in both treatment arms, occurred in patients >65 years of age. The causes of death varied and included worsening and/or complications of infection and underlying conditions. The cause of the mortality imbalance has not been established [see Warnings and Precautions (5.1)].

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In Trial 1, a total of 23/382 (6.0%) patients treated with NUZYRA and 26/388 (6.7%) patients treated with moxifloxacin experienced serious adverse reactions. Discontinuation of treatment due to any adverse reactions occurred in 21/382 (5.5%) patients treated with NUZYRA and 27/388 (7.0%) patients treated with moxifloxacin.

Most Common Adverse Reactions: Table 4 lists the most common adverse reactions occurring in ≥2% of patients receiving NUZYRA in Trial 1.

#### Table 4: Adverse Reactions Occurring in ≥2% of Patients Receiving **NUZYRA** in Trial 1

Adverse Reaction	NUZYRA (N = 382)	Moxifloxacin (N = 388)	
Alanine aminotransferase increased	3.7	4.6	
Hypertension	3.4	2.8	
Gamma-glutamyl transferase increased	2.6	2.1	
Insomnia	2.6	2.1	
Vomiting	2.6	1.5	
Constipation	2.4	1.5	
Nausea	2.4	5.4	
Aspartate aminotransferase increased	2.1	3.6	
Headache	2.1	1.3	



Judith E. Tintinalli Award for **Outstanding Contribution in Education** 

Tracy G. Sanson, MD, FACEP

Dr. Sanson is a board-certified emergency physician who practices clinically as an independent contractor. She heads her own consulting firm, specializing in leadership training, personal and faculty development, and wellness.

She has served in leadership positions with the Society for Academic Emergency Medicine (SAEM), the Council of Residency Directors (CORD), and ACEP. She has been a member of the ACEP faculty for many years. She is a past president of the Government Services Chapter of ACEP and has been a Board of Directors member and past chair of the Education Com- ; ecutive director of the Virginia College of ; with part-time executive directors.

: mittee for the Florida Chapter of ACEP.

Dr. Sanson completed her medical degree and emergency medicine residency training at the University of Illinois at Chicago. She has held director positions in the U.S. Air Force, the University of South Florida, and TeamHealth. She was education director for the Joint Military Medical Centers Emergency Medicine program (now SAUSHEC) in San Antonio, Texas, and the University of South Florida Emergency Medicine program in Tampa.



Diane K. Bollman **Chapter Advocate** Award

Bob Ramsey, CAE

Fifty years ago, Mr. Ramsey, the retired ex-

Emergency Physicians (VACEP), entered association management as a way to fulfill his passion for helping others. Mr. Ramsey has been a certified association executive for 42 years. His leadership was recognized by the Virginia Society of Association Executives (Outstanding Association Executive 2018), his U.S. Navy flight class (Regimental Commander), his : college (Outstanding Senior Award, Alumni Achievement Award), and his fraternity (National Achievement Award).

VACEP hired Mr. Ramsey in 2013 to increase : its position and influence in Virginia's house of medicine. VACEP's leadership adopted a new, cost-saving chapter business model resulting in a substantial increase in revenue. Physician engagement expanded as the chapter nearly doubled in size. He also partnered : with ACEP to find ways of supporting chapters

**Council Meritorious Service Award** 

Michael McCrea, MD, FACEP

Dr. McCrea earned his MD from the Medical College of

Ohio at Toledo in 2004. He has been an ACEP member since 2004, when he began his emergency medicine residency at The Ohio State

After finishing residency in 2007, he joined a large community practice in Mansfield, Ohio. In 2009, he became core faculty in the emergency medicine residency at St. Vincent's in Toledo. He became assistant program director in 2012 and associate program director in 2020.

Dr. McCrea was medical director of rural Wood County Hospital in Bowling Green, Ohio, from 2013 to 2014.

He became involved with Ohio ACEP in 2010. He is a current Ohio ACEP Board member and served two terms as chapter President.

He began his service to national ACEP in 2010 as an alternate Councillor for the Ohio Chapter and has served as a Councillor ever since, serving on both Council Reference and Steering Committees. Most recently, he was selected to lead the Task Force on Council Size in 2019. In addition to Council service, he also serves national ACEP on the State Legislative and Regulatory Committee and the Bylaws Committee.



**Disaster Medical Sciences Award** 

Irving "Jake" Jacoby, MD, **FACEP** 

Dr. Jacoby is emeritus clinical professor of emergency medicine at UC San Diego (UCSD) School of Medicine and attending physician at the department of emergency medicine and hyperbaric medicine center at UCSD.

He is a graduate of the Johns Hopkins University School of Medicine in Baltimore. He completed an internal medicine residency at Boston City and the Peter Bent Brigham hospitals and an infectious disease fellowship at Brigham. He has attended in the emergency department for more than 30 years.

Dr. Jacoby is commander of the California-4 Disaster Medical Assistance Team and has deployed on nearly two dozen major disasters under the National Disaster Medical System.

Dr. Jacoby is the author of multiple articles, editorials, and textbook chapters on emergency and disaster medicine, infectious diseases, and hyperbaric medicine. He has received multiple awards and was elected to Fellowship of the Undersea & Hyperbaric Medical Society in 2018.

#### **Honorary Membership Award** Pat Hughes, CMP

Ms. Hughes began her career

at ACEP in 1988 as an accounting assistant in the finance department. She spent four years in that role until moving to the educational meetings department as planning and implementation coordinator. Her role was expanded to include meeting planning for the Emergency Department Directors Academy. In 2009, Ms. Hughes shifted her skills to the academic affairs department. She was promoted to the academic affairs meetings manager in 2014, where she remained until her retirement on July 1, 2020.

**CONTINUED** on page 25

#### NUZYRA® (omadacycline) injection for intravenous use NUZYRA® (omadacycline) tablets, for oral use

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In the pooled ABSSSI trials, serious adverse reactions ocurred in 16/691 (2.3%) of patients treated with NUZYRA and 13/689 (1.9%) of patients treated with comparator. Discontinuation of treatment due to adverse events occurred in 12 (1.7%) NUZYRA treated patients, and 10 (1.5%) comparator treated patients. There was 1 death (0.1%) reported in NUZYRA treated patients and 3 deaths (0.4%) reported in linezolid patients in ABSSSI trials.

