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OCTOBER 2019

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## A PERILOUS PUFF

What you need to know  
 about the current epidemic  
 of vaping-associated  
 pulmonary injury

by JOSHUA FARKAS, MD

Using electronic cigarettes, or vaping, has become increasingly popular within the past several years. Within the past few months, an outbreak of vaping-associated pulmonary injury (VAPI) has been recognized in locations across the United States. The number of patients involved has rapidly increased to the hundreds, and several deaths have been reported.

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## WHEN PATIENTS TURN VIOLENT

Violence against health care workers is everywhere, but we can reduce it

by AMISH SHAH, MD, MPH

When I took my first job as an attending emergency physician at Mount Sinai Hospital in New York, the man who hired me, the late, great Dr. Sheldon Jacobson, put it to me squarely: “Here’s the deal—I take good care of you, and you take good care of the patients.” One problem I never expected is that some patients don’t take care of us in turn.

A few years ago, I was working a night shift when a woman in her twenties presented for mild alcohol intoxication. She was alert and spoke clearly. We had a pleasant conversation, and I told her we would provide some Tylenol and IV fluids. She was appreciative. I sat down and began to type my note just a few feet away.

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# NEWS FROM THE COLLEGE

## UPDATES AND ALERTS FROM ACEP

### Breaking Down AUC Program and Its Emergency Exemption

You may have heard about the upcoming Medicare requirement to consult Appropriate Use Criteria (AUC) through approved clinical decision support mechanisms prior to ordering advanced imaging services. You may have even heard that you have to do this for all your Medicare patients to comply with federal regulations. Visit [www.acep.org/federal-advocacy/federal-advocacy-overview/acep4u/acep4u-electronic-health-records-ehr](http://www.acep.org/federal-advocacy/federal-advocacy-overview/acep4u/acep4u-electronic-health-records-ehr) to read how ACEP advocated for and received an exemption for individuals with emergency medical conditions and to download a sample letter to help explain this exemption to your hospital administrators.

### Reimbursement Changes for Emergency Care of Veterans

The Veterans' Emergency Care Fairness Act of 2009 provided payment for veterans enrolled in Department of Veterans Affairs (VA) care who used a non-VA facility for emergency care, but an internal VA regulation blocked those payments. Recently, the U.S. Court of Appeals ruled that the VA must reimburse for emergency care of veterans at non-VA facilities.

It's important to identify veterans who are receiving care at a VA facility, plus those who would qualify for care if they enrolled. The eligibility rules are complicated, and the process is not always straightforward. Once enrolled, the veteran can receive many benefits, including pharmacy, home care, and end-of-life care. Many veterans use non-VA emergency departments because of distance or not knowing they are eligible for care. Now that the VA system has been ordered to reimburse emergency departments for this care, it may be reasonable to add questions about veteran status to your patient registration process and encourage identified veterans to check their eligibility with the VA.

### ACEP Urges Policymakers to Remove Obstacles to Treatment for Opioid Use Disorder

As the U.S. Department of Health and Human Services compiles a report for Congress on treating opioid use disorder, ACEP urges policymakers to consider steps to remove obstacles to appropriate care in the emergency department, including removing the "X waiver," modifying the "three-day rule," and

removing preauthorization requirements. Read the full comment letter at [www.acep.org/federal-advocacy/access-to-emergency-medicine](http://www.acep.org/federal-advocacy/access-to-emergency-medicine). Turn to page 18 to read more about the X waiver and why you should get waived.

### Emergency Physician's Name Added to 9/11 Memorial Wall

Michael G. Guttenberg, MD, who passed away in October 2017 from pancreatic cancer attributed to his work as a first responder at 9/11 Ground Zero, was added to the FDNY World Trade Center Memorial Wall in Brooklyn during a ceremony Sept. 6, 2019. Despite his diagnosis, Dr. Guttenberg served as medical director of Northwell Health's clinical preparedness and Center for Emergency Medical Services until days before his death.

### Regulatory News: Patient Confidentiality for Substance Use Disorder

The U.S. Department of Health and Human Services recently released the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed regulation to modify 42 CFR Part 2, which governs the confidentiality of patient records for the treatment of substance use disorder (SUD). One of the major policy debates around 42 CFR Part 2 has been whether this set of regulations should be modified to align more closely with HIPAA, and the proposed regulation does not do so. Instead, SAMHSA proposes smaller modifications to 42 CFR Part 2 aimed at advancing care coordination for patients with SUD and clarifying existing policies for 42 CFR Part 2 treatment programs (federally assisted alcohol or drug abuse programs) and other health care providers. Visit the ACEP regulatory blog archive at [www.acep.org/regsandeggs](http://www.acep.org/regsandeggs) to catch up on all the latest news.



### ACEP Launches New Website for External Audience

ACEP has reimaged *Emergency Care for You* to create a new, comprehensive external website. [EmergencyPhysicians.org](http://EmergencyPhysicians.org) is a one-stop shop for the public to get the latest news, advocacy updates, and public health and safety tips directly from emergency physicians. 📌

## ACEP Now Wins Awards for Editorial Excellence

ACEP Now has received several editorial awards:

- APEX Grand Award for "Two Accounts of Vegas Mass Shooting," interviews with an emergency physician who treated victims of the 2017 mass shooting at the Route 91 Harvest country music festival in Las Vegas and a victim of the shooting.
- APEX Award of Excellence for "More Than Just 'I Do,'" about an emergency physician and his partner's journey to get married before same-sex marriage was legal nationwide.
- APEX Award of Excellence and EXCEL Gold Award for "Private Matters?" by Susan T.

Haney, MD, FACEP, FAAEM, about her 10-year fight to keep her medical license after voluntarily reporting an adverse drug reaction related to chronic depression.

Read the winning articles at [ACEPNow.com](http://ACEPNow.com).

The annual APEX Awards are given by Communication Concepts to recognize excellence in writing, digital content, graphic design, social media, public relations, and marketing. The annual EXCEL Awards are given by Association Media & Publishing to recognize excellence and leadership in nonprofit association media, publishing, marketing, and communications. 📌

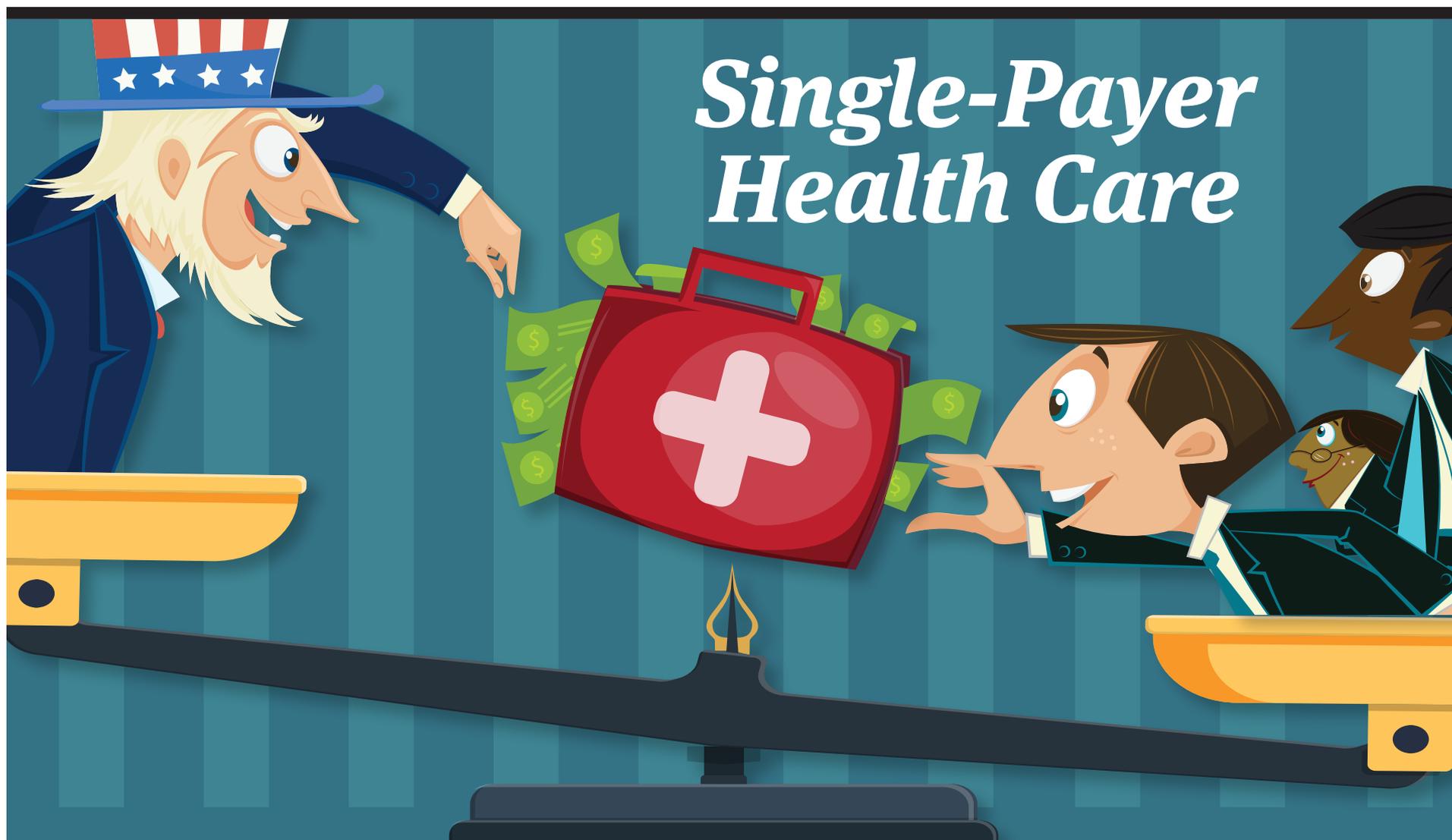


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PRO

## SINGLE-PAYER'S TIME HAS COME

The status quo is increasingly unaffordable

by JAMES C. MITCHINER, MD, MPH, FACEP

Fundamentally, single-payer insurance is about changing the way we pay for the health care we already have. By consolidating the administrative costs of some 1,200 private health plans—each of which duplicates what the others do—we’d capture economies of scale and use the savings to expand access to more people and more services. Sometimes known as Medicare-for-all, single-payer advocates for expanding and improving our existing Medicare program to provide universal, cost-effective, and comprehensive care to all Americans.

To understand how single-payer works, emergency physicians only need to contemplate their own practices since the emergency department is a de facto single-payer environment. What we do, and how we do it, is enshrined in the basic principles of single-payer financing. Our emergency departments are open to all (universality); we treat out-of-town visitors who get sick or injured while staying with family or friends (portability); we have no cost barriers to care (open access); patients, as a general rule, can pick their emergency department (freedom of choice); and we treat all patients alike, regardless of age, income, employment, or pre-existing conditions (equality and equity).

Beyond what’s already cited, single-payer would have the following salutary effects:

- Comprehensive coverage, including

preventive care, dental, vision, mental health, rehabilitation, substance abuse, and long-term care

- Severance of the link between employment and health insurance
- Elimination of narrow networks and “surprise billing”
- Ability to negotiate for lower prescription drug prices
- Progressive tax financing
- Enhanced ability of domestic firms to compete globally
- Payment for mandated EMTALA services
- Reduction in medical malpractice premiums
- Support for primary care
- Mitigation of physician burnout

Single-payer proposals in the U.S. Congress (H.R. 1384, introduced by Rep. Pramila Jayapal [D-WA] and Rep. Debbie Dingell [D-MI], and S. 1804, sponsored by Sen. Bernie Sanders [I-VT]), have so far enjoyed popular support, but also have engendered potent opposition, particularly by the insurance and pharmaceutical industries. Opponents of this legislation, and of single-payer in general, focus on its supposed defects, some of which I’ll summarize below as “The Seven Myths of Single-Payer.”

**Myth #1:** “Single-payer is socialized medicine.” This, the most overused takedown of

CONTINUED on page 6

CON

## HEALTH CARE TRANSFORMATION IN THE UNITED STATES

Single-payer would be detrimental to emergency physicians and could cause an economic disaster

by TODD B. TAYLOR, MD, FACEP

*If you think health care is expensive now, wait till it’s free.*

—P.J. O’Rourke

By the common definition, America currently has “universal health care.” Health care services are largely available to almost all Americans via a combination of publicly and privately funded systems based on individual demographics. However, not all Americans choose to avail themselves of the options for health insurance to pay for these services and protect their assets.

Prior to the Affordable Care Act (ACA), or Obamacare, about 83 percent of Americans had some form of health insurance. Of the remaining 17 percent, half could have had coverage if they had chosen to pay a modest monthly premium (eg, to add family coverage at work) or simply applied for Medicaid. After ACA, the uninsured rate dropped to about 10 percent, largely due to expansion of Medicaid.<sup>1</sup> As before ACA, perhaps another 5 percent could be covered if they choose.

With these facts in mind, the current discussion on health care is really about how to fund it and not about universal coverage. This brings us to the crux of the issue. How you fund health care directly determines what health care you get (or is even available). Nationalization of the health care system in America (eg, via “single-payer”) will be much

different than our current private health insurance market. And much of this simply comes down to choice.

In a single-payer system (government funded, regulated, managed, and defined), politicians largely determine health care services and their costs. This is a “regulated monopsony.” In a market-based approach (even one that is highly regulated), individuals (or groups of individuals, eg, employers) largely determine services, and to some extent, the laws of supply and demand determine prices. Individuals have choices regarding insurance benefits or whether it is even worth the cost to purchase insurance.

### Common Sense Analysis of Single-Payer Health Care

It is impossible to read, let alone analyze, everything that has been written about single-payer health care. Further, while various other countries are used as examples, the largest such country by GDP with single-payer is Japan, whose health care system (by total spend) is only about 9 percent of that of the United States. England is about 3 percent. We cannot be so naive as to believe a country the size of the United States can simply wholesale adopt a system that works for countries a fraction of our size. Even by pop-

CONTINUED on page 6

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single-payer, has no basis in fact. “Socialized medicine” refers to a system where the government owns the hospitals and clinics, and the physicians are paid as civil servants. Our version of single-payer, on the other hand, implies public financing of care that remains privately delivered by existing hospitals and private-practice physicians, who would be paid by negotiated fee-for-service, capitation, or salary, as they are now.

**Myth #2:** “Single-payer is one-size-fits-all, government-controlled health care.” Given that Medicare is government-financed healthcare, I ask my emergency medicine colleagues these questions: How many times in your career have you been forced to contact the feds to get permission to admit a Medicare beneficiary? How many times have you called

Given the enormous and growing cost of the status quo (\$3.5 trillion annually), and the failure of previous reforms to control costs and fund universal coverage, perhaps the more salient question is, how can we afford not to have a single-payer system?

a consultant, only to have them tell you, “Sorry, I don’t treat Medicare patients.”? And how many calls did you get from pharmacists last year, informing you that Medicare didn’t cover the prescription you just wrote for the senior you treated in your emergency department? Now compare your answers to those you would give for your managed care patients. Yes, Medicare does have payment penalties if you don’t order aspirin for heart attacks or antibiotics for pneumonia, but these are legitimate, evidence-based therapies that have been thoroughly vetted by medical specialty organizations.

**Myth #3:** “Single-payer would eliminate choices.” Really? Choice of what? Most working Americans are covered by employer-based insurance, which limits your choice to a doctor or hospital that’s in-network. If you want care from a non-network provider, you have to cover the expenses out-of-pocket. Under single-payer, there’d be no such thing as “network,” and the choice of provider would be up to you.

**Myth #4:** “Things are so bad in Canada.” Cross-border comparisons in health care generally are driven by population-based statistics. In that sense, despite spending 55 percent of what we do on a per-capita basis, Canada has a higher life expectancy, lower infant mortality rate, and overall comparable quality metrics to the United States. Yes, Canadians do have to wait for hip or knee replacements and MRIs. But Canadians are not wait-listed for emergency procedures, and no one stands in line for an emergency aneurysm repair. Polls show that Canadians, in general, are happier with their health system than we are with ours. Canadian physicians are not emigrating to the United States in large numbers. And if we adopted a Canadian-style system and funded it to the tune of \$10,000 per person, it’s likely there wouldn’t be long waits for MRIs, even if many of them were medically unnecessary.

**Myth #5:** “Single-payer would stifle innovation.” There is no basis for this false belief. Many of the discoveries that drive modern American medicine originated in countries with single-payer variants: CT and MRI came from the United Kingdom; laparoscopic cholecystectomy came from Germany; coronary angioplasty originated in Switzerland; and the link between *H. pylori* infection and peptic ulcer disease was elucidated by an Australian physician. The country with the most medical journal articles per capita is Sweden. And in the United States, the largest single funding source for medical research is the government—ie, the National Institutes of Health.

**Myth #6:** “Under single-payer, physicians would get paid peanuts.” My friend and chief single-payer adversary, Dr. Todd Taylor, likes to remind everyone that single-payer is a monopsony—a single buyer—which means the government would control our remuneration (as if private insurers don’t already?). But the implication that we would be paid at Medicaid rates is unfounded. First, organized medicine, at the state level, would play a major role in negotiating fee-for-service rates with the government (as is done in Canada) and reject Medicaid-level fees. Second, no serious single-payer proposal has us getting paid at Medicaid rates. And third, being paid at uniform Medicare rates would balance the decrease in fees we would have received for treating patients previously covered by commercial insurance with an increase in fees for treating patients previously covered by Medicaid and those previously uninsured.

**Myth #7:** “We can’t afford it.” Some studies suggest single-payer would cost much more than what we spend currently, while others conclude it would cost less. It all depends on how you measure administrative savings, reduced pharmaceutical costs, and increased utilization under single-payer. But given the enormous and growing cost of the status quo (\$3.5 trillion annually), and the failure of previous reforms to control costs and fund universal coverage, perhaps the more salient question is, how can we afford *not* to have a single-payer system?

In summary, single-payer is government-financed care rather than government-controlled care. Thus, it is not socialized medicine any more than the federal interstate highway system is socialized transportation. The additional taxes required to finance single-payer would be levied progressively, and their financial impact would be zeroed out by the elimination of health insurance premiums, copays, coinsurance, and deductibles, providing financial advantage to an estimated 95 percent of Americans. It is well beyond time the United States joined the world’s other democracies in providing high-quality, affordable, and accessible health care to all its citizens, a goal I believe can be achieved only through a single-payer Medicare-for-all program. Single-payer appears inevitable, and I believe ACEP should play a major role in creating it. ☺



**DR. MITCHINER** is an attending physician in the emergency department at St. Joseph Mercy Hospital in Ann Arbor and Chelsea.

ulation, the United States ranks third, and neither the first (China) nor second (India) most populous country has universal health care. There is simply no way to assume we can know the impact of adopting single-payer health care in the United States, and not just on health care but the entire economy and U.S. way of life.

The fact is, America has already largely achieved universal health care as defined as “available access to health care services.” Some simply choose not to avail themselves of readily available health insurance to protect against financial ruin due to an unexpected health care crisis. Failing to buy health insurance is like owning a car and failing to buy auto insurance. Then when you get into an accident, you complain about not having a car and suffering financial ruin after being sued by the other driver you hit.

Rather, the challenge with health care today is finding *affordable* insurance and/or care, a problem which largely stems from the ACA’s comprehensive coverage mandates and a lack of an efficient health care services market. Pharmaceuticals remain artificially expensive due to various federal policies.<sup>2,3</sup> Direct hospital services are artificially expensive due to government price controls (cost shifting) and predatory pricing from some health plans.<sup>4</sup> In fact, all of health care is artificially expensive due to a lack of a true market. Imagine how expensive anything might be if you could not comparison-shop because you did not know the price until after the goods and services were delivered. Amazon and eBay have revolutionized commerce, but health care has failed to keep pace. Nevertheless, a market-based approach will eventually prevail in virtually all aspects (including cost) if left alone to follow market forces. As noted, ACA mandates severely influence the upward trend in the cost of health insurance.<sup>4</sup>

**Now, Back to Single-Payer**

Rather than argue with unverifiable “facts,” I will simply appeal to common sense.

First, “single-payer” is not the same conversation as “universal health care.” I have been a proponent of universal health care (aka, equal access to health care) my entire career. Where I differ is in how to achieve universal health care, ie, how to fund it.

Single-payer may seem to make sense until you explain how it might work. In fact, much of the health care, insurance, and funding debate is steeped in ignorance. Most cannot even differentiate between health *care* and health *insurance*.

“Single-payer” is largely government-controlled and -funded health care (via taxes). The reason I am not in favor of this mechanism is the current state of government-run health care. As it stands now, publicly funded health care represents about 50 percent of current health care spending.<sup>5</sup> Let’s break down how well these current government-run systems are doing:

**Medicare:** The trust fund is projected to be insolvent in 2026, three years earlier than predicted last year.<sup>6</sup> While seniors tend to like Medicare, if you include the time value of money for the amount paid in Medicare

taxes over a lifetime, plus the rising out-of-pocket cost, Medicare is more costly than private insurance (based on \$150/month paid in Medicare taxes for 45 years, invested at 5 percent APR = ~\$300,000 at age 65 divided by 25 years = ~\$1,000 per month).

**Medicaid:** While most Medicaid enrollees are satisfied with their health care services, most Americans would not choose to be on Medicaid.<sup>7</sup> And for this audience, how would you like for Medicaid to be your sole payer for the services you provide?

**Indian Health Service (IHS):** “Indian Health Service clinics don’t have enough doctors or nurses to provide quality and timely health care to American Indian and Alaska Native people. IHS data show an average vacancy rate for physicians, nurses,

In fact, all of health care is artificially expensive due to a lack of a true market. Imagine how expensive anything might be if you could not comparison shop because you did not know the price until after the goods and services were delivered.

and other care providers of 25 percent.”<sup>8</sup>

**VA:** “[The Government Accountability Office (GAO)] designated VA health care as a high-risk area in 2015 due to five areas of concern regarding VA’s ability to provide timely access to safe, high-quality health care for veterans: (1) ambiguous policies and inconsistent processes; (2) inadequate oversight and accountability; (3) [information technology] challenges; (4) inadequate staff training; and (5) unclear resource needs and allocation priorities. In 2017, GAO reported that while VA had taken some actions to address these issues, little progress had actually been made.”<sup>9</sup>

**Military Health System:** “The Department of Defense faces significant challenges ensuring that all members of the military, as well as their families, receive appropriate health care for everything from general health and well-being to specialized clinical care for deployment related injuries such as amputations, chemically induced illnesses, and post-traumatic stress disorder...only 50-60% rate their health plan at 8/10 or better.”<sup>10</sup>

If the above were *your* résumé, you would be fired. But like many government-run services, health care is apparently good enough for government work. But the question we now face is, do we really want to turn over the remaining 50 percent of health care in America to the government, based on current evidence of mismanagement of the other 50 percent?

If we learn anything from the current silliness in American politics, it’s that we do not want politicians in charge of health care.

**A Few Other Considerations**

**Single-Payer=Tax-Funded Health Care:** The progressive tax system in America means the largest burden of the “health care tax” will fall on higher-income individuals. It is de facto income redistribution, which may seem great until you run out of every-

body else's money. As providers, you may get paid for more people (albeit much less for each), and on the other side, you are also paying their bill (via taxes).

**Single-Payer=Universal Health Care Monopsony:** A monopsony is a market structure in which a single buyer substantially controls the market as the major purchaser of goods and services. This single entity has market power over sellers as the only purchaser, much in the same manner that a monopolist can influence the price for its buyers in a monopoly, in which only one seller faces many buyers. As noted, 50 percent of U.S. health care is already publicly funded (taxes). These programs are regulated limited monopsonies in defined populations. Due to little, if any, coordination among these various government programs, they currently do not have the same effect that a true universal monopsony would. In other words, health care providers still have considerable freedom for whom they wish to provide services and at what price. A true single-payer environment would dramatically change these economics. By definition, a monopsony eliminates choice and competition. The government sets the rates. You take it or leave it. If there are not enough "takers," people wait in line for care (or go to the emergency department).<sup>11</sup>

**Single-Payer=Aspirational (versus Politically Viable=Reality):** Some have called for a physician-friendly single-payer plan. I believe that is a false hope; one might say bait and switch. The fact is, we have no idea what the implications and outcomes might be of implementing single-payer health care in the

United States. In the end, it's all conjecture (or, perhaps more accurately, rhetoric). A lot of promises and projections have been made with every major government program, and to my knowledge, they have nearly always been wrong, and not for the better. The most recent health care example: What would the ACA vote have been if we knew then what we know now? "You can keep your doctor, your hospital, your health plan." "Premiums will be lower." "It will increase choice." All (grossly) false promises.

**Net-Net for Emergency Physicians:** Under single-payer, we may have lower (perhaps much lower) compensation, deal with patients experiencing a delay in receiving services, and pay (much) higher individual taxes. If we are going to propose a single-payer system, we need to own up to these realities and not act like they will not happen "if done right." These things will necessarily happen because that is doing it right under single payer.

**Single-Payer=Economic Disaster:** Health care is now the largest private-sector industry in the United States, and in some cities it represents more than 25 percent of all jobs.<sup>12,13</sup> In 2017, \$3.3 trillion (\$10,348/person and 17.9 percent GDP) was spent on health care.<sup>14</sup> Private health insurance represented 34 percent (\$1.122 trillion) of that spend.<sup>15</sup> You do not have to be a genius to know what would happen if you "nationalize" a >\$1 trillion segment of the health care industry (about 6 percent of GDP). How would United Healthcare (\$245 billion market cap), WellPoint (\$232 billion), Aetna (\$177

billion), CIGNA (\$178 billion), Humana (\$293 billion), and all the other insurance companies and shareholders respond to nationalization from a government program (eg, Medicare-for-all)? A government takeover like this would clearly be unprecedented in American history.

Single-payer will never happen, and if it does, it would precipitate an economic depression. But the good news is you would have free mental health services for your emotional depression. ☺

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**DR. TAYLOR** is an independent consultant based on Phoenix, Arizona, specializing in EMTALA, health care information technology, and emergency medicine administration. He authored the landmark paper "Universal Access as a Solution for America's Uninsured" in 2001.

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# ACEP4U: Improving Patient Access to Mental Health Care

CROSS-DEPARTMENTAL COLLABORATIONS ARE ADDRESSING THIS PROBLEM FROM MULTIPLE FRONTS



by JEFFREY DAVIS  
AND JORDAN GRANTHAM

Nearly one in five American adults struggles with some form of mental illness, and ED visits for children who attempted suicide or had suicidal thoughts are increasing. The current health care system is failing too many of these patients, making it difficult for them to find appropriate care. Emergency departments are often their only option, although many emergency departments aren't optimized to provide psychiatric care. Patients with mental health concerns often remain in emergency departments for hours, sometimes days, as follow-up transfers or community care options are secured.

ACEP has prioritized these issues, advocating for legislative and regulatory changes that would help reduce barriers to treatment and provide more tools and resources for physicians to help meet their patients' needs. At the same time, we've been developing clinical tools and resources to help emergency physicians manage mental health patients in the emergency department. Like many other public health concerns, patient access to mental health care in the emergency department is a complicated problem that requires multi-pronged solutions.

## Advocating for Change

As ACEP advocates for comprehensive mental health care reform, we have seen many ACEP-supported provisions included in House and Senate legislative efforts to enact mental health care reforms in the past few years, including:

- Creating an Assistant Secretary for Mental Health and Substance Use and the National Mental Health and Substance Use Policy Lab
- Extending the Assisted Outpatient Treatment grants and instituting grants for assertive community treatment
- Establishing liability protections for health professional volunteers at community health centers
- Extending suicide prevention programs
- Reauthorizing grants to help train emergency medical personnel to recognize individuals with mental health issues and

CONTINUED on page 10

## Clinical Resources for Managing Mental Health Patients

As our advocacy team has been working to improve patient access to mental health care through legislative and regulatory channels, ACEP's clinical affairs department has been focused on helping emergency physicians manage mental health patients.

### ICAR<sup>2</sup>E Bedside Tool for Managing Suicidal Patients in the ED (2018)

iCAR<sup>2</sup>E helps physicians identify suicide risk, communicate effectively, reduce risk, and extend care beyond the emergency department. This app is available in a web-based format ([www.acep.org/patient-care/iCar2e](http://www.acep.org/patient-care/iCar2e)) or can be accessed as a native app by downloading emPOC, ACEP's new point-of-care (POC) app with five bedside tools that can be downloaded in the App Store or Google Play.

### ADEPT Bedside Tool for Managing Confusion and Agitation in the Elderly ED Patient (2018)

ADEPT, a point of care tool available in both the web-based format ([www.acep.org/patient-care/adept/](http://www.acep.org/patient-care/adept/)) and on the emPOC app, helps physicians assess, diagnose, prevent, and treat delirium in elderly ED patients.

### Clinical Policy for Adult Patients: Critical Issues in the Diagnosis and Management of the Adult Psychiatric Patient in the Emergency Department (2017)

Read the full statement and view the related eCME options at [www.acep.org/patient-care/clinical-policies/Psychiatric-Patient](http://www.acep.org/patient-care/clinical-policies/Psychiatric-Patient).

### Policy Statement: Pediatric Mental Health Emergencies in the Emergency Department (2018)

View the full statement at [www.acep.org/patient-care/policy-statements/pediatric-mental-health-emergencies-in-the-emergency-medical-services-system](http://www.acep.org/patient-care/policy-statements/pediatric-mental-health-emergencies-in-the-emergency-medical-services-system).

### Policy Statement: Use of Patient Restraints (2014)

ACEP supports the careful and appropriate use of patient restraints or seclusion. View ACEP's principles regarding patient restraints at [www.acep.org/patient-care/policy-statements/use-of-patient-restraints](http://www.acep.org/patient-care/policy-statements/use-of-patient-restraints).

## Information Papers

View the following in full at [www.acep.org/by-medical-focus/mental-health--substance-abuse/information-papers](http://www.acep.org/by-medical-focus/mental-health--substance-abuse/information-papers):

- Care of the Psychiatric Patient in the ED: A Review of the Literature (2014)
- Practical Solutions to Boarding Psychiatric Patients in the Emergency Department (2018)
- Suicide Contagion in Adolescents: The Role of the Emergency Department (2018)

## Sobering Centers

Sobering centers provide a safe, supportive environment for mostly uninsured, homeless, or marginally housed publicly intoxicated individuals to become sober, with a goal of decreasing the number of inappropriate ED visits for homeless, alcohol-dependent individuals. Learn more at [www.acep.org/by-medical-focus/mental-health--substance-abuse/sobering-centers](http://www.acep.org/by-medical-focus/mental-health--substance-abuse/sobering-centers).

## Behavioral Emergencies for the Emergency Physician (2013)

This book by Leslie S. Zun, MD, offers a thorough overview on managing patients with a variety of mental health concerns. Find it in the ACEP Bookstore at <http://bookstore.acep.org/behavioral-emergencies-for-the-emergency-physician-amazon-479935>.

## Coalition on Psychiatric Emergencies

The Coalition on Psychiatric Emergencies (CPE) is a group of more than 30 national leaders in emergency medicine, psychiatry, and patient advocacy who are focused on improving the treatment of psychiatric emergencies for patients and emergency providers. The coalition hosts annual pre-conference sessions during ACEP Scientific Assembly to address knowledge gaps in acute medical care for emergency psychiatrists and topics on emergency psychiatry for emergency physicians along with other relevant topics. CPE recently collaborated with the American Foundation for Suicide Prevention to create a new award recognizing innovations in the acute care setting for suicide prevention. Learn more at [www.acep.org/who-we-are/acep-awards/leadership-and-excellence/innovation-in-acute-care-suicide-prevention-award](http://www.acep.org/who-we-are/acep-awards/leadership-and-excellence/innovation-in-acute-care-suicide-prevention-award).

# FACEPs IN THE CROWD

More than 12,000 ACEP members have achieved Fellow status with the College and use the FACEP designation with pride! Here, we highlight ACEP Fellows who have fascinating hobbies and passions outside the emergency department.

