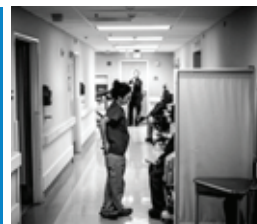




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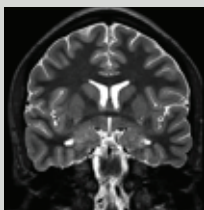
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EM LITERATURE
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EMBRACING THE POWER TO CHANGE

Update from the
2019 Leadership
& Advocacy
Conference

by L. ANTHONY CIRILLO,
MD, FACEP

The ACEP Leadership & Advocacy Conference (LAC) gives ACEP members a unique opportunity to learn more about what it takes to be a leader and provides updates on the key national and state issues affecting the practice of emergency medicine. This year, we descended on Capitol Hill

May 5–8 to amplify the

CONTINUED on page 6



Advocacy, Strategy, & Shared Purpose

Midyear report from
ACEP President Dr.
Vidor Friedman

Leading an organization as large and diverse as ACEP requires a focus on both the urgent problems of the moment and the long-term health of the organization and its members. For ACEP President Vidor E. Friedman, MD, FACEP, centering his efforts on improving life for emergency physicians and advocating for shared areas of concern have allowed him to tackle both current issues and long-term strategy initiatives.

From a leadership perspective, Dr. Friedman has accomplished much in a short time. Instead of spending the usual year as ACEP President-Elect, he only spent three months in the role before assuming the presidency in September 2018. He was elected by the ACEP Board of Directors in June 2018 to serve as President-Elect following the resignation of former ACEP President-Elect, John Rogers, MD, FACEP.

Dr. Friedman recently sat down with

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FINANCIAL ADVANTAGES FOR EMERGENCY PHYSICIANS

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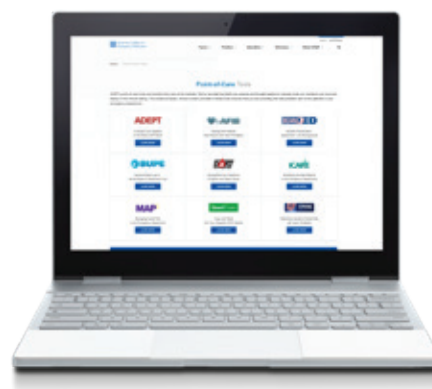
UPDATES AND ALERTS FROM ACEP

Congrats, ACEP's Outstanding Medical Students

The winners of our 2019 Outstanding Medical Student Awards have been announced! This honor recognizes students who excel in compassionate care of patients, professional behavior, and service to the community and/or specialty. Winners receive a year of free ACEP membership and free registration to the Scientific Assembly. This year's winners are:

- **Arthur Broadstock**, The Ohio State University College of Medicine
- **Alexandria Gregory**, Saint Louis University School of Medicine
- **Jonathan Lee**, University of California, Irvine
- **Andrea Quiñones-Rivera**, University of California, San Francisco
- **Stephanie Winslow**, University of Florida College of Medicine

The following students received honorable mentions: Adrienne Caiado (Penn State College of Medicine), Reed Macy (University of Texas Southwestern), and Dylan Lukato (University of Wisconsin School of Medicine and Public Health).



Now Available: New POC Tools for Buprenorphine, AFIB

ACEP recently added two new point-of-care (POC) tools to its growing library. BUPE is a quick and easy tool to assess patients for opioid withdrawal and the use of buprenorphine. It provides indications, side effects, and expected responses to buprenorphine. Eric Ketcham, MD, FACEP, presented the new buprenorphine tool at the Rx Drug Abuse & Heroin Summit in Atlanta this April.

The AFIB tool helps determine the best way to control rapid atrial fibrillation and assists with identifying patients who can be converted to sinus rhythm in the emergency department. Find both of these resources in our library of bedside tools at www.acep.org/PointOfCareTools.

Advocacy Alert: Seeking Cosponsors for Bill to Improve Mental Health Access from ED

Contact your legislators to cosponsor S. 1334/H.R. 2519, the Improving Mental Health Access from the Emergency Department Act. This ACEP-drafted legislation was introduced May 3, 2019, and would provide additional resources for patients with acute mental health needs who seek care in the ED due to a critical shortage of inpatient and outpatient resources. It was introduced in the House of Representatives by Rep. Raul Ruiz, MD (D-CA), who is also

a board-certified emergency physician, and in the Senate by Sens. Shelley Moore Capito (R-WV) and Maggie Hassan (D-NH). Contact your legislators at www.acepadvocacy.org/actionalerts.aspx.

ACEP to Host Event with Key Health IT Stakeholders

ACEP is hosting the HIT Summit on July 8, 2019, to bring the industry together to build a collaborative 10-year vision for emergency care through digital transformation. Stakeholders from diverse groups, including physicians, hospital representatives, medical specialty societies, researchers, academic physicians, IT vendors, electronic health record (EHR) vendors, government officials, quality experts, and payers, have been invited to participate. This collaborative vision aims to address some of the biggest issues facing technology in health care, including interoperability and data liquidity, EHR usability and workflow, and big data and what it means in emergency medicine. Look for a recap of the event in an upcoming edition of *ACEP Now*.

Geriatric ED Accreditation Grants for VA Facilities

With a grant from the John A. Hartford Foundation and West Health, ACEP is offering to accredit 20 VA facilities as geriatric emergency departments at no cost. ACEP's Geriatric ED Accreditation Program was developed by leaders in emergency medicine to ensure our older patients receive well-coordinated quality care, specific to the needs of the geriatric population, during every ED encounter. Learn more about the program at www.acep.org/geda.

ACEP Meets with OSHA to Address ED Violence

ACEP held a meeting with the Occupational Safety and Health Administration (OSHA) to discuss strengthening protections for health care workers, especially those in the emergency department, from workplace violence. Currently, no such federal regulation exists, but OSHA has begun to explore its development. ACEP has long advocated for such protections; most recently, ACEP drew attention to the issue by releasing results of a survey that reported nearly half of emergency physicians polled had been physically assaulted, with more than 60 percent of assaults occurring in the past year. ACEP worked with congressional offices to refine H.R. 1309, The Workplace Violence Prevention for Health Care and Social Service Workers Act, and recently sent a letter of support asking Congress to consider how emergency departments, in particular, are staffed to ensure the important provisions of this legislation are implemented appropriately. Stay updated on this issue at www.acep.org/EDsafety. ➔

CORRECTION

Our May issue erroneously claimed that *ACEP Now* has the #1 readership position in emergency medicine. *ACEP Now* is #1 in advertising. We apologize for the error.

United States Constitution Versus FDA

OFF-LABEL DISCUSSIONS MAY NO LONGER BE FAUX PAS

by KENNETH ALAN TOTZ, DO, JD, FACEP

The First Amendment to the U.S. Constitution states in totality, “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.” This freedom of speech, so often cited, is not absolute. For example, you cannot legally yell, “Fire!” in a crowded movie theater, intentionally publish untruthful facts about another person, or untruthfully advertise commercial products.

Recently, commercial speech has been the center of much debate in medical-legal circles.

HISTORICAL REVIEW

The Food and Drug Administration (FDA) received its congressional power to regulate medicines and medical devices through the Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938.¹ Through this act, the FDA controls the commercialization of new medical products through a rigorous multistage approval process. The process not only allows entry of products into the stream of commerce but also determines the labeling of those products. Product labeling articulates the specifically approved uses supported by previously performed medical research, along with side effects and other precautions to be considered. Unapproved indications or off-label uses communicated in the product labeling will identify the product as being mislabeled or misbranded and subject the manufacturer to FDA scrutiny and penalties. Although the approval process may yield additional product benefits, only FDA-approved indications are permitted on the label.

The FDA recognized that significant costs and lengthy approval times precluded many manufacturers from pursuing additional useful indications for their medical products. As such, the FDA introduced the FDA Modernization Act (FDAMA) of 1997, which allowed manufacturers to disseminate literature and have discussions regarding off-label uses of its medical products. Unfortunately, any communications regarding off-label uses had to occur following the filing or imminent filing of a supplemental new drug appli-

cation (sNDA).

Until recently, discussions of off-label uses between pharmaceutical representatives and medical professionals outside the scope of the FDAMA were considered criminal offenses. Dissemination of off-label medical product usages were limited to discussions at non-pharmaceutical-sponsored continuing medical education events, independent drug compendia resources, peer-reviewed journal articles, and other non-pharmaceutical manufacturer internet resources.

RECENT DEVELOPMENTS

All this changed in 2017 when the Arizona legislature passed HB 2382, the Free Speech in Medicine Act. The law forbids punishment by any Arizona state agency of a pharmaceutical manufacturer, its representatives, or medical health professional for the “truthful promotion of an off-label use of a drug, biological product, or device.” Proponents of the bill touted the free speech protections of the First Amendment that should allow such open conversations and the ability to freely pass along any beneficial alternate uses of the medical products as foundational support for its adoption.²

Opponents of the law feared drug makers would use the off-label pathway as an easier route to widespread drug adoption without the rigorous oversight of the traditional multistage FDA approval process. Challengers to the law also opined that the pharmaceutical industry would be disincentivized to share adverse medical information regarding off-label uses, culminating in another Fen-Phen disaster.