Most Common Adverse Reactions: Table 5 includes the most common adverse reactions occurring in  $\geq$ 2% of patients receiving NUZYRA in Trials 2 and 3

#### Table 5: Adverse Reactions Occurring in ≥2% of Patients Receiving **NUZYRA** in Pooled Trials 2 and 3

Adverse Reaction	NUZYRA (N = 691)	Linezolid (N = 689)
Nausea*	21.9	8.7
Vomiting	11.4	3.9
Infusion site reactions**	5.2	3.6
Alanine aminotransferase increased	4.1	3.6
Aspartate aminotransferase increased	3.6	3.5
Headache	3.3	3.0
Diarrhea	3.2	2.9

\*In Trial 2, which included IV to oral dosing of NUZYRA, 40 (12%) patients experienced nausea and 17 (5%) patients experienced vomiting in NUZYRA treatment group as compared to 32 (10%) patients experienced nausea and 16 (5%) patients experienced vomiting in the comparator group. One patient (0.3%) in the NUZYRA group discontinued treatment due to nausea and vomiting.

 $^*$ In Trial 3, which included the oral loading dose of NUZYRA, 111 (30%) patients experienced nausea and 62 (17%) patients experienced vomiting in NUZYRA treatment group as compared to 28 (8%) patients experienced nausea and 11 (3%) patients experienced vomiting in the linezolid group. One patient (0.3%) in the NUZYRA group discontinued treatment due to nausea and vomiting.

\*\*Infusion site extravasation, pain, erythema, swelling, inflammation, irritation, peripheral swelling and skin induration

Selected Adverse Reactions Occurring in Less Than 2% of Patients Receiving NUZYRA in Trials 1, 2 and 3: The following selected advers reactions were reported in NUZYRA-treated patients at a rate of less than 2% in Trials 1, 2 and 3. Cardiovascular System Disorders: tachycardia, atrial fibrillation; Blood and Lymphatic System Disorders anemia, thrombocytosis; Ear and Labyrinth Disorders: vertigo Gastrointestinal Disorders: abdominal pain, dyspepsia; General Disorders and Administration Site Conditions: fatigue; Immune System Disorders: hypersensitivity; Infections and Infestations: oral candidiasis, vulvovagina mycotic infection; Investigations: creatinine phosphokinase increased bilirubin increased, lipase increased, alkaline phosphatase increased, Nervous System Disorders: dysgeusia, lethargy; Respiratory, Thoracic, and Mediastinal disorders: oropharyngeal pain, Skin and Subcutaneous Tissue Disorders: pruritus, erythema, hyperhidrosis, urticaria.

#### DRUG INTERACTIONS

**Anticoagulant Drugs**-Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therap nay require downward adjustment of their anticoagulant dosage while also taking NUZYRA.

 $\textbf{Antacids and Iron Preparations} \hbox{-} Absorption of oral tetracyclines, including}$ NUZYRA, is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate, and iron containing preparations

#### **USE IN SPECIFIC POPULATIONS**

**Pregnancy:** <u>Risk Summary</u>—NUZYRA, like other tetracycline-class antibacterial drugs, may cause discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the se and third trimester of pregnancy.

The limited available data of NUZYRA use in pregnant women is insufficient to inform drug associated risk of major birth defects and miscarriages. Animal studies indicate that administration of omadacycline during the period of organogenesis resulted in fetal loss and/or congenital malformations in pregnant rats and rabbits at 7 times and 3 times the mean AUC exposure, respectively, of the clinical intravenous dose of 100 mg and the oral dose of 300 mg. Reductions in fetal weight occurred in rats at all administered doses (see *Data*). In a fertility study, administration to rats

during mating and early pregnancy resulted in embryo loss at 20 mg/kg/day; systemic exposure based on AUC was approximately equal to the clinical sposure level. Results of studies in rats with omadacycline have shown tooth discoloration.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15-20%.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence embryotoxicity also has been noted in animals treated early in pregnancy.

Lactation: Risk Summary - There is no information on the presence of omadacycline in human milk, the effects on the breastfed infant or the effects on milk production. Tetracyclines are excreted in human milk however, the extent of absorption of tetracyclines, including omadacyc by the breastfed infant is not known.

Because there are other antibacterial drug options available to treat CABP and ABSSSI in lactating women and because of the potential for serious adverse reactions, including tooth discoloration and inhibition of bone growth, advise patients that breastfeeding is not recommended during treatment with NUZYRA and for 4 days (based on half-life) after the last dose.

Females and Males of Reproductive Potential

<u>Contraception</u> Females: NUZYRA may produce embryonic or fetal harm. Advise patients to use an acceptable form of contraception while taking NUZYRA.

 $\underline{\mathsf{Infertility}}\, \mathit{Males} : \mathsf{In}\, \mathsf{rat}\, \mathsf{studies}, \mathsf{injury}\, \mathsf{to}\, \mathsf{the}\, \mathsf{testis}\, \mathsf{and}\, \mathsf{reduced}\, \mathsf{sperm}\, \mathsf{counts}$ and motility occurred in male rats after treatment with omadacycline Females: In rat studies, omadacycline affected fertility parameters in female rats, resulting in reduced ovulation and increased embryonic loss at intended human exposures.

Pediatric Use-Safety and effectiveness of NUZYRA in pediatric patients below the age of 18 years have not been established. Due to the adverse effects of the tetracycline-class of drugs, including NUZYRA on tooth development and bone growth, use of NUZYRA in pediatric patients less than 8 years of age is not recommended.

Geriatric Use-Of the total number of patients who received NUZYRA in the Phase 3 clinical trials (n=1073), 200 patients were ≥65 years of age, including 92 patients who were ≥75 years of age. In Trial 1, numerically lower clinical success rates at early clinical response (ECR) timepoint for NUZYRA-treated and moxifloxacin-treated patients (75.5% and 78.7%, respectively) were observed in CABP patients ≥65 years of age as compared to patients <65 years of age (85.2% and 86.3%, respectively). Additionally, all deaths in the CABP trial occurred in patients >65 years of age. No significant difference in NUZYRA exposure was observed between healthy elderly subjects and younger subjects following a single 100 mg IV dose of NUZYRA.