## LANE PATTEN, MD, FACEP



Lane Patten, MD, FACEP, an emergency physician at North Memorial Health in Minneapolis, **started a food blog** ([www.withtwospoons.com](http://www.withtwospoons.com)) with fellow emergency physician Holly Schrupp Berg, MD, when she was struggling with burnout and needed a creative outlet. The two physicians love that the blog furthers their mission to help people “form connections over food.” Dr. Patten concedes that the stakes are much lower in the kitchen than in her level 1 trauma center: “We mess up a batch of cookies—no big deal!”

## FREDERICK BLUM, MD, FACEP



Frederick Blum, MD, FACEP, professor in the department of emergency medicine at West Virginia University in Morgantown, calls himself a “Renaissance hillbilly” because of his wide variety of hobbies. He’s an avid **photographer and oil painter**, and he also writes **poetry and practices archery**. Dr. Blum learned and competed in archery as a child, and these days, it helps him relax and wind down: “Archery is a form of meditation for me.” He likes to teach archery to children at summer camps.

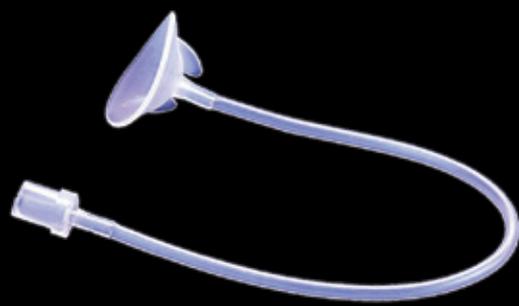
## MELISSA KOHN, MD, FACEP



Melissa Kohn, MD, FACEP, an emergency physician at Einstein Medical Center in Philadelphia and medical director for Collingdale Fire Company No. 1 in Delaware County, started running to clear her head and spend more time outdoors. She’s **running the New York City Marathon** this November as part of her goal of running a half marathon in all 50 states. Her toughest race ever? The Nike Women’s Half in San Francisco. “The hills were brutal!”

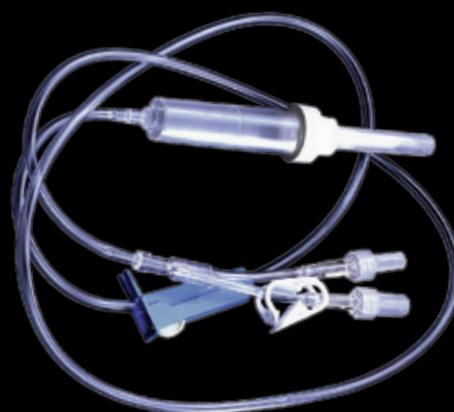
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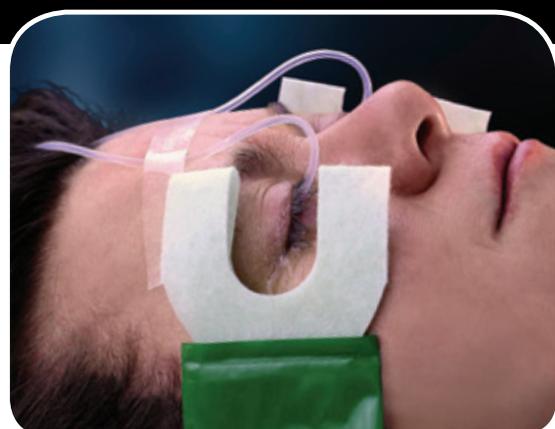


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how to intervene

- Encouraging the Centers for Disease Control and Prevention to improve its National Violent Death Reporting System
- Expanding the mental health workforce
- Clarifying HIPAA privacy rules for patients with mental illness and their caregivers
- Eliminating the Medicaid same-day exclusion
- Seeking additional information about Medicaid managed care plan provision of services for adults at an institution for mental diseases
- Studying participation in the Medicaid Emergency Psychiatric Demonstration project
- Enhancing compliance with mental health and substance use disorder insurance coverage

During the 2019 ACEP Leadership & Advocacy Conference, 500 ACEP members asked their legislators to support H.R. 2519, Improving Mental Health Access from the Emergency Department Act. This important piece of legislation, developed by ACEP, would:

- Expedite transition to post-emergency care through expanded coordination with regional service providers, assessment, peer navigators, bed availability tracking and management, transfer protocol development, networking infrastructure development, and transpor-



tation services;

- Increase the supply of inpatient psychiatric beds and alternative care settings such as regional emergency psychiatric units;

and

- Expand approaches to providing psychiatric care in the emergency department, including tele-psychiatric support and other remote psychiatric consultations, peak period crisis clinics, or creating dedicated psychiatric emergency service units.

On June 26, the U.S. House Committee on Ways and Means unanimously approved a bill, H.R. 3417, Beneficiary Education Tools, Telehealth, and Extenders Reauthorization (BETTER) Act, to provide patient improvements for rural services provided by Medicare. This bill incorporated a provision based on the ACEP-supported Mental Health Telemedicine Expansion Act that would improve treatment of mental health by providing telehealth services to individuals at home.

#### Recent Regulatory Efforts

ACEP continues to ask Congress and the Centers for Medicare & Medicaid Services (CMS) to expand Medicare coverage of emergency telehealth services, including tele-psychiatry services.

- **April 2018:** ACEP members met with CMS to share how innovative psychiatric ED models throughout the country have improved coordination among appropriate providers to improve care for patients experiencing a psychiatric emergency and helped reduce the prevalence of psychiatric boarding.
- **June 2018:** ACEP members shared the aforementioned psychiatric ED models with key members of Congress.
- **December 2018:** ACEP responded to a request for comments from the Federal Communications Commission (FCC) related to the National Suicide Hotline Improvement Act of 2018. We supported creating a new three-digit dialing code for mental health emergencies because it could improve access to appropriate care and reduce psychiatric boarding. In August 2019, the FCC issued a formal report to Congress recommending the creation

of such a three-digit number.

- **April 2019:** ACEP responded to a request for information from the bipartisan Congressional Telehealth Caucus. We asked Congress to expand the use of emergency telehealth services, including tele-psychiatry in the emergency department, and we provided several recommendations for upcoming telehealth legislation.
- **August 2019:** ACEP and the Society for Academic Emergency Medicine responded to the National Institutes of Health's request seeking input from the community about their use of telehealth in general hospital emergency medical care settings to facilitate the care of individuals with suicide risk.

View these comments in full at [www.acep.org/federal-advocacy/mental-health](http://www.acep.org/federal-advocacy/mental-health).

#### State Advocacy Efforts

As emergency departments deal with issues related to the inability to transfer psychiatric patients out of the emergency department, many states have sought legislative solutions. The State Legislative/Regulatory Committee set out to help chapters with legislative efforts in states that grant emergency physicians authority to involuntarily hold and/or transfer psychiatric patients to an appropriate facility when medically indicated. The committee developed a document that details four legislative approaches to remove barriers and expedite evaluation of psychiatric patients in the emergency department. This resource focuses on involuntary holds, detailing criteria and time limits, along with emergency physician authority and liability.

That document and a variety of other resources including current state bills related to psychiatric holds are available at [www.acep.org/state-advocacy/psychiatric-holds](http://www.acep.org/state-advocacy/psychiatric-holds). **+**

**MR. DAVIS** is ACEP director of regulatory affairs. **MS. GRANTHAM** is ACEP communications manager.

## Become a Reviewer

Become a peer reviewer for the *Journal of the American College of Emergency Physicians Open (JACEP Open)*, a new Open Access journal in the field. Reviewers are critical to the publishing process, helping to shape the credibility and reputation of the journal through evaluation of the quality, relevance, and merit of submitted papers. *JACEP Open* is seeking peer reviewers for a range of expertise in emergency medicine to ensure the journal is presenting novel, sound research that will positively impact the field.

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- Agree to review the first revision of a manuscript for which he/she provided the initial review.

If interested in serving as a reviewer, please email Martha Villagomez, [mwillagomez@acep.org](mailto:mwillagomez@acep.org), and include with your message the following attachments in Microsoft Word or PDF:

- Current electronic resume or curriculum vitae;
- List of areas of expertise/focus that will help assign appropriate articles to reviewers;
- Brief statement outlining previous peer review/editing experience and why you are interested in reviewing for *JACEP Open*.



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# Emergency Physician Compensation to Increase in 2020

by MICHAEL GRANOVSKY, MD, FACEP; AND DAVID MCKENZIE, CAE

The Centers for Medicare and Medicaid Services (CMS) has released two long awaited proposed rules: the *2020 Physician Fee Schedule (PFS)* and the *2020 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System*. ACEP provided extensive commentary on these proposed rules, and CMS is expected to finalize these provisions by early November 2019. Overall, CMS has recognized that emergency medicine is providing higher-intensity care and, as a result, our work relative value units (RVUs) will be increasing.

You can read ACEP-submitted commentary on the proposed PFS rule at [www.acep.org/globalassets/sites/acep/media/advocacy/federal-advocacy-pdfs/acep-response-to-cy-2020-pfs-and-qpp-proposed-rule.pdf](http://www.acep.org/globalassets/sites/acep/media/advocacy/federal-advocacy-pdfs/acep-response-to-cy-2020-pfs-and-qpp-proposed-rule.pdf).

## 2020 Conversion Factor Increase

For 2020, CMS proposes a Medicare PFS conversion factor of \$36.0896 representing a small increase from the 2019 conversion factor of \$36.0391. Note that the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provided 0.5% base updates to the conversion factor through 2019. Those base updates have now expired, leading to this relatively smaller increase.

## 2020 RVUs Increase for ED E/M Services

Each year, RVU values for physician services are updated. This year, CMS had concerns that the emergency department evaluation and management (E/M) Current Procedural Terminology (CPT) codes were undervalued and requested that the American Medical Association's Relative Value Update Committee (RUC) perform a survey and revalue the work RVUs associated with the relevant codes.

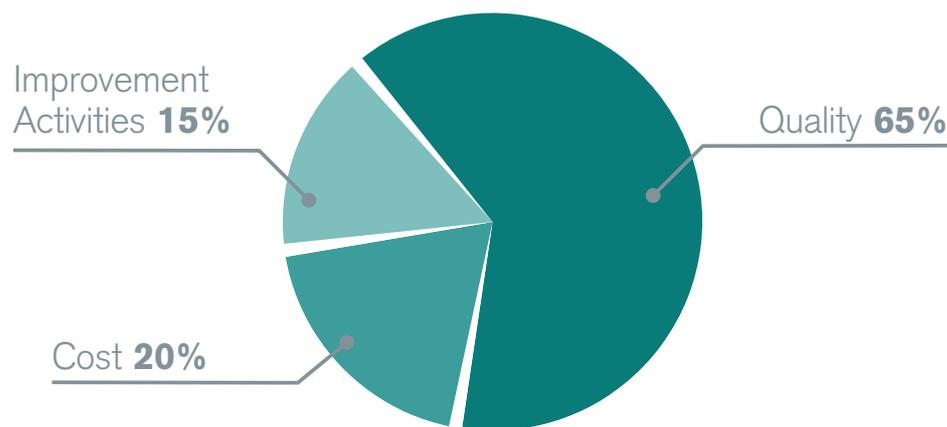
"In the CY 2018 PFS final rule, we finalized a proposal to nominate CPT codes 99281–99285 as potentially misvalued based on information suggesting that the work RVUs for emergency department visits may not appropriately reflect the full resources involved in furnishing these services (FR 82 53018)." — *2019 Physician Proposed Rule, page 420*

ACEP undertook an extensive survey process and mounted compelling arguments describing the increased complexity of the patients we treat every day in

**Table 1: 2020 Proposed Increases to ED Work RVUs**

CODE	2019 WORK RVUS	2020 PROPOSED WORK RVUS	% INCREASE IN WORK RVUS IN 2020	ECONOMIC IMPACT FOR 2020
99281	0.45	0.48	6.67%	+1.4%
99282	0.88	0.93	5.68%	+2.22%
99283	1.34	1.42	5.97%	+4.78%
99284	2.56	2.60	1.56%	+1.97%
99285	3.80	3.80	0.00%	+2.05%

**Figure 1: 2020 MIPS Category Weighting for Typical ED Providers**



the nation's emergency departments. (Read more about ACEP's efforts to increase emergency physicians' reimbursement rates at [www.acepnow.com/category/acep4u](http://www.acepnow.com/category/acep4u).) In good news for emergency medicine, CMS has proposed to revalue the codes based on the RUC recommended work values (see Table 1). (To read behind-the-scenes information about how our ACEP volunteers and staff formed the winning arguments, read our previous ACEP4U article from the September 2019 issue at [www.acepnow.com/article/acep4u-how-acep-works-behind-the-scenes-to-ensure-appropriate-medicare-reimbursement/](http://www.acepnow.com/article/acep4u-how-acep-works-behind-the-scenes-to-ensure-appropriate-medicare-reimbursement/).)

A more detailed fact sheet on the 2020 PFS payment proposals can be found at <https://shar.es/aXAGIG>.

## Merit-Based Incentive Payment System

The Merit-Based Incentive Payment System (MIPS) is a payment mechanism that provides for annual reimbursement adjustments related to CMS quality program requirements in four categories: quality, cost, promoting interoperability, and clinical practice improvement activities. For the 2020 performance year (affecting 2022 payments), the relevant MIPS categories for typical emergency medicine groups will include (see Figure 1):

- **Quality:** 65 percent
- **Cost:** 20 percent
- **Improvement activities:** 15 percent

In the proposed rules, CMS also advances some significant changes to MIPS, including:

## 2020 CMS PROPOSED RULES CONTAIN BUMPS FOR PHYSICIAN PAYMENTS, EMERGENCY SERVICES

### MIPS Performance Thresholds Increasing, Making It Harder to Avoid a Penalty

- CMS proposes to increase the MIPS performance threshold, which is the minimum number of points needed to avoid a negative payment adjustment, from 30 points in 2019 to 45 points in 2020 and 60 points in 2021 (see Figures 2 and 3).
- CMS also proposes to increase the exceptional performance threshold (which allows for extra bonus dollars) from 75 points in 2019 to 80 points in 2020 and 85 points in 2021.
- CMS proposes to increase the quality measure data completeness reporting requirement from 60 percent to 70 percent of applicable patients.

### Quality Category Goes Down, Cost Goes Up

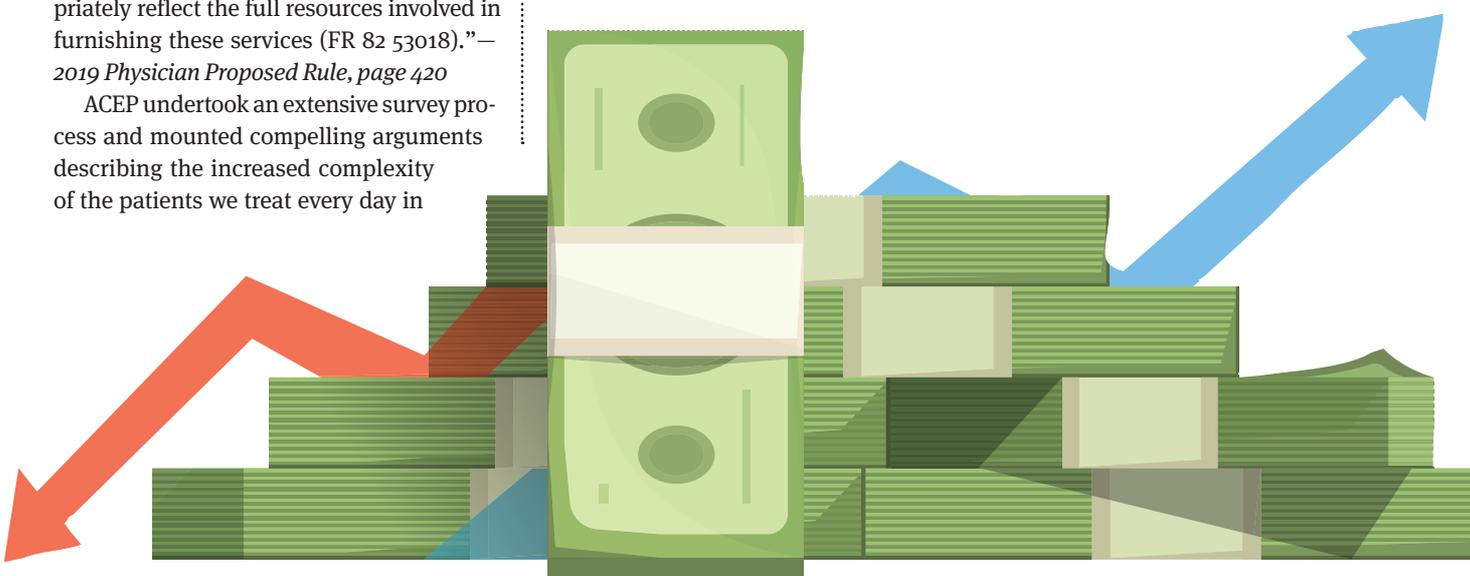
- CMS proposes to reduce the weight of the quality category for general medical providers from 50 percent to 40 percent in 2020, 35 percent in 2021, and 30 percent in 2022 while correspondingly increasing the weight and impact of the cost category.
- For each individual quality measure, a provider's raw percentage of meeting the measure's requirements is benchmarked against the universe of providers reporting that measure to yield a decile score. Each decile is then converted to a MIPS quality point score on a scale of 1–10. Your "quality points" are then added to your total MIPS score based on the weighting of the quality category for your reporting entity.

The cost category is calculated based on 10 measures:

- » Total per capita costs for all attributed beneficiaries measure
- » Medicare spending per beneficiary measure
- » Elective outpatient percutaneous coronary intervention
- » Knee arthroplasty
- » Revascularization for lower extremity chronic critical limb ischemia
- » Routine cataract removal with intraocular lens implantation
- » Screening/surveillance colonoscopy
- » Intracranial hemorrhage or cerebral infarction
- » Simple pneumonia with hospitalization
- » ST-elevation myocardial infarction with percutaneous coronary intervention

### CMS Proposes Multiple Changes to Emergency Medicine–Focused Quality Measures

- To remove the following measures from the emergency medicine specialty set, meaning that CMS no longer views these as relevant to emergency physicians: #91: acute otitis externa: topical therapy; and #255: Rh immunoglobulin (Rhogam) for Rh-negative pregnant women at risk of fetal blood exposure.



- To remove the claims-based version of measure #415: emergency department utilization of CT for minor blunt head trauma for patients aged 18 years and older from MIPS due to topped-out status but to maintain the measure for registry reporting.
- To remove emergency department patients from inclusion in measure #326: atrial fibrillation and atrial flutter: chronic anticoagulation therapy.

### CEDR Can Help

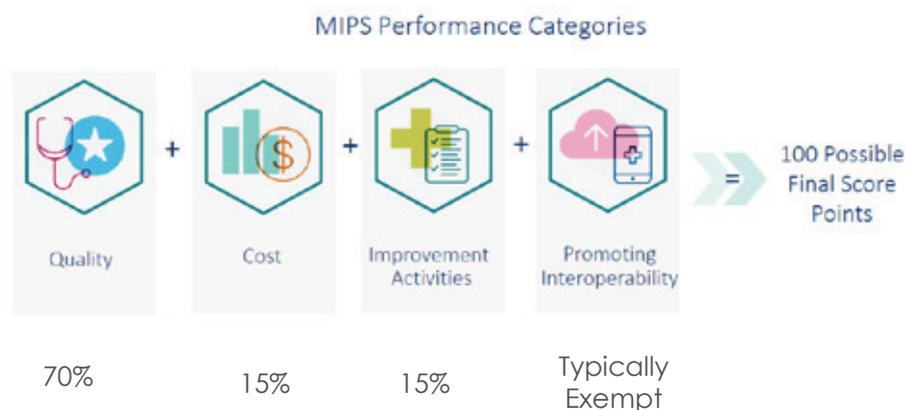
The penalty for not meeting MIPS requirements in 2020 will be 9 percent for typical ED groups. ACEP Clinical Emergency Data Registry (CEDR) is available as an EM-specific reporting mechanism to take care of your MIPS reporting requirements. Learn more at [www.acep.org/cedr](http://www.acep.org/cedr).

### MIPS Value Pathways Framework

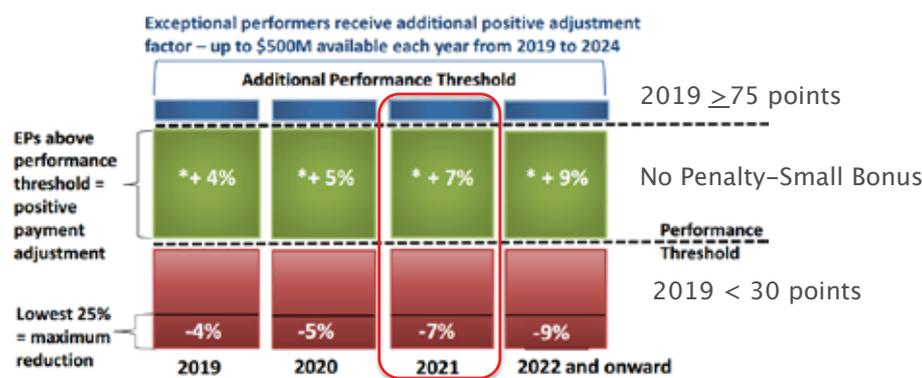
CMS has published a brand-new term, the “MIPS Value Pathways Framework” (MVPs). As part of the proposed rules, CMS is seeking feedback on its new MVPs, which aims to move MIPS toward a new set of measures that are more clinically relevant for each provider.

CMS proposes that a clinician or group has the choice to opt into an MVP associated with their specialty or opt into a clinical condition. Providers would be reporting on the same measures and activities as other clinicians and groups in the MVP that the provider has opted into. Each MVP “track” would connect measures and activities across the various MIPS performance categories and could rely on a mix of specialty-specific measures as well as population-based administrative

**Figure 2: How MIPS Points Are Calculated for Emergency Physicians**



**Figure 3: MIPS Point Thresholds**



claims-based measures automatically calculated by CMS. MVPs would also include more robust and timely performance feedback to better prepare clinicians for transitioning to risk-based alternative payment models. MVPs could begin to apply as early as the 2021 performance year.

A more detailed fact sheet on proposed changes to the quality payment pro-

gram can be found at [www.logixhealth.com/Files/2020%20QPP%20Proposed%20Rule%20Fact%20Sheet.pdf](http://www.logixhealth.com/Files/2020%20QPP%20Proposed%20Rule%20Fact%20Sheet.pdf).

### Hospital Price Transparency

As part of the proposed OPPS rule, CMS published a series of proposals that collectively aim to increase the transparency of hospital charges. Notably, CMS is proposing require-

ments that would force hospitals to make their private-payer negotiated (contracted) rates (for “shoppable” services) available to the public.

### Hospital Clinic, Emergency Department, and Critical Care Payments

CMS proposed no major changes for hospital-based clinics and emergency department facility payments as well as facility critical care services and trauma activation services. The policies for these services would also remain generally unchanged.

A more detailed fact sheet regarding both the payment and quality proposals in the OPSS rule can be found at <https://shar.es/aXAtbr>.

### Need More Help?

Resources for these and other topics can be found on the reimbursement section of the ACEP website, [www.acep.org/administration/reimbursement](http://www.acep.org/administration/reimbursement). ACEP Director of Reimbursement David McKenzie, CAE, can field questions at 800-708-1822, ext. 3233. Finally, ACEP offers well-attended and highly recommended coding and reimbursement educational conferences annually, with the next conference scheduled for Jan. 27–31 in Austin, Texas. Visit [www.acep.org/rc](http://www.acep.org/rc) for details. 📍

**DR. GRANOVSKY** is president of LogixHealth, an ED coding and billing company, and currently serves as the course director of ACEP’s Coding and Reimbursement courses. He may be reached at [mgranovsky@logixhealth.com](mailto:mgranovsky@logixhealth.com).

**MR. MCKENZIE** is ACEP director of reimbursement.



Designed to address the continuum of care of the injured person. Attendees will gain knowledge about their own specialties along with an increased appreciation of the work of others on the trauma team. Topics will include:

- Pre-hospital care of the injured patient: transport and resuscitation
- Pain and sedation management of the injured patient
- Management of complex traumatic injuries
- Gun and domestic violence: policy and prevention
- Homeland security role in trauma management

For a complete list of topics and speakers, or to register, visit [DetroitTrauma.org](http://DetroitTrauma.org)



# ABEM's New President on MyEMCert and More

Dr. Jill Baren tackles critical EM certification issues for *ACEP Now*



**T**ransforming the way emergency physicians learn and stay certified is one of the most critical and exciting missions of the American Board of Emergency Medicine (ABEM), according to Jill M. Baren, MD, MBA, the new ABEM President, who was elected in July and will serve for the 2019–2020 term.

Currently professor of emergency medicine, pediatrics, and medical ethics at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia, as well as the provost's faculty leadership development fellow there, Dr. Baren has been a member of the ABEM Board of Directors since July 2012 and was elected to the Executive Committee in 2016.

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

## **What are your goals during your year as ABEM President?**

Thank you very much for this opportunity. It's a pleasure to share my thoughts with the EM community in *ACEP Now*.

ABEM has two primary strategic objectives for this coming year. First, we have a record number of physicians to assess and need to make sure it's done in a high-quality, fair, and valid way. Second is the development of MyEMCert (the alternative to the ConCert Exam) to keep pace with new advances that are integrated into our clinical practice. MyEMCert has the potential to transform the adoption of new information into our practices, something ABEM recognizes as high priority.

## **You are well-known as an academic emergency physician, but 75 percent of ABEM-certified physicians are community physicians. How do you assure community physicians that you understand their challenges?**

Yes, 75 percent of ABEM-certified physicians are community physicians, and the ABEM Board includes several physicians who practice in a community setting. Additionally, almost 60 percent are involved in teaching medical students, residents, or fellows. That means the majority of ABEM-certified physicians are committed teachers, which is a perfect fit for our specialty. Emergency physicians are inherently the type of people who want to share what they know with other physicians and their patients. More important, the core of EM practice is similar across most community hospital and academic medical center settings.

Also, every emergency physician on the ABEM Board of Directors and all of our volunteer physicians, such as oral examiners, *must* be clinically active.

My clinical time is very important to me. As an ABEM Board member working shifts in the emergency department, I am subject to the same rules, regulations, pressures, and stresses that all frontline emergency physicians face.

## **What can you tell us about MyEMCert, the alternative to the ConCert Exam?**

MyEMCert is our highest-priority development project—and it's coming along nicely. MyEMCert will provide an option to the current program, which is the Lifelong Learning and Self-Assessment plus the 10-year ConCert Exam track. With MyEMCert, physicians will need to complete four modules every five years to keep their certification in good standing. MyEMCert modules will include about 50 questions and focus on specific topics, such as abdominopelvic presentations. Modules will also focus on new advances in the specialty. We are assembling a panel of EM experts—journal and textbook editors and evidence-based medicine specialists who will review new advances submitted by practicing emergency physicians. Many physicians said that they want continuing certification to help them become better doctors. We think MyEMCert is one way to do that.

## **What is emergency medicine's most exciting opportunity? Conversely, what are the specific threats to our field that ABEM can address?**

From ABEM's vantage point, emergency medicine's most exciting opportunity is to revolutionize knowledge translation in our specialty.

Through MyEMCert, we can accomplish that goal. Our efforts are catalyzed and expanded when organizations such as ACEP provide a complementary emphasis in their educational programs. ABEM needs ACEP and other organizations as partners to continue to create a high-level educational environment in our specialty.

There are many threats to our specialty, but the ones I think are particularly concerning involve ED boarding and physician burnout. We must continue to attract the best and the brightest physicians into emergency medicine and ensure that we have the right landscape in our training and practice environments to support them. I also want to acknowledge that ACEP has been a leader in calling for protected time for residency core faculty and in taking on the issue of surprise billing.

## **Women and many minorities continue to be underrepresented in emergency medicine. What can ABEM do about that?**

ABEM tracks residency demographic data closely and publishes an annual report in the *Annals of Emergency Medicine*. ABEM can set an example by encouraging and supporting women and underrepresented minorities to enter the profession. I am extremely proud that we have a very diverse Board and our newly elected Executive Committee is composed of 50 percent women, and about 75 percent of ABEM staff leadership are women. Most recently, all of the physicians selected to join our test-writing group are women. But we can always strive to do better. ABEM just formed a Diversity and Inclusion Expertise Task Force that will work to keep diversity and inclusion a priority for the Board.

ABEM also works hard to make sure that our physician assessment processes are not unfairly biased against certain groups. We perform detailed analyses to ensure that our test questions don't contain ethnic or cultural biases. We've also analyzed our oral examination scores and found no difference in examiner scoring for men and women exam candidates.

## **Is there such a thing as too many emergency physicians? Too many residency programs? Does ABEM have a position on this?**

Workforce is an important issue for our specialty, but ABEM does not offer policy opinions about it. ABEM is resolute that we will not adjust our examination passing standards to regulate the workforce.

I think ACEP is wise to be working with Edward Salsberg, the leading national expert on physician workforce issues, [on its Emergency Medicine Workforce Task Force project]. ABEM provided ACEP and other organizations data to help inform the specialty about workforce trajectories, especially as it involves certified physicians.

## **What can you share about yourself so that the EM community can get to know you even better?**

I feel very fortunate to have combined clinical care, teaching, research, department chair administration, and service to the specialty throughout my 27-year career! I was one of the first emergency physicians to train and become subspecialty certified in pediatric emergency medicine. Although subspecialty certification provided me with a niche focus for my clinical and academic work, I continued to see the entire spectrum of emergency patients in my practice. It's given me such an appreciation for the nuances involved in caring for different patients and learning how to be the best patient advocate possible. Getting involved and becoming a leader in various EM organizations allowed me to connect with colleagues across the country and listen to and consider their different viewpoints, which constantly reaffirms the importance of and my commitment to diversity and inclusion. I don't regret the immense time commitment that it took to become a leader in our specialty; it's been very rewarding. But I've always placed huge emphasis on family life and being physically active outdoors. My family and I enjoy travel, skiing, dining out, and sports events and try to do those things together as much as possible.

In closing, I want to make sure that everyone knows that ABEM is celebrating its 40th anniversary this year. Our success as a certifying body is the direct result of the efforts and quality practice of emergency physicians. We believe that ABEM-certified physicians are the best individuals to provide safe, high-quality emergency care. 🍀



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# 2019–2020 EMERGENCY PHYSICIAN COMPENSATION REPORT

Salaries continue to rise, but more jobs are open to primary care board-certified physicians

by BARB KATZ

Emergency physician incomes in most areas of the United States continue to increase. In 2009–2010, the national average was \$141 per hour. This year, the national average is \$221 per hour, a 36 percent increase over 10 years. At the same time, the average full-time hourly requirement is decreasing from 1,632 to 1,560 clinical hours a year. I found several employers offering full-time equivalent hours as low as 1,240 a year. Of course, the fewer hours worked, the lower the annual compensation.

Also tracking with huge gains are the number of employers open to hiring primary care board-certified (PC-BC) physicians for their emergency department openings. At 53 percent, it's an increase of nearly 20 percent from last year. I believe the continuing supply-and-demand market in emergency medicine is driving these numbers. Employers in "geographically challenged" locations have no choice. As long as the 2,200 emergency medicine residency graduates continue to focus their job search on the same 15 locations, this issue will continue to grow. I also tracked the multistate large contract group penetration of the market. As of this year, 63 percent of jobs available in the specialty are with these large national contract groups (NCGs).

I want to thank all the groups, employers, and physicians who contributed to the research on this report. Getting real numbers is becoming more and more difficult, with fewer than 20 percent of job listings on all of the web job sites and classified ads providing any income information. Perhaps the competition in the job market has increased to a point where employers are afraid to be forthcoming. Recruiters, take note: From an impromptu survey I ran with physicians who were job searching this year, I discovered 83 percent are more likely to answer a job listing with compensation information than one without.