In any event, the Arizona law received the attention of many other state legislatures that ultimately moved to pass their own versions of the Free Speech in Medicine Act. Missouri, Mississippi, Tennessee, and Colorado have recently proposed similar versions of the Arizona law, but only Tennessee’s version had become law at press time.

The federal courts have similarly ruled favorably for the pharmaceutical industry when it has been prosecuted under the off-label restrictions of the FFDCA. In *United States v. Caronia*, an appeals court overturned the lower district court’s conviction of a pharmaceutical representative who had discussed off-label usages of a

previously FDA-approved narcolepsy drug, Xyrem. The court held, “The government cannot prosecute pharmaceutical manufacturers and their representatives under the FFDCA for speech promoting the lawful, off-label use of an FDA-approved drug.”³ The U.S. Court of Appeals for the Second Circuit further clarified that any false or misleading promotions would not be entitled to similar First Amendment protections.

In contrast to the defensive posture of the defendant in the *Caronia* case, Amarin Pharmaceuticals went on the offensive against the FDA in *Amarin Pharma, Inc. v. United States FDA*, after the FDA failed to approve one of its cholesterol medications for extended indications. The FDA insisted it would consider the drug misbranded should Amarin elect to share any of its favorable research data with physicians.⁴ In *Amarin*, the district court dealt another blow to the FDA by reaffirming its earlier findings in *Caronia*—that is, that First Amendment commercial speech protections apply to truthful and non-misleading speech.

So the next time your favorite drug rep comes calling, feel free to discuss off-label uses of their medical products. You may be quite surprised to learn some of your colleagues have found some novel and helpful uses for common medications and/or medical devices in your emergency department.

Note: No information within this report should be construed as medical or legal advice. Independent medical and/or legal advice should be sought based on each individual’s particular circumstances. ➕

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DR. TOTZ is facility medical director at First Choice Emergency Room at Adepts Health in Texas.



ILLUSTRATION: CHRIS WHISSEN

Expert Witness Misleads Jury in Pediatric Sepsis Case

STANDARD OF CARE REVIEW PANEL WEIGHS IN

by CHARLES F. PATTAVINA, MD, FACEP

A boy age 3 years and 4 months was brought to the emergency department at 6:40 a.m. with complaints of cold symptoms, including congestion, runny nose, and a fever for two days. His past medical history included typical childhood illnesses, and his immunizations were up-to-date.

Vital signs were temperature 103.6°F, heart rate (HR) 156, and respiratory rate (RR) 40, and he weighed 14.6 kg. Other than nasal congestion, his exam was normal. It was documented that he was alert, making good eye contact, and cooperative. His heart, lung, abdomen, extremity, and neurological examinations were all normal. Notably absent were meningismus, Kernig's, and Brudzinski's signs.

He was given an antipyretic and observed, during which time his temperature decreased to 101.4°F and then 98.9°F. He remained awake, alert, and appropriate. He was diagnosed with an upper respiratory infection, and his parents were told to follow up with his primary care physician (PCP) in one to two days or return to the emergency department if he became worse.

That afternoon, he was seen by his PCP for persistent fever and cough. His exam was unchanged, and symptomatic treatment was continued.

The next day at 7:10 a.m., he was brought back to the emergency department with complaints of rapid breathing and weakness. His history included fever, cough, and vomiting six times. In addition, his shortness of breath was reported to be increasing. Sore throat and chest and abdominal pain were denied.

Vital signs were temperature 100.8°F, HR 155, RR 38, blood pressure 124/91, and oxygen saturation of 99 to 100 percent on room air. He weighed 14 kg. He again made good eye contact, and other than the nasal congestion, his exam was unremarkable. Specifically, he had moist mucous membranes, no rash, and no focal neurological or meningeal signs, and he was consolable.

At 7:30 a.m., he was given trimethoprim for nausea and an oral fluid challenge. At 8:30 a.m., a point-of-care glucose test was 97. At 9:41 a.m., a chest X-ray and urinalysis were obtained, and the child was noted to have difficulty bearing weight.

At 10 a.m., an IV was started, and labs were

drawn. The boy's urine was positive for glucose, protein, and ketones. His hemoglobin was 14.2, and the white blood cell count was 0.6. The decision was made to transfer him to a hospital with a pediatric intensive care unit (PICU), and he received ceftriaxone and a 300 ml (20 mL/kg) IV fluid bolus. A lumbar puncture (LP) was performed, yielding cloudy fluid, which later grew *Streptococcus pneumoniae*.

At 11:30 a.m., the patient was placed in an ambulance. His most recent vital signs were temperature 101.4°F, HR 138, and RR 54. Following the 10-minute transfer, as he was being wheeled to the PICU, he arrested and was resuscitated. However, he died later that day. A lawsuit was subsequently filed, and the plaintiffs were awarded more than \$1 million as a settlement.

Expert Witness Statements/ Allegations About Standard of Care and ACEP Guidelines

ACEP has two options to review expert witness testimony (plaintiff or defense). If the witness and referring physician are both ACEP members, a formal ethics complaint can be filed.

The testimony is then reviewed by the Ethics Committee in the context of ACEP's policy Expert Witness Guidelines for the Specialty of Emergency Medicine. Its recommendation is then reviewed by the Board of Directors, and an adverse decision can lead to a private or public letter of censure or suspension of membership. The member may request an appeal hearing prior to an action taking effect.

If the witness is not an ACEP member, the testimony can be referred to the Standard of Care Review Panel, which will then review the testimony and report its findings in *ACEP Now*. This is done to reduce the chance that such testimony erroneously establishes the standard

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discharge did not constitute a source of infection. In addition, the panel identified the following issues in the 300 pages of transcribed testimony:

- An inappropriate, inflammatory tone and word choices amounting to hyperbole; outlandish statements (including unsupported claims); and apparent pandering to the plaintiffs were noted. Also, with regard to several key aspects of the presentation, the witness gave significantly more weight to the recollections of the parents than to the medical record.
- The expert witness also stated that a complete blood count (CBC) can differentiate between viral and bacterial infections, rhinorrhea is generally due to allergies and not a respiratory infection, and fever cannot cause an elevated respiratory rate. He also suggested a head CT is required prior to an LP.
- He also said he thought the ACEP Expert Witness Guidelines did not apply to him, even though he was an ACEP member at the time of the testimony.

Issues Considered by the Standard of Care Review Panel

- The witness's manner of speaking and tone
- Reliance on the recollections of lay relatives over the medical record
- Application of SIRS and sepsis criteria to children
- The making of broad, unsupported statements and suggestions including:
 - » A CBC can differentiate between viral

and bacterial infection

- » Rhinorrhea is generally due to allergies and is not a symptom of an upper respiratory infection
- » Fever cannot cause an elevated respiratory rate
- » A CT is required prior to an LP, including in the context of this case
- The witness's statement that the ACEP Expert Witness Guidelines did not apply to him

Conclusions of the Panel

Physicians may provide expert opinion to the court, and they have a right to be compensated fairly for their time and effort in doing so. Expert testimony is based on the expert's opinion but must be supported by the medical evidence to a reasonable degree of certainty. Hyperbole, insults, name calling, inflammatory language, and attacks on the character of others have no place in medicine (including expert testimony).

While observations of patients and family members are very important and sometimes vital to the care of patients, it is inappropriate to use their recollections to discredit or supersede a medical record unless there is an independent reason to doubt the veracity of the record.

Much is written about the approach to febrile children, particularly those without a source for the fever. There are no SIRS criteria to apply to children, and it was inaccurate and misleading to insist such a standard existed. It is false to say this child required a sepsis workup due to his vital signs.

The panel felt none of the four other statements above were supported by any literature, and all were incorrect:

- A CBC is one piece of information that can be helpful in determining whether a serious illness exists, particularly an infection. It is not automatically required in a child of this age with a fever, even with an elevated heart rate and respiratory rate.
- Rhinorrhea may be a symptom of upper respiratory infection, including viral infection.
- It is generally accepted that fever alone can cause an elevated respiratory rate as well as an elevated heart rate.
- The literature does not support CT prior to LP without suspicion of a space-occupying lesion, and the radiation exposure most likely outweighs any benefit in the pediatric population.

When applicable, ACEP policies apply to all members, and that includes the Expert Witness Guidelines, as the policy itself makes clear. Apparently, the witness either changed his mind about this or contradicted his testimony by subsequently resigning his ACEP membership, possibly to avoid sanction by the College. The consensus of the Standard of Care Review Panel was that the physicians treating the patient in this case met the standard of care. +



DR. PATTAVINA is an emergency physician at St. Joseph Hospital in Bangor, Maine, and immediate past President of the Maine Medical Association.