**Hepatic Impairment**-No dose adjustment of NUZYRA is warranted in patients with mild, moderate, or severe hepatic insufficiency (Child-Pugh classes A.B. or C)

Renal Impairment - No dose adjustment of NUZYRA is warranted in patients with mild, moderate, or severe renal impairment, including patients with end stage renal disease who are receiving hemodialysis

 $\begin{tabular}{ll} \textbf{OVERDOSAGE} & No specific information is available on the treatment \\ \end{tabular}$ of overdosage with NUZYRA. Following a 100 mg single dose intravenous administration of omadacycline, 8,9% of dose is recovered in the dialysate.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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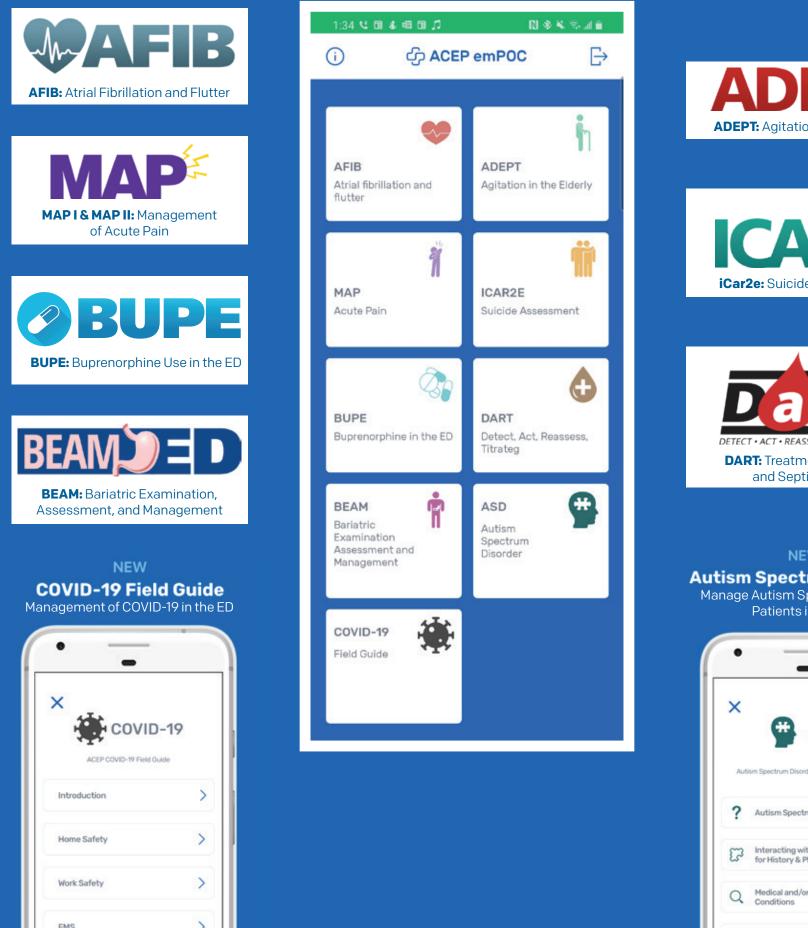
# emPOC App **Expanded**

App update includes COVID-19 Field Guide and more point-of-care tools

CEP just released an expanded version of its emPOC app, and now it includes many more helpful bedside tools and the popular COVID-19 Field Guide. Free for ACEP members, this app is available on iTunes and Google Play.

#### What are these bedside tools?

ACEP recruited top experts to develop tools our members can trust and deploy in the clinical setting. The evidence-based clinical content provided in these tools ensures that you are providing the best possible care to the patients in your emergency department. You may already be utilizing these tools in the desktop format (www.acep.org/pointofcaretools), but adding them to the emPOC app provides access while working offline or dealing with an inconsistent internet connection. •







EM LITERATURE OF NOTE

# PEARLS FROM THE MEDICAL LITERATURE



**DR. RADECKI** is an emergency physician and informatician with Christchurch Hospital in Christchurch, New Zealand. He is the *Annals of Emergency Medicine* Podcast co-host and Journal Club editor and can be found on Twitter at @emlitofnote.

# (Don't) Let the Air Out

What's the best intervention for primary spontaneous pneumothorax?



by RYAN PATRICK RADECKI, MD, MS

here are always times when our attempts to educate individual patients on evidence-based medicine fall short. This leads to a range of acceptable practice variation, with each clinician making their best judgment regarding the care of a patient. This variation is on impressive display with respect to the management of primary spontaneous pneumothorax (PSP).

The options for treatment of PSP range from hospitalization after the placement of a large-bore chest tube to outpatient management with naught but close follow-up. These could all be considered reasonable options absent high-quality data regarding the safety of any individual approach. But recently, researchers have provided several pieces of clarifying evidence.

The management of an otherwise stable but symptomatic patient with PSP typically boils down to a few key decisions. First, is any intervention required? Secondly, if so, what sort of invention: standard chest tube, narrow-bore chest tube, or aspiration? Finally, should a patient be discharged home or remain in the hospital for observation?

#### **Historical Data**

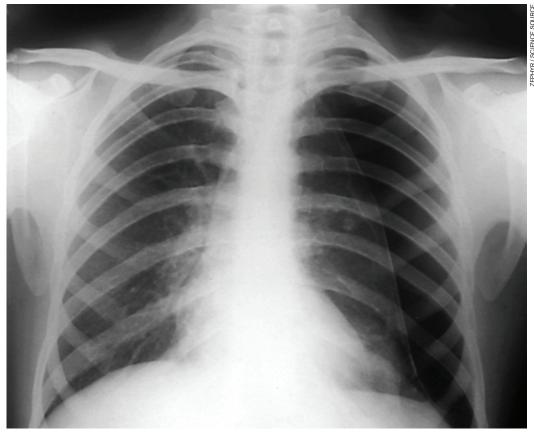
The historical data are best summarized in an *Annals of Emergency Medicine* article by Mummadi et al, who recently performed a systematic review and network meta-analysis. These authors collated 12 studies, accounting for 781 patients, and applied statistical techniques in an attempt to compare three strategies for intervention: large-bore chest tube ( $\ge$ 14 French), narrow-bore (<14 French), or needle aspiration. The authors defined the success of a strategy in terms of resolution of symptoms, adequate lung re-expansion, and the ability for discharge from the emergency department.