## Trends for the 2019–2020 Recruiting Year

- The \$300+ hourly rate is alive and well and growing nationwide.
- Overall availability of jobs this year is down 18 percent nationally.
- The highest concentrations of pediatric emergency physician jobs are in Florida and New Jersey.
- The highest rate of income is \$395 per hour in New Mexico.
- The lowest rate is \$130 per hour in New York City.
- Sign-on bonuses are topping out at \$150,000, with the average closer to \$40,000.

The following figures are based on first-year incomes for 1,560 clinical hours a year, down 72 hours from last year's norm of 1,632. This change has impacted the annual package numbers, which are based on the 1,560 clinical hours, plus basic benefits valued at \$30,000. The hourly averages include defined bonuses and RVU comp where applicable but do not reflect any sign-on bonuses or relocation or loan assistance. Rankings are based on state hourly averages, not the sporadic highs and lows. ➕



There is a tie for top regional income average, beginning with the usual leader, the **SOUTHEAST**, with an average salary of \$234 per hour/\$395,000 annually. NCGs are providing 80 percent of the jobs this season, and 56 percent of them are open to PC-BC physicians. The regional average is down 4 percent. There is a lot of activity in the Miami and Tampa areas.

**ALABAMA:** \$272/hr., \$454,000 ann.; 50% PC-BC; 60% NCG; high of \$300/hr.; up 14%

**ARKANSAS:** \$208/hr., \$354,000 ann.; 87% PC-BC; 87% NCG; no significant highs; down 9%

**FLORIDA:** \$219/hr., \$372,000 ann.; 12% PC-BC; 82% NCG; high of \$350/hr.; down 5%

**GEORGIA:** \$267/hr., \$446,000 ann.; 71% PC-BC; 90% NCG; high of \$365/hr.; up 11%

**LOUISIANA:** \$234/hr., \$395,000 ann.; 53% PC-BC; 50% NCG; no significant highs; up 9%

**MISSISSIPPI:** \$266/hr., \$446,000 ann.; 50% PC-BC; 50% NCG; high of \$330/hr.; no change

**NORTH CAROLINA:** \$218/hr., \$370,000 ann.; 59% PC-BC; 74% NCG; no significant highs; down 5%

**SOUTH CAROLINA:** \$207/hr., \$353,000 ann.; 50% PC-BC; 70% NCG; no significant highs; down 19%

**TENNESSEE:** \$217/hr., \$369,000 ann.; 71% PC-BC; 89% NCG; high of \$330/hr.; no change



Also averaging \$234 per hour/\$395,000 annually is the **WEST/SOUTHWEST REGION**, with 62 percent of jobs open to PC-BC physicians and 72 percent of jobs being offered by NCGs. The regional average is up 6 percent, with a lot of activity in Houston and Phoenix. As usual, Utah remains tight as a vault, with no job openings or income information to be found.

**ARIZONA:** \$256/hr., \$430,000 ann.; 12% PC-BC; 64% NCG; high of \$321/hr.; up 15%

**CALIFORNIA:** \$240/hr., \$405,000 ann.; 73% PC-BC; 75% NCG; high of \$300/hr.; up 10%

**COLORADO:** \$198/hr., \$310,000 ann.; 67% PC-BC; 83% NCG; no significant high; up 17%

**HAWAII:** \$205/hr., \$349,000 ann.; 33% PC-BC; 66% NCG; no significant high; up 12%

**NEVADA:** \$224/hr., \$379,000 ann.; 75% PC-BC; 83% NCG; no significant high; down 11%

**NEW MEXICO:** \$285/hr., \$475,000 ann.; 100% PC-BC; 60% NCG; high of \$395/hr.; no change

**OKLAHOMA:** \$215/hr., \$365,000 ann.; 50% PC-BC; 70% NCG; no significant high; no change

**TEXAS:** \$251/hr., \$422,000 ann.; 88% PC-BC; 76% NCG; high of \$325/hr.; no change

**UTAH:** No jobs open or information available



The **PACIFIC NORTHWEST** averages are up 15 percent from last year at \$231 per hour/\$390,000 annually. Overall, 50 percent of the jobs open this year are available to PC-BC physicians, and 42 percent of them are with NCGs. There was no compensation information available for Alaska or Montana.

**ALASKA:** No compensation information available; 33% PC-BC; 33% NCG

**IDAHO:** \$260/hr., \$435,000 ann.; 100% PC-BC; 100% NCG; no significant high; up 14%

**MONTANA:** No compensation information available

**OREGON:** \$215/hr., \$365,000 ann.; 50% PC-BC; 50% NCG; high of \$220/hr.; up 14%

**WASHINGTON:** \$219/hr., \$371,000 ann.; 35% PC-BC; 29% NCG; high of \$250/hr.; up 21%

**WYOMING:** \$230/hr., \$404,000 ann.; 33% PC-BC; no NCG; high of \$250/hr.; no change



The 13 states of the **MIDWEST** average \$225 per hour/\$381,000 annually, with 60 percent of the jobs open to PC-BC physicians and 54 percent of the jobs offered by NCGs. The regional average is up 10 percent. North Dakota was unavailable, but look for some high activity in Chicago.

**ILLINOIS:** \$226/hr., \$382,000 ann.; 36% PC-BC; 58% NCG; high of \$269/hr.; down 3%

**INDIANA:** \$213/hr., \$362,000 ann.; 42% PC-BC; 75% NCG; high of \$245/hr.; down 7%

**IOWA:** \$238/hr., \$400,000 ann.; 43% PC-BC; 45% NCG; high of \$273/hr.; up 20%

**KANSAS:** \$225/hr., \$381,000 ann.; 62% PC-BC; 77% NCG; high of \$265/hr.; up 16%

**KENTUCKY:** \$227/hr., \$384,000 ann.; 79% PC-BC; 92% NCG; high of \$365/hr.; no change

**MICHIGAN:** \$206/hr., \$351,000 ann.; 70% PC-BC; 75% NCG; high of \$225/hr.; up 5%

**MINNESOTA:** \$205/hr., \$350,000 ann.; 66% PC-BC; 33% NCG; no significant high; no change

**MISSOURI:** \$234/hr., \$396,000 ann.; 63% PC-BC; 38% NCG; high of \$315/hr.; up 12%

**NEBRASKA:** \$223/hr., \$378,000 ann.; 66% PC-BC; 33% NCG; no significant high; up 15%

**NORTH DAKOTA:** No jobs open or information available

**OHIO:** \$241/hr., \$406,000 ann.; 56% PC-BC; 82% NCG; high of \$260/hr.; up 9%

**SOUTH DAKOTA:** \$154/hr., \$270,000 ann.; 100% PC-BC; no NCG; \$100,000 sign-on; no comparison available

**WISCONSIN:** \$239/hr., \$402,000 ann.; 41% PC-BC; 45% NCG; high of \$300/hr.; up 10%

The MID-ATLANTIC states are up 10 percent, with a regional average of \$212 per hour/\$360,000 annually. The District of Columbia is silent this season, but both Philadelphia and Baltimore are active. Overall, 31 percent of jobs are open to PC-BC physicians, and 65 percent of the jobs are with NCGs.



**DELAWARE:** \$166/hr., \$290,000; no PC-BC; 50% NCG; no significant high; *no change*

**DISTRICT OF COLUMBIA:**  
*No jobs open or information available*

**MARYLAND:** \$213/hr., \$362,000 ann.; 9% PC-BC; 50% NCG; high of \$266/hr.; *up 14%*

**NEW JERSEY:** \$208/hr., \$356,000 ann.; 19% PC-BC; 86% NCG; high of \$270/hr.; *no change*

**PENNSYLVANIA:** \$223/hr., \$378,000 ann.; 27% PC-BC; 52% NCG; high of \$300/hr.; *no change*

**VIRGINIA:** \$232/hr., \$392,000 ann.; 30% PC-BC; 69% NCG; no significant high; *down 10%*

**WEST VIRGINIA:** \$230/hr., \$388,000 ann.; 100% PC-BC; 85% NCG; high of \$236/hr.; *up 16%*

Only 21 percent of jobs in the NORTHEAST are open to PC-BC physicians, and the NCG penetration is only 32 percent. Regional averages are up 5 percent at \$192 per hour/\$330,000 annually. Both Boston and New York City show activity.



**CONNECTICUT:** \$198/hr., \$337,000 ann.; 16% PC-BC; 28% NCG; high of \$216/hr.; *up 10%*

**MAINE:** \$190/hr., \$326,000 ann.; 25% PC-BC; 20% NCG; no significant high; *up 9%*

**MASSACHUSETTS:** \$210/hr., \$357,000 ann.; 5% PC-BC; no NCG; high of \$250/hr.; *up 12%*

**NEW HAMPSHIRE:** \$186/hr., \$320,000 ann.; 21% PC-BC; 43% NCG; no significant high; *no change*

**NEW YORK:** \$216/hr., \$367,000 ann.; 29% PC-BC; 60% NCG; high of \$275/hr.; *up 4%*

**RHODE ISLAND:** \$165/hr., \$287,000 ann.; 50% PC-BC; 75% NCG; no significant high; *no change*

**VERMONT:** \$180/hr., \$310,000 ann.; no PC-BC; no NCG; no significant high; *no change*

Figure 1. States Offering the Most and Least Compensation

#### TOP 10 STATES FOR COMPENSATION

1. New Mexico
2. Alabama
3. Georgia
4. Mississippi
5. Idaho
6. Arizona
7. Texas
8. Ohio
9. California
10. Wisconsin



#### BOTTOM 10 STATES FOR COMPENSATION

1. South Dakota
2. Rhode Island
3. Delaware
4. Vermont
5. New Hampshire
6. Maine
7. Colorado
8. Connecticut
9. Hawaii
10. Minnesota



MS. KATZ is president of The Katz Company EMC, a member of ACEP's Workforce and Career sections, and a frequent speaker and faculty at conferences and residency programs. Contact her at [katzco@cox.net](mailto:katzco@cox.net).



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US-NUA-0193 08/19

# Get X Waivered! (Also, Ban the X Waiver!)



SUSAN R. SYMONDS FOR MAINFRAME PHOTOGRAPHICS

A 2000 law that allows physicians to prescribe Suboxone for addiction is better than nothing but is now more of a barrier than a conduit

by JEREMY SAMUEL FAUST, MD, MS

**H**ow many saves do we really make? We count the dramatic ones, like that rare thoracotomy that worked out. But we often forget to count less flashy saves that play out long after an ED visit, say, that patient who quit smoking because we took a few minutes to chat about it. We tend to overestimate how much of our careers are about the former and underestimate how much are about the latter.

Today, few actions that emergency physicians can take have a higher mortality benefit than obtaining an X waiver. The X waiver permits physicians to prescribe Suboxone (buprenorphine/naloxone) for opioid use disorder patients. The training takes about a day, is inexpensive, and saves lives.

Consider the impact. Of emergency patients who receive naloxone for an opioid overdose, a staggering 5 percent will be dead within one year.<sup>1</sup> Can you think of an acute disease that we routinely discharge that has such a high

one-year mortality rate? Studies suggest that maintenance therapies (like Suboxone) can save many of those lives.<sup>2</sup> Opioid use disorder stands alone as the only major substance abuse disorder in which abstinence is more dangerous than agonist treatment with agents like buprenorphine and methadone. Opioid agonist therapy is the gold standard for opioid use disorder treatment. It reduces relapses—and reduces mortality. If we went into business to save lives but are not willing to do this, we're failing. If we don't think that these patients deserve our time or efforts, we are letting our biases and blind spots get in the way. More than 70,000 Americans died from opioid misuse in 2018. This cannot stand.

Sadly, for many of our patients, a near-death experience from opioid use is not a one-time occurrence. As soon as they're revived, they're ready to go. You've probably seen this kind of patient many times. They're glad you revived them, they are sometimes—but not always—outwardly grateful, and they're not

interested in treatment. Some take us up on our offer to take a free Narcan kit to go. But others are actually ready to quit. How can we find these patients? It's easy. Just ask them. For these individuals, prescribing Suboxone in the emergency department is the single best way we can help them.

If I want to save the most lives during my career, mastering my cricothyrotomy and thoracotomy skills is a huge waste of time compared with being waived and having “the talk” with opioid use disorder patients.

### So Why Ban the X Waiver?

Getting the X waiver is a small but worthwhile hassle. It takes about eight hours and a couple hundred bucks, and you have to do a small amount of electronic paperwork. ACEP and many other groups offer these courses. Do this now! I did it last year, and I haven't regretted it for a nanosecond. I have started a small number of patients on Suboxone. I may have already saved one or more lives by doing so.

During that time, I have had zero successful thoracotomies. If we are keeping track of otherwise healthy lives saved, buprenorphine is clearly winning—if not already, then certainly in the long run.

But I also freely admit that getting that waiver was indeed a “small” hassle. And even that small hassle appears to be preventing physicians who want to get waived from doing so. For any armchair behavioral economists out there, this is a prime example of what Nobel Prize-winning economist Richard Thaler has termed “sludge.” Sludge is “excessive or unjustified frictions that make it more difficult for consumers, employees, employers, students, patients, clients, small businesses, and many others to get what they want or to do as they wish.” Sludge is what keeps you from signing up for things you actually want, like that tax shelter for your medical expenses or child care. Everyone hates sludge. But emergency physicians are particularly averse to it. The X waiver requirement would not pass

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what economist Cass Sunstein calls a “sludge audit,” an exercise designed to determine whether any barriers preventing a particular action are reasonable and worthwhile. (Mr. Sunstein and I published an opinion this month in *The Boston Globe* calling for removing the X waiver requirement on this basis).

For that reason, I join many experts in calling for the X waiver requirement itself to be erased from the law books. This summer, the American College of Medical Toxicology made this stance its official policy. ACEP endorsed the position and now has its own statement to the same effect. Bipartisan legislation in both chambers of Congress has been proposed. Let’s urge our lawmakers to move forward on this.

While the fate of the X waiver is unknown, it’s unlikely to go away immediately. In the meantime, I encourage you to take any and all steps to help our opioid use disorder patients. Go and get your X waiver! Also: Ban the X waiver! 🇺🇸

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—Bonnie Kaplan, MD, MA, residency director

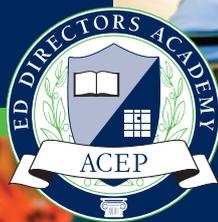
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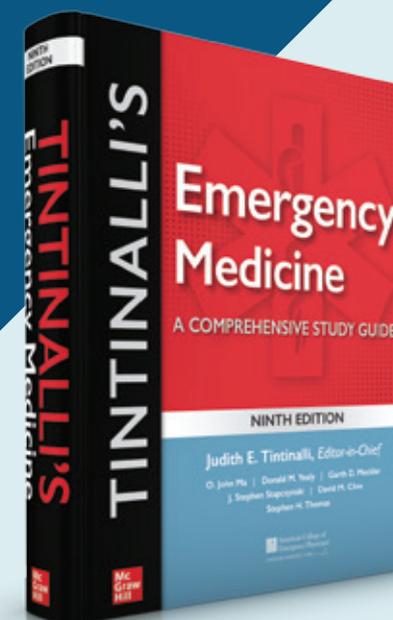
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# SPOT AND TREAT COMPARTMENT SYNDROME

IT'S A TOUGH DIAGNOSIS BUT DANGEROUS TO MISS

by BRIT LONG, MD, FACEP;  
AND ALEX KOYFMAN, MD

## The Case

A 28-year-old male presents after a motorcycle crash. He has right lower leg pain and tenderness. His pulses and nerve function are intact. An X-ray shows a tibial shaft fracture. After splinting the leg and calling orthopedics, the physician finds the patient is anxious and reporting worsening pain despite IV morphine. His leg has become pale and cool, with absent pulses.

## Clinical Presentation

This textbook presentation of compartment syndrome seems easy. Real cases often are not. In emergency medicine, we deal with critically ill patients who may require sedation and/or intubation, and diagnosing compartment syndrome in patients can require some finesse. Not only can compartment syndrome cause major complications, but frighteningly, 23 percent of medicolegal cases involving compartment syndrome were due to misdiagnosis, while 32 percent of cases were due to delayed treatment.<sup>1</sup>



**LOW-PREVALENCE  
HIGH-RISK**

Compartment syndrome is due to excessive pressure in a fascial compartment, either through increased volume in a fixed compartment (edema, hematoma) or reduced size of a compartment (tight cast, wound dressings, poor body positioning, etc.).<sup>2-4</sup> As pressure builds, lymphatic, capillary, and venous blood flow decrease.<sup>5,7</sup> This results in reduced arterial blood flow and tissue ischemia, followed by necrosis, neurological damage, contractures, and, in severe circumstances, need for amputation.<sup>8-11</sup> Rhabdomyolysis may also occur with muscle breakdown.<sup>8-11</sup> Unfortunately, muscle necrosis can occur quickly; in one study, one-third of cases experienced muscle necrosis within three hours of injury.<sup>12</sup>

The most commonly affected region is the anterior compartment of the lower leg, and compartment syndrome can occur in up to 10 percent of patients with tibial fracture.<sup>5,6,13-15</sup> Male patients age 20 to 40 years are particularly at risk, as this age group has a higher risk of high-energy injuries, greater muscle bulk (more swelling), and stronger fascia. However, the elderly are also at higher risk due to baseline hypertension and reduced compartment perfusion.<sup>4</sup> Fractures are the most common etiology. Open fractures can also cause compartment syndrome, as the small fascial/skin breaks do not adequately release pressure.<sup>13,16-18</sup> Other causes are shown in Table 1.

How useful are historical features? Unfortunately, early findings can be subtle or not detected in patients with altered mental status, major trauma, substance use, and extremes of age.<sup>2-4,18</sup> Classically, the earliest symptom is pain out of proportion to the exam (as with other conditions including necrotizing fasciitis and mesenteric ischemia). Patients typically describe this pain as a deep, severe pain that worsens with passive stretch.<sup>3,19-21</sup> While this seems relatively straightforward, data suggest that severe pain has poor sensitivity, as pain is typically subjective.<sup>19</sup> If ischemia develops, pain may vanish with necrosis.<sup>18</sup> Other late symptoms include sensory changes/paresthesias and focal motor deficits.<sup>5,6,19</sup>

The most commonly affected region is the anterior compartment of the lower leg, and compartment syndrome can occur in up to 10 percent of patients with tibial fracture.<sup>5,6,13-15</sup> Male patients age 20 to 40 years are particularly at risk, as this age group has a higher risk of high-energy injuries, greater muscle bulk (more swelling), and stronger fascia. However, the elderly are also at higher risk due to baseline hypertension and reduced compartment perfusion.<sup>4</sup> Fractures are the most common etiology. Open fractures can also cause compartment syndrome, as the small fascial/skin breaks do not adequately release pressure.<sup>13,16-18</sup> Other causes are shown in Table 1.

**Table 1: Risk Factors Associated with Compartment Syndrome**

Blunt soft-tissue injuries
Burns
Casts
Contrast media extravasation
Deep venous thrombosis
Electromyography
Exercise
Fractures
Hematologic diseases (ie, hemophilia)
Infections
Insect bites
Intramuscular hematomas
Intravenous or intraosseous infusions
Osteotomies
Prolonged immobilization
Skin and skeletal traction
Snake bites
Vascular procedures

## Diagnosis

Is your bedside exam reliable? While we are taught about the classic findings of pain with passive stretch, a tense/firm compartment, swelling, focal motor/sensory changes, and decreased pulses, these are not always present and have poor sensitivity.<sup>3-5,14,19</sup> Digital palpation has a sensitivity under 50 percent for detection of compartment syndrome affecting the hand and under 25 percent for the leg.<sup>22,23</sup> Paralysis and absent pulses are rare, and palpating a tense or firm compartment is not reliable. Swelling of the affected area may be present in only half of patients.<sup>3,14,19</sup> Table 2 demonstrates the sensitivity and specificity of exam findings.<sup>19</sup>

As you can see from Table 2, many classic findings are highly specific but poorly sensitive.

What happens if you combine signs and symptoms? A combination of pain with passive stretch, pain at rest, and paresthesias has a sensitivity of 93 percent for diagnosis, and the addition of paresthesias increases sensitivity to 98 percent.<sup>19</sup> However, do not rely on the absence of any classic isolated findings. Other items that complicate diagnosis based on history and exam include clinician inexperience, sedation, polytrauma, and intoxication.<sup>8,19,24,25</sup>

What about other tools? Abnormal pulse oximetry may indicate compartment syndrome.<sup>3,18,19</sup> However, you cannot use this to exclude the condition. Rhabdomyolysis is present in up to 40 percent of patients with compartment syndrome, so be sure to check creatine kinase levels, renal function, and electrolytes.<sup>26-28</sup>

The most reliable bedside data can be obtained by measuring intracompartmental pressure. Options include a solid-state transducer intracompartmental catheter (STC) device (eg, a Stryker monitor) or other needle manometer/arterial line setups.<sup>4-6,19</sup> The Stryker monitor has a diagnostic sensitivity around

**Table 2: Diagnostic Accuracy of Exam Findings<sup>19</sup>**

FINDING	SENSITIVITY	SPECIFICITY
Severe pain	19%	97%
Pain with passive stretch	19%	97%
Paresis	13%	97%
Paresthesia	13%	98%

**Table 3: Clinical Signs Suggestive of Compartment Syndrome**

Intracompartmental pressure >30 mm Hg or $\Delta P$ <20 mm Hg; a $\Delta P$ <30 mm Hg is also concerning but not strictly diagnostic
Intracompartmental pressure >20 mm Hg with hypotension
Interrupted arterial perfusion for $\geq 4$ hours

## TAKE-HOME POINTS

- History and exam findings in isolation have poor sensitivity, but in combination, their reliability improves.
- The go-to assessment is intracompartmental measurement.
- Treatment includes orthopedic consultation, analgesia, resuscitation, removal of external compression, and elevation of the affected extremity. Definitive treatment is fasciotomy.

95 percent, with specificity greater than 98 percent.<sup>29-31</sup> Make sure to place the catheter within 5 cm of the fracture/injury level. However, the catheter tip should be outside the actual site of the fracture. Also ensure the pressure transducer and catheter tip are at the same height.<sup>24,32-35</sup>

After obtaining the intracompartmental pressure, you can use an absolute intracompartmental pressure of 30–40 mm Hg as diagnostic, but using a true intracompartmental pressure alone is problematic, as different compartments have varying pressure thresholds and patients may have varying absolute pressures.<sup>5,6,18,36</sup> Some advocate using a perfusion pressure or differential pressure, which is calculated by subtracting the intracompartmental pressure from the diastolic pressure.<sup>4-6,19</sup> A differential pressure ( $\Delta P$  = compartmental pressure – diastolic blood pressure) of <20 mm Hg is diagnostic. While higher intracompartmental pressures can cause severe damage over a short time period, relatively lower but elevated intracompartmental pressures for long time periods can also cause severe tissue damage. Also, an absolute intracompartmental pressure >20 mm Hg in the setting of hypotension should be considered diagnostic.<sup>4-6,19,24</sup> If the initial pressure is normal but the clinical picture fits compartment syndrome, a repeat measurement as well as pressure measurements in surrounding compartments are recommended.<sup>4-16,24</sup> Table 3 shows situations that are diagnostic of compartment pressure.

## Treatment

If you suspect compartment syndrome for any reason, emergently consult orthopedics. Once a motor nerve deficit is present, full recovery is rare.<sup>3,4,24</sup> The orthopedic surgeon will most likely want to obtain their own pressure assessment, so the earlier you discuss the case with the surgeon, the better. If or

## MEASURING COMPARTMENT PRESSURE



CASE REP ORTHOP.

**Figure 1:** Stryker intracompartmental pressure monitoring device. To measure the pressure in a particular compartment, set the device to zero, insert the needle into the compartment and perpendicular to the skin, inject 0.3 mL sterile saline, and read the pressure displayed on the screen.



DELMASBOLIN

**Figure 2:** Stryker intracompartmental pressure monitoring device being inserted into the lower leg.



JACOCCBY/SA3.0

**Figure 3:** Lower leg fasciotomy

thopedics is unavailable, discuss the case with a surgeon able to complete fasciotomy.

Definitive therapy is fasciotomy. In the emergency department, provide analgesia, resuscitate the patient, remove any constrictive dressings/bandages, reduce fractures, and elevate the affected extremity to heart level.<sup>3,5,17,26</sup> Removing an external compressive device such as a tight cast can reduce pressure by up to 85 percent.<sup>5,6,38,39</sup>

### Case Resolution

The patient has a firm lower leg with absent pulses. Passive movement of the foot causes extreme pain. Orthopedic surgery is consulted, and the patient is taken immediately to the operating room.

*The views expressed in this publication do not reflect the views or opinions of the U.S. government, Department of Defense, U.S. Army, U.S. Air Force, Brooke Army Medical Center, or SAUSHEC EM Residency Program. ☛*

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# By the Numbers

## MOTORCYCLE CRASH FATALITIES

# 5,172

motorcyclists were killed in traffic crashes in 2017, a

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Compiled by Michael J. Mello, MD, professor of emergency medicine, and Dina Burstein, MD, MPH, CPSTI, FAA, assistant professor of emergency medicine, Warren Alpert Medical School of Brown University in Providence, Rhode Island.

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# 2019 ACEP Leadership AWARD WINNERS



Congratulations to the 2019 recipients of the College's most prestigious awards. The winners will be honored during ACEP19 in Denver.



### John G. Wiegenstein Leadership Award

*Sandra M. Schneider, MD, FACEP*

Dr. Schneider is currently the associate executive director for clinical affairs at ACEP and adjunct professor of emergency medicine at the University of Pittsburgh. She remains clinically active as a part-time attending with Integrative Emergency Services at John Peter Smith Hospital in Fort Worth, Texas.

Dr. Schneider is a graduate of the University of Pittsburgh School of Medicine and board-certified in internal medicine and emergency medicine. After residency, she served in the U.S. Public Health Service in Hazard, Kentucky. She then returned to the faculty at the University of Pittsburgh and was the medical director for the emergency department at Montefiore (University) Hospital. She was then recruited to be the founding chair of the department of emergency medicine and professor of emergency medicine at the University of Rochester in New York. Just prior to moving to Texas, she was the senior research director and professor of emergency medicine at the North Shore LIJ Department of Emergency Medicine.

Dr. Schneider is a past President of ACEP, the Society for Academic Emergency Medicine, and the Association of Academic Chairs of Emergency Medicine. She is also a past chair of the Residency Review Committee for Emergency Medicine and the Emergency Medicine Foundation. Her husband owns an ice cream store and her adult daughter is a crime analyst in Burlison, Texas.



### John A. Rupke Legacy Award

*Juan A. González-Sánchez, MD, FACEP*

Dr. González-Sánchez was born in the Presbyterian Hospital in Santurce, Puerto Rico. He completed his pre-college years at the public school Luis Hernaiz Verone, graduating in 1978 with high honors. He was accepted at the University of Puerto Rico, Río Piedras campus, in 1978 and graduated magna cum laude in 1982 with a bachelor's degree in biology and a minor in physical education. In 1982, he was accepted at the School of Medicine of the University of Puerto Rico, from which he graduated in 1986. He then started a residency in emergency medicine there in 1986, from which he graduated in 1989. Immediately after graduation, he started to work as assistant medical director at the Puerto Rico Medical Center Emergency Room and as ad honorem attending of the emergency medicine residency program. Later, in 1991, a scholarship was granted to him by ACEP and the Emergency Medicine Foundation to attend the University of Texas Southwestern Medical

Center for a teaching fellowship which he completed in 1992. Also in 1991, he was appointed program director and chief of the section of the recently created University of Puerto Rico Emergency Medicine Section and Residency Program. From 1991 to 1993, Dr. González-Sánchez worked as the only full-time attending of the emergency medicine residency program, and together with a group of residents, he tried to get the residency program out of a probation status it had been in since 1990.

Unfortunately, the program was not accredited and closed in 1993. One year later, with the support of the School of Medicine of the University of Puerto Rico, the Department of Health, and the leadership of Dr. González-Sánchez, the emergency medicine program was reinstated and has been open for the last 25 years. This program has graduated a total of 220 residents and has been the source of more than 90 percent of emergency medicine specialists who work on the island.

In 2002, under the leadership of Dr. González-Sánchez, the emergency medicine section of the department of surgery became the clinical department of emergency medicine at the School of Medicine of the University of Puerto Rico. Following this, he was appointed department chair and residency program director. Under his leadership and with the support of both the faculty and residents, the department created the first emergency medicine elective for second-, third-, and fourth-year medical students in which more than 3,000 students have participated. It has off-service rotations for other residency programs in which more than 2,500 residents have participated and rotations for international emergency medicine residents from the Dominican Republic. The department had served as a role model for residency programs in the Dominican Republic and gives full support for new ones to come under the leadership of Dr. González-Sánchez. Also since 2002, under the leadership of Dr. González-Sánchez, the University of Puerto Rico Emergency Department has been the sponsor of the annual "Simposio Puertorriqueño de Medicina de Emergencia" meeting with more than 1,600 participants. This program has been one of the main sources of bilingual emergency medicine physicians for the mainland.



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

*Peter J. Jacoby, MD, FACEP*

Dr. Jacoby is the chairman of emergency medicine at Saint Mary's Hospital in Waterbury, Connecticut. He is a past Council Speaker for ACEP and is an assistant professor in the department of traumatology and emergency medicine at the University of Connecticut School of Medicine and at the department of

medical sciences of the Frank H. Netter MD School of Medicine at Quinnipiac University.

Dr. Jacoby is a past winner of the Phil Stent Award given annually to the Emergency Physician of the Year in Connecticut and the 2005 recipient of the ACEP Council Meritorious Service Award. He was named one of ACEP's "Heroes of Emergency Medicine" in celebration of its 40th year, as well as a "Healthcare Hero" by the Connecticut Hospital Association.

Dr. Jacoby is a member of the board of directors of the Saint Mary's Hospital Foundation, a member of the board of directors of Wellmore, chairman of the board of directors of the National Emergency Medicine Political Action Committee (NEMPAC), and chairman of the Palace Theater in Waterbury. His hobbies include travel, photography, and cooking. He is married to Kristen Jacoby, and together, they reside in Woodbury, Connecticut.



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

*William "Ken" Milne, MD*

Dr. Milne is the chief of staff at South Huron Hospital Association in Exeter, Ontario, Canada. He has been doing research for more than 30 years, publishing on a variety of topics. He is passionate about skepticism and critical thinking. He is the creator of the knowledge translation project The Skeptics' Guide to Emergency Medicine ([www.TheSGEM.com](http://www.TheSGEM.com)). Dr. Milne is also part of the faculty for Emergency Medicine and Acute Care Course series and EMRAP. He is married to Barb and has three amazing children.



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

*Ramon W. Johnson, MD, FACEP*

Dr. Johnson is board-certified in emergency medicine and pediatrics and currently practices emergency medicine at a level 2 trauma center in Mission Viejo, California. He has been in practice for 35 years and has been involved both at the state and national level in organized medicine throughout his career. Dr. Johnson is a past president of California ACEP and also served on the national Board of Directors and as Chair of the Board from 2010 to 2011. He has served as the College's liaison to the Disaster and the Pediatric Emergency Medicine committees, as well as to the Disaster, Tactical, and Pediatric sections. Dr. Johnson has been an emergency medicine board examiner for almost two decades, and four years

ago, he was elected to the Board of Directors of the American Board of Emergency Medicine, and just began his second term. He also serves as the liaison to the Pediatric Emergency Medicine sub-board.