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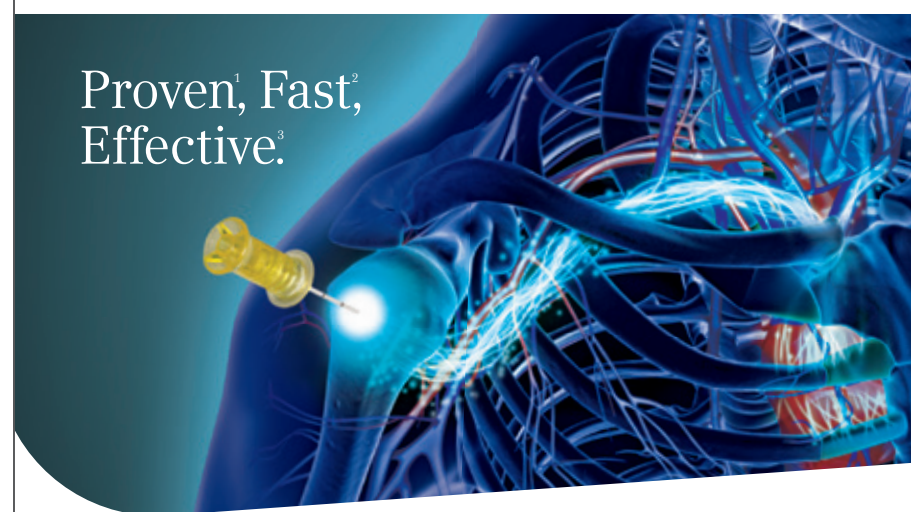
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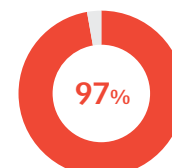
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LAC19: A First-Timer's Perspective

by VALERIE A. PIERRE, MD

LAC19 was an amazing networking and professional opportunity that solidified my interest in emergency medicine policy. As the health care landscape in America rapidly evolves, emergency physicians can no longer adequately care for our patients within the confines of our departments. To best serve our diverse and unique patient populations, we must become advocates outside the ED as well.

The Health Policy Primer sponsored by EMRA and ACEP's Young Physicians Section gave me a better perspective of the importance of leadership and advocacy in our field. There is an increasing focus on mental health, its complex interface with substance abuse, and one's physical health, in addition to the rising health care costs and their effect on our economy.

Steven Stack, MD, MBA, FACEP, the first emergency physician to serve as president of the AMA, reaffirmed what I now know to be true when he said, "If you don't have a seat at the table, you're probably on the menu."

We must be involved, continue to humbly gain time and experience in our field, and be pragmatic about our approach to the issues we are facing. Our society is changing, and we can no longer be silent on things that matter. Our patients' lives literally depend on us. +

DR. PIERRE is an emergency medicine resident at Brookdale Hospital Medical Center in Brooklyn, New York.

LAC | CONTINUED FROM PAGE 1

voice of emergency medicine with members of Congress on the issues of surprise billing and our country's mental health crisis.

The Prep

With nearly 150 EM residents and medical students included in the 500-plus attendees at the conference, the Emergency Medicine Residents' Association (EMRA) and ACEP's Young Physicians Section (YPS) once again started the action on Sunday with their Health Policy Primer program. This half-day session started with a keynote talk by Steven Stack, MD, MBA, FACEP, the only emergency physician to be president of the American Medical Association. Dr. Stack challenged attendees to be "doers" who turn their words into action. Attendees got an introduction to several key issues—the opioid epidemic, prudent layperson, surprise billing, and the road to universal health care—during the lighting rounds.

As a new addition to the conference, ACEP developed a "Chapter Leadership Session" providing information and advice for current and future chapter leaders to more effectively engage members and strategically lead their chapters.

The Kickoff

The Leadership Summit challenged us to take the lead on creating positive change in the health care arena. Brian Williams, MD, a trauma surgeon from Texas, provided a very personal and emotional description of advancing through the medical education system as an African American male. He described what it was like to play a central role caring for the Dallas police officers wounded by a gunman who was reportedly angry over police shootings of African American men. During that shooting, which occurred at the end of a protest against the police killings of Alton Sterling in Louisiana and Philando

Castile in Minnesota, five police officers were killed and nine were injured. Dr. Williams' touching comments at the press conference after the shooting resonated with people across the country, and his LAC session was riveting.

The Deep Dive

Monday's afternoon session kicked off with a panel discussion about the public health crisis of firearm-related injuries and deaths and the emotionally-charged political and policy issues that influence attempts to better understand and reduce injuries from firearms. Demonstrating how emergency physicians can "walk the walk," Roneet Lev, MD, FACEP, who was recently appointed chief medical officer of the White House Office of National Drug Control Policy, and Gerard R. Cox, MD, MHA, deputy undersecretary of health for the Veterans Health Administration, discussed the critical importance of emergency physicians being willing to serve in the public sector and how those who serve can become key policymakers in health care.

The final full group session of the day brought staff members from both congressional members and key House and Senate committee offices to talk about the increasing activity on out-of-network/surprise billing legislation at the federal level. These speakers are key thought leaders and senior policymakers in Congress. The opportunity to provide them the emergency medicine perspective was critically important to ensure that they understand the unique challenges facing our specialty as the 24/7/365 safety net for the country.

On the Hill

Tuesday's meetings on Capitol Hill were perfectly timed. We asked members of Congress to co-sponsor ACEP-crafted legis-

CONTINUED on page 8





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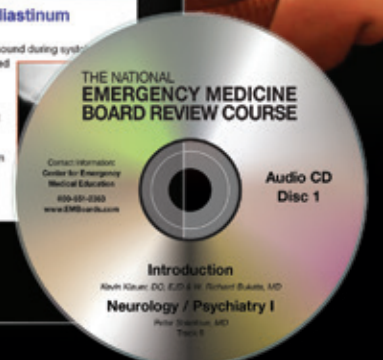
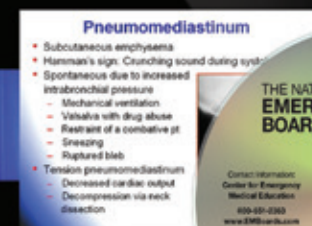
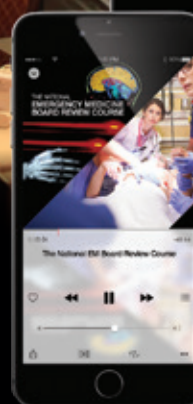
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lation to improve the community resources available for patients needing mental health care. The Improving Mental Health Access from the Emergency Department Act, sponsored in the House by emergency physician Rep. Raul Ruiz, MD (D-CA), and in the Senate by Sen. Shelley Capito-Moore (R-WV), would provide grant funding to communities to bolster outpatient and inpatient behavioral health care services.

As we met with legislators, our second request was for support for a fair and reasonable legislative solution to the issue of out-of-network balance billing. ACEP is advocating for a framework solution that protects patients from additional financial risk when they receive out-of-network care in an ED but ensures providers receive a fair payment from insurers for the care provided. This is a rapidly-developing issue. See the sidebar to catch up with the surprise billing developments since LAC.

Be There Next Year

LAC is a great opportunity to educate yourself on the political and policy issues affecting how we care for patients. It is a tremendous opportunity to be a strong voice for your patients and your profession by speaking directly with members of Congress and other federal policymakers.

Save the date: The next Leadership & Advocacy Conference is April 25, 2020. +

DR. CIRILLO is a member of the ACEP Board of Directors and the director of government affairs for US Acute Care Solutions.



L. Anthony Cirillo, MD, FACEP, (left) and Valerie A. Pierre, MD.

The Surprise Billing Battle: What You Need to Know

Surprise billing (also known as out-of-network billing) is one of the most important issues facing emergency physicians today. The decisions being made in Washington, D.C., could have a far greater impact on how we care for our patients than even EMTALA did in 1986.

For more than a year, surprise billing has been a central focus of ACEP's federal advocacy efforts, building on years of state-level advocacy already done on this issue. Much of this conflict over surprise billing is playing out in the media, and insurers have been trying to paint emergency physicians in a bad light. Our public relations team is working diligently to make sure the physician side of the story is fairly portrayed both in the press and in Congress.

We've seen a flurry of legislative activity after LAC19. In response to the May 9, 2019, release of the White House's principles regarding surprise billing, ACEP President Vidor Friedman, MD, FACEP, said "ACEP shares the administration's view that improving transparency is critical to stopping surprise bills ... Still, the principles the White House laid out do not go far enough to protect patients."

On May 17, 2019, we responded to the STOP Surprise Medical Bills Act of 2019 introduced by several senators, saying it would tilt a proposed arbitration process in the insurer's favor.

The surprise billing debate is changing daily, and ACEP's advocacy efforts are ongoing. To stay current on what's happening in D.C., visit www.acep.org/surprise-billing. +

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Scenic view of the city market in Erbil. Left to right: Dr. Greg Jacobs; John Miller; and Dr. Balentine.

MISSION KURDISTAN

A recent medical mission trip opened my eyes and expanded my worldview

by BRYAN BALENTINE, MD, FACEP

Of your top 10 international travel destinations, where does Kurdistan rank? It wasn't initially on my list at all. After all, who would want to spend their own money to travel to a war-torn country with Islamic extremists just waiting to harm someone from the United States? At least that is what I surmised after following years of international news. Trying to understand the complexity of the Islamic State of Iraq and Syria (ISIS), Syria, Syrian rebels, Turkey, Russia, and the United States, all with their own agendas fighting in a very concentrated area of the world, is a challenge when only familiar with the U.S. perspective.

In the middle of all this enter John Miller and One Vision International. Even while the war was active against ISIS in northern Iraq, he would travel, usually alone, and coordinate humanitarian-aid shipments of water filters, coats for the cold winters, shoes, children's clothes, wheelchairs, and crutches to help everyone displaced from the war. Through these experiences, he witnessed the need for a medical mission trip.