Following the applicable statistics, the authors reached only one solid conclusion: the large-bore chest tube is clearly the least preferable of the options. Within the bounds of their combined small sample, the large-bore tube was certainly successful at management. However, that strategy was also associated with higher complication rates than the equally successful but safer narrow-bore tube. Needle aspiration, on the other hand, was neither obviously superior nor inferior. The latter strategy lacked the immediate success of the others, primarily due to diminished re-expansion, but had the advantage of being associated with far fewer complications than its competitors.

#### **New Data**

Published in the months following that review, however, two additional trials comprising 552 patients have now been added to this sparse body of evidence, providing further insight. The first of these trials is arguably the more important of the two.<sup>2</sup> In that study, the authors effectively presumed the adequacy of a small-bore chest tube and compared it against conservative management. In perfectly stark terms, "conservative management" means "do nothing," with only a hint of hyperbole.

Patients were eligible for this trial if they had moderate to large pneumothoracies, defined as at least 32 percent collapse, calculated on chest radiography. In the intervention group, patients underwent placement of a ≤12 French Seldinger-style chest tube, were rechecked after four hours, and could have the chest tube removed and be discharged if demonstrating clinical and radiological improvement. In contrast, patients in the comparison group were simply observed for four hours for clinical or radiologic deterioration, and, if none occurred, were discharged home. In this trial, the primary endpoint was resolution of the pneumothorax by eight weeks, but all patients had in-person assessments at frequent intervals in the interim.



Frontal chest X-ray of a patient with a pneumothorax.

As it turns out, "doing nothing" is nearly as good as, and : maybe even better than, doing something. Of those randomized to conservative management, 84.6 percent completed follow-up without undergoing a procedure for their pneumothorax. At the eight-week follow-up for the primary outcome, 94.4 percent of those managed conservatively had full lung re-expansion, compared with 98.8 percent of those who underwent intervention. However, this small advantage in radiographical resolution is offset by multiple resource- and patient-oriented outcomes favoring conservative management. Those who underwent an invasive procedure spent more days in the hospital; underwent more chest radiographs; required more days off work; and, potentially more importantly, had twice the pneumothorax recurrence rate within 12 months, 16.8 percent versus 8.8 percent. These long-term observations, even as a secondary outcome, probably tip the scales toward conservative management.

That said, not all patients were able to be discharged following an initial attempt at conservative management. This leads us to the second trial. This trial took a bit of a different tack, testing a specific small-bore ambulatory device against treatment, which follows guidelines by the British Thoracic Society (BTS). BTS guidelines permit the treating clinician to perform an aspiration procedure, place a small-bore chest tube, or both. The primary outcome in this trial was length of hospital stay within 30 days.

As might be expected, those randomized to the strategy placing an emphasis on the ambulatory device had dramatically fewer days in the hospital. Two-thirds of those randomized to ambulatory management were able to be discharged on the day of presentation as compared to one-third otherwise. Clinicians attempted aspiration in two-thirds of those randomized to standard care, but half of those were ultimately managed with a chest tube and hospital admission. During the month of follow-up, recurrences were greater in those undergoing guideline-based standard care, as was the need for any additional procedures.

The interpretation of this trial is a bit muddier than the first.

Whereas patients in the first trial could undergo chest tube

placement and removal and be subsequently discharged, that was not an option in the standard care arm in the second trial. Then the ambulatory management cohort also recorded more adverse events than the standard care arm, 55 percent to 39 percent, including all of the serious adverse events. Fortunately, none of the serious events included death or significant disability but nonetheless lead to reasonable framing of the ambulatory strategy as a balance of competing risks and benefits.

#### **Conclusions**

Combining all the evidence from the systematic review and these trials, a few consistent points appear to emerge. The vast majority of patients presenting with a primary spontaneous pneumothorax do not need to be hospitalized but can be safely managed as outpatients following initial assessment and interventions, if indicated. If an intervention is necessary, the smallest-bore chest tube is preferred, and this may include a strategy in which a patient is discharged with devices designed for ambulatory management in place. Most important, these data indicate that nonintervention strategy is sound and reasonable in many instances. The pneumothoracies included for evaluation were large, representing nearly 65 percent of the hemithorax, yet still demonstrated uncomplicated recoveries. In an otherwise appropriate patient with a stable, nonenlarging pneumothorax, the best intervention may be the lack thereof

The opinions expressed herein are solely those of Dr. Radecki and do not necessarily reflect those of his employer or academic affiliates.  $\bullet$ 

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EM PICS WORTH A

### **IMAGES IN EM**



DR. THOMAS is an attending physician in the emergency department at Kaiser Permanente (Greater Southern Alameda area).



# Mistakes Are Harsh Teachers

No one can avoid all mistakes, but we can minimize and learn from ours

by BENJAMIN THOMAS, MD

"The hardest thing about being a doctor is that you learn best from your mistakes, mistakes made on living people."

−Dr. Karen Delgado¹

emergency medicine, no one ever wants to make a mistake. We assume worst first because at any minute a life could be at stake. As a resident, I was no stranger to making some mistakes. I had cases with bad outcomes, yet the impact of the cases seemed



to always be shielded by the umbrella of working with another attending. I don't think I ever appreci-

ated how high the stakes were until my name was the sole one on the chart. My first "miss" as an attending made me understand the gravity of even the smallest decisions I make as a physician.