At the state level, Dr. Johnson co-authored the legislation establishing the Emergency Medical Services for Children Technical Advisory Committee and has served on the committee for the past 27 years. This year, the committee successfully passed state regulations to improve the care of children throughout the state. He also served on a task force for the California Department of Health Care Services that wrote the state's first strategic plan for disaster preparedness and response, is currently on the state's Joint Advisory Committee on Terrorism and has been actively involved in the oversight of the state's hospital and public health preparedness grants for disaster planning. Dr. Johnson served two eight-year terms on the state's Commission on Emergency Medical Services and chaired a subcommittee creating guidelines for hospitals and local EMS agencies on disaster preparedness for children. He has been involved as a consultant on numerous state grants and private projects, specializing in pediatric care, trauma program development, and disaster preparedness, as well as ED efficiency, patient safety initiatives, and physician engagement. He has also published and lectured on the national and international level on topics including pediatrics, disaster preparedness, patient safety, and health policy.

Dr. Johnson completed his health care MBA in Paris, France, five years ago and completed a dissertation that evaluated the readiness of hospitals in Europe to care for children. He is currently pursuing his interests in health plan management, serving on the board of California Health & Wellness (a Centene health insurance subsidiary) as well as biotech innovation, and serving as chief medical officer for Harbor MedTech (a wound care product company). Dr. Johnson loves international travel and teaching about wine appreciation and physician leadership development.



### Diane K. Bollman Chapter Advocate Award

*Elena Lopez-Gusman, JD*

Ms. Lopez-Gusman is the executive director of California ACEP and has been with the organization since 2007. She directs the chapter's advocacy efforts including multiple litigation efforts, regulatory advocacy, and legislative advocacy, also working as a registered lobbyist. Additionally, she oversees the chapter's two sponsored political action committees and their strategic efforts to elect and reelect champions of emergency medicine.

She brings more than 20 years of legislative, political, and policy experience to her advocacy on behalf of emergency physicians and their patients. She spent 10 years working in the California State Legislature for Assembly Speaker Antonio Villaraigosa and Sen. Joe Dunn.

She worked on a variety of legislative policy areas and developed an expertise in immigration and health care issues. She first began her collaboration with California ACEP when staffing legislation to ensure that California's tobacco litigation settlement funds would be

spent on health care.

Ms. Lopez-Gusman has extensive campaign experience dating back to 1998 when she served as volunteer coordinator for the Assembly Democratic Campaign. She subsequently worked on Measure H in Orange County to dedicate local tobacco settlement funds to health care; Proposition 16 of 2000—the Veterans Home Bond Act; Proposition 61 of 2004—the Children's Hospital Bond Act; Proposition 67 of 2007—the Emergency and Medical Services Funding; and the state controller's race in 2006.

Prior to her service in the legislature, she was a legislative staff attorney for the Mexican American Legal Defense and Education Fund and supervised its Sacramento office.

Ms. Lopez-Gusman earned her BA in sociology and her JD from the University of California, Davis, and is a member in good standing of the State Bar of California and the American Association of Medical Society Executives.



### Outstanding Contribution in Research Award

*Rebecca M. Cunningham,  
MD, FACEP*

Dr. Cunningham is director of the CDC-funded University of Michigan Injury Prevention Center, interim vice president of research for the University of Michigan, professor in the University of Michigan's department of emergency medicine, and professor in health behavior and health education at the University of Michigan School of Public Health in Ann Arbor.

Dr. Cunningham has a distinguished career in researching injury prevention, particularly in youth and young adult populations. Her focus on brief interventions in the emergency room and health systems has included using technology to overcome barriers to reaching youth to prevent substance use and violent injury (SafERTeens intervention/National Institute on Alcohol Abuse and Alcoholism), and longitudinal studies of youth seeking ED care with assault injury (including firearm injury)/National Institute on Drug Abuse. She is the principal investigator of the 2017 National Institute of Child Health and Human Development-funded Firearm-Safety Among Children and Teens Consortium (FACTS). This grant brings together firearm researchers across the country to build capacity in this field.



### Outstanding Contribution in Research Award

*Gail D'Onofrio, MD, FACEP*

Dr. D'Onofrio is professor and chair of the department of emergency medicine at Yale University in New Haven, Connecticut, and physician-in-chief of emergency services at Yale New Haven Hospital. Boarded in emergency and addiction medicine, she is internationally known for her work in substance use disorders, women's cardiovascular health, and mentoring physician scientists in developing independent research careers. For the past 25 years, she has developed and tested interventions for alcohol, opioids, and other substance use disorders, serving as principal investigator on several large National Insti-

tutes of Health, Substance Abuse and Mental Health Services Administration, and Centers for Disease Control and Prevention studies that have changed clinical practice.

Dr. D'Onofrio has a long track record of mentoring junior and senior faculty members both at Yale and throughout the United States in multiple specialties. She is the principal investigator of a National Institute on Drug Abuse-funded K12 establishing the Yale Drug use, Addiction and HIV Research Scholars (Yale-DAHRS) program, a three-year postdoctoral, interdisciplinary, mentored career development program with focused training in prevention and treatment of drug use, addiction, and HIV in general medical settings.

She has received multiple clinical, leadership, and mentorship awards including the Excellence in Mentoring award from the Association for Medical Education and Research in Substance Abuse (2008), Advancing Women in Emergency Medicine award (2016), and the Department of Emergency Medicine Advancement of Women Award (2018) from the Society of Academic Emergency Medicine. She is a founding Board member of Addiction Medicine, now recognized as a new subspecialty by the American Board of Medical Specialties. An advocate for individuals with opioid use disorder, she is one of the architects of Connecticut governor's strategic plan to reduce opioid deaths, working with multiple agencies regionally and nationally to change policies and introduce interventions to combat

the opioid crisis.



### Outstanding Contribution in EMS Award

*Robert E. O'Connor, MD,  
FACEP*

Dr. O'Connor is professor and chair of emergency medicine at the University of Virginia in Charlottesville. He was born in Pittsburgh, attended secondary school in Philadelphia, and received his baccalaureate degree from Haverford College. He earned his medical degree from the Medical College of Pennsylvania and completed residency training in emergency medicine at the Medical Center of Delaware.

He has worked as an emergency physician for over 30 years and has served as a state EMS medical director, department research director, medical student clerkship director, EMS fellowship director, and residency program director. Dr. O'Connor has served as principal or co-investigator on over 50 extramural and multicenter-funded projects, and has presented more than 400 research papers and lectures at local, national, and international meetings. He has more than 150 published manuscripts, co-authored six books, and served as editor in chief of three textbooks. He has served as a peer reviewer for more than 20 journals.

CONTINUED on page 24

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Dr. O'Connor is a past member of the ACEP Board of Directors and is a past Chair of the Board. He is a former board member and past President of the National Association of EMS Physicians and Advocates for EMS as well as a past Chair of its Emergency Cardiac Care (ECC) Committee. In addition, he served on both the Scientific Advisory Council and the Manuscript Oversight Committee for the American Heart Association. He also serves on the 3CPR Council for the American Heart Association. His primary research and professional interests are in resuscitation, prehospital care, and EMS systems. He is a member of a number of academic societies and is the recipient of numerous honors and awards. He enjoys active clinical practice and is a member of the medical staff at the University of Virginia Medical Center in Charlottesville.



**Community  
Emergency  
Medicine Excellence  
Award**

Andrew G. Southard, MD,  
FACEP

Dr. Southard attended medical school at the University of Colorado and completed residency training in emergency medicine at the University of New Mexico. He is the department chair of emergency medicine and medical director for Saint Alphonsus Regional Trauma Center in Boise, Idaho. He works clinically both at the trauma center as well as the community and rural emergency departments throughout the Treasure Valley in the Saint Alphonsus Health System. He is also the owner of FireDoc, which provides medical direction and training to EMS personnel, and serves as the medical director for the Boise, Salmon-Challis, and Sawtooth national forests. Before medicine, Dr. Southard worked as a wildland firefighter, EMT-B, and wilderness guide throughout the west and Alaska.



**Honorary  
Membership Award**

Lowell Gerson, PhD

Dr. Gerson is a professor emeritus of family and community medicine at Northeast Ohio Medical University in Rootstown. He received his doctorate from Case Western Reserve University. His overall academic focus is effective and efficient delivery of medical services and prevention of injury and disease. He has a particular interest in emergency care of older patients, and he is regarded as one of the founders of that specialty. The Academy of Geriatric Emergency Medicine recognized this when it created the Gerson-Sanders Award for outstanding achievement in geriatric emergency medicine.

In 1981, Dr. Gerson identified the disproportionate use of emergency medical services by older patients. His observation, one of the first to identify older persons as a special population, was cited in early research on the topic. In 1992, he published the results of his study investigating the value of case finding by paramedics for problems in older patients. Today, emergency medical services identify older patients with conditions that put them at risk for additional problems.

Dr. Gerson was a member of the original Society for Academic Emergency Medicine (SAEM) Geriatric Task Force. Later, he chaired that task force. From 2001 to 2014, he was the SAEM representative to the American Geriatrics Society Council for the Section on Surgical and Related Medical Specialties. In that capacity, he advocated for increased attention to geriatric issues, mentored early-career faculty, and encouraged greater participation in the Jahnigen and GEMSSTAR career development awards.

Dr. Gerson's past appointments include senior scientist in the department of emergency medicine, Summa Health System—Akron City

Hospital; associate professor, faculty of medicine, Memorial University of Newfoundland; associate professor, McMaster University; visiting fellow, South Australia Health Commission; and visiting senior scientist at the Centers for Disease Control and Prevention.

In 1999, he was appointed associate editor of *Academic Emergency Medicine*. He subsequently was promoted to senior associate editor, a position he held until 2019. He is a member of the MEDICC Review Editorial Board.

He has researched and written more than 250 published articles. Since retiring to a golf community in southwest Florida, Dr. Gerson has remained active in efforts to increase

wellness and reduce illness and injury in his community, and he advocates for improved emergency care for older persons. Dr. Gerson and his wife of 55 years, Francine, an acclaimed fused-glass artist, have two children and two granddaughters.



**Honorary  
Membership Award**

Laura Gore

Ms. Gore served as the public relations director for ACEP for more than 20 years.

**Available Nationwide**



*When treating life-threatening or uncontrolled bleeds in patients on apixaban or rivaroxaban*

**RAPID  
REVERSAL  
Is Within Reach**

**INDICATION**

ANDEXXA (coagulation factor Xa (recombinant), inactivated-zhzo) is a recombinant modified human factor Xa (FXa) protein indicated for patients treated with apixaban or rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies that demonstrate an improvement in hemostasis in patients.

Limitations of Use

ANDEXXA has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban or rivaroxaban.

**Please see additional Important Safety Information on adjacent page and Brief Summary of full Prescribing Information including Boxed Warning on following page.**

**For further information, please visit [ANDEXXA.com](http://ANDEXXA.com)**



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2/19

**SELECT IMPORTANT SAFETY INFORMATION**

**WARNING: THROMBOEMBOLIC RISKS, ISCHEMIC RISKS, CARDIAC ARREST, AND SUDDEN DEATHS**

*See full prescribing information for complete boxed warning*

**Treatment with ANDEXXA has been associated with serious and life-threatening adverse events, including:**

- Arterial and venous thromboembolic events
- Ischemic events, including myocardial infarction and ischemic stroke
- Cardiac arrest
- Sudden deaths

**Monitor for thromboembolic events and initiate anticoagulation when medically appropriate. Monitor for symptoms and signs that precede cardiac arrest and provide treatment as needed.**

**WARNINGS AND PRECAUTIONS**

**Thromboembolic and Ischemic Risks**

The thromboembolic and ischemic risks were assessed in 185 patients who received the Generation 1 product and in 124 patients who received the Generation 2 product. The median time to first event was six days, and patients were observed for these events for 30 days following the ANDEXXA infusion. Of the 86 patients who received Generation 1 product and were re-anticoagulated prior to a thrombotic event, 11 (12.7%) patients experienced a thromboembolic, ischemic event, cardiac event or death.

During that time, she significantly raised ACEP's public profile among its external audiences, such as health policy media in Washington, DC. An expert in developing news hooks, Ms. Gore led her team to conduct two to three major media campaigns every year, engaging the use of opinion polls, social media, and advertising. As a result, ACEP's media coverage on strategic issues doubled and tripled for many consecutive years.

She grew ACEP's Spokespersons' Network to more than 500 media-trained emergency physicians across the country and trained ACEP's physician leaders to be effective on news programs such as *Good Morning America* and CNN, as well as to conduct desk-side briefings with *The New York Times* and *USA Today*.

Ms. Gore led ACEP's evolution into so-

cial media, producing professional video for ACEP's YouTube channel and growing the external Twitter feed to nearly 20,000 followers.

ACEP's YouTube channel generated more than 600,000 views in one year, following the release of the organization's first viral video. She also oversaw ACEP's branding process and development of the organization's tagline, "Advancing Emergency Care." An expert in crisis communications, Ms. Gore was ever vigilant to protect the white hat image of emergency physicians and ACEP.

Ms. Gore wrote or edited all content for ACEP's two external websites—newsroom.acep.org and EmergencyCareforYou.org. She developed messaging on policy issues, based on research and focus group testing.

Ms. Gore previously worked in the execu-

tive office of the president communicating articles about the president's national drug control strategy. She also served as a press aide to two governors of Florida, editor of a science journal, and editorial director for a social science research firm.



### Council Meritorious Service Award

John H. Proctor, MD, FACEP

Dr. Proctor is clinical executive consultant for Sound Emergency Medicine. He is a diplomat of the American Board of Emergency Medicine, with sub-board certification in pediatric emergency medicine, and is a clinical assistant professor of emergency medi-

cine for the University of Tennessee Health Science Center. He is a member of the American Medical Association Reimbursement Update Committee and the Joint Commission Ambulatory Accreditation Professional Technical Advisory Committee. Dr. Proctor has held numerous leadership and educational roles with prestigious health care organizations.



### Disaster Medical Sciences Award

Richard C. Hunt, MD, FACEP

Dr. Hunt served as director for medical preparedness

CONTINUED on page 26

## Available Nationwide



## Rapid reversal of anti-FXa activity within 2 minutes

following bolus administration in older, healthy volunteers on apixaban or rivaroxaban.<sup>1,2</sup>



**Expert guidance** recommends Andexxa for first-line therapy to reverse apixaban or rivaroxaban in patients with life-threatening or uncontrolled bleeds.<sup>3</sup>

### SELECT IMPORTANT SAFETY INFORMATION

#### Thromboembolic and Ischemic Risks (continued)

Monitor patients treated with ANDEXXA for signs and symptoms of arterial and venous thromboembolic events, ischemic events, and cardiac arrest. To reduce thromboembolic risk, resume anticoagulant therapy as soon as medically appropriate following treatment with ANDEXXA.

The safety of ANDEXXA has not been evaluated in patients who experienced thromboembolic events or disseminated intravascular coagulation within two weeks prior to the life-threatening bleeding event requiring treatment with ANDEXXA. Safety of ANDEXXA also has not been evaluated in patients who received prothrombin complex concentrates, recombinant factor VIIa, or whole blood products within seven days prior to the bleeding event.

#### Re-elevation or Incomplete Reversal of Anti-FXa Activity

The time course of anti-FXa activity following ANDEXXA administration was consistent among the healthy volunteer studies and the ANNEXA-4 study in bleeding patients. Compared to baseline, there was a rapid and substantial decrease in anti-FXa activity corresponding to the ANDEXXA bolus. This decrease was sustained through the end of the ANDEXXA continuous infusion. The anti-FXa activity returned to the placebo levels approximately two hours after completion of a bolus or continuous infusion. Subsequently, the anti-FXa activity decreased at a rate similar to the clearance of the FXa inhibitors.

Thirty-eight patients who received the Generation 1 product were anticoagulated with apixaban and had baseline levels of anti-FXa activity >150 ng/mL. Nineteen of these 38 (50%) patients experienced a >93% decrease from baseline anti-FXa activity after administration of ANDEXXA. Eleven patients who were anticoagulated with rivaroxaban had baseline anti-FXa activity levels >300 ng/mL. Five of the 11 patients experienced a >90% decrease from baseline anti-FXa activity after administration of ANDEXXA. Anti-FXa activity levels for patients who received the Generation 2 product were not available.

#### ADVERSE REACTIONS

The most common adverse reactions (≥5%) in patients receiving ANDEXXA were urinary tract infections and pneumonia.

The most common adverse reactions (≥3%) in healthy volunteers treated with ANDEXXA were infusion-related reactions.

#### Immunogenicity

As with all therapeutic proteins, there is the potential for immunogenicity. Using an electrochemiluminescence (ECL)-based assay, 145 Generation 1 ANDEXXA-treated healthy subjects were tested for antibodies to ANDEXXA as well as antibodies cross-reacting with Factor X (FX) and FXa. Low titers of anti-ANDEXXA antibodies were observed in 26/145 healthy subjects (17%); 6% (9/145) were first observed at Day 30 with 20 subjects (14%) still having titers at the last time point (Days 44 to 48). To date, the pattern of antibody response in patients in the ongoing ANNEXA-4 study who received the Generation 1 product has been similar to that observed in healthy volunteers with 6% (6/98) of the patients having antibodies against ANDEXXA. None of these anti-ANDEXXA antibodies were neutralizing. No antibodies cross-reacting with FX or FXa were detected in healthy subjects (0/145) or in bleeding patients (0/98) to date. There is insufficient data to assess for the presence of anti-ANDEXXA antibodies for subjects who received the Generation 2 product.

To report SUSPECTED ADVERSE REACTIONS, contact Portola Pharmaceuticals, Inc. at 1-866-777-5947 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**References:** 1. ANDEXXA [prescribing information]. South San Francisco, CA: Portola Pharmaceuticals Inc.; 2018. 2. Siegal DM et al. *N Engl J Med*. 2015;373(25):2413-2424. 3. American College of Cardiology. Guidance for anticoagulation reversal. [https://www.acc.org/-/media/Non-Clinical/Images/Tools and Practice Support/Mobile Resources/ManageAnticoag/B18120\\_ManageAnticoag\\_App\\_Fact\\_Sheet.pdf](https://www.acc.org/-/media/Non-Clinical/Images/Tools and Practice Support/Mobile Resources/ManageAnticoag/B18120_ManageAnticoag_App_Fact_Sheet.pdf). Updated July 2018. Accessed November 15, 2018.

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**Andexxa**  
Coagulation Factor Xa  
(Recombinant), Inactivated-zhzo

and response policy on the National Security Council staff for the White House from 2013 to 2015. At the White House, he led the development and launch of Stop the Bleed and played a critical role in the response to the Ebola crisis. He represented the National Security Council's interests in the National Academies report "A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury."

Dr. Hunt currently serves as senior medical advisor for national healthcare preparedness programs in the Office of the Assistant Secretary for Preparedness and Response,

U.S. Department of Health and Human Services, where he is developing a course on the medical response to overwhelming no-notice trauma events and supports the response to high-consequence infectious diseases. Dr. Hunt was distinguished consultant and director of the division of injury response at Centers for Disease Control and Prevention (CDC) Injury Center, where he led medical preparedness initiatives for terrorist bombings including the guidance "In a Moment's Notice: Surge Capacity for Terrorist Bombings, and the Tale of Our Cities conferences." He led CDC's national guidelines for field triage of injured patients.

Prior to federal service, he was professor and chair of the department of emergency medicine at SUNY Upstate Medical University in Syracuse, New York. With ACEP, he served as chair of the Trauma Care and Injury Control Committee and was ACEP's first liaison to the American College of Surgeons Committee on Trauma. He is a past President of the National Association of EMS Physicians and was vice chair of the Commission on Accreditation of Medical Transport Systems. Dr. Hunt is board-certified in emergency medicine, holds a master of science degree, and is an adjunct professor of emergency medicine at Emory University School of Medicine in Atlanta.



**Pamela P. Bensen**  
Trailblazer Award

Andrew I. Bern, MD, FACEP

My life was forever changed in 1979 when I left my residency in New York to start the emergency medicine residency at the University of Louisville, Kentucky. Soon after my program began, I joined the Emergency Medicine Residents' Association (EMRA). My election to the EMRA Board of Directors was life-changing because of the dynamic and visionary leaders I met who mentored me over the years. I had contact with the founders and leaders of the College who were there at the start of the organization when it was chartered in 1968.

One of those leaders was Pam Bensen, MD, MS, FACEP, the first woman to complete an EM residency program, who was active in the Council and ultimately became a national Board of Directors member. Her vision, passion, persistence, creativity, and mentorship helped shape who I am today. It has come full circle that I will be the first to receive the Pamela B. Benson Trailblazer Award.

Over my 41 years in the practice of emergency medicine, I have held one principle: "One person can make a difference."

Within ACEP, my focus has been in four areas:

**Membership:** To help members achieve more within the organization, I established the concept of sections of membership. The Disaster Medicine Section was the first section established in 1988. Today, there are 38 sections representing member interests that are as broad as emergency medicine. The specialty has benefited from the work these sections have done, but it was not easy. The concept was first brought to the Board in 1983 and each subsequent year until it was adopted in 1988. More than half of today's College membership participates in and belongs to a section.

**Grants:** I have been a long-time advocate of the grant process. Over the years, I worked to achieve Board support for hiring a dedicated individual to head up the College's grant efforts. I also was involved in creating a grant program for sections. The College has brought in more than \$10 million under the leadership of Cynthia Singh, Dean Wilkerson, and the professional ACEP staff.

**Advocacy:** I have been involved in the College's advocacy program since the beginning, participating in the 911 network within my state and nationally. I am still active in these efforts and participate in both the Federal Government Affairs and the State Legislative Affairs committees.

**Council:** I learned of the important work the Council does from John Rupke, MD; John Wiegenstein, MD; Dr. Bensen; Ron Krome, MD, FACEP; Jack Page, MD, FACEP; and others. Our representative body helps distill important ideas that go to the Board of Directors for study and implementation. It also builds leadership for our College.

After all this time, I can definitely confirm "one person can make a difference in your life's career in emergency medicine and for our future patients." +



**ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo)**  
Lyophilized Powder for Solution For Intravenous Injection

Rx Only

**BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION.**

This does not include all the information needed to use ANDEXXA® safely and effectively. See full Prescribing Information for ANDEXXA®.

**WARNING: THROMBOEMBOLIC RISKS, ISCHEMIC RISKS, CARDIAC ARREST, AND SUDDEN DEATHS**

See full prescribing information for complete boxed warning

Treatment with ANDEXXA has been associated with serious and life threatening adverse events, including:

- Arterial and venous thromboembolic events
- Ischemic events, including myocardial infarction and ischemic stroke
- Cardiac arrest
- Sudden deaths

Monitor for thromboembolic events and initiate anticoagulation when medically appropriate. Monitor for symptoms and signs that precede cardiac arrest and provide treatment as needed.

**INDICATIONS AND USAGE**

ANDEXXA is indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies to demonstrate an improvement in hemostasis in patients.

**Limitation of Use**

ANDEXXA has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban or rivaroxaban.

**CONTRAINDICATIONS**

None.

**WARNINGS AND PRECAUTIONS**

**Thromboembolic and Ischemic Risks**

The thromboembolic and ischemic risks were assessed in 185 patients who received the Generation 1 product and in 124 patients who received the Generation 2 product. The median time to first event was six days, and patients were observed for these events for 30 days following the ANDEXXA infusion. Of the 86 patients who received Generation 1 product and were re-anticoagulated prior to a thrombotic event, 11 (12.7%) patients experienced a thromboembolic, ischemic event, cardiac event or death.

Monitor patients treated with ANDEXXA for signs and symptoms of arterial and venous thromboembolic events, ischemic events, and cardiac arrest. To reduce thromboembolic risk, resume anticoagulant therapy as soon as medically appropriate following treatment with ANDEXXA.

The safety of ANDEXXA has not been evaluated in patients who experienced thromboembolic events or disseminated intravascular coagulation within two weeks prior to the life-threatening bleeding event requiring treatment with ANDEXXA. Safety of ANDEXXA also has not been evaluated in patients who received prothrombin complex concentrates, recombinant factor VIIa, or whole blood products within seven days prior to the bleeding event.

**Re-elevation or Incomplete Reversal of Anti-FXa Activity**

The time course of anti-FXa activity following ANDEXXA administration was consistent among the healthy volunteer studies and the ANNEXA-4 study in bleeding patients. Compared to baseline, there was a rapid and substantial decrease in anti-FXa activity corresponding to the ANDEXXA bolus. This decrease was sustained through the end of the ANDEXXA continuous infusion. The anti-FXa activity returned to the placebo levels approximately two hours after completion of a bolus or continuous infusion. Subsequently, the anti-FXa activity decreased at a rate similar to the clearance of the FXa inhibitors.

Thirty-eight patients who received the Generation 1 product were anticoagulated with apixaban and had baseline levels of anti-FXa activity > 150 ng/mL. Nineteen of these 38 (50%) patients experienced a > 93% decrease from baseline anti-FXa activity after administration of ANDEXXA. Eleven patients who were anticoagulated with rivaroxaban had baseline anti-FXa activity levels > 300 ng/mL. Five of the 11 patients experienced a > 90% decrease from baseline anti-FXa activity after administration of ANDEXXA. Anti-FXa activity levels for patients who received the Generation 2 product were not available.

**ADVERSE REACTIONS**

The most common adverse reactions (≥ 5%) in patients receiving ANDEXXA were urinary tract infections and pneumonia.

The most common adverse reactions (≥ 3%) in healthy volunteers treated with ANDEXXA were infusion-related reactions.

**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 clinical practice.

In the pooled safety analysis of clinical trials of ANDEXXA, 223 healthy volunteers received FXa inhibitors followed by treatment with ANDEXXA. The frequency of adverse reactions was similar in the ANDEXXA-treated group (120/223, 54%) and the placebo-treated group (54/94, 57%). Infusion-related adverse reactions occurred in 18% (39/223) of the ANDEXXA-treated group, and was the only adverse reaction that occurred more frequently than in the placebo group. No serious or severe adverse reactions were reported.

The ANNEXA-4 study is an ongoing multinational, prospective, open-label study using ANDEXXA in patients presenting with acute major bleeding and who have recently received an FXa inhibitor. To date, safety data are available for 185 patients who received the Generation 1 product and for

124 subjects who received the Generation 2 product. Fifty-nine percent of the 185 patients who received the Generation 1 product and 69% of the 124 patients who received the Generation 2 product were older than 75 years. Patients had received either apixaban (98/185; 53%) or rivaroxaban (72/185; 40%) as anticoagulation treatment for atrial fibrillation (143/185; 77%) or venous thromboembolism (48/185; 26%). In the majority of patients, ANDEXXA was used to reverse anticoagulant therapy following either an intracranial hemorrhage (106; 57%) or a gastrointestinal bleed (58; 31%), with the remaining 21 patients (11%) experiencing bleeding at other sites. Patients were assessed at a Day 30 follow-up visit following infusion of ANDEXXA.

**Deaths**

In the ongoing ANNEXA-4 study, there were 25 deaths (14%) amongst the 185 patients receiving the Generation 1 product. These deaths occurred prior to the Day 30 follow-up visit. Eight patients died within ten days after the ANDEXXA infusion. The percentage of patients, by bleeding type, who died prior to the Day 30 follow-up visit was: 14% for intracranial bleeding, 10% for gastrointestinal bleeding, and 19% for other bleeding types. There were 23 deaths (18%) amongst the 124 patients who received Generation 2 that occurred prior to the Day 30 follow-up visit.

**Thromboembolic Events**

In the ongoing ANNEXA-4 study, 33/185 (17.8%) patients receiving the Generation 1 product experienced one or more of the following overall thromboembolic events: deep venous thrombosis (11/33; 33%), ischemic stroke (9/33; 24%), acute myocardial infarction (5/33; 15%), pulmonary embolism (5/33; 15%), cardiogenic shock (3/33; 9%), sudden death (2/33; 6%), congestive heart failure (2/33; 6%), acute respiratory failure (2/33; 6%), cardiac arrest (1/33; 3%), cardiac thrombus (1/33; 3%), embolic stroke (1/33; 3%), iliac artery thrombosis (1/33; 3%), and non-sustained ventricular tachycardia (1/33; 3%). The median time to the first event in these 33 subjects was six days. Eleven of 33 (33%) patients were on antithrombotic therapy at the time of the event. Patients who received the Generation 2 product experienced a similar rate of overall thromboembolic events (17.7%) as the Generation 1 product.

No thromboembolic events were observed in 223 healthy volunteers who received FXa inhibitors and were treated with ANDEXXA.

**Infusion-related Reactions**

Infusion-related reactions occurred in 18% (39/223) of ANDEXXA-treated healthy volunteers vs. 6% (6/94) of placebo-treated subjects. These reactions were characterized by a range of symptoms including flushing, feeling hot, cough, dysgeusia, and dyspnea. Symptoms were mild to moderate in severity, and 90% (35/39) did not require treatment. One subject with a history of hives prematurely discontinued ANDEXXA after developing mild hives.

**Immunogenicity**

As with all therapeutic proteins, there is the potential for immunogenicity. Using an electrochemiluminescence (ECL)-based assay, 145 Generation 1 ANDEXXA-treated healthy subjects were tested for antibodies to ANDEXXA as well as antibodies cross-reacting with Factor X (FX) and FXa. Low titers of anti-ANDEXXA antibodies were observed in 26/145 healthy subjects (17%); 6% (9/145) were first observed at Day 30 with 20 subjects (14%) still having titers at the last time point (Days 44 to 48). To date, the pattern of antibody response in patients in the ongoing ANNEXA-4 study who received the Generation 1 product has been similar to that observed in healthy volunteers with 6% (6/98) of the patients having antibodies against ANDEXXA. None of these anti-ANDEXXA antibodies were neutralizing. No antibodies cross-reacting with FX or FXa were detected in healthy subjects (0/145) or in bleeding patients (0/98) to date. There is insufficient data to assess for the presence of anti-ANDEXXA antibodies for subjects received the Generation 2 product.

Detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ANDEXXA with the incidence of antibodies to other products may be misleading.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

**Risk Summary**

There are no adequate and well-controlled studies of ANDEXXA in pregnant women to inform patients of associated risks. Animal reproductive and development studies have not been conducted with ANDEXXA.

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 to 20%, respectively.

**Clinical Considerations**

**Labor or Delivery**

The safety and effectiveness of ANDEXXA during labor and delivery have not been evaluated.

**Lactation**

**Risk Summary**

There is no information regarding the presence of ANDEXXA in human milk, the effects on the breastfed child, or the effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ANDEXXA and any potential adverse effects on the breastfed child from ANDEXXA or from the underlying maternal condition.

**Pediatric Use**

The safety and efficacy of ANDEXXA in the pediatric population have not been studied.

**Geriatric Use**

Of the 185 patients who received the Generation 1 product in the ANNEXA-4 study of ANDEXXA, 161 were 65 years of age or older, and 113 were 75 years of age or older. Of the 124 subjects who received the Generation 2 product, 92 subjects were 75 years of age or older. No overall differences in safety or efficacy were observed between these subjects and younger patients, and other reported clinical experience has not identified differences in responses between elderly and younger patients; however, greater sensitivity of some older individuals cannot be ruled out. The pharmacokinetics of ANDEXXA in older (65 years; n=10) patients were not different compared to younger (18-45 years; n=10) patients.

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Global Emergency Care Initiative  
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



Global Health Institute  
UNIVERSITY OF WISCONSIN-MADISON



Members of the Academic Consortium for Emergency Systems.

# Worldwide Emergency Medicine

ACEP supports two new international emergency medicine courses at ACEP19

The consortium's original organizing principle was to coordinate trainees' education and programmatic implementation for academic programs that could not independently fully support such efforts.

by EMILIE J. CALVELLO HYNES, MD, MPH; SEAN KIVLEHAN, MD, MPH; ANDREA TENNER, MD, MPH, FACEP; AND JANIS P. TUPESIS, MD, FACEP, FAAEM

A decade ago, the World Health Assembly adopted Resolution 60.22 titled "Health Systems: Emergency Care Systems." This resolution, passed by the member states of the World Health Organization (WHO), created a framework outlining a path to improving access to emergency care worldwide. Within the WHO, the Emergency, Trauma, and Acute Care program is "dedicated to strengthening the emergency care systems that serve as the first point of contact with the health system for so much of the world, and to supporting the development of quality, timely emergency care accessible to all."