I traveled with John and One Vision International multiple times to Haiti and the Dominican Republic. On some of these trips, one

of my best friends from residency, Greg Jacobs, DO, came along. When John approached me about a trip to Kurdistan in northern Iraq, I said no multiple times for the reasons listed above. After each of his trips, he would provide me with an update, and I learned more and more about the kind and welcoming people there who were in need. After multiple invitations and a retreating ISIS, I finally said yes in mid-2018, and we started planning. One conversation later, Greg was on board.

The Trip

Day 1: We visited a military base and treated 100 soldiers for various medical problems. Several of these individuals had fought against ISIS in the recent past. They were extremely kind and appreciative of our time and efforts. We joined them in the "mess hall" and ate good-quality food, better than expected, on the typical metal tray often seen on television.

Day 2: John mentioned beforehand that his local hospital had requested Greg and I provide a lecture for their physicians. We would be speaking to their EM residents and attendings, with the goal of decreasing complications of central line placement by teaching them how to perform the procedure with ul-

trasound. The lecture also included peripheral IV placement with ultrasound to allow them to more successfully place peripheral IVs on patients with difficult anatomy.

In my limited experience, most international hospitals have ultrasound in the facility, but ED-provider utilization varies. Dr. Ben Smith from the University of Tennessee at Chattanooga graciously loaned me an excellent vascular access lecture. Greg and I tag-teamed the delivery and it was well-received.

We met the emergency department director, Dr. Dilshad Al-Sheikh, who gave us a hospital tour, including the emergency department seeing 700 patients a day. We were pleasantly greeted by several staff physicians and learned of their EM residency training program. I was amazed at how they functioned with limited resources. CT scanner? Broken. A new GE machine had been donated but was still in several boxes upstairs. (I recently learned that a GE representative was scheduled to visit soon to install the scanner.)

Day 3: We returned to the same facility and conducted a hands-on ultrasound workshop. They had two donated high-quality portable machines that were almost right out of the box. Greg taught them the focused assessment with



Dr. Balentine teaching peripheral IV access with ultrasound to attendings and residents.



Dr. Greg Jacobs teaching the FAST exam.



The trauma hospital in which Dr. Balentine worked with the ED attendings and residents.

sonography in trauma (FAST) exam, and I focused on vascular access. It was so rewarding watching the faces of the residents and attendings light up as they quickly learned their new skills.

Later that evening, we were invited into the home of a lady John affectionately called "Mom" who fed us an amazing meal that had taken 10 hours to prepare. During our conversation, we discussed the recent war and learned of the many atrocities committed by ISIS in her country. As one resident recounted: "ISIS came in quickly to Sinjar region where a high concentration of Yazidis are located. They killed the men and took the women and children for use as sex slaves. Over 3,000 women are still missing. Some of the women who have escaped or have been "bought" back tell stories of multiple rapes and of being sold to many different men. They took them to Syria and other places as trophies. Those that could fled to Sinjar mountain, where many died of heat, thirst, and lack of food. Many women who could not escape committed suicide." Our host relayed that Christians and Muslims had lived

CONTINUED on page 18

A Driving Force for EM Education in the Americas

DR. HAYWOOD HALL HAS DEVOTED HIS CAREER TO IMPROVING EMERGENCY CARE FOR SPANISH-SPEAKING AND MARGINALIZED POPULATIONS

Not every career path in medicine follows a straight line, but the twists and turns can make one a better, more compassionate physician. Haywood Hall, MD, FACEP, FIFEM, FAAEM, didn't finish high school, dropping out to work a variety of jobs in New York City. One day, while working outside of a Brooklyn emergency department, he decided he could be an emergency physician. He got his GED, completed his medical training, and joined the ranks of emergency medicine. However, he never lost the appreciation of diversity and community that he developed from his childhood in Mexico and early work in New York, and the desire to help and support communities infuses his work to this day.

Dr. Hall recently sat down with Andrea Green, MD, FACEP, an emergency physician and chair of ACEP's Diversity, Inclusion, and Health Equity Section, to discuss his career. Here are some highlights from that discussion.

AG: From the beginning of your career to being acknowledged as a hero of the specialty was quite an interesting journey. How did you get started in EM?

HH: I was raised in Mexico and come from a multicultural family. I went to 12 different schools by the time I was in 10th grade and actually dropped out and became a musician, a piano tuner, a mechanic, and I was even a New York cab driver. All of these things were me trying to find where I fit in the world. As I got older, I realized that being able to work in a multicultural environment, like New York, is a very important skill.

One day, I was reading electric meters outside of a hospital ED in Brooklyn and I realized, "Wow, I could be doing this," because I always had an interest in science. I always had an interest in different cultures and being able to find a way to help. That was just part of my DNA. Suddenly, it struck me like a bolt of lightning, and I got a GED with the idea of becoming an emergency physician.

AG: Tell us about how you see the social impact of emergency medicine.

HH: The ED is such a central part of the community wherever you are. We really get to see everything that's wrong and everything that's not working; it's not just a particular illness or particular medical condition. It could be that there are no pediatricians in the community and you have all the kids in the ED, or it could be a new wave of drugs that comes in. I really see the emergency department and emergency care as a barometer of what is happening in the community on a public health level.

AG: You're a fellow of the International Federation for Emergency Medicine (IFEM). What inspired your interest in international emergency medicine?

HH: I, like many people, was very idealistic



Dr. Haywood Hall (right) with PACE MD advisory board member Dr. Judith Tintinalli.

about health care, but I felt limited in trying to find new solutions that would require developing health care and health care systems in various places. I respect the kind of metro-centric big city and big medical center part because that's clearly the base, but I felt the challenge to go out to where those things are not and to figure out how to make an impact there.

Having been raised in Mexico, I always felt there was something missing in my life in the U.S. I was on vacation and came across a big car accident in an isolated place in Mexico. Very few people seemed to know what to do. An ambulance came, and I wound up decompressing somebody's chest who had a pneumothorax. I was struck with the idea that my skills and knowledge might be able to go very far here if I started a training center.

AG: You founded the Pan American Collaborative Emergency Medicine Development (PACE MD) program in 2002 with the goal of improving the quality of emergency care patients receive in underserved areas of Latin America. Can you briefly describe the program?

HH: We started off just by making ourselves available to the health ministry in Guanajuato, Mexico. They were working on a prehospital system. Before long, we had some students who came on to help with the project who wanted to learn Spanish, so we created this medical Spanish program. When they came down, we started working on different projects, and then over time, we became a training center. We started buying mannequins, and we became a training center for the American Heart Association.

We started an advanced life support for obstetrics program, and we've trained 17,000 people in that program. Altogether, we've trained 35,000 people in the various modular programs we've developed. We established the first public-access defibrillator program in Latin America, and we also set up a technical conference on forensic emergency care, especially

as it relates to sexual assault. We've helped set up a series of conferences and actually did the vast majority of the work for the successful bid for the International Conference on Emergency Medicine held in Mexico City last year.

A big role that I took within the IFEM was going country by country, finding where residency programs existed and where they were recognized by the government, and encouraging them to become voting members of the IFEM. We did that for Panama, the Dominican Republic, Cuba, Ecuador, and Venezuela. On the ground, it was really training people in emergency care, which could make a big difference in the outcomes.

AG: Congratulations on receiving the IFEM Humanitarian Award through your work with PACE MD. Can you summarize your relationship with the federation?

HH: Emergency medicine is a relatively new specialty, and we take it for granted that this exists everywhere, but that's not the case. Until recently, there were four countries, the United States, Canada, England, and Australia, that really had any development of our specialty. The work that we've done at PACE MD for Latin America has been happening all over the world, and now there are some 60 countries that recognize the specialty of emergency medicine and have training programs. IFEM is sort of the World Health Organization of EM.

AG: What opportunities exist for residents and physicians from the United States to participate in PACE MD?

HH: People could come as medical student electives or residents. We started providing CME, and we even have a pre-professional program to encourage people to go into health care and to understand the cultural aspects of care. We're not just a language school; we're actually a medical operation, and so we're able to, through the medical Spanish program (www.medspanish.com), have people

learn what is now an essential medical skill. There are 50 million Spanish speakers in the United States.

AG: So residents who participate in the PACE MD program get credits for their residency as a rotation?

HH: They have to clear it with their dean of students if they're medical students, or their residency program director, but yes.

AG: How do practicing emergency physicians get involved with PACE MD?

HH: They can contact us through www.pacemd.org or contact me at Haywood.Hall@pacemd.org. They can get the CME credit provided through the University of New Mexico. We can provide up to 50 CME credits, and physicians are primarily here to learn how to communicate with Spanish-speaking patients. I do have to point out that we're not licensed physicians in Mexico. Our role is really putting emergency physicians in contact with the physicians who actually have responsibilities for these patients.

AG: Can you say a little bit about what you're seeing on the border?

HH: I've always said that I'm sort of a migrant worker, tongue-in-cheek, but it's actually quite real. I've spent a lot of my career flying up to the border on the Mexican side and crossing the bridge twice a month. The emergency departments on the border have a very special burden. Migrants—and some are undocumented—have been through hell, and they're scared to death. They wouldn't have shown up in the emergency department if they didn't feel there was a serious problem. I've seen some unusual things, like people showing up needing dialysis, and the ED had to somehow find a way to dialyze them. They're not U.S. citizens, and they're not in the system. Some emergency departments actually have dialysis units.