The patient was a middle-aged woman with a history of chronic pain, fibromyalgia, and bipolar disorder who presented with constipation and abdominal pain. She was over a week out from a laparoscopic appendectomy. Prior to her emergency department arrival, she had an outpatient CT for abdominal pain that was negative and she had met with her surgeon the day prior. She reported three days of :

constipation, two episodes of nonbloody and : her go. At that point, I was a year out of resi-: nonbilious vomiting, and diffuse abdominal pain. She was taking an oral opioid around the clock for pain. Her last bowel movement was the night prior, and she was tolerating liquids. On exam, she was mildly tender to palpation throughout, and her abdomen was slightly distended. My initial thought was that she was suffering from an opioid-induced ileus. I considered a small bowel obstruction, but she was still passing gas, tolerating oral intake, and having bowel movements. Her exam wasn't worrisome, and she didn't have any concerning signs of a deeper infection.

Her labs were reassuring, and she had a kidney, ureter, and bladder test that seemed consistent with an ileus. She remained in the emergency department for some hours and, after a few attempts, still could not have a successful bowel movement. I discharged her home with return precautions. Several hours later, she came back in distress. A subsequent CT scan showed a high-grade obstructed volvulus with perforation and a large amount of intraperitoneal air. She was rushed to the operating and had almost 70 cm of necrotic bowel removed. She had a prolonged and complicated hospital course. She would ultimately survive and leave the hospital, but her life was never the same after.

I was devastated after hearing the news of this case. I kept thinking I shouldn't have let:

dency and had no outcomes like this. My confidence was crushed, and I needed to find a way to rebuild. An attending once told me that I would make more mistakes than I could remember and would be named in at least one lawsuit in the course of my career. I remember being skeptical of this as a resident-more so at the notion of making so many mistakes rather than being sued. Of course, no one can expect a physician to make the right decision 100 percent of the time. To err is to be human,

What I now find more important is the way in which we address and mitigate our mistakes. Dr. Jerome Groopman poignantly said, "Every doctor makes mistakes in diagnosis and treatment. But the frequency of those mistakes, and their severity, can be reduced by understanding how a doctor thinks." We gain expertise not only through sustained practice over time but also by receiving feedback that helps us understand technical errors, bias, and misguided diagnosis. Self-aware physicians learn to admit to their mistakes, analyze them, and keep them accessible at all times.1

I can now look back at this case and understand that my encounter with this patient was fraught with bias. From premature closure to anchoring, there were so many mental shortcuts taken that could have been avoided. As emergency physicians, we are especially susceptible to cognitive errors and bias. The emergency department is full of land mines that can distract us, be it abrupt traumas, nursing orders, code blues, or belligerent patients, to name a few. One study noted that health care professionals in the emergency department were interrupted 30 times on average in a three-hour work period.2 Despite our work environment, there are a number of ways to avoid errors like this in the emergency department. Asking simple questions such as:

- Am I feeling fatigued right now?
- Was this patient handed off to me?
- Have I effectively ruled out must-not-miss diagnoses?

More formal checklists can help prevent diagnostic errors.3

We often learn best from our mistakes, yet in our line of work, the cost of mistakes can be high. This was a practice-changing event for me and one that I will likely never forget. I hope to keep my future mistakes to a minimum but appreciate that through these mistakes, I will become a better physician. •

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PROTECT
YOURSELF FROM
LEGAL RISK

#### MEDICOLEGAL MIND



**DR. PENSA** is clinical associate professor of emergency medicine at the Warren Alpert Medical School of Brown University in Providence, Rhode Island; associate director (education) of the Emergency Digital Health Innovation program at Brown; and creator and host of the podcast "Doctors and Litigation: The L Word."

# Litigation in the Era of COVID-19

How physicians can protect against liability during the pandemic

by GITA PENSA, MD

hysicians are used to seeing billboards and daytime television advertisements for plaintiff's attorney firms. Our reactions to these ads usually range from indifference to annoyance. But recently, plaintiff's attorneys were called out publicly for advertisements actively soliciting COVID-19 malpractice cases. A few of these advertisements were shared widely on social media, with resultant incensed commentary from physicians and the public alike. This eventually forced a retraction and public apology from at least one firm.

Health care workers, particularly physicians, are preyed upon by unethical attorneys all the time, yet we rarely raise any public outcry. Why did *this* cause such vocal protest?

Physicians are caring for COVID-19 patients while risking our own health and the health of our families, often with inadequate personal protective equipment. We are being strained



in unprecedented ways. Also, the adverse outcomes in this pandemic are largely out of our control. Treatment options for COVID-19 are few and unproven. The virus has an unpredictable course, and unexpected deaths are common. Scarcity of resources can also affect outcomes. Surge plans may leave emergency physicians

working in the ICU or medical floor or managing improvised pop-up ICUs in their own departments. Many external factors ensure that undesirable outcomes will be increased overall—and yet, these advertisements suggest that physicians, as always, should be the scapegoats when anything goes wrong.

Consider this hypothetical case: A middle-aged man presents with influenza-like symptoms in the setting of the COV-ID-19 pandemic. He is febrile, with otherwise normal vitals. A chest X-ray is normal. A COVID-19 test is sent but will not return for several days. He is discharged to home, with return precautions and outpatient follow-up. At home, he worsens. He returns to the emergency department several days later and dies after a cardiac arrest at the time of intubation. Setting aside the grief of the patient's family and the physician at this terrible outcome, can the physician be sued?

Can the physician be held liable for malpractice?

#### **Tricky Question of Liability**

Yes, the physician can be sued, even in states with new liability protections in place that relax the legal standard for malpractice. However, whether that physician is held *liable* is determined by a jury at the time of trial. Juries eventually determine liability based on instructions given to them by the court on how to weigh evidence and what rules to follow. New emergency declarations in many states offer liability protections during the pandemic, sometimes using the term "immunity." Most of these are based in some fashion on model federal legislation (the Model State Emergency Health Powers Act, or MSEHPA) from 2001, which was drafted to help states prepare for the possibility of bioterrorism or other public health emergencies.

Physicians would like the word "immunity" to mean that patients cannot file lawsuits against them during this time. But sadly, that is not the case. Anyone can file a malpractice lawsuit, liability protections notwithstanding. And once the suit has been filed, it will need to be defended. If you are served, you will have to go through the stress of litigation until the case is tried in court and your liability is determined—or until the case is settled or dropped.