This program has been transformational in focusing the world's eyes on emergency care. The program's advocacy was manifest in the successful adoption in May 2019 of World Health Assembly Resolution 72.16, "Emergency care systems for universal health coverage: ensuring timely care for the acutely ill and injured," which brought further clarity and specificity to the implementation of emergency care in resource-limited settings.

More explicit integration of emergency care into health systems and universal health care coverage is essential to meeting the WHO Sustainable Development Goals. In an effort to support trainees who are learning how to engage in these efforts, the Academic Consortium for Emergency Systems (ACES) was established in 2018. This group is made up of six US-based academic medical centers with a substantial focus on global emergency care development. The overall goals of the consortium are to organize the aforementioned academic medical centers' collaborative

efforts to train the next generation of emergency care advocates and implementers; support our partner countries' ministries of health, local universities, and other institutions in their efforts to strengthen their emergency care systems; and support the work of the WHO Emergency, Trauma and Acute Care program. The consortium's original organizing principle was to coordinate trainees' education and programmatic implementation for academic programs that could not independently fully support such efforts. Consortium objectives include:

1. Facilitate academic partnerships in a new and emerging field of emergency care systems development with local academic partners.
2. Contribute to the body of knowledge for all activities related to emergency care systems in collaboration with consortium partners, including developing professional papers, technical reports, databases, and online tools.
3. Support consortium partners' efforts via provision of volunteers, academic consultation, and grant preparation to promote research and field implementation projects.
4. Ensure a standardized, trained, and accountable workforce that is qualified to conduct implementation science research of emergency care solutions in resource-limited settings.
5. Provide coordination and continuity in the training of global health faculty, fellows, and learners.

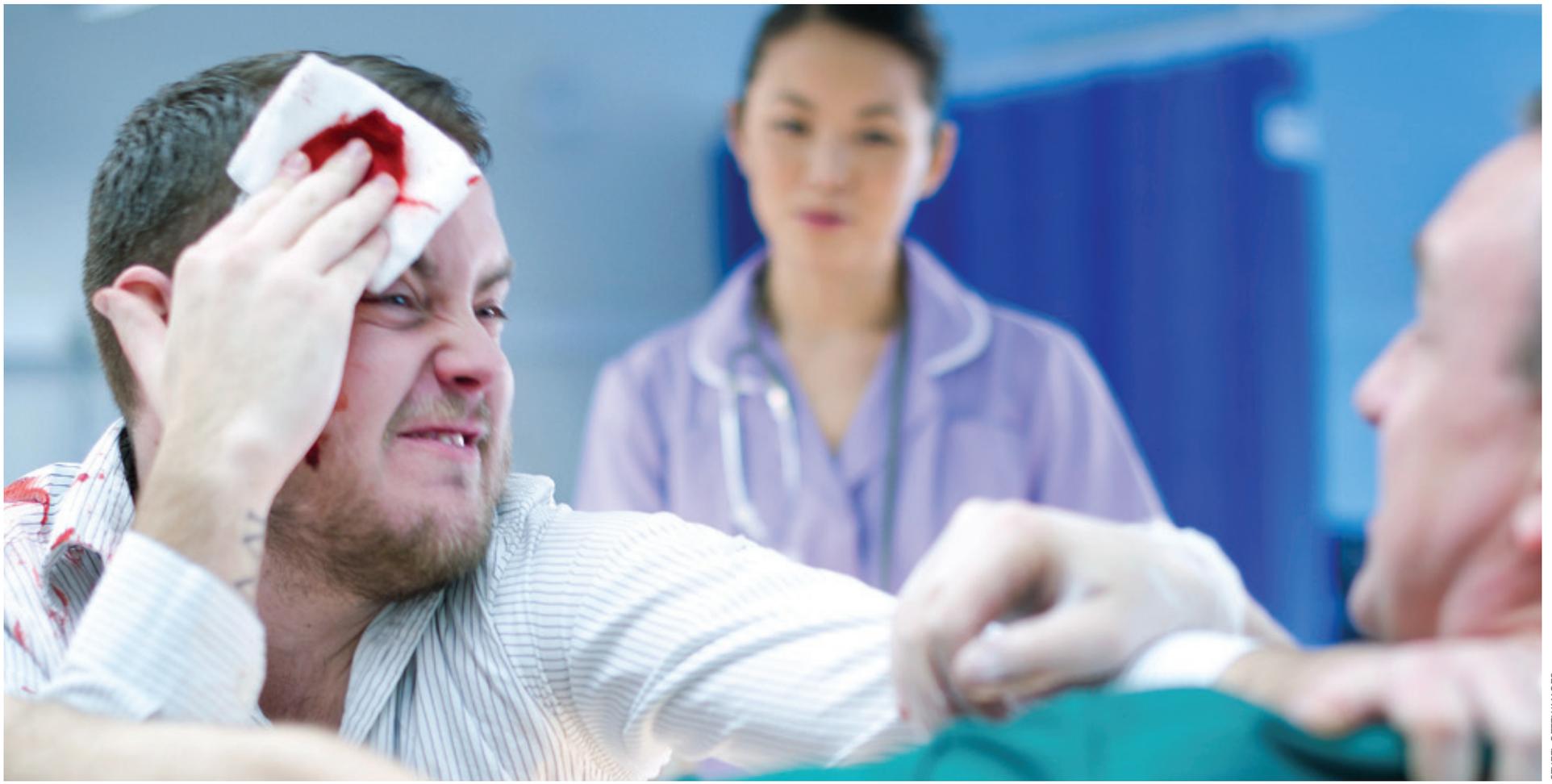
The consortium seeks to provide trainees with consolidated technical expertise and local implementing organizations with an organized workforce ready to promote improvement in the quality of and access to emergency care worldwide.

Two ACES-led events at ACEP19 will mark a paradigm shift in the way ACEP approaches capacity building in emergency care systems. By

partnering with a consortium of academic medical centers and numerous other international professional organizations, ACEP hopes to advance the discipline of emergency care worldwide and to promote the recent landmark resolutions adopted by member states at the World Health Assembly.

In conjunction with ACEP's International Section and the ACEP International Ambassador program, ACES will offer the WHO's Basic Emergency Care Facilitator Course. It was developed by WHO and the International Committee of the Red Cross, in collaboration with the International Federation for Emergency Medicine, as a syndrome-based content and skills training intended for frontline health care providers managing acute illness and injury with limited resources. Additionally, ACES will offer the Fellows Bootcamp for Understanding Emergency Systems, a one-day primer focused on postgraduate trainees in global health that will review core concepts for building emergency care systems in resource-limited settings. More information is available at <https://coloradoglobalem.org/acep-2019-preconference-workshops>.

**DR. CALVELLO** is associate professor of emergency medicine at the University of Colorado School of Medicine. **DR. KIVLEHAN** is attending physician at Brigham and Women's Hospital and clinical instructor at Harvard Medical School. **DR. TENNER** is associate professor, global health fellowship director, and co-director of the UCSF WHO Collaborating Centre for Emergency and Trauma Care in the department of emergency medicine at the University of California, San Francisco. **DR. TUPESIS** is associate director of the Global Health Institute at the University of Wisconsin-Madison and faculty in the BerbeeWalsh department of emergency medicine at the University of Wisconsin School of Medicine and Public Health.



STURTI, GETTY IMAGES

## WHEN PATIENTS TURN VIOLENT | CONTINUED FROM PAGE 1

Just a few moments later, the nurse approached her to start the IV. The patient asked why she had taken so long and used a demeaning word. I overheard the exchange and was surprised at her sudden change in attitude. I walked over to deescalate the situation, and she responded with a racial epithet toward me. My nurse indicated that her behavior was inappropriate. The patient then punched her in the face. She then went on a verbal tirade and spat on me. We called the police, and she was arrested. Fortunately, neither my colleague nor I sustained any serious injuries.

How, I wondered, are we supposed to take care of our patients humanely if they fail to see the humanity *in us*? We do it because it's our job and it is part of our moral code.

But that doesn't make abusive behavior from patients OK.

### Pervasive Violence Against Providers

Many health care workers will relate to these scenarios. Verbal assaults are so common that they are shrugged off as merely part of the job. We often even tolerate what should be unacceptable statements that are racist, sexist, homophobic—you name it. We often even try to let literal threats roll off our backs. But over the last few years, several studies have highlighted an epidemic of violence toward health care professionals. This we can never learn to tolerate.

Sadly, I fear, we have done just that. Back in the 1980s, workplace violence was first rigorously assessed in the emergency medicine literature. But by 2018, little progress had been made in addressing and reducing violence. Omar et al published data showing that the problem remained equally prevalent despite an increase in security measures over the previous decade.<sup>1</sup> (Just imagine if we didn't have such measures in place!)

According to one study, nearly 80 percent of emergency department physicians had either been the victims of workplace violence (which included threats, battery, outside work confrontations, and even stalking) or had witnessed it firsthand in the preceding 12 months.<sup>2</sup> In another study, 100 percent of emergency department nurses reported verbal threats, and 82 percent had been assaulted in the preceding year alone.<sup>3</sup>

Most of us—including myself—have been assaulted multiple times. The Occupational Safety and Health Administration (OSHA) tells us that health care workers are at higher risk of violence in the workplace than those in any other industry. The February issue of *Annals of Emergency Medicine* featured a frightening story by Amy Costigan, MD, of an ambush-type assault on an emergency physician.<sup>4</sup> While awareness of violence against health care providers may be increasing, the is-

## No Silence on ED Violence

ACEP and the Emergency Nurses Association (ENA) are working to minimize the violent attacks on physicians, nurses, and patients in our nation's emergency departments. Watch for more details in next month's issue about the "No Silence on ED Violence" campaign and learn how you can help ACEP and ENA protect ED professionals.

sue is not being adequately addressed.

Currently, I am a freshman member of the Arizona House of Representatives. The focus of my campaign was to listen to people at a grassroots level, and to that end, I personally knocked on more than 8,000 doors. After being elected, I asked a few nurses during a shift about their biggest concerns. The very first thing they mentioned was workplace violence. Their stories were plentiful and frightening.

Specifically, my colleagues emphasized that we have developed a culture that discourages reporting. Many of us have the impression that reporting will not have any effect and the perpetrator will simply go free. These concerns are valid because currently in Arizona, as in many states, these crimes are often pleaded down to misdemeanors and the consequences are modest. But in the emergency department setting, we have the additional concern that some perpetrators will stalk us or retaliate since we are federally mandated to take all comers regardless of their past illegal behavior toward us.

### Taking Action

To address their concerns, I authored a bill to protect all health care workers from assault. With the help of the Arizona Nurses Association and many other health care groups, our bill passed

out of the House of Representatives with bipartisan support. Though it stalled in the Senate this term, we will continue to push forward again next year.

There are many potential ways to decrease this problem, from stiffer penalties to administrative reporting requirements. Even mandating signage that clearly communicates the law would be a step in the right direction. Since becoming involved with this issue, I have received countless emails from health care workers with their own harrowing stories and offers of support. And these letters of frustration and support keep on rolling in.

We are lucky to work in an amazing field with kind, caring, dedicated professionals, many of whom I consider personal friends. For all their sacrifices, they have the right to feel safe at work.

We as physicians are often viewed as captains of the team, so the burden is upon us to take the lead. If my experience here in my state can be of use elsewhere, please let me know by writing to me at [amishforarizona@gmail.com](mailto:amishforarizona@gmail.com).

Most of all, please join the effort to end violence in health care any way that you can. That may mean creating awareness at work, raising the issue with your state and local ACEP chapters, contacting your legislative representatives, or doing what I did and becoming one. The more our colleagues get involved, the better our chances are. +

### References

1. Omar H, Yue R, Amen AA, et al. 368 reassessment of violence against emergency physicians. *Ann Emerg Med.* 2018;72(4 Suppl):S144.
2. Behnam M, Tillotson RD, Davis SM, et al. Violence in the emergency department: a national survey of emergency medicine residents and attending physicians. *J Emerg Med.* 2011;40(5):565-579.
3. May DD, Grubbs LM. The extent, nature, and precipitating factors of nurse assault among three groups of registered nurses in a regional medical center. *J Emerg Nurs.* 2002;28(1):11-17.
4. Costigan AD. My job: a courtroom victim impact statement. *Ann Emerg Med.* 2019;73(2):204-205.

**DR. SHAH** is an attending physician at Dignity Health and a member of the Arizona House of Representatives for Legislative District 24.

## RESOURCES FOR FURTHER READING

- Violence in Emergency Departments Is Increasing, Harming Patients, New Research Finds: <http://newsroom.acep.org/2018-10-02-Violence-in-Emergency-Departments-Is-Increasing-Harming-Patients-New-Research-Finds>
- Violence in the Emergency Department: Resources for a Safer Workplace: [www.acep.org/administration/violence-in-the-emergency-department-resources-for-a-safer-workplace](http://www.acep.org/administration/violence-in-the-emergency-department-resources-for-a-safer-workplace)

**Eliquis**<sup>®</sup>  
(apixaban) tablets 5mg  
2.5mg

# In the emergency department, both safety and efficacy matter

For appropriate patients with DVT/PE, consider **ELIQUIS** at discharge



DVT=deep vein thrombosis; PE=pulmonary embolism.

## INDICATION

ELIQUIS is indicated for the treatment of deep vein thrombosis and pulmonary embolism.

## IMPORTANT SAFETY INFORMATION

**WARNING: (A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA**

(A) Premature discontinuation of any oral anticoagulant, including ELIQUIS, increases the risk of thrombotic events.

If anticoagulation with ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

(B) Epidural or spinal hematomas may occur in patients treated with ELIQUIS who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- a history of traumatic or repeated epidural or spinal punctures
- a history of spinal deformity or spinal surgery
- optimal timing between the administration of ELIQUIS and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated.

Please see additional Important Safety Information and Brief Summary of Full Prescribing Information, including **Boxed WARNINGS**, on adjacent pages.

## AMPLIFY<sup>1,2</sup> Study Design

A randomized, double-blind, phase III trial to determine whether ELIQUIS was noninferior to enoxaparin/warfarin for the incidence of recurrent venous thromboembolism (VTE)\* or VTE-related death in 5400 patients with objectively confirmed, symptomatic proximal DVT/PE. 2693 patients were randomized to ELIQUIS 10 mg orally twice daily for 7 days followed by 5 mg orally twice daily for 6 months, and 2707 patients were randomized to standard of care, which was initial enoxaparin 1 mg/kg twice daily subcutaneously for at least 5 days (until INR  $\geq 2$ ), followed by warfarin (target INR range: 2.0-3.0) orally for 6 months. The primary efficacy endpoint was recurrent VTE\* or VTE-related death, and the primary safety endpoint was major bleeding.

≈90% of patients in the AMPLIFY trial had an unprovoked DVT/PE at baseline.<sup>1</sup>

- The 10% of patients with a provoked DVT/PE were required to have an additional ongoing risk factor in order to be randomized†

\*Recurrent symptomatic VTE (nonfatal DVT or nonfatal PE).

†Risk factors included previous episode of DVT/PE, immobilization, history of cancer, active cancer, and known prothrombotic genotype.

To learn more about ELIQUIS, visit [hcp.eliquis.com](http://hcp.eliquis.com)

## IMPORTANT SAFETY INFORMATION (CONT'D)

### CONTRAINDICATIONS

- Active pathological bleeding
- Severe hypersensitivity reaction to ELIQUIS (e.g., anaphylactic reactions)

### WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events after Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including ELIQUIS, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in atrial fibrillation patients. If ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Bleeding Risk:** ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding.
  - Concomitant use of drugs affecting hemostasis increases the risk of bleeding, including aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs.
  - Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.
  - The anticoagulant effect of apixaban can be expected to persist for at least 24 hours after the last dose (i.e., about two half-lives). An agent to reverse the anti-factor Xa activity of apixaban is available. Please visit [www.andexxa.com](http://www.andexxa.com) for more information on availability of a reversal agent.
- **Spinal/Epidural Anesthesia or Puncture:** Patients treated with ELIQUIS undergoing spinal/epidural anesthesia or puncture may develop an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS. The next dose of ELIQUIS should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of ELIQUIS for 48 hours.

Monitor patients frequently and if neurological compromise is noted, urgent diagnosis and treatment is necessary. Physicians should consider the potential benefit versus the risk of neuraxial intervention in ELIQUIS patients.

- **Prosthetic Heart Valves:** The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves and is not recommended in these patients.
- **Acute PE in Hemodynamically Unstable Patients or Patients who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of ELIQUIS is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.
- **Patients with Antiphospholipid Syndrome (APS):** Direct-acting oral anticoagulants (DOACs) including ELIQUIS are not recommended for patients with a history of thrombosis who are diagnosed with APS. The efficacy and safety of ELIQUIS in patients with APS have not been established.

### ADVERSE REACTIONS

- The most common and most serious adverse reactions reported with ELIQUIS were related to bleeding.

### TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

- ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be noncritical in location and easily controlled. Bridging anticoagulation during the 24 to 48 hours after stopping ELIQUIS and prior to the intervention is not generally required. ELIQUIS should be restarted after the surgical or other procedures as soon as adequate hemostasis has been established.

### DRUG INTERACTIONS

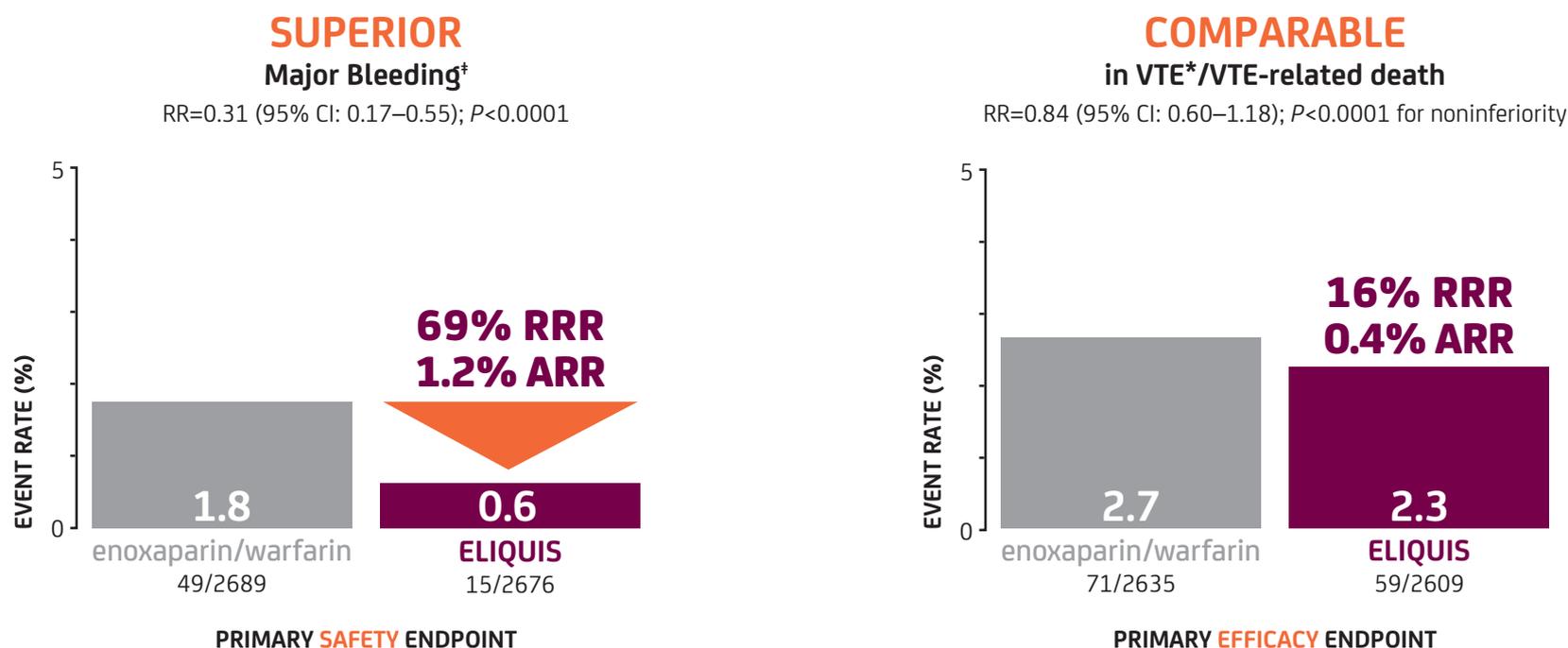
- **Combined P-gp and Strong CYP3A4 Inhibitors:** Inhibitors of P-glycoprotein (P-gp) and cytochrome P450 3A4 (CYP3A4) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, or ritonavir). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with combined P-gp and strong CYP3A4 inhibitors.

#### *Clarithromycin*

Although clarithromycin is a combined P-gp and strong CYP3A4 inhibitor, pharmacokinetic data suggest that no dose adjustment is necessary with concomitant administration with ELIQUIS.

## FOR THE TREATMENT OF DVT/PE

Only **ELIQUIS** demonstrated **BOTH** superiority in major bleeding events **AND** comparable efficacy vs enoxaparin/warfarin<sup>1</sup>



### ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding<sup>1</sup>

- Discontinuation rate due to bleeding events: 0.7% in ELIQUIS-treated patients vs 1.7% with enoxaparin/warfarin<sup>1</sup>
- In AMPLIFY, the most commonly observed adverse reactions in ELIQUIS-treated patients (incidence  $\geq 1\%$ ) were epistaxis, contusion, hematuria, menorrhagia, hematoma, hemoptysis, rectal hemorrhage, and gingival bleeding<sup>1</sup>

### Major bleeding was defined as clinically overt bleeding accompanied by at least one of the following<sup>2,3</sup>:

- 1) A decrease in hemoglobin of  $\geq 2$  g/dL; 2) A transfusion of 2 or more units of packed red blood cells; 3) Bleeding that occurred in at least 1 of the following critical sites: intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, or retroperitoneal; 4) Fatal bleeding

ARR=absolute risk reduction; CI=confidence interval; HR=hazard ratio; INR=international normalized ratio; RR=relative risk; RRR=relative risk reduction.  
\*Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### DRUG INTERACTIONS (cont'd)

- **Combined P-gp and Strong CYP3A4 Inducers:** Avoid concomitant use of ELIQUIS with combined P-gp and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban.
- **Anticoagulants and Antiplatelet Agents:** Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

### PREGNANCY

- The limited available data on ELIQUIS use in pregnant women are insufficient to inform drug-associated risks of major birth defects, miscarriage, or adverse developmental outcomes.

Treatment may increase the risk of bleeding during pregnancy and delivery, and in the fetus and neonate.

- *Labor or delivery:* ELIQUIS use during labor or delivery in women who are receiving neuraxial anesthesia may result in epidural or spinal hematomas. Consider use of a shorter acting anticoagulant as delivery approaches.

### LACTATION

- Breastfeeding is not recommended during treatment with ELIQUIS.

**References:** 1. Eliquis [package insert]. Bristol-Myers Squibb Company, Princeton, NJ, and Pfizer Inc, New York, NY. 2. Agnelli G, Buller HR, Cohen A, et al; for AMPLIFY Investigators. Oral apixaban for the treatment of acute venous thromboembolism. *N Engl J Med*. 2013;369(9):799-808. Supplement available at [http://www.nejm.org/doi/suppl/10.1056/NEJMoa1302507/suppl\\_file/nejmoa1302507\\_appendix.pdf](http://www.nejm.org/doi/suppl/10.1056/NEJMoa1302507/suppl_file/nejmoa1302507_appendix.pdf). Accessed December 5, 2018. 3. Agnelli G, Buller HR, Cohen A, et al. Apixaban for extended treatment of venous thromboembolism. *N Engl J Med*. 2013;368(8):699-708. Supplement available at [http://www.nejm.org/doi/suppl/10.1056/NEJMoa1207541/suppl\\_file/nejmoa1207541\\_appendix.pdf](http://www.nejm.org/doi/suppl/10.1056/NEJMoa1207541/suppl_file/nejmoa1207541_appendix.pdf). Accessed December 18, 2018.

Please see Brief Summary of Full Prescribing Information, including **Boxed WARNINGS**, on adjacent pages.



**Eliquis**  
(apixaban) tablets 5mg/2.5mg

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## ELIQUIS® (apixaban) tablets, for oral use

Rx ONLY

**Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.**

<p><b>WARNING: (A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS</b></p> <p><b>(B) SPINAL/EPIDURAL HEMATOMA</b></p> <p><b>(A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS</b></p> <p>Premature discontinuation of any oral anticoagulant, including ELIQUIS, increases the risk of thrombotic events. If anticoagulation with ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see <i>Dosage and Administration, Warnings and Precautions, and Clinical Studies (14.1)</i> in full Prescribing Information].</p> <p><b>(B) SPINAL/EPIDURAL HEMATOMA</b></p> <p>Epidural or spinal hematomas may occur in patients treated with ELIQUIS who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:</p> <ul style="list-style-type: none"> <li>• use of indwelling epidural catheters</li> <li>• concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants</li> <li>• a history of traumatic or repeated epidural or spinal punctures</li> <li>• a history of spinal deformity or spinal surgery</li> <li>• optimal timing between the administration of ELIQUIS and neuraxial procedures is not known</li> </ul> <p>[see <i>Warnings and Precautions</i>]</p> <p>Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary [see <i>Warnings and Precautions</i>].</p> <p>Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated [see <i>Warnings and Precautions</i>].</p>
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### INDICATIONS AND USAGE

**Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation**—ELIQUIS® (apixaban) is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

**Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery**—ELIQUIS is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.

**Treatment of Deep Vein Thrombosis**—ELIQUIS is indicated for the treatment of DVT.

**Treatment of Pulmonary Embolism**—ELIQUIS is indicated for the treatment of PE.

**Reduction in the Risk of Recurrence of DVT and PE**—ELIQUIS is indicated to reduce the risk of recurrent DVT and PE following initial therapy.

### DOSAGE AND ADMINISTRATION (Selected information)

#### Temporary Interruption for Surgery and Other Interventions

ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding [see *Warnings and Precautions*]. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be non-critical in location and easily controlled. Bridging anticoagulation during the 24 to 48 hours after stopping ELIQUIS and prior to the intervention is not generally required. ELIQUIS should be restarted after the surgical or other procedures as soon as adequate hemostasis has been established. (For complete *Dosage and Administration* section, see full Prescribing Information.)

### CONTRAINDICATIONS

ELIQUIS is contraindicated in patients with the following conditions:

- Active pathological bleeding [see *Warnings and Precautions and Adverse Reactions*]
- Severe hypersensitivity reaction to ELIQUIS (e.g., anaphylactic reactions) [see *Adverse Reactions*]

### WARNINGS AND PRECAUTIONS

#### Increased Risk of Thrombotic Events after Premature Discontinuation

Premature discontinuation of any oral anticoagulant, including ELIQUIS, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in atrial fibrillation patients. If ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see *Dosage and Administration (2.4)* and *Clinical Studies (14.1)* in full Prescribing Information].

#### Bleeding

ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding [see *Dosage and Administration (2.1)* in full Prescribing Information and *Adverse Reactions*].

Concomitant use of drugs affecting hemostasis increases the risk of bleeding. These include aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, and nonsteroidal anti-inflammatory drugs (NSAIDs) [see *Drug Interactions*].

Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.

#### Reversal of Anticoagulant Effect

An agent to reverse the anti-factor Xa activity of apixaban is available. The pharmacodynamic effect of ELIQUIS can be expected to persist for at least 24 hours after the last dose, i.e., for about two drug half-lives. Prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa may be considered, but have not been evaluated in clinical studies [see *Clinical Pharmacology (12.2)* in full Prescribing Information]. When PCCs are used, monitoring for the anticoagulation effect of apixaban using a clotting test (PT, INR, or aPTT) or anti-factor Xa (FXa) activity is not useful and is not recommended. Activated oral charcoal reduces absorption of apixaban, thereby lowering apixaban plasma concentration [see *Overdosage*].

Hemodialysis does not appear to have a substantial impact on apixaban exposure [see *Clinical Pharmacology (12.3)* in full Prescribing Information]. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of apixaban. There is no experience with antifibrinolytic agents (tranexamic acid, aminocaproic acid) in individuals receiving apixaban. There is no experience with systemic hemostatics (desmopressin and aprotinin) in individuals receiving apixaban, and they are not expected to be effective as a reversal agent.

#### Spinal/Epidural Anesthesia or Puncture

When neuraxial anesthesia (spinal/epidural anesthesia) or spinal/epidural puncture is employed, patients treated with antithrombotic agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS. The next dose of ELIQUIS should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of ELIQUIS for 48 hours.

Monitor patients frequently for signs and symptoms of neurological impairment (e.g., numbness or weakness of the legs, or bowel or bladder dysfunction). If neurological compromise is noted, urgent diagnosis and treatment is necessary. Prior to neuraxial intervention the physician should consider the potential benefit versus the risk in anticoagulated patients or in patients to be anticoagulated for thromboprophylaxis.

#### Patients with Prosthetic Heart Valves

The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves. Therefore, use of ELIQUIS is not recommended in these patients.

### Acute PE in Hemodynamically Unstable Patients or Patients who Require Thrombolysis or Pulmonary Embolectomy

Initiation of ELIQUIS (apixaban) is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

### Patients with Antiphospholipid Syndrome

Direct-acting oral anticoagulants (DOACs) including ELIQUIS are not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome (APS). In particular for patients that are triple positive (positive for lupus anticoagulant, anticardiolipin, and anti-β<sub>2</sub>-glycoprotein I antibodies), treatment with DOACs can be associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy. The efficacy and safety of ELIQUIS in patients with APS have not been established.

### ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the prescribing information.

- Increased risk of thrombotic events after premature discontinuation [see *Warnings and Precautions*]
- Bleeding [see *Warnings and Precautions*]
- Spinal/epidural anesthesia or puncture [see *Warnings and Precautions*]

### 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.

#### Reduction of Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation

The safety of ELIQUIS was evaluated in the ARISTOTLE and AVERROES studies [see *Clinical Studies (14)* in full Prescribing Information], including 11,284 patients exposed to ELIQUIS 5 mg twice daily and 602 patients exposed to ELIQUIS 2.5 mg twice daily. The duration of ELIQUIS exposure was ≥12 months for 9375 patients and ≥24 months for 3369 patients in the two studies. In ARISTOTLE, the mean duration of exposure was 89 weeks (>15,000 patient-years). In AVERROES, the mean duration of exposure was approximately 59 weeks (>3000 patient-years).

The most common reason for treatment discontinuation in both studies was for bleeding-related adverse reactions; in ARISTOTLE this occurred in 1.7% and 2.5% of patients treated with ELIQUIS and warfarin, respectively, and in AVERROES, in 1.5% and 1.3% on ELIQUIS and aspirin, respectively.

#### Bleeding in Patients with Nonvalvular Atrial Fibrillation in ARISTOTLE and AVERROES

Tables 1 and 2 show the number of patients experiencing major bleeding during the treatment period and the bleeding rate (percentage of subjects with at least one bleeding event per 100 patient-years) in ARISTOTLE and AVERROES.

**Table 1: Bleeding Events in Patients with Nonvalvular Atrial Fibrillation in ARISTOTLE\***

	ELIQUIS N=9088 n (per 100 pt-year)	Warfarin N=9052 n (per 100 pt-year)	Hazard Ratio (95% CI)	P-value
Major†	327 (2.13)	462 (3.09)	0.69 (0.60, 0.80)	<0.0001
Intracranial (ICH)‡	52 (0.33)	125 (0.82)	0.41 (0.30, 0.57)	-
Hemorrhagic stroke§	38 (0.24)	74 (0.49)	0.51 (0.34, 0.75)	-
Other ICH	15 (0.10)	51 (0.34)	0.29 (0.16, 0.51)	-
Gastrointestinal (GI)¶	128 (0.83)	141 (0.93)	0.89 (0.70, 1.14)	-
Fatal**	10 (0.06)	37 (0.24)	0.27 (0.13, 0.53)	-
Intracranial	4 (0.03)	30 (0.20)	0.13 (0.05, 0.37)	-
Non-intracranial	6 (0.04)	7 (0.05)	0.84 (0.28, 2.15)	-

\* Bleeding events within each subcategory were counted once per subject, but subjects may have contributed events to multiple endpoints. Bleeding events were counted during treatment or within 2 days of stopping study treatment (on-treatment period).