I don't think people understand the magnitude of this problem. All politics aside, there's somewhere around 40,000 or so unaccompanied minors who show up across the border every year, and they're almost all from Central America. The unaccompanied minors are not coming from Mexico, and that's creating a whole other burden. A few children have died in custody, and so now ICE is sending them to emergency departments to get medical clearance. This is a very large number of people. We occasionally see tetanus, rabies, and tropical illnesses like dengue.

AG: Thank you so much for all the work that you've done. ☺

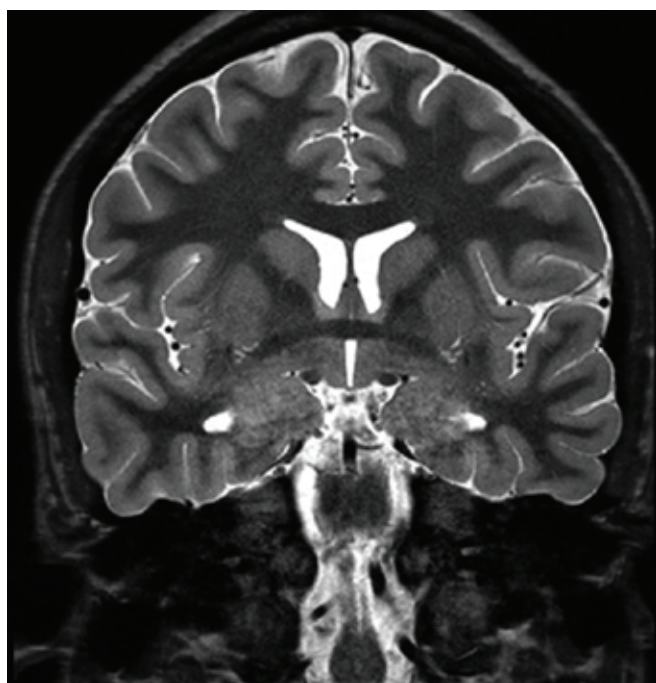
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DR. RADECKI is an emergency physician and informatician at Kaiser Permanente NW and is affiliated with the McGovern Medical School at UTHealth. He blogs at Emergency Medicine Literature of Note and can be found on Twitter @emlitofnote.

It's Not "Demonic Possession" Any Longer



A T2 coronal MRI of a patient with limbic encephalitis, displaying right amygdala enlargement and hyperintensity.

ACTA NEUROL SCAND.
2017;135(1):134-141. REPRINTED
WITH PERMISSION.

Diagnostic advances and awareness of autoantibody-mediated encephalitis answer long-standing conundrum

by RYAN PATRICK RADECKI, MD, MS

A few years ago, a best-selling autobiographical work, *Brain on Fire*, chronicled one of the first instances of diagnosis for N-methyl-D-aspartate (NMDA) encephalitis. The story depicted by the author is one of a young woman's descent into mad-

ness caused by encephalitis before its relatively novel cause is determined by a New York neurologist.¹ The book details her recovery,

and the story has even been developed into a feature film on Netflix.

In historical times, such cases may have been responsible for reported incidents of "demonic possession." In 2009, when the events of *Brain on Fire* transpired, this diagnosis remained obscure. Now, in 2019, this diagnosis, under the umbrella classification of autoantibody-mediated encephalitis, is prominently featured in the educational series of one of the largest critical care conferences in the world.² The past decade has seen both a heightened recognition of these syndromes and also the necessary laboratory advancements required for diagnosis. This related collection of syndromes is almost certainly more common than any of us were aware during our medical education, and it is important to recognize them because early immunotherapy can profoundly improve recovery.

Unfortunately, recognizing the conditions or performing diagnostic testing for these syndromes isn't terribly straightforward.³ The overlap between autoantibody-mediated encephalitis and more common clinical syndromes such as delirium, dementia, and substance abuse-related psychosis is substantial. The most prudent consideration for these diagnoses would be in a specific subset of patients with altered mental status for whom another clinical diagnosis is not fully supported by all manifested symptoms and testing hasn't identified a cause. Some of the clinical features most commonly seen in combination for autoantibody-mediated encephalitis include:

- Acute or subacute onset of cognitive impairment and/or memory loss
- New-onset seizures or status epilepticus
- Acute psychiatric illness, including psy-

chosis, with rapid progression

- Unusual movement disorders
- Autonomic dysfunction, hyperexcitability, or insomnia

The type of autoantibody-mediated encephalitis featured in *Brain on Fire* was limbic encephalitis, of which antibodies against the NMDA receptor are but one culprit. The phenotype expressed by limbic involvement skews toward the cognitive and psychiatric spectrum, followed by seizures. Antibodies against the NMDA receptor are the most common, followed by antibodies against leucine-rich glioma-inactivated 1 and contactin-associated protein 2, components of voltage-gated potassium channel complexes.⁴ Interestingly, many of these autoantibody-mediated syndromes have paraneoplastic associations. Almost 40 percent of antibodies against the NMDA receptor are associated with ovarian teratomas, making this association a potential red flag for limbic encephalitis in the appropriate clinical context.

The brainstem encephalitides are likewise included in the spectrum of autoantibody-mediated disease. These syndromes typically display features associated with abnormal eye movements and inflammation of the cranial nerves. The most prominent and common of these syndromes includes the neuromyelitis optica spectrum disorders, characterized by anti-aquaporin-4 or anti-ganglioside GQ1b antibodies. The latter antibody has been found to be the causative etiology for Bickerstaff brainstem encephalitis, which was described more than half a century ago and typically includes ataxia and ophthalmoparesis in the context of altered consciousness.

Once alternative diagnoses have been fully and appropriately evaluated, most proposed diagnostic strategies for the autoantibody-mediated encephalitides include neuroimaging and cerebrospinal fluid (CSF) evaluation as critical to identifying the diagnosis.⁵ Several subtypes of encephalitis include specific abnormal findings on magnetic resonance imaging, while CSF pleocytosis or the presence of oligoclonal bands raises suspicion for central nervous system inflammation. Commercial assays for CSF antibody detection are available, and specialist consultation can help determine the most appropriate tests to order for a specific phenotype. Finally, electroencephalogram may be a useful diagnostic modality but

CONTINUED on page 14

WHAT KEEPS YOU UP AT NIGHT?

Emergency physicians face challenges on every shift:

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DR. FRIEDMAN Q&A | CONTINUED FROM PAGE 1

ACEP Now Medical Editor in Chief Kevin Klauer, DO, EJD, FACEP, to discuss his goals as ACEP President. Here are some highlights from their conversation.

KK: Let's talk about your initial goals as ACEP President. What did you really want to try to accomplish in this year?

VF: Well, these were interesting times. The reality is that most president-elects have a year to prepare. I only had three months to prepare, following John Rogers' transition out of the role. I didn't have as much time to think about what my personal goals were for the presidency. I wanted to do what I could in this year to improve life for emergency physicians and particularly for future emergency physicians. I think most presidents go into it thinking of the things that they would like to accomplish. However, the crises of the moment that we have to deal with have a tendency to hijack the agenda to a certain extent.

There were internal things that I wanted to try to accomplish this year. My goal was to help the Board be more strategic in its operations. What I mean by that is over the last 10 years, the Board has become very operational. I'm glad that our annual Board retreat went well and that we were able to focus on how to help the Board become more strategic in its functioning.

In terms of what's happened since I've assumed office, I knew going into it that the issues around out-of-network billing were going to be important this year. There's a tremendous bipartisan desire to do something in that arena. In fact, it's including the White House and the Secretary of Health and Human Services. They've decided that [surprise] billing is something they're going to focus on.

I've been advocating for our profession and our College in Washington, D.C., at least once or twice a month since the annual meeting. That doesn't include multiple phone calls trying to bring all the parties to the table internally around this issue, which we have struggled with as a profession. I think we've made some good progress. Having said that, I think we have to be realistic that the forces against us are pretty significant. But we'll continue to fight for our right to take care of patients in the way we want to care for them, for our profession, and for our right to be fairly compensated. That's really been the central focus so far in my presidency.

KK: I'm certain you had imagined "the day in the life" of your presidency. How has that changed for you?


VF: I think the biggest difference is that I didn't anticipate the amount of time that would be required during this presidency for our lobbying efforts in D.C. Our D.C. office is doing a tremendous job, and I don't intend to take anything away from their efforts. However, as president, I'm the spokesperson for our College, and I need to be there articulating things from the physician's perspective that are best delivered by the president. I knew this would be a piece of what I did this year but didn't realize it was going to be such a big piece. Like you said, the issues of the day really help define the presidency.

I'll try to highlight some of the things that I would like to see the College do. One area that I would encourage the College to be engaged in is firearm injury prevention and fire-

arm safety. I recently met with the American College of Surgeons (ACS) last month. They put together a meeting of 49 medical specialties and societies to discuss this issue. I really have to give the ACS kudos that they internally did a deep dive and were able to come to some consensus on the things they did agree on around firearm safety. That helped their leadership be more focused and more proactive. I want our College to do that as well. Are we going to agree 100 percent on everything? No. But instead of focusing on the issues that split us apart, I'd like us to be clear about the things that we do agree on so that we can ad-


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FROM HOSPITAL TO HOME

FOR YOUR ADULT PATIENTS WITH CABP AND ABSSSI



VISIT [NUZYRA.COM/AVAILABLE-NOW](https://www.nuzyra.com/available-now) TO EXPLORE THE CLINICAL DATA AND SIGN UP FOR MORE INFORMATION

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 *Chlamydia pneumoniae*.