So what *does* immunity mean during the COVID-19 emergency, if it doesn't mean you can't be sued?

Ordinarily, juries determine liability using the "standard of care," which is defined differently in different states and generally means what a minimally competent and similarly



trained physician might do in circumstances similar to the one in question. In many states that have enacted liability protection, the physician is immune from liability *except* in the setting of "gross negligence or willful misconduct." These terms also are defined differently in each state, but in general, willful misconduct means a physician intentionally harmed someone, while gross negligence is showing wanton disregard for basic care of human beings.

The actual degree of liability protection varies from state to state, so it is important to know the current law where you practice. Some states are granting immunity to any care rendered during the pandemic, while others apply it only to COVID-19 patients. Still others require you to be working on behalf of the state in order to be protected.

In terms of federal legislation, on March 17, 2020, a declaration was published under the 2005 Public Readiness and Emergency Preparedness (PREP) Act to provide liability immunity for activities related to "medical countermeasures" against the ongoing COVID-19 pandemic. This is not thought to protect physicians from usual care rendered during COVID-19, but this will be considered on a case-by-case basis. In general, the liability immunity applies to those involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in the declaration. However, you should always document that you *are* potentially caring for COVID-19 patients in case the act might apply in some way in your defense should a lawsuit be filed.

Even though lawsuits still may be filed, these new protections are potentially helpful. Plaintiff's attorneys know that any case related to care during this time will be a very steep climb for them, and hopefully, this will be a significant deterrent. Juries are unlikely to forget the esteem that the public holds health care workers in right now, even if a trial is years away. These protections are not ironclad, but they may give you more peace of mind.

In states with no additional protections in place, the worst-case scenario is that a physician is held to the usual standard of care. But it is critical to remember that the standard of care changes with context and circumstances. The circumstances right now are pandemic circumstances. Juries will take that into account.

#### **Protection in Documentation**

The best advice I have for risk mitigation—other than taking you have taken the necessary steps to take care of yourself. •

good care of your patients—is to document well. COVID-19 care documentation is required to even consider application of the PREP Act. Be sure to explain any deviations from usual practice that are due to the pandemic. Document if hospital capacity or concern for the nosocomial transmission of COVID-19 factored into any decisions to discharge or admit a patient. Make sure your patients understand their discharge instructions and return precautions, and document that as well. Even for non-COVID-19 patients, consider charting a statement such as "... as this patient was seen during the COVID-19 pandemic, they were queried about fever, cough, [etc.]." This makes it clear that the patient is being seen at a time when hospital capabilities may not be at their norm.

There are other important ways to protect yourself legally. If you find yourself practicing outside of your usual environment, it is crucial that you are in touch with your insurance carrier to apprise them of those changes. You want to be assured *in writing* that you have coverage extending to any new activities.

Last spring, many physicians volunteered in hard-hit areas across state lines; some physicians even came out of retirement to help. In these situations, there are some federal protections against liability, and some states have their own sets of protections for volunteers. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act became active law; it includes Good Samaritan language that provides additional federal liability protections. Physicians and other health care professionals who provide *volunteer* medical services during the pandemic will not be held liable for care relating to COVID-19—again, except in cases of gross negligence or willful misconduct. The federal law supersedes any state laws that are less protective.

While all of this is helpful for volunteers, do *not* rely exclusively on these protections. You must have adequate malpractice insurance coverage for your volunteer activities. If a lawsuit is filed, it is crucial that you are covered, as an attorney will be required to defend your case and demonstrate whether these acts even apply. Attorney's fees will be thousands of dollars if paid out of pocket. It is much better to have proof of insurance coverage in writing, likely through your volunteering program. It is also important that your license is fully in order to practice in whatever state you may find yourself working.

Take proactive steps to protect yourself the best you can. Then go back to taking good care of your patients, knowing you have taken the necessary steps to take care of yourself. •



Honorary Membership Award

Jane Scott, ScD, MSN

Dr. Scott has worked in emergency care settings for

years, starting as a nurse in the Duke University emergency department, the Hillsborough, North Carolina, Volunteer EMS squad, and the Johns Hopkins emergency department as a nurse practitioner. After obtaining a doctorate from Johns Hopkins School of Public Health, Dr. Scott joined the Agency for Health Research and Quality as a program officer.

In 2005, Dr. Scott joined the National Institutes of Health (NIH) as director of the office of research training in the division of cardiovascular sciences at the National Heart, Lung, and Blood Institute (NHLBI). In 2008, she started to create the NHLBI K12 program in emergency care research. Since then, she has managed the K12 program and worked extensively with the emergency medicine researchers.



Honorary Membership Award Hugh Dean Wilkerson, JD, MBA, CAE

A native Arkansan, Mr. Wilkerson has spent most of his life in Texas. He earned a bachelor's degree at the University of Arkansas, MBA from the University of California at Berkeley, and a law degree from the University of Texas.

In the 1980s, Mr. Wilkerson practiced corporate law with a large Dallas law firm and served on the city council and as mayor pro tem of Coppell, Texas. In 1990, Mr. Wilkerson became the general counsel of Mothers Against Drunk Driving (MADD). Three years later, he became the national CEO of MADD.

He left MADD to become the executive director of ACEP. Being part of the EM family has been the most enjoyable period of his 40-year



Innovative Change in Practice Management Award Rahul Sharma, MD, MBA, FACEP

Dr. Sharma is professor and chair of the department of emergency medicine at Weill Cornell Medicine in New York City. He is also the emergency physician in chief at NewYork-Presbyterian/Weill Cornell Medical Center. In addition, he serves as chief and medical director for the NewYork-Presbyterian EMS enterprise and in several other executive roles, including as a member of the New York State Board for Medicine and as president of the NewYork-Presbyterian Hospital Medical Board.

Since 2016, he has founded and launched several telemedicine programs including the award-winning Emergency Department Telehealth Express Care and the Center for Virtual Care. Most recently, he led efforts to transform emergency medicine health care delivery in response to the COVID-19 pandemic.