† Defined as clinically overt bleeding accompanied by one or more of the following: a decrease in hemoglobin of ≥2 g/dL, a transfusion of 2 or more units of packed red blood cells, bleeding at a critical site: intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, retroperitoneal or with fatal outcome.

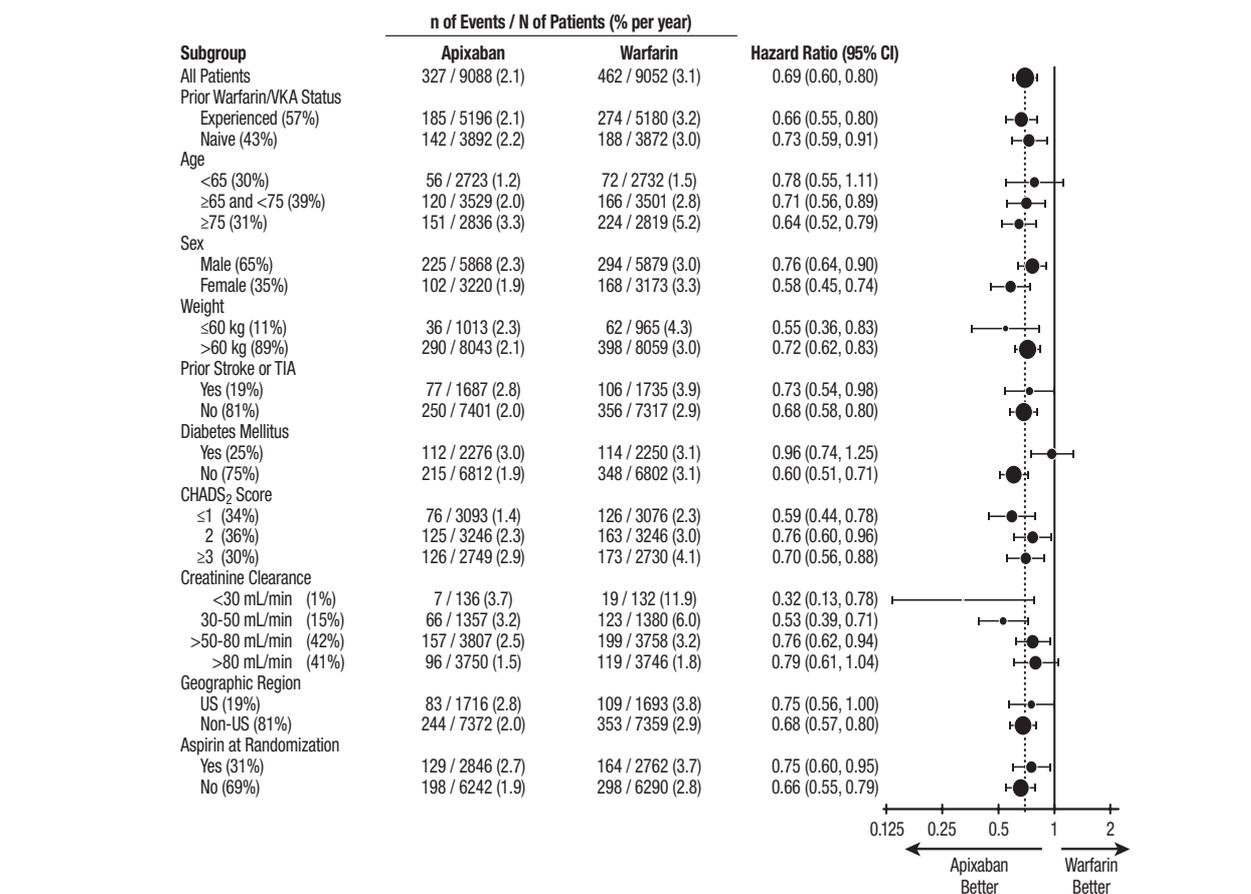
‡ Intracranial bleed includes intracerebral, intraventricular, subdural, and subarachnoid bleeding. Any type of hemorrhagic stroke was adjudicated and counted as an intracranial major bleed.

§ On-treatment analysis based on the safety population, compared to ITT analysis presented in Section 14 in the full Prescribing Information.

¶ GI bleed includes upper GI, lower GI, and rectal bleeding.

\*\* Fatal bleeding is an adjudicated death with the primary cause of death as intracranial bleeding or non-intracranial bleeding during the on-treatment period.

**Figure 1: Major Bleeding Hazard Ratios by Baseline Characteristics – ARISTOTLE Study**



Note: The figure above presents effects in various subgroups, all of which are baseline characteristics and all of which were prespecified, if not the groupings. The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be over-interpreted.

In ARISTOTLE, the results for major bleeding were generally consistent across most major subgroups including age, weight, CHADS<sub>2</sub> score (a scale from 0 to 6 used to estimate risk of stroke, with higher scores predicting greater risk), prior warfarin use, geographic region, and aspirin use at randomization (Figure 1). Subjects treated with apixaban with diabetes bled more (3.0% per year) than did subjects without diabetes (1.9% per year).

**Table 2: Bleeding Events in Patients with Nonvalvular Atrial Fibrillation in AVERROES**

	ELIQUIS (apixaban) N=2798 n (%/year)	Aspirin N=2780 n (%/year)	Hazard Ratio (95% CI)	P-value
Major	45 (1.41)	29 (0.92)	1.54 (0.96, 2.45)	0.07
Fatal	5 (0.16)	5 (0.16)	0.99 (0.23, 4.29)	-
Intracranial	11 (0.34)	11 (0.35)	0.99 (0.39, 2.51)	-

Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

### Other Adverse Reactions

Hypersensitivity reactions (including drug hypersensitivity, such as skin rash, and anaphylactic reactions, such as allergic edema) and syncope were reported in <1% of patients receiving ELIQUIS.

### Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

The safety of ELIQUIS has been evaluated in 1 Phase II and 3 Phase III studies including 5924 patients exposed to ELIQUIS 2.5 mg twice daily undergoing major orthopedic surgery of the lower limbs (elective hip replacement or elective knee replacement) treated for up to 38 days.

In total, 11% of the patients treated with ELIQUIS 2.5 mg twice daily experienced adverse reactions.

Bleeding results during the treatment period in the Phase III studies are shown in Table 3. Bleeding was assessed in each study beginning with the first dose of double-blind study drug.

**Table 3: Bleeding During the Treatment Period in Patients Undergoing Elective Hip or Knee Replacement Surgery**

Bleeding Endpoint*	ADVANCE-3 Hip Replacement Surgery		ADVANCE-2 Knee Replacement Surgery		ADVANCE-1 Knee Replacement Surgery	
	ELIQUIS 2.5 mg po bid 35±3 days	Enoxaparin 40 mg sc qd 35±3 days	ELIQUIS 2.5 mg po bid 12±2 days	Enoxaparin 40 mg sc qd 12±2 days	ELIQUIS 2.5 mg po bid 12±2 days	Enoxaparin 30 mg sc q12h 12±2 days
	First dose 12 to 24 hours post surgery	First dose 9 to 15 hours prior to surgery	First dose 12 to 24 hours post surgery	First dose 9 to 15 hours prior to surgery	First dose 12 to 24 hours post surgery	First dose 12 to 24 hours post surgery
All treated	N=2673	N=2659	N=1501	N=1508	N=1596	N=1588
Major (including surgical site)	22 (0.82%)†	18 (0.68%)	9 (0.60%)‡	14 (0.93%)	11 (0.69%)	22 (1.39%)
Fatal	0	0	0	0	0	1 (0.06%)
Hgb decrease ≥2 g/dL	13 (0.49%)	10 (0.38%)	8 (0.53%)	9 (0.60%)	10 (0.63%)	16 (1.01%)
Transfusion of ≥2 units RBC	16 (0.60%)	14 (0.53%)	5 (0.33%)	9 (0.60%)	9 (0.56%)	18 (1.13%)
Bleed at critical site§	1 (0.04%)	1 (0.04%)	1 (0.07%)	2 (0.13%)	1 (0.06%)	4 (0.25%)
Major + CRNM¶	129 (4.83%)	134 (5.04%)	53 (3.53%)	72 (4.77%)	46 (2.88%)	68 (4.28%)
All	313 (11.71%)	334 (12.56%)	104 (6.93%)	126 (8.36%)	85 (5.33%)	108 (6.80%)

\* All bleeding criteria included surgical site bleeding.

† Includes 13 subjects with major bleeding events that occurred before the first dose of apixaban (administered 12 to 24 hours post-surgery).

‡ Includes 5 subjects with major bleeding events that occurred before the first dose of apixaban (administered 12 to 24 hours post-surgery).

§ Intracranial, intraspinal, intraocular, pericardial, an operated joint requiring re-operation or intervention, intramuscular with compartment syndrome, or retroperitoneal. Bleeding into an operated joint requiring re-operation or intervention was present in all patients with this category of bleeding. Events and event rates include one enoxaparin-treated patient in ADVANCE-1 who also had intracranial hemorrhage.

¶ CRNM = clinically relevant nonmajor.

Adverse reactions occurring in ≥1% of patients undergoing hip or knee replacement surgery in the 1 Phase II study and the 3 Phase III studies are listed in Table 4.

**Table 4: Adverse Reactions Occurring in ≥1% of Patients in Either Group Undergoing Hip or Knee Replacement Surgery**

	ELIQUIS (apixaban), n (%) 2.5 mg po bid N=5924	Enoxaparin, n (%) 40 mg sc qd or 30 mg sc q12h N=5904
Nausea	153 (2.6)	159 (2.7)
Anemia (including postoperative and hemorrhagic anemia, and respective laboratory parameters)	153 (2.6)	178 (3.0)
Contusion	83 (1.4)	115 (1.9)
Hemorrhage (including hematoma, and vaginal and urethral hemorrhage)	67 (1.1)	81 (1.4)
Postprocedural hemorrhage (including postprocedural hematoma, wound hemorrhage, vessel puncture-site hematoma and catheter-site hemorrhage)	54 (0.9)	60 (1.0)
Transaminases increased (including alanine aminotransferase increased and alanine aminotransferase abnormal)	50 (0.8)	71 (1.2)
Aspartate aminotransferase increased	47 (0.8)	69 (1.2)
Gamma-glutamyltransferase increased	38 (0.6)	65 (1.1)

Less common adverse reactions in apixaban-treated patients undergoing hip or knee replacement surgery occurring at a frequency of ≥0.1% to <1%:

*Blood and lymphatic system disorders:* thrombocytopenia (including platelet count decreases)

*Vascular disorders:* hypotension (including procedural hypotension)

*Respiratory, thoracic, and mediastinal disorders:* epistaxis

*Gastrointestinal disorders:* gastrointestinal hemorrhage (including hematemesis and melena), hematochezia

*Hepatobiliary disorders:* liver function test abnormal, blood alkaline phosphatase increased, blood bilirubin increased

*Renal and urinary disorders:* hematuria (including respective laboratory parameters)

*Injury, poisoning, and procedural complications:* wound secretion, incision-site hemorrhage (including incision-site hematoma), operative hemorrhage

Less common adverse reactions in apixaban-treated patients undergoing hip or knee replacement surgery occurring at a frequency of <0.1%:

Gingival bleeding, hemoptysis, hypersensitivity, muscle hemorrhage, ocular hemorrhage (including conjunctival hemorrhage), rectal hemorrhage

*Treatment of DVT and PE and Reduction in the Risk of Recurrence of DVT or PE*

The safety of ELIQUIS has been evaluated in the AMPLIFY and AMPLIFY-EXT studies, including 2676 patients exposed to ELIQUIS 10 mg twice daily, 3359 patients exposed to ELIQUIS 5 mg twice daily, and 840 patients exposed to ELIQUIS 2.5 mg twice daily.

Common adverse reactions (≥1%) were gingival bleeding, epistaxis, contusion, hematuria, rectal hemorrhage, hematoma, menorrhagia, and hemoptysis.

AMPLIFY Study

The mean duration of exposure to ELIQUIS was 154 days and to enoxaparin/warfarin was 152 days in the AMPLIFY study. Adverse reactions related to bleeding occurred in 417 (15.6%) ELIQUIS-treated patients compared to 661 (24.6%) enoxaparin/warfarin-treated patients. The discontinuation rate due to bleeding events was 0.7% in the ELIQUIS-treated patients compared to 1.7% in enoxaparin/warfarin-treated patients in the AMPLIFY study.

In the AMPLIFY study, ELIQUIS was statistically superior to enoxaparin/warfarin in the primary safety endpoint of major bleeding (relative risk 0.31, 95% CI [0.17, 0.55], P-value <0.0001).

Bleeding results from the AMPLIFY study are summarized in Table 5.

**Table 5: Bleeding Results in the AMPLIFY Study**

	ELIQUIS N=2676 n (%)	Enoxaparin/Warfarin N=2689 n (%)	Relative Risk (95% CI)
Major	15 (0.6)	49 (1.8)	0.31 (0.17, 0.55) p<0.0001
CRNM*	103 (3.9)	215 (8.0)	
Major + CRNM	115 (4.3)	261 (9.7)	
Minor	313 (11.7)	505 (18.8)	
All	402 (15.0)	676 (25.1)	

\* CRNM = clinically relevant nonmajor bleeding.

Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

Adverse reactions occurring in ≥1% of patients in the AMPLIFY study are listed in Table 6.

**Table 6: Adverse Reactions Occurring in ≥1% of Patients Treated for DVT and PE in the AMPLIFY Study**

	ELIQUIS N=2676 n (%)	Enoxaparin/Warfarin N=2689 n (%)
Epistaxis	77 (2.9)	146 (5.4)
Contusion	49 (1.8)	97 (3.6)
Hematuria	46 (1.7)	102 (3.8)
Menorrhagia	38 (1.4)	30 (1.1)
Hematoma	35 (1.3)	76 (2.8)
Hemoptysis	32 (1.2)	31 (1.2)
Rectal hemorrhage	26 (1.0)	39 (1.5)
Gingival bleeding	26 (1.0)	50 (1.9)

AMPLIFY-EXT Study

The mean duration of exposure to ELIQUIS was approximately 330 days and to placebo was 312 days in the AMPLIFY-EXT study. Adverse reactions related to bleeding occurred in 219 (13.3%) ELIQUIS-treated patients compared to 72 (8.7%) placebo-treated patients. The discontinuation rate due to bleeding events was approximately 1% in the ELIQUIS-treated patients compared to 0.4% in those patients in the placebo group in the AMPLIFY-EXT study.

Bleeding results from the AMPLIFY-EXT study are summarized in Table 7.

**Table 7: Bleeding Results in the AMPLIFY-EXT Study**

	ELIQUIS 2.5 mg bid N=840 n (%)	ELIQUIS 5 mg bid N=811 n (%)	Placebo N=826 n (%)
Major	2 (0.2)	1 (0.1)	4 (0.5)
CRNM*	25 (3.0)	34 (4.2)	19 (2.3)
Major + CRNM	27 (3.2)	35 (4.3)	22 (2.7)
Minor	75 (8.9)	98 (12.1)	58 (7.0)
All	94 (11.2)	121 (14.9)	74 (9.0)

\* CRNM = clinically relevant nonmajor bleeding.

Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

Adverse reactions occurring in ≥1% of patients in the AMPLIFY-EXT study are listed in Table 8.

**Table 8: Adverse Reactions Occurring in ≥1% of Patients Undergoing Extended Treatment for DVT and PE in the AMPLIFY-EXT Study**

	ELIQUIS (apixaban) 2.5 mg bid N=840 n (%)	ELIQUIS 5 mg bid N=811 n (%)	Placebo N=826 n (%)
Epistaxis	13 (1.5)	29 (3.6)	9 (1.1)
Hematuria	12 (1.4)	17 (2.1)	9 (1.1)
Hematoma	13 (1.5)	16 (2.0)	10 (1.2)
Contusion	18 (2.1)	18 (2.2)	18 (2.2)
Gingival bleeding	12 (1.4)	9 (1.1)	3 (0.4)

Other Adverse Reactions

Less common adverse reactions in ELIQUIS-treated patients in the AMPLIFY or AMPLIFY-EXT studies occurring at a frequency of ≥0.1% to <1%:

*Blood and lymphatic system disorders:* hemorrhagic anemia

*Gastrointestinal disorders:* hematochezia, hemorrhoidal hemorrhage, gastrointestinal hemorrhage, hematemesis, melena, anal hemorrhage

*Injury, poisoning, and procedural complications:* wound hemorrhage, postprocedural hemorrhage, traumatic hematoma, periorbital hematoma

*Musculoskeletal and connective tissue disorders:* muscle hemorrhage

*Reproductive system and breast disorders:* vaginal hemorrhage, metrorrhagia, menometrorrhagia, genital hemorrhage

*Vascular disorders:* hemorrhage

*Skin and subcutaneous tissue disorders:* ecchymosis, skin hemorrhage, petechiae

*Eye disorders:* conjunctival hemorrhage, retinal hemorrhage, eye hemorrhage

*Investigations:* blood urine present, occult blood positive, occult blood, red blood cells urine positive

*General disorders and administration-site conditions:* injection-site hematoma, vessel puncture-site hematoma

#### DRUG INTERACTIONS

Apixaban is a substrate of both CYP3A4 and P-gp. Inhibitors of CYP3A4 and P-gp increase exposure to apixaban and increase the risk of bleeding. Inducers of CYP3A4 and P-gp decrease exposure to apixaban and increase the risk of stroke and other thromboembolic events.

#### Combined P-gp and Strong CYP3A4 Inhibitors

For patients receiving ELIQUIS 5 mg or 10 mg twice daily, the dose of ELIQUIS should be decreased by 50% when coadministered with drugs that are combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir) [see *Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in full Prescribing Information*].

For patients receiving ELIQUIS at a dose of 2.5 mg twice daily, avoid coadministration with combined P-gp and strong CYP3A4 inhibitors [see *Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in full Prescribing Information*].

#### Clarithromycin

Although clarithromycin is a combined P-gp and strong CYP3A4 inhibitor, pharmacokinetic data suggest that no dose adjustment is necessary with concomitant administration with ELIQUIS [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

#### Combined P-gp and Strong CYP3A4 Inducers

Avoid concomitant use of ELIQUIS with combined P-gp and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

#### Anticoagulants and Antiplatelet Agents

Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding.

APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk, post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo. The rate of ISTH major bleeding was 2.8% per year with apixaban versus 0.6% per year with placebo in patients receiving single antiplatelet therapy and was 5.9% per year with apixaban versus 2.5% per year with placebo in those receiving dual antiplatelet therapy.

In ARISTOTLE, concomitant use of aspirin increased the bleeding risk on ELIQUIS from 1.8% per year to 3.4% per year and concomitant use of aspirin and warfarin increased the bleeding risk from 2.7% per year to 4.6% per year. In this clinical trial, there was limited (2.3%) use of dual antiplatelet therapy with ELIQUIS.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

##### Risk Summary

The limited available data on ELIQUIS use in pregnant women are insufficient to inform drug-associated risks of major birth defects, miscarriage, or adverse developmental outcomes. Treatment may increase the risk of bleeding during pregnancy and delivery. In animal reproduction studies, no adverse developmental effects were seen when apixaban was administered to rats (orally), rabbits (intravenously) and mice (orally) during organogenesis at unbound apixaban exposure levels up to 4, 1 and 19 times, respectively, the human exposure based on area under plasma-concentration time curve (AUC) at the Maximum Recommended Human Dose (MRHD) of 5 mg twice daily.

The estimated background risk of major birth defects and miscarriage for the indicated populations 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% to 20%, respectively.

##### Clinical Considerations

##### *Disease-associated maternal and/or embryo/fetal risk*

Pregnancy confers an increased risk of thromboembolism that is higher for women with underlying thromboembolic disease and certain high-risk pregnancy conditions. Published data describe that women with a previous history of venous thrombosis are at high risk for recurrence during pregnancy.

##### *Fetal/Neonatal adverse reactions*

Use of anticoagulants, including apixaban, may increase the risk of bleeding in the fetus and neonate.

##### *Labor or delivery*

All patients receiving anticoagulants, including pregnant women, are at risk for bleeding. ELIQUIS use during labor or delivery in women who are receiving neuraxial anesthesia may result in epidural or spinal hematomas. Consider use of a shorter acting anticoagulant as delivery approaches [see *Warnings and Precautions*].

##### Data

##### *Animal Data*

No developmental toxicities were observed when apixaban was administered during organogenesis to rats (orally), rabbits (intravenously) and mice (orally) at unbound apixaban exposure levels 4, 1, and 19 times, respectively, the human exposures at the MRHD. There was no evidence of fetal bleeding, although conceptus exposure was confirmed in rats and rabbits. Oral administration of apixaban to rat dams from gestation day 6 through lactation day 21 at maternal unbound apixaban exposures ranging from 1.4 to 5 times the human exposures at

the MRHD was not associated with reduced maternal mortality or reduced conceptus/neonatal viability, although increased incidences of peri-vaginal bleeding were observed in dams at all doses. There was no evidence of neonatal bleeding.

##### Lactation

##### Risk Summary

There are no data on the presence of apixaban or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Apixaban and/or its metabolites were present in the milk of rats (see Data). Because human exposure through milk is unknown, breastfeeding is not recommended during treatment with ELIQUIS (apixaban).

##### Data

##### *Animal Data*

Maximal plasma concentrations were observed after 30 minutes following a single oral administration of a 5 mg dose to lactating rats. Maximal milk concentrations were observed 6 hours after dosing. The milk to plasma AUC (0-24) ratio is 30:1 indicating that apixaban can accumulate in milk. The concentrations of apixaban in animal milk does not necessarily predict the concentration of drug in human milk.

##### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

##### Geriatric Use

Of the total subjects in the ARISTOTLE and AVERROES clinical studies, >69% were 65 years of age and older, and >31% were 75 years of age and older. In the ADVANCE-1, ADVANCE-2, and ADVANCE-3 clinical studies, 50% of subjects were 65 years of age and older, while 16% were 75 years of age and older. In the AMPLIFY and AMPLIFY-EXT clinical studies, >32% of subjects were 65 years of age and older and >13% were 75 years of age and older. No clinically significant differences in safety or effectiveness were observed when comparing subjects in different age groups.

##### Renal Impairment

##### *Reduction of Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation*

The recommended dose is 2.5 mg twice daily in patients with at least two of the following characteristics [see *Dosage and Administration (2.1) in full Prescribing Information*]:

- age greater than or equal to 80 years
- body weight less than or equal to 60 kg
- serum creatinine greater than or equal to 1.5 mg/dL

##### Patients with End-Stage Renal Disease on Dialysis

Clinical efficacy and safety studies with ELIQUIS did not enroll patients with end-stage renal disease (ESRD) on dialysis. In patients with ESRD maintained on intermittent hemodialysis, administration of ELIQUIS at the usually recommended dose [see *Dosage and Administration (2.1) in full Prescribing Information*] will result in concentrations of apixaban and pharmacodynamic activity similar to those observed in the ARISTOTLE study [see *Clinical Pharmacology (12.3) in full Prescribing Information*]. It is not known whether these concentrations will lead to similar stroke reduction and bleeding risk in patients with ESRD on dialysis as was seen in ARISTOTLE.

##### *Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery, and Treatment of DVT and PE and Reduction in the Risk of Recurrence of DVT and PE*

No dose adjustment is recommended for patients with renal impairment, including those with ESRD on dialysis [see *Dosage and Administration (2.1) in full Prescribing Information*]. Clinical efficacy and safety studies with ELIQUIS did not enroll patients with ESRD on dialysis or patients with a CrCl <15 mL/min; therefore, dosing recommendations are based on pharmacokinetic and pharmacodynamic (anti-Fxa activity) data in subjects with ESRD maintained on dialysis [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

##### Hepatic Impairment

No dose adjustment is required in patients with mild hepatic impairment (Child-Pugh class A). Because patients with moderate hepatic impairment (Child-Pugh class B) may have intrinsic coagulation abnormalities and there is limited clinical experience with ELIQUIS in these patients, dosing recommendations cannot be provided [see *Clinical Pharmacology (12.2) in full Prescribing Information*]. ELIQUIS is not recommended in patients with severe hepatic impairment (Child-Pugh class C) [see *Clinical Pharmacology (12.2) in full Prescribing Information*].

##### OVERDOSAGE

Overdose of ELIQUIS increases the risk of bleeding [see *Warnings and Precautions*].

In controlled clinical trials, orally administered apixaban in healthy subjects at doses up to 50 mg daily for 3 to 7 days (25 mg twice daily for 7 days or 50 mg once daily for 3 days) had no clinically relevant adverse effects.

In healthy subjects, administration of activated charcoal 2 and 6 hours after ingestion of a 20-mg dose of apixaban reduced mean apixaban AUC by 50% and 27%, respectively. Thus, administration of activated charcoal may be useful in the management of apixaban overdose or accidental ingestion. An agent to reverse the anti-factor Xa activity of apixaban is available.

##### PATIENT COUNSELING INFORMATION

*Advise patients to read the FDA-approved patient labeling (Medication Guide).*

Advise patients of the following:

- Not to discontinue ELIQUIS without talking to their physician first.
- That it might take longer than usual for bleeding to stop, and they may bruise or bleed more easily when treated with ELIQUIS. Advise patients about how to recognize bleeding or symptoms of hypovolemia and of the urgent need to report any unusual bleeding to their physician.
- To tell their physicians and dentists they are taking ELIQUIS, and/or any other product known to affect bleeding (including nonprescription products, such as aspirin or NSAIDs), before any surgery or medical or dental procedure is scheduled and before any new drug is taken.
- If the patient is having neuraxial anesthesia or spinal puncture, inform the patient to watch for signs and symptoms of spinal or epidural hematomas [see *Warnings and Precautions*]. If any of these symptoms occur, advise the patient to seek emergent medical attention.
- To tell their physicians if they are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed during treatment with ELIQUIS [see *Use in Specific Populations*].
- How to take ELIQUIS if they cannot swallow, or require a nasogastric tube [see *Dosage and Administration (2.6) in full Prescribing Information*].
- What to do if a dose is missed [see *Dosage and Administration (2.2) in full Prescribing Information*].

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by LANDON JONES, MD; AND RICHARD M. CANTOR, MD, FAAP, FACEP

The best questions often stem from the inquisitive learner. As educators, we love, and are always humbled by, those moments when we get to say, "I don't know." For some of these questions, you may already know the answers. For others, you may never have thought to ask the question. For all, questions, comments, concerns, and critiques are encouraged. Welcome to the Kids Korner.



## Herpes Cases in Newborns

### Question 1: In neonates infected with herpes simplex virus (HSV), how common is a maternal history of genital herpes?

Data published in 1980 from the National Institute of Allergy and Infectious Diseases (NIAID) Collaborative Antiviral Study Group by Whitley et al included 56 HSV-infected newborns.<sup>1</sup> While an important goal of this collaborative multicenter database was evaluating antiviral outcomes in HSV-infected newborns, maternal characteristics were also documented, and 29 of 56 (52 percent) mothers were asymptomatic—without a history of either genital or nongenital HSV. Regarding genital HSV only, 34 of 56 (61 percent) mothers of HSV-infected newborns had no history of genital HSV infections. Subsequent data from that same NIAID registry published in 1988 demonstrated no maternal history of genital HSV infections in 236 of 291 (81 percent) HSV-infected neonatal cases over a 15-year period.<sup>2</sup>

In 1984, the Centers for Disease Control and Prevention established the National Neonatal HSV Infection Surveillance System and retrospectively collected data from 3,157 hospitals that self-reported cases of neonatal HSV over an 18-month period. The data were published by Stone et al and demonstrated similar findings, with 108 of 140 (77 percent) without a ma-



Herpes simplex virus infection.

ternal history of genital herpes.<sup>3</sup> A more recent retrospective case-control study by Mark et al evaluated all children from Washington state via birth certificate data from 1987 to 2002 and identified 91 HSV-infected neonatal cases, of which 67 (74 percent) had no history of maternal genital herpes.<sup>4</sup>

### Conclusion

In HSV-infected neonates, approximately 60 to 80 percent of mothers have no history of genital herpes. Ⓢ

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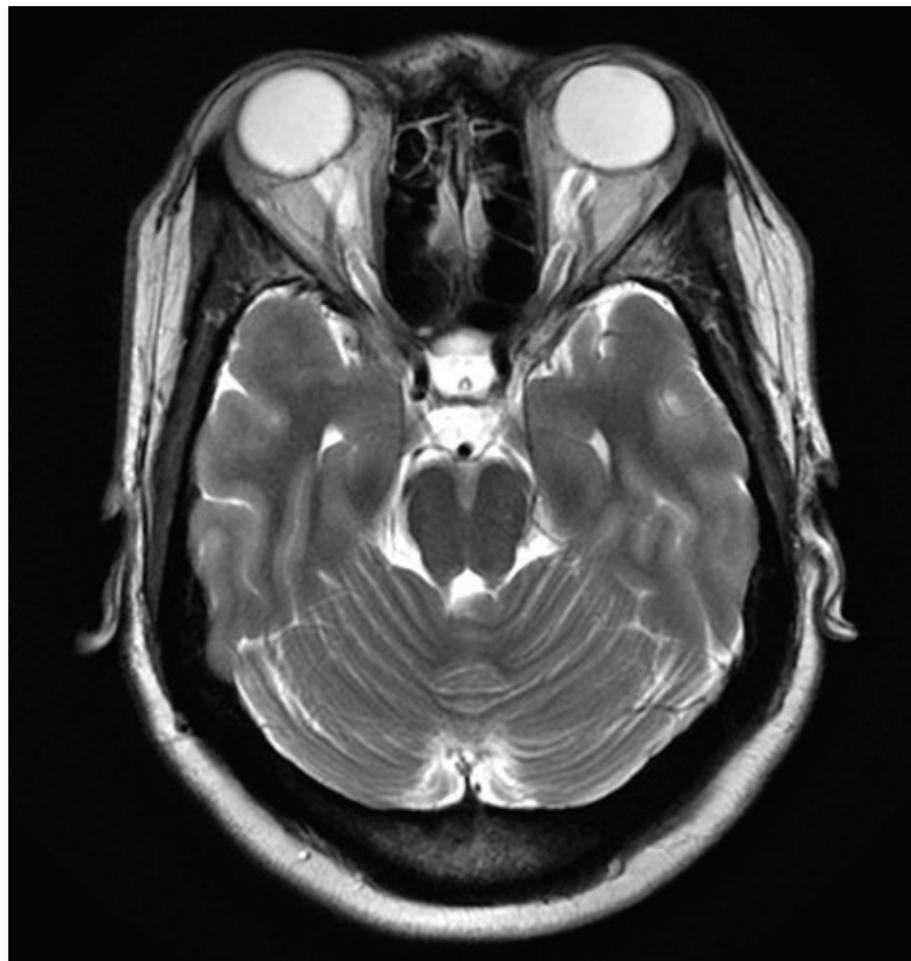
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## Link Between Idiopathic Intracranial Hypertension and Obesity in Kids

### Question 2: In children with idiopathic (or primary) intracranial hypertension (IIH)—previously called pseudotumor cerebri syndrome—are the typical patients obese as they are in the adult population with this disease?