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*.

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 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 pregnancy, infancy and childhood to the age of 8 years) may cause 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. 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 reaction occurs.

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 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 constipation.

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 following pages.



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has variable positive and negative likelihood ratios for different subtypes of autoantibody-mediated encephalitis.

The immediate care for these patients is typically undertaken without the results of antibody tests, as the turnaround time is, at best, several days. Treatment options include high-dose corticosteroids, plasma-pheresis, intravenous immunoglobulin, or a combination, all in consultation with a specialist. As many of these syndromes are precipitated by, or associated with, malignancy, appropriate imaging of the chest, abdomen, and pelvis may further inform the diagnosis.

Small-cell lung cancers are most frequently implicated, along with thymomas, breast cancer, and Hodgkin’s lymphoma. Patients presenting to facilities without access to such specialty care may benefit from transfer to a tertiary center.

Of course, the first step in diagnosing any of these syndromes is inclusion in the differential diagnosis. There are differing opinions regarding the incidence of these diagnoses, with proponents reporting that, particularly in the young, the frequency may exceed that of the infectious encephalitides.⁶ However, even considering such elevated frequency,

the approximate incidence is still only one per 100,000 person-years. A mid-sized city might see 10 cases of autoimmune encephalitis per year, meaning the frequency of an individual emergency physician encountering this diagnosis might be once per decade. Therefore, while awareness of this condition is important, caution should be exercised to avoid overtesting as a result of availability bias (believing something is more common than it actually is simply because we are more aware of it).

At the very least, no need to call an exorcist! ➡

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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 parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia 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 proven 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 data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

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 in Patients with Community-Acquired Bacterial Pneumonia-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.

Tooth Discoloration and Enamel Hypoplasia-The use of NUZYRA during tooth development (last half of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term 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 pregnancy.

Inhibition of Bone Growth-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. 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 shown 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 with NUZYRA.

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 reaction occurs.

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 of *C. difficile*. *C. 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 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.

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 widely 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

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In the pooled ABSSSI trials, serious adverse reactions occurred in 16/691 (2.3%) of patients treated with NUZYRA and 13/689 (1.9%) of patients treated with comparator. Discontinuation of treatment

vocate for those together. We can advocate better if we have a clear understanding of where our membership stands on the issues.

KK: How do you meet the needs of the membership on such a polarizing topic without disenfranchising a component of the membership?

VF: Well, you’re never going to meet everyone’s needs 100 percent of the time. That’s a fool’s errand. However, we can ask them where they stand on particular aspects of this issue and try to get a clear understanding of where the majority, hopefully the vast ma-

jority, does agree. That’s a reasonable place to start, which may be accomplished by doing a survey of our Council, the representative body of our College. [Editor’s note: At its April meeting, the ACEP Board of Directors voted to survey the Council for a representative viewpoint on firearm-associated research, safety, and policy.]

I don’t think anyone wants our patients to continue to suffer from firearm injuries. It’s just a question of what we see as reasonable solutions. Frankly, we know that there’s a paucity of research in this area. I think that there’s broad consensus that supporting re-

search into firearm injury prevention is worth doing. That’s one example of a place where I believe there to be consensus.

KK: You’re so right. You can provide the greatest benefit, perhaps, by tackling some of the most challenging topics, so I’m glad you’ve taken it on. Moving to another topic, are there any successes that you’d like to share with the membership?

VF: Well, I can’t really take credit for it, but it happened on my watch. The conversations that we had with The Joint Commission about the ability to eat in the emergency depart-

ment on your shift may be the thing that I’m most remembered for as president. That’s a huge success.

KK: Well, I personally will thank you and our staff for that one, Vidor.

VF: You’re very welcome, Kevin. I had little to do with it. But since I get to take all the credit for the things that go wrong, I might as well take a little credit for some of the stuff that goes well.

KK: That’s fair enough.

VF: I think we have continued to improve and deepen our collaborative efforts with other specialties and with the American Medical Association (AMA). I think that we have worked very diligently to position ourselves well within the AMA over the last decade. Our AMA delegation continues to grow and be very impactful.

Another area I feel strongly about is emergency physician well-being. Physician suicide is the endpoint of a predictable continuum. Depressed physicians have a difficult time accessing appropriate resources to deal with that depression. One of the things that I’m pushing us to do is to help our chapters advocate to state medical boards to refine their questionnaires for licensure. Similar efforts should be taken with the hospital credentialing procedures.

Many, if not most, processes ask, “Have you ever been treated for mental illness?” An affirmative response is often interpreted as a red flag for patient safety. Being treated for medical or mental illness is no one’s business unless it will prevent you from doing your job safely.

I’d like us to work with the AMA to expand the offerings that physicians have, improving access to resources when they’re in trouble. Burnout is a big issue in emergency medicine, with depression being a key component.

KK: What do you hope to accomplish with the remaining time you have, Vidor?

VF: I’ve been working with our staff to develop end-of-life care initiatives. There’s a tremendous need to decrease health care costs in this country, and we, as emergency physicians, have a better understanding of where some of that excess cost exists. Most people don’t have end-of-life care orders. This is partly because up until two years ago, physicians in the United States were not reimbursed for conducting advanced care planning discussions. That’s changing, but slowly. I think it would behoove us, and our membership, to accelerate the adoption of conducting those important conversations while patients are still in a position to do so. This is an area that I’d like to work on.

I also want to continue to work on physician wellness, not just around resiliency, but to work on the environmental causes that lead to burnout. I think our BalancED conference was a really good start, and I hope we’ll be able to continue that effort in the coming years.

KK: Those are all wonderful goals. If anyone can accomplish that much in the second half of a presidential term, it’s Vidor Friedman. Thanks for the time, Vidor, and thank you for your service and excellent leadership. 🙌

**NUZYRA™ (omadacycline) injection for intravenous use
NUZYRA™ (omadacycline) tablets, for oral use**

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 ≥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 adverse 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, vulvovaginal 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, urticarial.

DRUG INTERACTIONS

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

Antacids and Iron Preparations—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: Risk Summary—NUZYRA, like other tetracycline-class antibacterial drugs, may cause discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the second 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 exposure 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 of 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 omadacycline, 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

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

Infertility Males: In rat studies, injury to the testis and reduced sperm 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.

OVERDOSAGE No specific information is available on the treatment of overdosage with NUZYRA. Following a 100 mg single dose intravenous administration of omadacycline, 8.9% of dose is recovered in the dialysate. Visit NUZYRA.com to learn more about 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

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Based on 10/2018 US-NUA-0032
US-NUA-0059 12/18



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Financial Advantages for Emergency Physicians

Considering the time value of money, EM comes out ahead

by JAMES M. DAHLE, MD, FACEP

Q. How are finances different for emergency physicians compared to other specialties?

A. I am looking forward to seeing many of you this October at ACEP19, where I will be speaking about personal finance for the early-career emergency physician. As I reflected on this opportunity to engage with so many emergency physicians, I began to think about all of the financial advantages we enjoy compared to our colleagues in other specialties.

Like most of you, when I chose to pursue residency training in emergency medicine 17 years ago, I was motivated primarily by my interest in diagnosing and treating acute medical issues. I wanted to be there to help on the worst day of people's lives and be one of the white knights of medicine who would take care of anyone, anywhere, anytime. It was a place where my "unique set of skills" (often derided as ADHD or a thirst for adrenaline) was an attribute, not a liability. The last thing I ever wanted was a job where I knew what I would be doing all day long before I ever pulled out of the driveway. Like most medical students, I didn't pay nearly enough attention to the future income prospects and lifestyle associated with my specialty choice. Today, I would like to review six financial advantages emergency physicians enjoy.

1. Emergency physicians have one of the highest hourly rates in medicine.

While emergency medicine generally shows up somewhere in the middle on salary surveys of the various medical specialties, what is not taken into account is the number of hours worked. While many specialists make more money than we do, they also work two or even three times as many hours to earn that money. On an hourly basis, our compensation is at or near the top of the list. This can be easily demonstrated by comparing surveys of hours worked among the various specialties to salary surveys. In the 2018 Medscape Physician Compensation Report, emergency medicine was ranked 13th of 29 specialties, with an average income of \$350,000. However, if you look at hours worked for the 12 highest-paying specialties using a 2011 Journal of the American Medical Association study, you will see those specialists worked an average of 216 to 1,183 more hours per year than the average emergency physician. Emergency physicians generally earn a total compensation of more than \$200 per hour and sometimes more than \$300 per hour.

2. Most emergency medicine training programs are three years long. The length of training for most specialties is longer, sometimes much longer. If you consider



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the other specialties that train for only three years (ie, family practice, internal medicine, and pediatrics), all of them are paid less than emergency physicians, both on an hourly and an annual basis. In fact, a typical community emergency physician makes more than many specialists who trained for four to six years! This opportunity to begin earning an income earlier in our careers decreases the total size of our student loan burdens and allows our savings to begin compounding earlier. Our hourly rate per year of training is so much higher than all of the other specialties that it might even make up for all of those shifts when you don't have time to eat, drink, or use the restroom.