Outstanding Contribution in Research Award

Alan E. Jones, MD, FACEP

Dr. Jones completed residency and a clinical research fellowship at Carolinas Medical Center in Charlotte, North Carolina, in 2001. He was on the faculty of the department of emergency medicine at Carolinas Medical Center for 10 years. He moved to the University of Mississippi Medical Center (UMMC) in 2011 and became chair of the department of emergency medicine in 2013. In 2017, he became the vice-chair of the council of clinical chairs, and in 2019, he was named chief operations physician at UMMC.

Dr. Jones has served as the executive medical director of Mississippi TelEmergency, executive medical director of the UMMC Mississippi Critical Care Organization, and the chief telehealth officer for the UMMC Center for Telehealth. In 2020, Dr. Jones stepped

down as chair and was named assistant vicechancellor for clinical affairs of the UMMC Health System.



Outstanding Contribution in EMS Award

James M. Atkins, MD

Dr. Atkins graduated from the University of Texas Southwestern Medical School in Dallas and performed his internship and residency in internal medicine and his subspecialty training in cardiology at Parkland Memorial Hospital in Dallas.

In 1972, he was asked to supervise part-time the internal medicine portion of the emergency department at Parkland Hospital, which he did for five years when he convinced the system to hire the first full-time staff for the emergency department. He has been involved in the American Heart Association (AHA) at the national and local levels, as well as with the American College of Cardiology Emergency Care Committee.

Dr. Atkins was medical director of the paramedic system in Dallas County for 27 years. He has been a professor of internal medicine and emergency medicine at the University of Texas Southwestern Medical School and works as a cardiologist at Parkland Memorial Hospital. •



The symposium is designed to address the continuum of care of the injured person. Topics will be relevant for physicians, nurses, EMTs and allied health providers who work together for interdisciplinary cooperation. While the online format is new, the caliber of presenters and quality of the content remains the same. Topics will include:

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- Vascular control and repair modalities for the ED, OR, and hybrid suite
- New transfusion therapies for trauma and the ICU
- New concepts in VTE in the trauma patient
- Adversity and building resistance in the trauma setting

For topics, speakers, CME credits and to register, visit **DetroitTrauma.org** 





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## **EM CASES**



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# 5 Tips on Testicular Torsion

#### Don't let myths lead to misdiagnosis

by ANTON HELMAN, MD, CCFP(EM), FCFP

20-year-old healthy man arrives at the emergency department at 4 a.m. complaining of one hour of excruciating right testicular pain that radiates to his right lower quadrant and right flank. He's been vomiting repeatedly. He has had no preceding lower urinary tract symptoms. Vitals are normal except for a heart rate of 115. His right testicle appears swollen with a

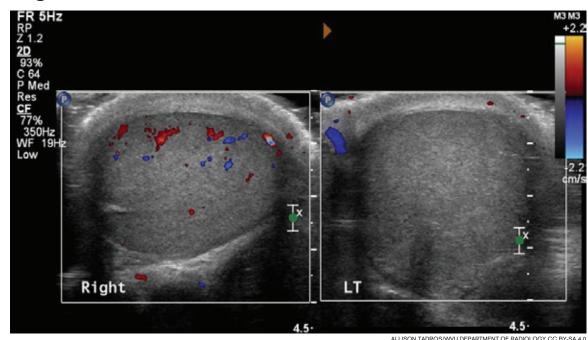


horizontal high-riding lie and is exquisitely tender to palpation. The cremasteric reflex is absent on the right side.

This is a relatively straightforward case for the diagnosis of testicular torsion, but un-

fortunately most cases of testicular torsion are not so clear-cut; the classic symptoms and signs often are not present. That is why 30 percent of the cases with failed

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Side-by-side ultrasound with Doppler imaging. Note the decreased Doppler flow of the left testicle indicating a torsion of the left testicle.

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testicular salvage can be attributed to misdiagnosis, with another 13 percent to delays in treatment after the diagnosis has been made.

# 1. Time counts, but salvageability is possible more than 48 hours after symptom onset.

Testicular torsion is a surgical emergency regardless of the time of onset. The spermatic cord twists, leading to impaired blood flow to the testicle, which causes ischemia and tissue necrosis. The degree of twisting and duration of symptoms are prognostic factors of testis salvage, with 96 percent success rates when perfusion is restored within four hours. Salvage is less than 10 percent if interventions are delayed for more than 24 hours.23 Nonetheless, salvageability has been shown beyond 48 hours after symptom onset, contrary to the historical teaching that symptoms of more than 24 hours are inconsistent with salvageable tissue. In delayed cases that are salvageable, there may be intermittent, rather than continuous, twisting of the spermatic cord, allowing reperfusion of the testicle. Therefore, it is incumbent on emergency physicians to manage all acute scrotum cases as surgical emergencies, even if the time from onset to presentation exceeds 24 hours.

#### 2. Testicular torsion can occur at any age.

Testicular torsion has a bimodal distribution: first year of life and in adolescence. I've had urologists tell me emphatically that testicular torsion does not occur in patients older than 40 years of age. Nonetheless, in a study of 469 closed malpractice claims with indemnity payment, the mean age was 23 years and there were four patients over the age of 40.4 The literature is rife with case reports of older patients with surgically confirmed testicular torsion.5-8

# 3. Testicular torsion can present with minimal, intermittent, or no scrotal pain.

While a sudden onset of severe, unrelenting unilateral scrotal pain radiating to the abdomen and/or flank is typical, the pain of testicular torsion can also be minimal or intermittent—again, attributed to intermittent twisting and untwisting of the spermatic cord that occurs in some cases. These pain honeymoons may partially account for poor clinical outcomes. As many as 20 percent of patients with testicular torsion present with isolated lower abdominal pain. In light of this, all male patients presenting with lower abdominal pain should have a genital examination for signs of torsion.