Although intracranial hypertension is associated with obesity, does this connection hold true in children? Balcer et al performed a retrospective chart review of 45 consecutive children younger than 18 years old who had IIH.<sup>1</sup> Heights and weights were recorded in 40 of these 45 patients, and obesity was defined as >120 percent of ideal body weight adjusted for age and sex. Of these 40 patients, children were divided into three age groups: 3–11 years, 12–14 years, and 15–17 years. By age group, obesity was documented in 6 of 14 (43 percent), 13 of 16 (81 percent), and 9 of 10 (90 percent), respectively, suggesting that obesity was a less common risk in children younger than 12 years of age. In older children with IIH, obesity was more common.

Another retrospective study of the Intracranial Hypertension Registry evaluated 142 pediatric primary intracranial hypertension (PIH) patients.<sup>2</sup> Of the 142 patients, 103 (72.5 percent) were female. Patient demographics were broken down between pre-pubertal (younger than 11 years old) and post-pubertal (11 years or older). While a specific percentage of obesity was not reported in pre-versus post-pubertal groups, the average body mass index in the pre-pubertal group was 21.6 while the average in the post-pubertal group



Axial T2-weighted MRI of a patient with idiopathic intracranial hypertension shows prominent cerebrospinal fluid surrounding the optic sheaths within both orbits.

was 30.7 (which is consistent with obesity), a statistically significant finding. The authors also note that the ratio of girls to boys in the pre-pubertal group was almost even at 1 to 1.04. A recent prospective population-based

cohort study evaluated 185 newly diagnosed cases of IIH in children age 1–16 years.<sup>3</sup> There were three demographic age categories: 4–6 years, 7–11 years, and 12–16 years. Obesity was present in 7 of 17 (41 percent) cases in the 4–6-year-old group, 29 of 58 (50 percent) cases in the 7–11-year-old group, and 84 of 110 (76 percent) in the 12–16-year-old group. This study suggests, again, that there is an association with obesity in older children with IIH but not necessarily in pre-pubertal children.

While the association between IIH and obesity is strong in older post-pubertal children, it appears less commonly associated in young children prior to puberty (typically less than 50 percent). Avoid disregarding the potential diagnosis of IIH in younger non-obese children with symptoms of the disease.

### Summary

Similar to adults, in older post-pubertal children, there is a common association of IIH with obesity. In younger pre-pubertal children, though, many are not obese. Ⓢ

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PROTECT  
YOURSELF FROM  
LEGAL RISK

## MEDICOLEGAL MIND



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# You Got Served

Survival tips for the first step of a malpractice lawsuit

by GITA PENSA, MD

*“They showed up at my door to serve me. ... I was in my pajamas.”*

*“I was at home, getting ready for Christmas Eve; my children were two and five, and they came to my door.”*

*“I was served by a sheriff at work, in front of my co-workers...”*

—physician interviews, “Doctors and Litigation” podcast

Receiving official notice of a lawsuit, or being “served,” is an event most physicians dread. The impact can be staggering; most physicians never forget when

and where they were first given notice. One physician described it as feeling like “being hit in the head with a two-by-four.”

Here are some tips for making it through the moment of being served and what you should (and should not) do soon afterward.

### The Basics of Being Served

“Service of process” is the mechanism by which, in civil litigation, one party officially notifies another that they have filed a “complaint” (lawsuit) against them. You, the defendant, are expected to respond to the complaint within a specified time frame; this will happen later via your attorney. Failure to respond results in a default judgment against you. Every jurisdiction has its own rules on how you may officially be given notice; it is crucial that you are informed in an official manner as part of constitutionally guaranteed due process.

In some areas, being served can be as simple as receiving a certified letter. Elsewhere, you may be served in person with

a formal notice from the court establishing its jurisdiction in the matter, known as a “process server.” A uniformed sheriff also might also deliver the notice, which is a particularly stressful method; be it at work or home, you will likely have no warning that they are coming.

Some plaintiff’s attorneys time their notice for maximum impact, such as on a holiday. Emergency physician Mark Plaster, MD, wrote about being served by a sheriff during Thanksgiving dinner in his introduction to *How to Survive a Medical Malpractice Lawsuit* by Ilene Brenner, MD. One physician I spoke with described being served on Christmas Eve with her small children beside her; another was served shortly after her father’s funeral (an event known by the small-town attorney).

The notices themselves are often jarring and accusatory in tone. This is no accident. Plaintiff’s attorneys are aware of the distress this process causes, and they leverage it. However, sometimes it is apparent that attorneys are not clear on how exactly you harmed the patient in question. Many lawsuits are hastily filed before the statute of limitations runs out, and the arguments are fleshed out later. Either way, the notice is their opening move in a long chess game, crafted to wear you down to where you would gladly settle once given the opportunity.

Recognizing their manipulation as a deliberate strategy is step one in gaining back your equilibrium.

However, that is a tall order. Regardless of merit, the very *accusation* of malpractice is enough to cause most physicians significant distress. Anxiety, sleeplessness, and even panic are common, particularly if the le-

gal world is a looming unknown or the case involves a poor patient outcome or death.

Do not isolate yourself. You are absolutely allowed to confide in friends and family. You may be told “not to talk about it,” but there is no actual *law* prohibiting discussing the medicine with others. However, you may be asked under oath at deposition who you’ve discussed case details with, and then they could be deposed, so it’s best to focus on your feelings and the legal events and to keep any discussions about the case itself vague and hypothetical.

Once the complaint is in your hand, what do you do?

### What to Do

#### 1. Call your insurance carrier and begin the process of establishing a “claim.”

They will speak with you about the case and find you an attorney. If you don’t know who your insurance carrier is or how to contact them, ask your employer (avoid revealing too much if they are a possible co-defendant with separate insurance). Your insurance carrier will advise you on your next steps and answer your questions.

2. **Obtain a lawyer you trust.** If you have a particular attorney in mind, tell your insurer. Otherwise, the insurer will help you find one. Make sure an experienced partner is at least peripherally involved in overseeing your case.

3. **Get a book.** There are numerous books on malpractice litigation written for doctors. Go online, read the reviews, buy one or more, and read them. You will find that this normaliz-

es the experience, and it arms you with knowledge to lessen your anxiety.

4. **Talk about it.** To reiterate, you should not face this alone. Confide in friends or family. If your hospital has a peer support group, utilize it. If you know someone who has been through litigation, call them. And if you have a history of substance use, talk to a confidante or sponsor as this is a very high-risk time for relapse. Please be proactive in getting extra support.

5. **Take care of yourself.** Make time for yourself to decompress away from work and do your best to exercise, eat well, sleep, and spend time with meaningful people in your life. If it means saying no to extra duties at work, say no for now.

### What Not to Do

1. **Do not access or alter the chart.** With electronic charts, it’s easy to see who accessed the chart and when. Your lawyer will be obtaining all the relevant charts for you as part of the discovery phase (which I will discuss in a future column).

2. **Do not contact the plaintiff or their family.** You may be tempted to speak with them in person. At this stage, do not directly contact them. Everything goes through the attorneys, no exceptions.

3. **Do not make any notes** about the case that are not specifically addressed to your attorney. Your attorney or insurance carrier may ask you to write down everything you remember within their confidential “attorney-client privilege” bubble, but do not keep private notes.

4. **Do not despair.** This is a long road, but it’s been well traveled by many excellent physicians. You may be angry because you feel you did everything right; you may be guilt-ridden, feeling you could have made different choices. In either case, many of us have been in your shoes, and these reactions are expected and justified. It’s time we told you so. +





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# The Latest ED Utilization Numbers Are In

CDC survey places emergency department visits back on the growth line

by JAMES AUGUSTINE, MD, FACEP

The Centers for Disease Control and Prevention (CDC) released its statistical survey of emergency department visits for 2016 on April 1. Called the National Hospital Ambulatory Medical Care Survey (NHAMCS), it is a wealth of information for emergency physicians and will guide the data and trends for the emergency services for which they are responsible.<sup>1</sup>

## The Numbers

ED visit estimates increased from 136.9 million in 2015 to 145.6 million in 2016, a jump of 6.4 percent. The 10-year volume change is 24.7 percent, and for the past 20 years, the increase has totaled 61.2 percent (the 1996 ED visit estimate was 90.3 million). The past 15 years of volume estimates appear in Table 1.

These data may not match the experience in every emergency department and every community. First, the CDC typically estimates the lowest volume of ED visits, and the NHAMCS does not include visits to freestanding emergency departments. Second, there are changing patterns of ED use based on community sources of unscheduled care. Third, the patchwork of primary care systems in the country influences the number of ED visits locally.

What is apparent from the CDC data is that the trend of emergency departments seeing older, sicker patients, combined with continued growth in retail clinics, telehealth, and other sources of care for nonemergent problems, will yield a net increase in the average severity and complexity of patients seen in full-service emergency departments.

## Who Are the Patients?

ED visits increased from 369 to 458 visits per 1,000 people between 1995 and 2016. High utilizers continue to include infants, nursing home residents, the homeless, black persons, and people over age 75.

Infants under age 1 had 987 visits per 1,000 persons. This is relatively high utilization and represents an opportunity for parent education.

There were roughly 2.2 million visits for patients who reside in nursing homes, for a utilization of 1,594 visits per 1,000 residents. Approximately 33 percent of nursing home patient ED visits resulted in hospital admission (739,000), with an average length of hospital stay of 5.7 days.

Persons classified as homeless represented a larger visit load for EDs compared with prior years. In 2016, homeless persons accounted for an estimated 1,446,000 visits, a rate of 2,630 visits per 1,000 estimated number of homeless persons. Those visits equal roughly 1 percent of total ED visits.

The CDC also categorized visit rates for white, black, Hispanic, and other races/ethnicities. The visit rate was 435 visits per 1,000 white people, 404 visits per 1,000 Hispanics, and 804 visits per 1,000 black people. The visit rate was 172 visits per 1,000 persons of other races (ie, Asian, native Hawaiian or other Pacific Islander, American Indian or Alaska native, and persons with more than one race).

The ED population is aging in line with national demographics. Persons over age 65 accounted for 15.8 percent of ED visits, and persons age 75 and older had 605 visits per 1,000 in 2016. Thus, emergency departments must prepare for larger numbers of patients and develop processes tailored to older persons. In addition, older patients require more workup, treatment, and, thus, more time in the department.

**Table 1: Estimated Annual ED Visits**

YEAR	NHAMCS ESTIMATED ED VISITS (MILLIONS)
2001	107.5
2002	110.2
2003	113.9
2004	110.2
2005	115.3
2006	119.2
2007	116.8
2008	123.8
2009	136.1
2010	129.8
2011	136.3
2012	130.9
2013	130.4
2014	141.4
2015	136.9
<b>2016</b>	<b>145.6</b>

Finally, because older patients are admitted to the hospital more often, they spend more time as ED boarders. Planning for new or renovating old emergency departments should account for these shifting demographics.

## Why Do They Come?

The acuity of visits to the emergency department continues to increase, with a mere 4.3 percent of ED visits classified as non-urgent (the highest rates of these visits were for patients under age 15).

The reasons for visits were coded using a classification system developed by the CDC's National Center for Health Statistics. The NHAMCS includes a set of tables that relate to that classification, and estimates are presented by age and sex. Injuries accounted for an estimated 42.2 million visits, or 29 percent of ED visits. By comparison, in 2009 there were an estimated 45 million encounters for injuries. This trend reflects the success of many injury prevention programs, leading to an ED population distribution that features less *injury* and more *illness*.

The leading causes of injury, poisoning, and adverse effect-related ED visits were falls (10.5 million visits, or 23 percent of total injury visits) and motor vehicle traffic crashes (3.7 million visits, or 8.1 percent of total injury visits).

When viewed through the lens of "presenting complaint," stomach and abdominal pain were the most common in 2016, accounting for around 9 percent of visits. Chest pain was next highest at 5 percent.

There were 5.5 million visits with a primary diagnosis of mental disorder noted in the emergency departments, of which 2.4 million visits included evaluation by a mental health provider.

## Quality Performance Measures

Roughly 3.2 million visits resulted in the patient leaving before treatment was complete, or about 2.2 percent of all ED visits.

There are hospital quality indicators related to ED revisits and hospital readmissions that ED leaders must be aware of. About 2.7 percent of visits were made by patients who had been seen in the same emergency department in the preceding 72 hours (down from an estimate of 5.7 percent in 2015), and the CDC estimates 4.9 percent of ED visits were for follow-up.

The CDC report in 2011 indicated 6.3 percent of patients admitted through emergency departments had been discharged from a hospital in the preceding seven days. In 2016, roughly 2.9 percent of ED visits that led to hospital admission were patients who had been in an emergency department within the prior 72 hours. That number is down from 4.7 percent in 2011.

There is an ongoing increase in the use of diagnostic tools in the emergency departments, especially ECGs. The use of CT scanning appears to have plateaued, but the use MRI and other special imaging procedures (such as ultrasound) is increasing.

## Planning for the Future of Emergency Care

Sources other than the CDC study document the growth of alternative care sites compared with full-service, hospital-based emergency departments. For example, a MedPAC report in June 2017 found an increasing number of freestanding emergency departments.<sup>2</sup> In 2016, there were 363 off-campus emergency departments in 35 states affiliated with 300 hospitals. MedPAC counted 203 independent freestanding emergency centers, mostly in Texas.

So far, there are no estimates of the total volume seen in freestanding emergency departments. However, the Emergency Department Benchmarking Alliance (EDBA) database in 2017 listed 237 hospital-owned freestanding emergency departments that saw approximately 3.6 million patients, for an average of 15,000 visits per site. This means hospital-owned and independent freestanding emergency departments may combine for around 8.5 million visits per year.<sup>3</sup>

There are also a growing number of urgent care centers. As of 2018, the Urgent Care Association counts 8,285 urgent care centers, amounting to 89 million visits and an \$18 billion industry.

The demand for emergency departments continues to rise, and there is continued growth in the percentage of overall hospital admissions presenting through the ED. The EDBA data survey found that roughly 69 percent of hospital inpatients are processed through the emergency department. This clearly demonstrates the emergency department has become the front door to the hospital.

The CDC findings should be discussed with hospital and community leaders so that adjustments needed to improve patient safety and service are made, and that the value of emergency services is clear. 📌

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# New Drug for Your Infection Toolkit

Hailing from veterinary medicine, pleuromutilins are a new antibiotic option

by RYAN PATRICK RADECKI, MD, MS

In medical school teaching for most of the last half century, the ascendant antibiotic in our armamentarium has been  $\beta$ -lactam. This happy marriage between the amide group and a carbonyl group, joined together by a ring, exhibits lethal effects on bacteria by inhibiting cell wall synthesis.

The most famous and early member of the family is penicillin, which has been followed in general use by cephe-  
mams, mono-



bactams, and carbapenems.

These compounds, however, are susceptible to  $\beta$ -lactamases, a family of hydrolytic enzymes widely manifested by bacteria, conferring antibiotic resistance. While many other antibiotic classes are available, resistance continues to emerge in such common pathogens as *Enterococcus* and *Neisseria*. Few new antibiotics are approved by the U.S. Food and Drug Administration (FDA), and over the past decade, these have typically been derivatives of antibiotic classes already in wide use.

Enter the pleuromutilins and the newest antibiotic utensil in our toolbox, lefamulin (Xenleta).<sup>1</sup> Pleuromutilins are not actually that novel; they were isolated from *Pleurotus mutilus* mushrooms in the 1950s and adapted for commercial use in the 1970s. The pleuromutilins inhibit ribosomal protein synthesis and bind to the same 50S ribosomal subunit as the amphenicols. Their effects are primarily against Gram-positive organisms, including community-acquired and resistant strains of *S. aureus*, multidrug-resistant *S. pneumoniae*, and vancomycin-resistant *Enterococcus faecium*. Activity is also noted against fastidious Gram-negatives such as *Haemophilus* spp., *Moraxella catarrhalis*, *Neisseria* spp., and *Legionella pneumophila*, as well as the mycoplasmas, ureaplasmas, and chlamydia. No clinically relevant activity is suspected against anaerobic organisms, eg, *Enterococcus faecalis*, *Enterobacteriaceae*, or nonfermenting Gram-negatives such as *Acinetobacter baumannii* and *Pseudomonas aeruginosa*.

The pleuromutilin antibiotics tiamulin and valnemulin have been in use in veterinary medicine, such as in pigs and poultry, for decades. For human use, a topical antibiotic, retapamulin, has been available in the United States since 2007 for the treatment of superficial wound and soft-tissue infections like impetigo. Now, lefamulin represents the first pleuromutilin available for intravenous and

oral human use, with FDA approval granted in August 2019 by priority review under the Qualified Infectious Disease Product designation.

## Clinical Trials

The approval of lefamulin stems from results observed in a pair of Phase III clinical trials, each noninferiority trial testing lefamulin against moxifloxacin: the Lefamulin Evaluation Against Pneumonia (LEAP) trials. LEAP 1 tested lefamulin versus moxifloxacin as intravenous treatment for inpatients, with transition to oral administration based on clinical criteria.<sup>2</sup> Supplemental treatment with linezolid in the moxifloxacin arm was authorized if methicillin-resistant *S. aureus* was suspected or confirmed by culture, while the lefamulin arm received matching placebo.

The most conspicuous feature of this trial is the very low acuity of patients enrolled. Most patients fell into Pneumonia Severity Index (PSI/PORT) risk class III, typically rec-

ommended for either inpatient or outpatient management depending on patient-specific factors. Clinical trial requirements issued by the FDA necessitate a minimum of 25 percent of trial patients in PORT class IV or V, and the trial population barely clears this regulatory bar. Exclusion criteria were likewise typical for a tightly controlled trial and excluded patients at elevated risk for deterioration such as nursing home residents, patients with immunosuppression, or those undergoing cytotoxic chemotherapy. It is, then, of little surprise the trial met its 10 percent regulatory margin for noninferiority, with 87.3 percent of lefamulin-treated patients classified as responders compared with 90.2 percent of those treated with moxifloxacin  $\pm$  linezolid.

LEAP 2 performed a similar comparison, except with an entirely oral outpatient regimen. A full peer-reviewed publication detailing these results was not available at the time of this writing, but results are highlighted in

two abstracts.<sup>3,4</sup> The trial enrolled patients with milder pneumonia and PORT scores of primarily II and III, and both lefamulin and moxifloxacin monotherapy were similarly efficacious, with response rates around 90 percent. This, again, easily met the regulatory margin for noninferiority.

Treatment-emergent adverse events (TEAEs) were more common in the lefamulin cohort, although few led to discontinuation in these trials. While TEAEs were similar in LEAP 1, diarrhea was observed in 12.2 percent of the lefamulin cohort of LEAP 2 compared with 1.1 percent of those treated with moxifloxacin. Smaller differences were noted with regard to nausea and vomiting in LEAP 2 but were still greater in those treated with lefamulin. No reliable difference in hepatobiliary injury or QT-interval prolongation was reported in either trial.

CONTINUED on page 44



PHOTO ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM



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# Sharing the Burden of Equity

Allies, advocates, and accomplices are critical parts of the quest for diversity and inclusion

by DARA KASS, MD

**We** have made significant strides toward emergency medicine workplace diversity. That cannot be denied. But given the time and effort we have been putting in, you would think we would have gotten even further. Many of our departments have an office of diversity and inclusion, a women’s wellness group, and programs that support



residents who identify as members of underrepresented groups in medicine.

Notice who runs your “diversity and inclusion” programs.

Do they identify with one of the underrepresented groups they were formed to support? The likely answer is yes. Since the inception of diversity and inclusion programs, we have tasked women, people of color, and historically marginalized people to drive the change we need to see. But what if, as a consequence, those who promote workplace and leadership diversity are also simultaneously and subtly punished for it? That’s what appears to be afoot, and it is worth unpacking.

Let’s explore how this might happen.

## A Case Example

A well-meaning white male chair promotes a mid-career nonwhite woman into a division chief position and, in addition, asks her to run the new women’s group in her department. She takes both opportunities, even though only one is compensated. Over the next year, she is asked to recommend two physicians for promotion at a leadership meeting. She recommends one white woman and one man who is a person of color. They are both objectively qualified.

According to research, this female division chief is more likely to receive negative professional evaluations on her leadership skills because of the demographics of these recommendations.<sup>1,2</sup> Meanwhile, research shows that the white male chair will have no consequences for promoting the woman of color into her job.

In short, when white men in power enhance workplace diversity, they are not punished for it. But when anyone else does it, other evaluators think that they are less effective managers and thus they are penalized.

## What We Can Do

What are some solutions? Here are two.

First, continue to support the work of those (white) men in power to embrace diversity and inclusion in the workplace. We should con-

## During the ACEP19 Opening General Session,

Dr. Kass will present “Perspectives from Female Physicians on Leadership, the Ascent of Women in Medicine and Women at the Forefront of Change.” She and a host of other speakers will be featured as part of FIX: FemInEm Idea Exchange, a conference-within-a-conference at ACEP19 that will provide a space for sharing the experiences of EM physicians whose voices are not traditionally amplified.

tinue to highlight this and encourage power brokers to continue and expand these efforts. We can engage these men within the “ally, advocate, accomplice” framework that I spoke about at this year’s FemInEM Idea Exchange in New York (#FIX19).

- An ally is someone who is not a target of oppression but still works to end it.
- An advocate is a person who publicly supports a change or policy.
- An accomplice is someone who supports the target of oppression when they are going out on a limb.

Second, we need to educate the health care workforce about the unconscious biases that lead to these promotion penalties. The inappropriate negative consequences for women and people of color for promoting or sponsoring underrepresented demographics must be addressed. Often, once harmful habits and trends are exposed, solutions follow.

Similar to the adage that “you can’t diagnose a disease you’ve never heard of,” you can’t move to address your own unconscious biases if no one has pointed them out.

In an environment in which nonwhite and female leaders are no longer subtly punished for hiring and promoting a more diverse workforce, the path toward equity will be a less steep climb. In the meantime, let’s identify allies, advocates, and accomplices who are so often steering the ship—those who can move things forward—and encourage them to act and celebrate when there are successes.

The equity movement has come a long way. Among those who themselves have not faced barriers of discrimination, we have seen the posture evolve from denial to recognition to a belief that equity matters. The next step is engaging these brokers to fully act on these beliefs so those who still face these barriers are not held back and not punished for helping others as well. By doing this, we will all benefit.

In the end, the equity equation is not just about lifting the oppressed. It’s the sum total of all of our parts, working together to make the professional landscape better than the one we inherited. ☺

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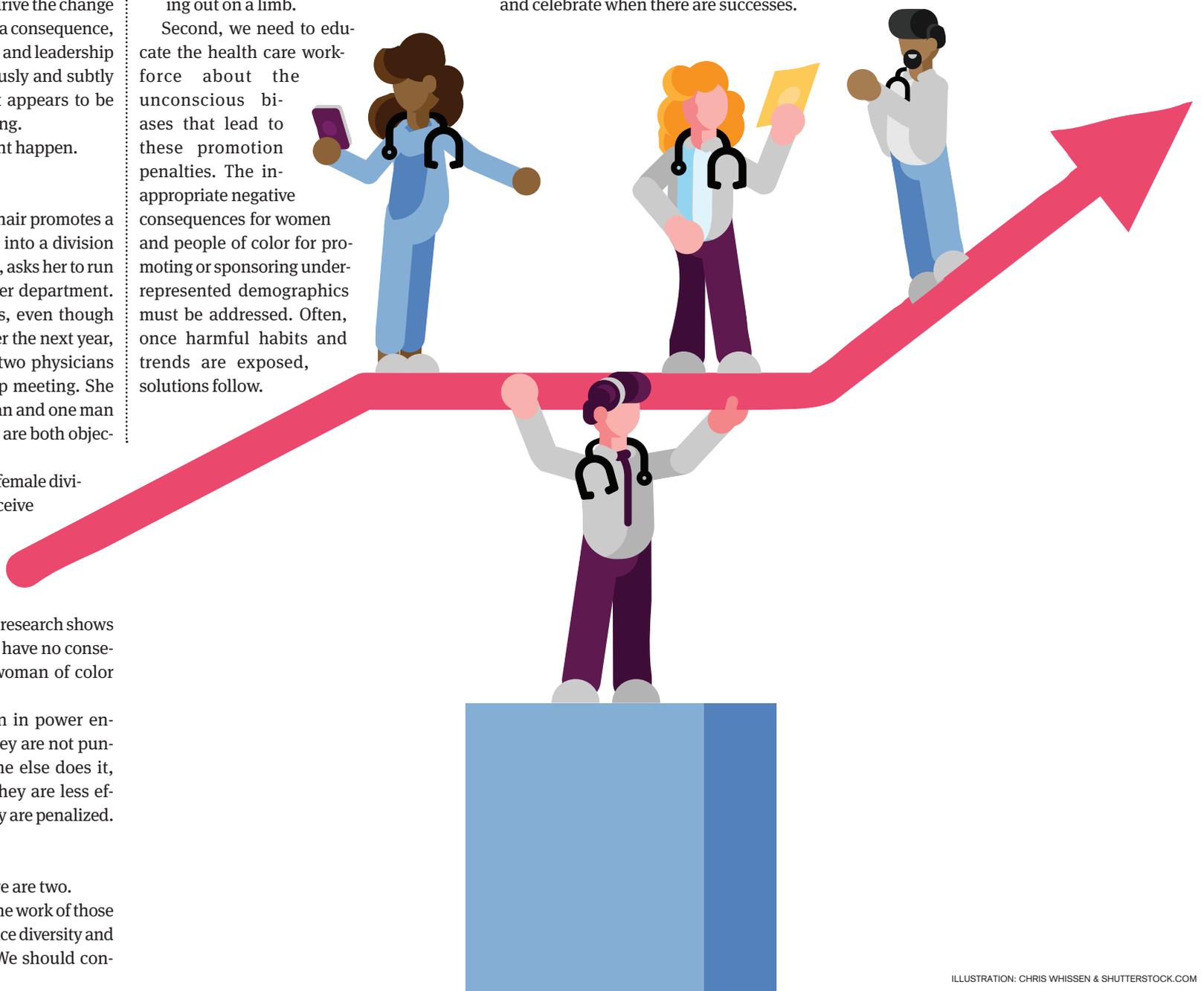


ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

...Patient seems confused...soot around mouth...

YOU SUSPECT YOUR PATIENT HAS  
**CYANIDE POISONING.\***  
TIME MAY BE RUNNING OUT.<sup>1</sup>

SHOULD I TREAT?  
SHOULD I WAIT?  
WHAT ARE THE SIDE EFFECTS?  
ARE THERE RISKS?



Suspect it? Treat with CYANOKIT.

CYANOKIT is approved for the treatment of known or suspected cyanide poisoning. If clinical suspicion of cyanide poisoning is high, administer CYANOKIT without delay.<sup>1</sup>

For more information, visit [CYANOKIT.com](http://CYANOKIT.com).

**CYANOKIT**<sup>®</sup>  
*(hydroxocobalamin for injection)*

\*Prior to administration of CYANOKIT, smoke inhalation victims should be assessed for exposure to fire or smoke in an enclosed area; presence of soot around the mouth, nose, or oropharynx; or altered mental status.<sup>1</sup>

#### IMPORTANT SAFETY INFORMATION

Cyanide poisoning may result from inhalation, ingestion, or dermal exposure. Prior to administration of CYANOKIT, smoke-inhalation victims should be assessed for: exposure to fire or smoke in an enclosed area; presence of soot around the mouth, nose, or oropharynx, and altered mental status. In addition to CYANOKIT, treatment of cyanide poisoning must include immediate attention to airway patency, adequacy of oxygenation and hydration, cardiovascular support, and management of any seizure activity.

Use caution in the management of patients with known anaphylactic reactions to hydroxocobalamin or cyanocobalamin. Consideration should be given to use of alternative therapies, if available. Allergic reactions may include: anaphylaxis, chest tightness, edema, urticaria, pruritus, dyspnea, and rash. Allergic reactions including angioneurotic edema have also been reported in postmarketing experience.

Acute renal failure with acute tubular necrosis, renal impairment and urine calcium oxalate crystals have been reported following CYANOKIT therapy. Monitor renal function for 7 days following CYANOKIT therapy.

Substantial increases in blood pressure may occur following CYANOKIT therapy. Elevations in blood pressure ( $\geq 180$  mmHg systolic or  $\geq 110$  mmHg diastolic) were observed in approximately 18% of healthy subjects receiving hydroxocobalamin 5 g and 28% of subjects receiving 10 g.

Usage may interfere with some clinical laboratory evaluations. Also, because of its deep red color, hydroxocobalamin may cause hemodialysis machines to shut down due to an erroneous detection of a "blood leak." This should be considered before hemodialysis is initiated in patients treated with hydroxocobalamin. Due to potential photosensitivity, patients should avoid direct sun until erythema resolves.

There are no adequate and well-controlled studies of CYANOKIT in pregnant women. CYANOKIT should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Safety and effectiveness of CYANOKIT have not been established in pediatric patients.

The most common adverse reactions ( $>5\%$ ) included transient chromaturia, erythema, oxalate crystals in urine, rash (predominantly acneiform), increased blood pressure, nausea, headache, decreased lymphocyte percentage, and injection site reactions.

Please see Brief Summary of Prescribing Information on adjacent pages.

You are encouraged to report negative side effects of prescription drugs to the US Food and Drug Administration (FDA). Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Reference:** 1. CYANOKIT (single 5-g vial) [package insert]. Columbia, MD: Meridian Medical Technologies, Inc.; 2017.

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**MERIDIAN**  
MEDICAL TECHNOLOGIES  
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# CYANOKIT®

(hydroxocobalamin for injection)

## BRIEF SUMMARY:

Consult full Prescribing Information for complete product information

### Use with Other Cyanide Antidotes

Caution should be exercised when administering other cyanide antidotes simultaneously with Cyanokit, as the safety of co-administration has not been established. If a decision is made to administer another cyanide antidote with Cyanokit, these drugs should not be administered concurrently in the same intravenous line.

### Incompatibility Information

Physical incompatibility (particle formation) and chemical incompatibility were observed with the mixture of hydroxocobalamin in solution with selected drugs that are frequently used in resuscitation efforts. Hydroxocobalamin is also chemically incompatible with sodium thiosulfate and sodium nitrite and has been reported to be incompatible with ascorbic acid. Therefore, these and other drugs should not be administered simultaneously through the same intravenous line as hydroxocobalamin.

Simultaneous administration of hydroxocobalamin and blood products (whole blood, packed red cells, platelet concentrate and/or fresh frozen plasma) through the same intravenous line is not recommended. However, blood products and hydroxocobalamin can be administered simultaneously using separate intravenous lines (preferably on contralateral extremities, if peripheral lines are being used).

## WARNINGS AND PRECAUTIONS

### Emergency Patient Management

In addition to Cyanokit, treatment of cyanide poisoning must include immediate attention to airway patency, adequacy of oxygenation and hydration, cardiovascular support, and management of any seizure activity. Consideration should be given to decontamination measures based on the route of exposure.

### Allergic Reactions

Use caution in the management of patients with known anaphylactic reactions to hydroxocobalamin or cyanocobalamin. Consideration should be given to use of alternative therapies, if available.

Allergic reactions may include: anaphylaxis, chest tightness, edema, urticaria, pruritus, dyspnea, and rash.

Allergic reactions including angioneurotic edema have also been reported in postmarketing experience.

### Renal Disorders

Cases of acute renal failure with acute tubular necrosis, renal impairment and urine calcium oxalate crystals have been reported. In some situations, hemodialysis was required to achieve recovery. Regular monitoring of renal function, including but not limited to blood urea nitrogen (BUN) and serum creatinine, should be performed for 7 days following Cyanokit therapy.

### Blood Pressure Increase

Many patients with cyanide poisoning will be hypotensive; however, elevations in blood pressure have also been observed in known or suspected cyanide poisoning victims.

Elevations in blood pressure (180 mmHg or greater systolic or 110 mmHg or greater diastolic) were observed in approximately 18% of healthy subjects (not exposed to cyanide) receiving hydroxocobalamin 5 g and 28% of subjects receiving 10 g. Increases in blood pressure were noted shortly after the infusions were started; the maximal increase in blood pressure was observed toward the end of the infusion. These elevations were generally transient and returned to baseline levels within 4 hours of dosing.