3. Our pathway to our peak level of earnings is very rapid. In most careers, even within medicine, it can take decades to reach your peak earning potential. Not so in emergency medicine, where we usually reach peak earnings within two years of graduation from residency, even in a group with a sweat-equity buy-in. In fact, due to a willingness to work more shifts and more undesirable shifts, young emergency physicians often make more than their older colleagues. Early peak earnings, especially when combined with financial literacy and discipline, help us to "take care of business" early on in our careers, paying off our student loans and mortgages and rapidly building a retirement nest egg.

4. More so than most specialties in the house of medicine, we are an interchangeable cog in the machine. While this has its downsides, such as the risk of small physician-owned groups being replaced by larger groups, the rare skill set of the compe-

tent board-certified, residency-trained emergency physician ensures the doc will only be without work for as long as it takes to get emergency credentialing (and perhaps a new state license). We have the ability to adjust very rapidly to a new department, even in the age of the electronic medical record. While no one job is all that secure, our ability to find a high-paying job somewhere is fairly certain.

5. One of the biggest downsides of emergency medicine is that it really isn't a "lifestyle" specialty. Only about a quarter of our shifts are worked during banker's hours. The rest are worked in the evening, at night, on weekends, and on holidays. However, this setup allows for a very unique opportunity; we have a lot of time off during regular business hours. While many emergency physicians use this time to recover for their next shift, take care of family responsibilities, engage in academic activities, and pursue hobbies (ski slopes, mountain bike trails, and lakes always seem deserted on weekday mornings), we also have the opportunity to engage in entrepreneurial pursuits. It is tough to start and run a business entirely on weekends and in the evenings, but it is relatively easy to do so during the day and then practice medicine in the evenings when most ED shifts are worked. Time off during the day also allows us to be able to competently care for our own investment portfolios and rental properties, saving thousands in advisory and management fees. By late career, many physicians are paying a month's salary each year just for investment management simply because they do not have the time that we have.

6. The flexibility of shift work provides for numerous burnout-reducing measures to be taken. While emergency medicine is traditionally ranked high on the percentage of doctors with burnout symptoms, when the severity of an individual's burnout is measured, we actually rank fairly low. In few other specialties is it as easy to cut back to three-quarter time or half-time to go on the "parenting track," do medical missionary work, or take a sabbatical.

Some groups have found innovative ways to reduce the effect of burnout-inducing night shifts on the group. Hiring a couple of nocturnists (and paying them well) can dramatically reduce shift-work sleep disorder. Innovative groups come up with solutions to ensure nobody is working shifts they do not wish to work. In my group, we have a large shift differential between day, evening, and night shifts. We simply let "the market" decide what each shift is worth. For us, it turns out a night shift is worth about 50 percent more than a day shift. The younger docs with high student loan burdens and new mortgages often volunteer to work all or mostly nights, and the older docs with fewer financial worries tend to work the day and evening shifts. If more docs start wanting to work day (or night) shifts, we simply adjust the differential until everybody is working exactly the shifts they want and being paid accordingly. This common-sense solution boosts career satisfaction, increases longevity, and builds a collegial sense of teamwork in the group.

Emergency medicine has significant financial advantages over other specialties. Take advantage in order to improve your career and financial situation. +



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



BENJAMIN THOMAS

Prepare for the Unexpected

Emergency medicine requires us to be ready for anything at any time

by BENJAMIN THOMAS, MD

One of the reasons I chose emergency medicine is because I love the spontaneity our specialty offers. No shift is exactly the same. Anything can happen at any given time. Unfortunately, that spontaneity can put you in situations that you might never expect.

I was working a shift in our rapid care area for low-acuity patients when I met a young man in his 20s who presented with the chief complaint of rash. His rash had started three days prior, and he had completed a course of amoxicillin for pharyngitis a week earlier. He denied fever, chills, recent travel, and exposure to known sick contacts. The rash started on his neck, spreading to his torso and extremities. He had no significant past medical or surgical history. He reported using amphetamines and cocaine recreationally. On exam, the patient was well-appearing. He had a diffuse erythematous palpable morbilliform rash



involving his face, torso, and extremities, sparing his palms and soles.

His history and exam prompted me to think that he had a simple drug reaction secondary to the amoxicillin. Drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome were also on my differential, but the patient was well appearing with no history concerning for systemic involvement. My initial gut reaction was to discharge him home with expectant management. Yet something about his story did not sit well with me.

I decided to consult dermatology to get rec-

ommendations on workup and management. After my consultation, their initial thought was that his presentation was likely due to a drug eruption. They recommended that I obtain a complete blood count, basic metabolic panel, liver function tests, HIV test, and urinalysis. Results were coming in, and my concern began to diminish. I was on the verge of printing his discharge paperwork when I got a call that changed everything.

"Doctor, your patient's HIV test is positive," said the lab tech over the phone. I was stunned; I assumed the test would be negative. An attending once told me to never order a study unless you have a plan for what to do with the result. That day, I did not have a plan for this HIV result. More specifically, I did not have an idea for how I was going to share the unexpected news with him.

I took the patient out of our crowded rapid care area to a private room. I sat him down in a chair and looked into his eyes and told him

his HIV test was positive. The look on his face was something I will never forget. The moment after sharing the news felt like an eternity. I watched the stages of grief unfold before my eyes as the patient tried to wrap his mind around this diagnosis. I tried to console the patient and inform him that he could live a long life with proper HIV treatment. Yet I felt my words fell on deaf ears. The hardest part about medicine is being able to bear witness to suffering.

After spending some time trying to coordinate this patient's follow-up, I walked back into the room to find it completely empty. He eloped. I can only imagine what was racing through his mind as he secretly walked out of the emergency department. I made frantic attempts to reach him by phone to no avail.

He left the emergency department with a result he was not expecting. I left the emergency department that day remembering to always expect the unexpected. ☕



DR. FAUST (@JEREMYFAUST) is a clinical instructor at Harvard Medical School, an attending physician in the department of emergency medicine at Brigham and Women's Hospital in Boston, and co-host of FOAMcast.



DR. WESTAFER (@LWESTAFER) is an attending physician and research fellow at Baystate Medical Center, clinical instructor at the University of Massachusetts Medical School in Worcester, and co-host of FOAMcast.

Fluoroquinolones in the FDA Spotlight Again

How unsafe are they when it comes to aortic aneurysms or dissections?



by JEREMY SAMUEL FAUST, MD, MS;
AND LAUREN WESTAFER, DO

During *FOAMcast*, we like to cover guidelines that affect emergency physicians. But we don't just cover the conclusions made by the authors. We like to do a deep dive into the data and see if we agree with their take. Often, we don't agree with the

conclusions made by the authors, even in prestigious journals.

Earlier this year, we reviewed a "safety communication" released by the U.S. Food and Drug Administration (FDA) about an apparent increased risk of

ruptures and tears in the aorta for certain patients who have taken fluoroquinolones.

The FDA has long had a beef with fluoroquinolones. In the past, it has released warnings related to the risks of tendon rupture, glycemic control, and central nervous system effects with fluoroquinolone use. In the past, the FDA advised against prescribing fluoroquinolones for conditions that most emergency physicians already do not treat with these agents (eg, sinus infections, bronchitis, and uncomplicated urinary tract infections). However, in a recent warning, which we covered on

our show, the FDA's concern about risks to the aorta led it to suggest that for older patients with certain conditions (ie, peripheral atherosclerotic vascular disease, hypertension, Marfan syndrome, and vascular-

type Ehlers-Danlos syndrome), this class of medication should be avoided altogether. The FDA made this recommendation based on several retrospective studies that seem to suggest a doubling of risk of either aortic aneurysms or aortic dissections.

The first problem we see with this FDA warning is that it puts aortic aneurysms and aortic dissections into the same bag. These are related conditions but are very different in terms of our level of concern in certain patients. New aneurysms can indeed be dangerous, but dissections of the aorta are so deadly that they are in a category of their own. When we looked deeper, it looked like the statistical signal does not hold up when you take away the far less dangerous aneu-

rysms, considering only dissections. We don't know how many of these aneurysms were actually new as opposed to chronic conditions.

The other question we have is just how serious is the risk in real life (ie, not just in terms of population-level epidemiology). Even if we accept a twofold risk of an aortic event associated with taking a fluoro-

quinolone, does that have any meaning at the level of the

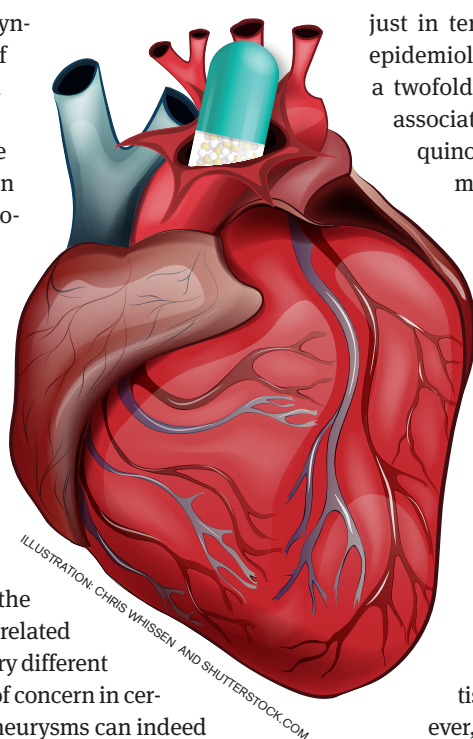
individual patient? The answer depends on just how common the conditions really are, and there is no consensus on this in the literature. If the actual rate of aortic syndromes is on the low end of the published estimates (nine events per 100,000 patients), a doubling in the rate of aneurysm or dissection is not even statistically significant. However, if these conditions truly

are as common as the higher-end estimates (300 events per 100,000 patients), that same twofold risk begins to have meaning for more patients because the "number needed to harm" (ie, the number of patients who would

have to take fluoroquinolones in order for one patient to develop an otherwise avoidable aortic syndrome) would be around 334.