# 4. There is no single symptom or sign or combination of clinical features that has adequate predictive value in ruling out testicular torsion.<sup>11</sup>

Of particular importance is that the presence of a cremasteric reflex does *not* rule out the diagnosis. Studies report varying sensitivities as low as 60 percent and odds ratios (ORs) from 4.8 to 27.8.<sup>12,13</sup> While the presence of an elevated testicle (OR=58.8) and a horizontal testicular lie increase the likelihood of testicular torsion, it is often difficult to palpate the testicle only, thereby determining its position relative to other adjacent structures.<sup>14</sup> Scrotal

erythema, edema, and testicular swelling are commonly reported in patients with torsion. However, these findings are also commonly found in patients with epididymitis and torsion of the appendix testis. Prehn's sign is the relief of pain with elevation of the testicle, historically thought to be common in patients with epididymitis. This physical examination finding does not reliably distinguish epididymitis from torsion. One cross-sectional study of 120 patients found the Prehn's sign was present in 91 percent of patients with torsion and 21 percent of those with epididymitis.

In 2013, an attempt at combining

clinical features of testicular torsion in a clinical decision tool for the diagnosis of testicular torsion yielded the TWIST (Testicular Workup for Ischemia and Suspected Torsion) score. While this score showed a 100 percent positive predictive value when all clinical findings were present, potentially obviating the need for Doppler ultrasound imaging confirmation of the diagnosis, it failed to show adequate negative predictive value in ruling out the diagnosis clinically. Hence, all patients with any suspicion for testicular torsion should have urgent Doppler ultrasound imaging and/or urological consultation.

# 5. Doppler ultrasound has significant limitations in the diagnosis of testicular torsion.

If clinical features cannot rule out torsion, can a Doppler ultrasound? Typically, Doppler ultrasound findings for testicular torsion include an enlarged, hyperemic testicle; decreased Doppler flow to the parenchyma of the testicle itself; and a "whirlpool sign" (a spiral-like pattern of the spermatic cord twisting).<sup>17,18</sup> Unfortunately, the test characteristics of Doppler ultrasound are far from perfect, and it is subject to false negatives; the spermatic cord may untwist while the ultrasound is being performed and re-twist afterwards.

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#### Rabies Immune Globulin (Human)

#### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HYPERRAB® safely and effectively. See full prescribing information for HYPERRAB. HYPERRAB [rabies immune globulin (human)] solution for infiltration and intramuscular injection Initial U.S. Approval: 1974

#### ----INDICATIONS AND USAGE---

HYPERRAB is a human rabies immune globulin indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

#### <u>Limitations of Use</u>

Persons previously immunized with rabies vaccine that have a confirmed adequate rabies antibody titer should receive only vaccine.

For unvaccinated persons, the combination of HYPERRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis.

Beyond 7 days (after the first vaccine dose), HYPERRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

#### ----DOSAGE AND ADMINISTRATION----

For infiltration and intramuscular use only. Administer HYPERRAB within 7 days after the first dose of rabies vaccine.

Postexposure	HYPERRAB	•	Administer as soon
prophylaxis,	20 IU/kg		as possible after
along with	body weight		exposure, preferably
rabies	OR		at the time of the first
vaccine, after	0.0665 mL/kg		rabies vaccine dose.
suspected	body weight	•	Infiltrate the full
exposure to	Single dose		dose of HYPERRAB
rabies	3		thoroughly in the
			area around and
			into the wound(s), if
			anatomically feasible.
		•	Inject the remainder, if
			any, intramuscularly.

#### -- DOSAGE FORMS AND STRENGTHS-----

300 IU/mL solution for injection supplied in 1 mL, 3 mL and 5 mL single-dose vials.

-----CONTRAINDICATIONS-----

None.

#### ----WARNINGS AND PRECAUTIONS-----

- Severe hypersensitivity reactions, including anaphylaxis, may occur with HYPERRAB. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions.
- HYPERRAB is made from human blood; it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

#### --ADVERSE REACTIONS-----

The most common adverse reactions in >5% of subjects in clinical trials were injection site pain, headache, injection site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

#### ---DRUG INTERACTIONS--

- Repeated dosing after administration of rabies vaccine may suppress the immune response to the vaccine.
- Defer live vaccine (measles, mumps, rubella) administration for 4 months.

#### GRIFOLS

Grifols Therapeutics LLC Research Triangle Park, NC 27709 USA U.S. License No. 1871 Alternatively, a partially-torsed testicle may exhibit arterial flow but no venous flow, or it may show an abnormal high-resistance pattern of arterial flow. The sensitivity of Doppler ultrasound ranges from 88 to 100 percent.17 When ultrasound is nondiagnostic and the clinical presentation remains concerning, urology consultation remains warranted. The gold standard for diagnosis and exclusion of testicular torsion is surgical exploration.

#### Conclusion

Next time you are faced with a patient with acute lower abdominal and/or scrotal pain, consider the diagnosis of testicular torsion regardless of age. Understand that the duration of symptoms should not guide urgency of management and that all cases of suspected testicular torsion must be treated:

as a surgical emergency. Remember that the presence of a cremasteric reflex does not rule out testicular torsion and that all clinical characteristics and even Doppler ultrasound have significant limitations in making or excluding the diagnosis. Urological consultation should always be obtained in equivocal cases.

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#### **Indication and Usage**

HYPERRAB® (rabies immune globulin [human]) is indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

#### Limitations of Use

Persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer should receive only vaccine.

For unvaccinated persons, the combination of HYPERRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis.

Beyond 7 days (after the first vaccine dose), HYPERRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

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#### For infiltration and intramuscular use only.

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HYPERRAB is made from human blood and may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The most common adverse reactions in >5% of subjects during clinical trials were injection-site pain, headache, injection-site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

Do not administer repeated doses of HYPERRAB once vaccine treatment has been initiated as this could prevent the full expression of active immunity expected from the rabies vaccine.

Other antibodies in the HYPERRAB preparation may interfere with the response to live vaccines such as measles, mumps, polio, or rubella. Defer immunization with live vaccines for 4 months after HYPERRAB administration.

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HyperRAB® (rabies immune globulin [human]) is indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

HyperRAB is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent that can cause disease. There is also the possibility that unknown infectious agents may be present in such products.