Finally, we are concerned about the notion of "contraindication creep." Many people talk about the idea of "indication creep" in the medical literature. Indication creep is when a therapy that has been shown to be effective on patients with a specific condition is given to patients with related but different conditions or in similar but different circumstances. For example, some data suggest that magnesium can help patients suffering from a migraine with an aura, but many physicians give magnesium to all patients with migraines whether or not an aura is present. Contraindication creep is the opposite. While the FDA specifically said that its warning about fluoroquinolones and aortic aneurysms or dissections should only be applied to patients with certain risks, we have already seen headlines that omit those qualifiers. While we, in general, support limiting the use of fluoroquinolones to conditions in which they are truly necessary, we worry that this warning will be over-applied and cause unnecessary hassles for physicians and patients.

What's your opinion on this FDA warning? Let us know by following us on @FOAM-podcast and be sure to check out our show on iTunes and our blog at FOAMcast.org. ➔



MISSION KURDISTAN | CONTINUED FROM PAGE 10

as neighbors for hundreds of years in Kurdistan. This obviously opened my eyes.

Day 4: John connected with a local community leader coordinating an effort to rebuild several villages damaged by the recent war. The hour-and-a-half drive took us past other destroyed villages and minefields behind the previous battle lines. The emotional weight was undeniable. I wasn't reading about this anymore—I was there, where the recent fighting had occurred.

After we arrived and treated another 100 patients, providing primary care services mostly for hypertension and diabetes, the local village invited us to share another amazing meal in traditional style, seated on the floor.

Day 5: Another community leader invited us to speak at their local community center about first aid. Where do you start with such a broad topic to the general public in Kurdistan? We decided to go with a Q&A session.

The first question: "What do I do when I come upon an auto accident, the driver is un-

conscious, and the car is on fire?" Greg and I responded with what anyone here would state. "Call 911," only to learn their EMS response time is one hour.

Next question: "My friend and I are walking, and he accidentally steps on a mine which blows off part of his leg. What do I do?"

After several similar questions, we quickly realized that these were not hypothetical situations, but real scenarios they occasionally faced. Greg and I offered basic maneuvers and temporizing measures until the patient is transported to a medical facility.

Several rounds of appreciation followed our Q and A. Two local governmental leaders arrived and formally handed us each an award, which read, "Thank you for visiting Kurdistan—your second country."

Members of the community center then performed and sang traditional songs for us, which included a traditional circle dance. I had a great time recording Greg as he was pulled to the front to join in. The video ended

when they pulled me into the circle. Thankfully, they were gracious and only provided us with an abbreviated example of a dance that traditionally could go on for hours. I left the event drenched and ready for bed.

Day 6: John arranged for us to see the huge, sprawling indoor market and arguably the oldest continually inhabited city in the world. Another local family invited us to lunch after another hours-on-end meal prep. We felt like royalty.

Lessons

So, what did I learn? Before my first medical mission trip in college, I had grand aspirations of how those people were going to benefit from my assistance as a premed student. Conversely, I returned home and began to unpack the truckload of emotions in how they positively impacted me.

Several trips and years later, I blazed another personal trail into a war-torn country as a boarded emergency physician. Despite

possessing additional medical knowledge, I braced myself for the potential impact that they would have on me. Hundreds of patients, residents, teas, amazing meals, group photos, hugs, and a few tears later, I processed the emotional onion of this wonderful experience one layer at a time.

I went from watching my back to being treated like family and, occasionally, a celebrity. Love, kindness, and appreciation were freely given from a country and people I had not previously known. What started as a once-in-a-lifetime trip is now hopefully an annual experience. Thank you, Kurdistan, for opening my eyes to a larger, more complete worldview. I cannot wait to see you again! ➔

DR. VALENTINE is assistant system medical director of emergency/hospitalist medicine at St. Vincent's Health System and facility medical director of emergency medicine at St. Vincent's Blount in Oneonta, Alabama, and St. Clair in Pell City, Alabama.

CODING WIZARD



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Editor's Note: Cutting through the red tape to make certain that you get paid for every dollar you earn has become more difficult than ever, particularly in our current climate of health care reform and ICD-10 transition. The ACEP Coding and Nomenclature Committee has partnered with ACEP Now to provide you with practical, impactful tips to help you navigate through this coding and reimbursement maze.

HOW TO DOCUMENT IV FLUIDS REQUIREMENT

by TYLER W. BARRETT, MD, MSCI, FACEP

Question: What do I need to document to ensure appropriate reimbursement when a patient receives intravenous fluids?

Answer: Incredibly, some payers are down-coding or, worse, denying facility charge payment for ED evaluations that do not clearly document the medical necessity for intravenous fluid administration.¹ Documentation of nausea, vomiting, or diarrhea alone may be insufficient to justify intravenous hydration.

To ensure appropriate reimbursement, emergency clinicians should include medical documentation supporting the need for intravenous hydration. The ED note should include

the standard history, physical examination, and medical decision-making elements that support the need for intravenous hydration. Common examples include physical examination or diagnostic testing results indicating acute dehydration, abnormal fluid losses, unstable vital signs, or systemic inflammatory response syndrome criteria (ie, fever, dry mucous membranes, skin tenting, delayed capillary refill, tachypnea, hypotension, or tachycardia) or abnormal laboratory testing such as an elevated white blood cell count, blood urea nitrogen and/or creatinine, glucose, creatine phosphokinase, sodium, calcium, or lactate. Additional supporting documentation may include the patient's inability to tolerate oral hydration, need for rapid intravascular volume expansion (ie, hypotension, sepsis, or shock), or treatment of other causes of abnormal fluids losses (eg, heat-related illness, thermal burns, or medication-related over-diuresis). ➔

Reference

1. Local coverage article: hydration services (A52732). Noridian Healthcare Solutions website. Available at: <https://med.noridianmedicare.com/documents/10546/12461379/Hydration+Services+Coverage+Article>. Accessed March 13, 2019.

DR. BARRETT is associate professor of emergency medicine at Vanderbilt University Medical Center in Nashville, Tennessee.

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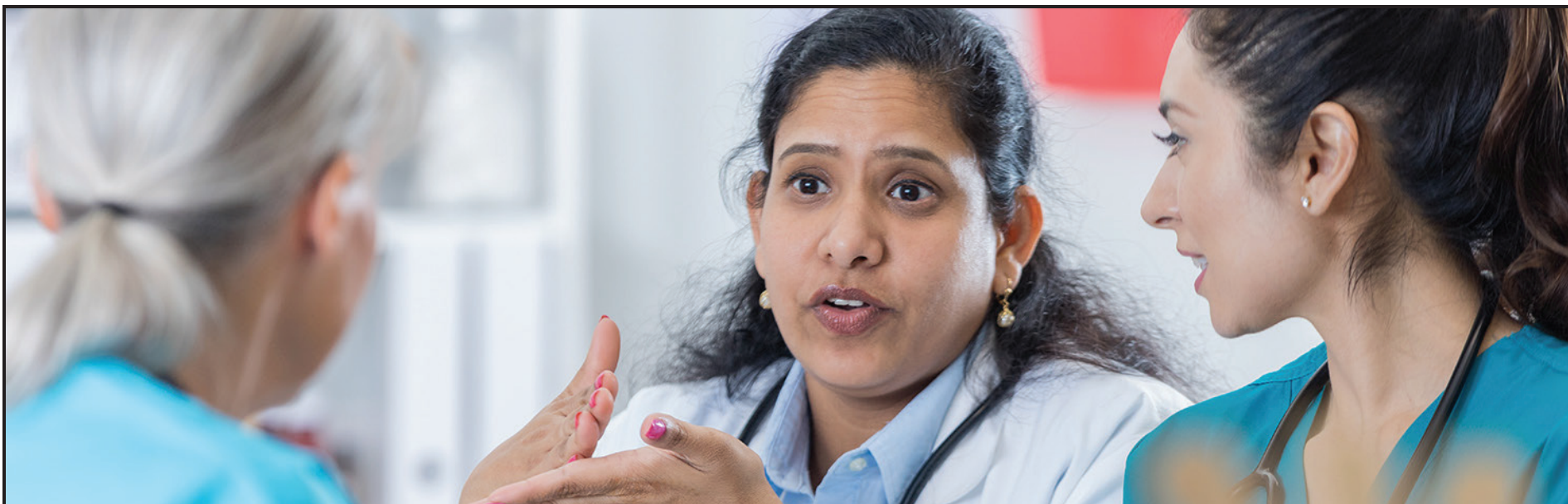
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