### Use of Blood Cyanide Assay

While determination of blood cyanide concentration is not required for management of cyanide poisoning and should not delay treatment with Cyanokit, collecting a pretreatment blood sample may be useful for documenting cyanide poisoning as sampling post-Cyanokit use may be inaccurate.

## Interference with Clinical Laboratory Evaluations and Clinical Methods

### Clinical Laboratory Evaluations

Because of its deep red color, hydroxocobalamin has been found to interfere with colorimetric determination of certain laboratory parameters (e.g., clinical chemistry, hematology, coagulation, and urine parameters). *In-vitro* tests indicated that the extent and duration of the interference are dependent on numerous factors such as the dose of hydroxocobalamin, analyte, methodology, analyzer, hydroxocobalamin concentration, and partially on the time between sampling and measurement.

Based on *in-vitro* studies and pharmacokinetic data obtained in healthy volunteers, the following table (Table 2) describes laboratory interference that may be observed following a 5 g dose of hydroxocobalamin. Interference following a 10 g dose can be expected to last up to an additional 24 hours. The extent and duration of interference in cyanide-poisoned patients may differ. Results may vary substantially from one analyzer to another; therefore, caution should be used when reporting and interpreting laboratory results.

**Table 2: Laboratory Interference Observed with *In-Vitro* Samples of Hydroxocobalamin**

LABORATORY PARAMETER			
Clinical Chemistry	Hematology	Coagulation	Urinalysis
<b>No Interference Observed</b>			
Calcium Sodium Potassium Chloride Urea GGT	Erythrocytes Hematocrit MCV Leukocytes Lymphocytes Monocytes Eosinophils Neutrophils Platelets		
<b>Artificially Increased*</b>			
Creatinine Bilirubin Triglycerides Cholesterol Total protein Glucose Albumin Alkaline phosphatase	Hemoglobin MCH MCHC Basophils		pH (with all doses) Glucose Protein Erythrocytes Leukocytes Ketones Bilirubin Urobilinogen Nitrite
<b>Artificially Decreased*</b>			
ALT Amylase			pH (with equivalent doses of <5 g)

Unpredictable			
Phosphate Uric Acid AST CK CKMB LDH		aPTT PT (Quick or INR)	
Duration of Interference			
24 hours with the exception of bilirubin (up to 4 days)	12-16 hours	24-48 hours	48 hours up to 8 days; color changes may persist up to 28 days

\*10% or greater interference observed on at least 1 analyzer

Analyzers used: ACL Futura (Instrumentation Laboratory), AxSYM®/Architect™ (Abbott), BM Coasys<sup>110</sup> (Boehringer Mannheim), CellDyn 3700® (Abbott), Clinitek® 500 (Bayer), Cobas Integra® 700, 400 (Roche), Gen-S Coultronics, Hitachi 917, STA® Compact, Vitros® 950 (Ortho Diagnostics)

### Clinical Methods

Because of its deep red color, hydroxocobalamin may cause hemodialysis machines to shut down due to an erroneous detection of a "blood leak." This should be considered before hemodialysis is initiated in patients treated with hydroxocobalamin.

### Photosensitivity

Hydroxocobalamin absorbs visible light in the UV spectrum. It therefore has potential to cause photosensitivity. While it is not known if the skin redness predisposes to photosensitivity, patients should be advised to avoid direct sun while their skin remains discolored.

## ADVERSE REACTIONS

Serious adverse reactions with hydroxocobalamin include allergic reactions, renal disorders and increases in blood pressure.

### Clinical Studies Experience

Because clinical trials were conducted under widely varying conditions, adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice.

### Experience in Healthy Subjects

A double-blind, randomized, placebo-controlled, single-ascending-dose (2.5, 5, 7.5, and 10 g) study was conducted to assess the safety, tolerability, and pharmacokinetics of hydroxocobalamin in 136 healthy adult subjects. Because of the dark red color of hydroxocobalamin, the two most frequently occurring adverse reactions were chromatemia (red-colored urine) which was reported in all subjects receiving a 5 g dose or greater; and erythema (skin redness), which occurred in most subjects receiving a 5 g dose or greater. Adverse reactions reported in at least 5% of the 5 g dose group and corresponding rates in the 10 g and placebo groups are shown in Table 3.

**Table 3: Incidence of Adverse Reactions Occurring in >5% of Subjects in 5 g Dose Group and Corresponding Incidence in 10 g Dose Group and Placebo**

ADR	5 g Dose Group		10 g Dose Group	
	Hydroxocobalamin N=66 n (%)	Placebo N=22 n (%)	Hydroxocobalamin N=18 n (%)	Placebo N=6 n (%)
Chromaturia (red colored urine)	66 (100)	0	18 (100)	0
Erythema	62 (94)	0	18 (100)	0
Oxalate crystals in urine	40 (61)	1 (4)	10 (56)	0
Rash*	13 (20)	0	8 (44)	0
Blood pressure increased	12 (18)	0	5 (28)	0
Nausea	4 (6)	1 (5)	2 (11)	0
Headache	4 (6)	1 (5)	6 (33)	0
Lymphocyte percent decreased	5 (8)	0	3 (17)	0
Infusion site reaction	4 (6)	0	7 (39)	0

\*Rashes were predominantly acneiform

In this study, the following adverse reactions were reported to have occurred in a dose-dependent fashion and with greater frequency than observed in placebo-treated cohorts: increased blood pressure (particularly diastolic blood pressure), rash, nausea, headache and infusion site reactions. All were mild to moderate in severity and resolved spontaneously when the infusion was terminated or with standard supportive therapies.

Other adverse reactions reported in this study and considered clinically relevant were:

- *Eye disorders:* swelling, irritation, redness
- *Gastrointestinal disorders:* dysphagia, abdominal discomfort, vomiting, diarrhea, dyspepsia, hematochezia
- *General disorders and administration site conditions:* peripheral edema, chest discomfort
- *Immune system disorders:* allergic reaction
- *Nervous system disorders:* memory impairment, dizziness
- *Psychiatric disorders:* restlessness
- *Respiratory, thoracic and mediastinal disorders:* dyspnea, throat tightness, dry throat
- *Skin and subcutaneous tissue disorders:* urticaria, pruritus
- *Vascular disorders:* hot flush

### Experience in Known or Suspected Cyanide Poisoning Victims

Four open-label, uncontrolled, clinical studies (one of which was prospective and three of which were retrospective) were conducted in known or suspected cyanide-poisoning victims. A total of 245 patients received hydroxocobalamin treatment in these studies. Systematic collection of adverse events was not done in all of these studies and interpretation of causality is limited due to the lack of a control group and due to circumstances of administration (e.g., use in fire victims). Adverse reactions reported in these studies listed by system organ class included:

- *Cardiac disorders*: ventricular extrasystoles
- *Investigations*: electrocardiogram repolarization abnormality, heart rate increased
- *Respiratory, thoracic, and mediastinal disorders*: pleural effusion

Adverse reactions common to both the studies in known or suspected cyanide poisoning victims and the study in healthy volunteers are listed in the healthy volunteer section only and are not duplicated in this list.

### Postapproval Experience

The following adverse reactions have been identified during postapproval use of Cyanokit. Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.

Cases of acute renal failure with acute tubular necrosis, renal impairment and urine calcium oxalate crystals have been reported in patients treated with Cyanokit.

### DRUG INTERACTIONS

No formal drug interaction studies have been conducted with Cyanokit.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

Pregnancy Category C. There are no adequate and well controlled studies of Cyanokit in pregnant women. In animal studies, hydroxocobalamin caused skeletal and visceral (soft tissue) abnormalities at exposures (based on AUC) similar to human exposures at the therapeutic dose. Cyanokit should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because cyanide readily crosses the placenta, maternal cyanide poisoning results in fetal cyanide poisoning. Timely treatment of the pregnant mother may be lifesaving for both mother and fetus.

In animal studies, pregnant rats and rabbits received Cyanokit (75, 150, or 300 mg/kg/d) during the period of organogenesis. Following intraperitoneal dosing in rats and intravenous dosing in rabbits, maternal exposures were equivalent to 0.5, 1, or 2 times the human exposure at the therapeutic dose (based on AUC). In the high dose groups for both species, maternal toxicity occurred, and there was a reduced number of live fetuses due to embryofetal resorptions. In addition, decreased live fetal weight occurred in high dose rats, but not in rabbits. Incomplete skeletal ossification occurred in both rats and rabbits. In rats, two fetuses of the high dose group and two fetuses of the mid dose group (each from a different litter) had short, rudimentary or small front or hind legs. Rabbit litters and fetuses exhibited a dose dependent increase in various gross soft tissue and skeletal anomalies. The main findings in rabbits were flexed, rigid flexor or medially rotated forelimbs or hindlimbs and domed heads at external examination; enlarged anterior or posterior fontanelles of the ventricles of the brain and flat, bowed or large ribs at skeletal examination; and dilated ventricles of the brain, and thick wall of the stomach at visceral examination.

#### Labor and Delivery

The effect of Cyanokit on labor and delivery is unknown.

#### Nursing Mothers

It is not known whether hydroxocobalamin is excreted in human milk. Cyanokit may be administered in life-threatening situations, and therefore, breast-feeding is not a contraindication to its use. Because of the unknown potential for adverse reactions in nursing infants, the patient should discontinue nursing after receiving Cyanokit.

#### Pediatric Use

Safety and effectiveness of Cyanokit have not been established in this population. In non-US marketing experience, a dose of 70 mg/kg has been used to treat pediatric patients.

#### Geriatric Use

Approximately 50 known or suspected cyanide poisoning victims aged 65 or older received hydroxocobalamin in clinical studies. In general, the safety and effectiveness of hydroxocobalamin in these patients was similar to that of younger patients. No adjustment of dose is required in elderly patients.

#### Renal Impairment

The safety and effectiveness of Cyanokit have not been studied in patients with renal impairment. Hydroxocobalamin and cyanocobalamin are eliminated unchanged by the kidneys.

#### Hepatic Impairment

The safety and effectiveness of Cyanokit have not been studied in patients with hepatic impairment.

### OVERDOSAGE

No data are available about overdose with Cyanokit in adults. Should overdose occur, treatment should be directed to the management of symptoms. Hemodialysis may be effective in such a circumstance, but is only indicated in the event of significant hydroxocobalamin-related toxicity. Because of its deep red color, hydroxocobalamin may interfere with the performance of hemodialysis machines.

### NONCLINICAL TOXICOLOGY

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of hydroxocobalamin. Hydroxocobalamin was negative in the following mutagenicity assays: *in-vitro* bacterial reverse mutation assay using *Salmonella typhimurium* and *Escherichia coli* strains, an *in-vitro* assay of the tk locus in mouse lymphoma cells, and an *in-vivo* rat micronucleus assay.

The effect of hydroxocobalamin on fertility has not been evaluated.

### PATIENT COUNSELING INFORMATION

Cyanokit is indicated for cyanide poisoning and in this setting, patients will likely be unresponsive or may have difficulty in comprehending counseling information.

#### Erythema and Chromaturia

Patients should be advised that skin redness may last up to 2 weeks and urine coloration may last for up to 5 weeks after administration of Cyanokit. While it is not known if the skin redness predisposes to photosensitivity, patients should be advised to avoid direct sun while their skin remains discolored.

#### Rash

In some patients, an acneiform rash may appear anywhere from 7 to 28 days following hydroxocobalamin treatment. This rash will usually resolve without treatment within a few weeks.

#### Renal Disorders

Patients should be advised that renal function will be monitored for 7 days following treatment with Cyanokit or, in the event of renal impairment, until renal function returns to normal.

#### Pregnancy and Breast-feeding

Patients should be advised that maternal cyanide poisoning results in fetal cyanide poisoning. Treatment for cyanide poisoning may be lifesaving for both mother and fetus. Patients should notify their physician if they were pregnant during therapy with Cyanokit. It is not known whether hydroxocobalamin is excreted in human milk.

This brief summary is based on CYANOKIT® (hydroxocobalamin for injection) Prescribing Information Version 180\_US\_20171\_NO, Issued: June 2017. For current package insert and further product information, please visit [www.cyanokit.com](http://www.cyanokit.com) or call Pfizer Medical Information toll-free at 1-800-438-1985.

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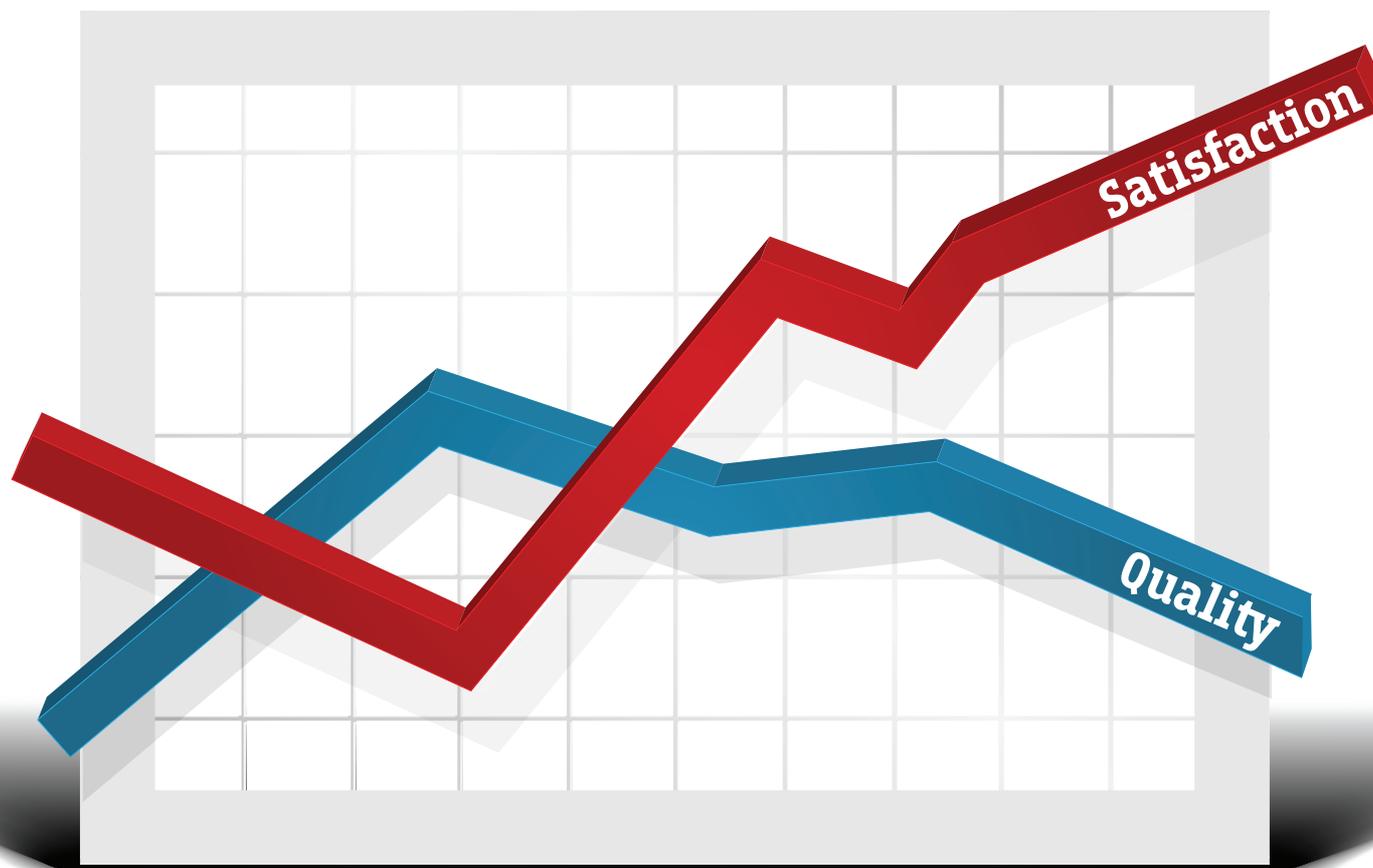
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**DR. DARK** is assistant professor of emergency medicine at Baylor College of Medicine in Houston and executive editor of PolicyRx.org.



## EMRA+POLICYRx HEALTH POLICY JOURNAL CLUB

### How Did Your Last Patient Rate You on Yelp?

by KIRSTIN WOODY SCOTT, MPHIL, PHD

Researchers recently leveraged Yelp ratings to provide a general idea of how satisfied patients are with the care they receive in emergency departments and urgent care centers (UCCs).<sup>1</sup> There were three key takeaways. First, people are indeed using Yelp as a way to comment on their experiences in these settings; there were more than 100,000 ratings across both settings between 2005 and 2017. Second, similar to all Yelp business reviews, ratings for both emergency departments and UCCs follow a bimodal pattern, ie, spikes in both 1-star (worst) and 5-star (best) ratings. UCCs had overall higher ratings than emergency departments (47 percent of users gave emergency departments 1-star ratings versus 30 percent for UCCs), and only 27 percent of users gave 5-star ratings to emergency departments (versus 51 percent for UCCs). Third, themes that emerged from the comments can inform what aspects of care correlate with high versus low ratings (eg, good bedside manner was associated with 5-star ratings).

To make sense of all the comments, researchers employed natural language processing tools to focus on the comments in the extreme ratings (1-star and 5-star), then used differential language analysis to match up the topics that were correlated with low and high ratings. For the emergency departments, topics related to quality of care were more likely to be correlated with high ratings whereas comments on service were more likely to be correlated with low ratings. The opposite was true for UCCs.

The authors rightfully acknowledge that Yelp can be easily dismissed as a data source since it is unverifiable and unstructured and cannot be considered to be truly representative of all patients. However, Yelp offers rich, narrative data and serves as a platform that allows people to share reflections in real time, unlike publicly inaccessible proprietary data sources such as Press Ganey.

Despite of these limitations, tens of thousands of people feel compelled to share their thoughts through online platforms, and as researchers and clinicians, we should figure out how to best listen and learn from these raw reflections. Further, in an era where patient satisfaction is increasingly considered an important quality measure (despite its perhaps surprising inverse relationship with actual quality of care), it will become important to more effectively analyze all data points—regardless of the source—to inform how we can better care for patients. ⚡

**DR. SCOTT** is a medical student at Harvard Medical School in Boston.

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# “Long Wait, Poor Service—1 Star”

Even if patient reviews don't correlate with quality care, it's unwise to ignore them

by CEDRIC DARK, MD, MPH

In response to a 2016 article exploring the themes common among Yelp reviews of emergency department visits, critics noted that “satisfaction correlates only weakly with quality.”<sup>1</sup> In fact, a 2012 study linked positive patient satisfaction with increased mortality—a dreadful outcome that suggests patient satisfaction itself is not necessarily a patient-centered outcome.<sup>2</sup> And while many physicians remain dissatisfied with the comments and scores left by patients on physician-rating sites, executives realize that these reviews might work to drive traffic toward or away from hospitals.

Multiple studies have discovered the key correlates of patient satisfaction: empathy, wait times, perceived technical skill, pain management, and communication.<sup>3,4</sup>

In this month's EMRA+PolicyRx Health Policy Journal Club article, Kirstin Woody Scott, MPhil, PhD, discusses a 2019 article that explored the use of Yelp reviews in comparing the patient experience in emergency departments versus urgent care centers. Spoiler alert: When patients reference the “service” received, we in the emergency department tend to lose.

It pains me to admit that hospitals need to behave more like Disneyland or the Cheesecake Factory, but there must be a reason

people keep going back to these places. So what is it that leads some organizations to create an indelible positive memory on their customers while the service we provide often yields negative thoughts?

After four years of medical school and several more years of residency training to perfect our craft, some physicians might consider it insulting that we have to cater to the whims and service expectations of our patients instead of simply providing high-quality care. For others, this has become demoralizing.<sup>5</sup> While board certification assures us that the scientific portion of our work is sound, our patients penalize us most when we fail at delivering the more subjective art of medicine.

The art of medicine, like beauty, is in the eye of the beholder. Each patient might want something different—having a great bedside manner, connecting with the patient and all of their companions in the exam room, managing expectations. With each patient encounter, we must create both a technical and aesthetic masterpiece. ⚡

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TIPS FOR BETTER PERFORMANCE

# SPECIAL OPS



**DR. WELCH** is a practicing emergency physician with Utah Emergency Physicians and a research fellow at the Intermountain Institute for Health Care Delivery Research. She has written numerous articles and three books on ED quality, safety, and efficiency. She is a consultant with Quality Matters Consulting, and her expertise is in ED operations.

Figure 1: Key Elements of UHS's Power Through! Plan



Figure 2: Sample Swim Lane Diagram of the Discharge Process

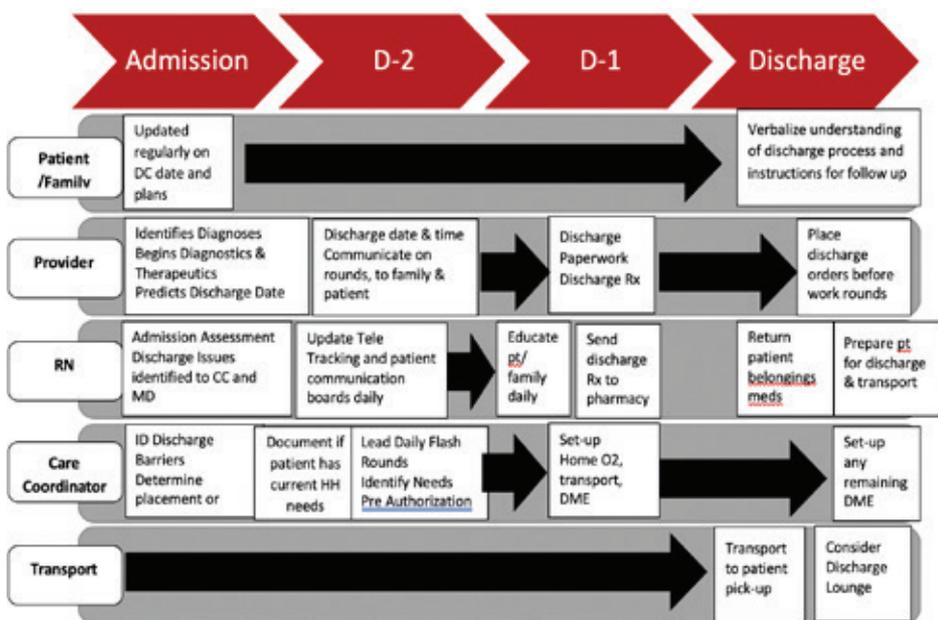
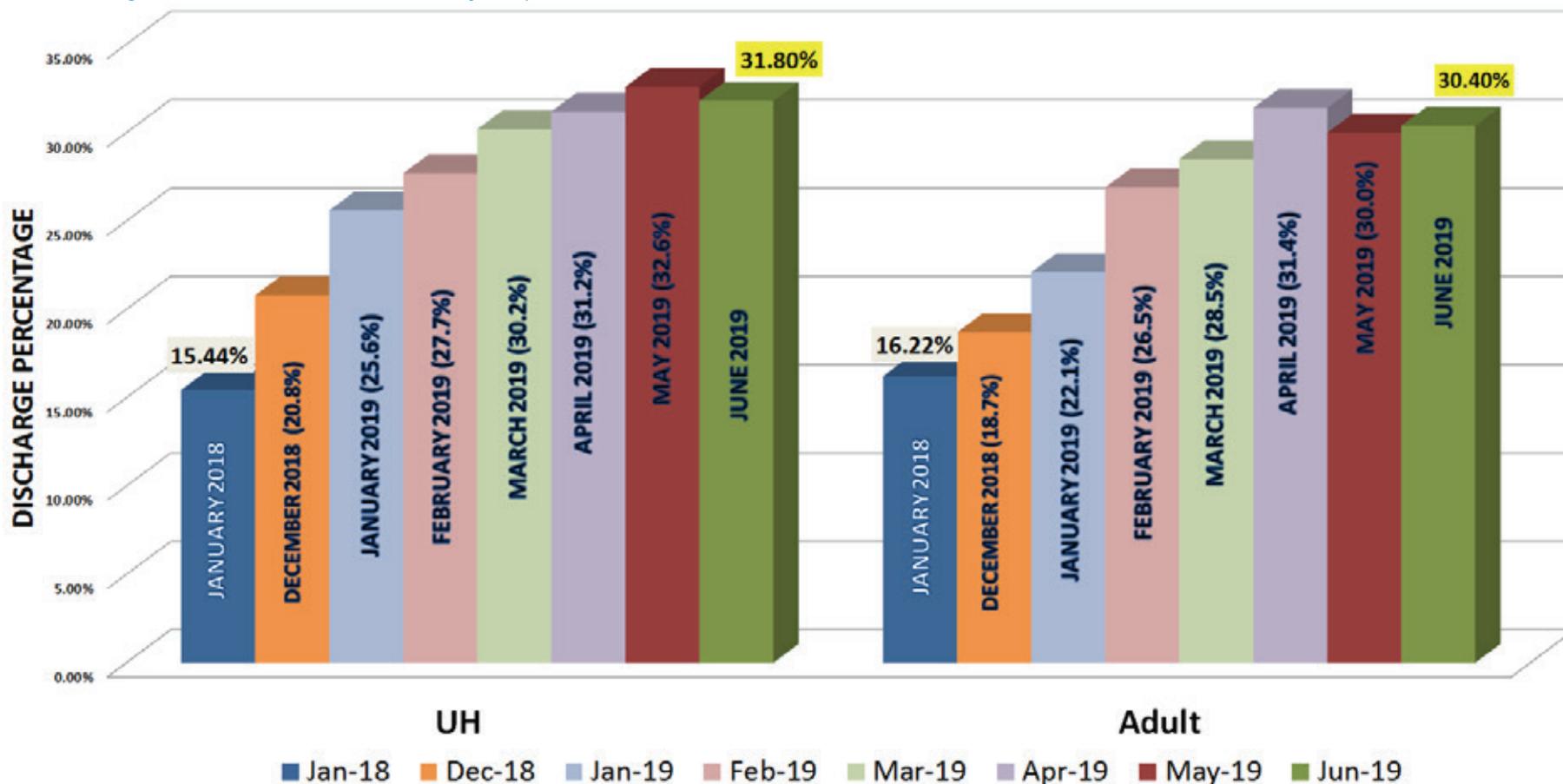


Figure 3: Discharge Before Noon Trends for University Hospital and Its Adult Services Unit



# The “Power Through!” Project

Beating boarding in San Antonio

by SHARI WELCH, MD, FACEP

It is well-recognized that delays in inpatient discharges result in ED boarding of admitted patients. Boarding has a negative impact on ED performance, clinical outcomes, and mortality. Improving the admissions process and decreasing the time patients spend in the emergency department after the decision has been made to admit have a downstream effect on decreasing inpatient length of stay (LOS). Like boarding, discharge delays are associated with increased mortality and adverse events.

The University Hospital (UHS) in the University of Texas-San Antonio health system had conducted a comprehensive ED improvement project, which dramatically improved door-to-doctor (D2D) times and LOS. Walkaways were reduced, and patient satisfaction soared as the timeliness of care was improved. Then the ED leaders—Andrew Muck, MD, and Steven Moore, MD—turned to the hospital for relief from high boarding levels. Their message was simple and powerful: “We fixed our house. Now can you help

us with boarding?”

On the heels of the success in the emergency department, hospital leadership responded to this request favorably. They set out to increase inpatient capacity by improving discharge by noon (DBN). Note that DBN is measured as the percent of discharged patients out of beds by noon, not merely those who have a discharge order. Most hospitals experience discharge delays because discharge processes have become complex, are poorly articulated, and are not well synchronized. Things that must happen before a patient goes home often occur in a random fashion, and task roles are unclear. This frequently results in patients leaving the hospital later in the day, long after the ED demand for inpatient beds has risen. This, above all, causes boarding.

Communication around discharge is also haphazard. Common barriers to early discharge include transportation, physical therapy, follow-up appointments, durable

CONTINUED on page 44

medical equipment, medications, and education. Coordinating all of these elements understandably proves challenging on the inpatient side.

**Cooperation and Coordination**

The improvement initiative at UHS (dubbed “Power Through!”) focused on the discharge process itself, with a goal of increasing DBN *without* increasing LOS. The team began in the fall of 2018 with a kickoff lecture by Katherine Hochman, MD, of New York University Medical Center in New York City, who has published her successful work. She was able to alleviate boarding by increasing early discharges from the inpatient hospitalist units. UHS asked each unit and service to address the process of discharge on their units, the communication around discharges, and tools necessary to facilitate that discharge (see Figure 1). A key element in Dr. Hochman’s work and the work at UHS was “discharge rounding”—the implementation of brief discharge-focused rounds that coordinate the discharge of a patient a day or two in advance of an anticipated discharge. Getting ahead of the discharge process and communicating about the discharge to all stakeholders were critical to the project’s success.

Rollout of this program included a retreat that helped to articulate unit level discharge processes, discharge communication, discharge rounds, and tools to support the work.

Figure 4: Trends in Discharge by Noon in the Adult Services Unit

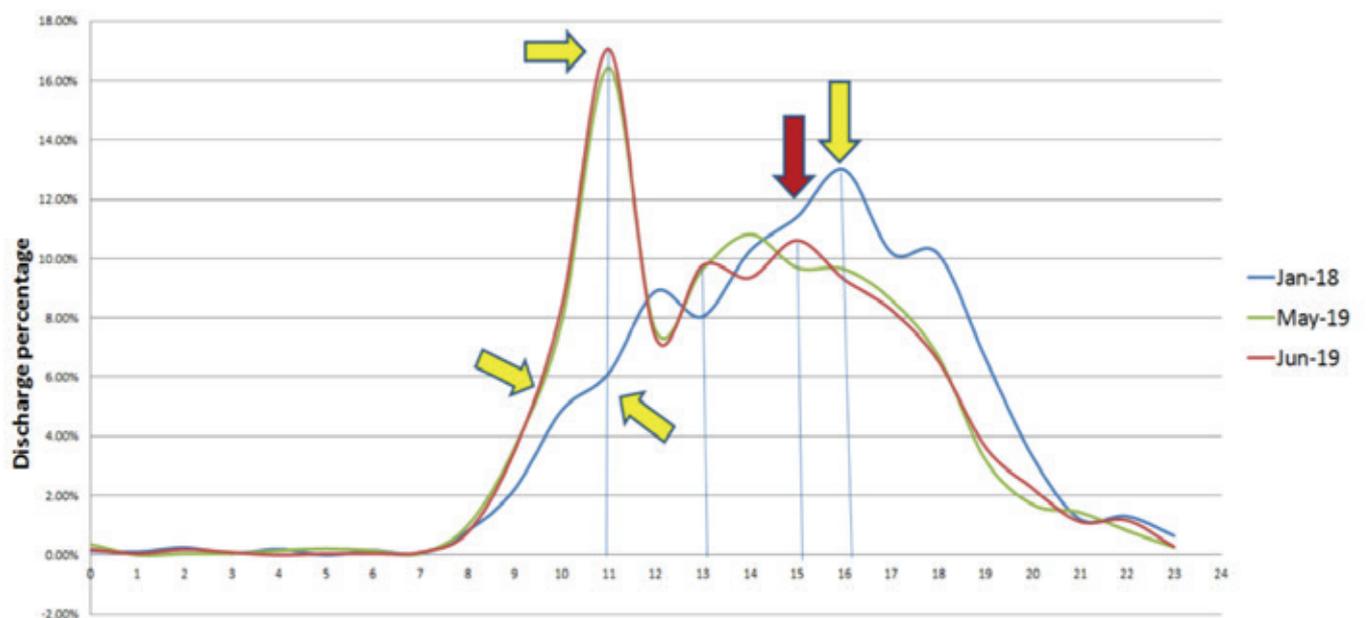


Figure 2 is a sample swim lane diagram articulating the discharge process on a typical unit.

**The Results**

The hospital at-large and the adult services unit performed particularly well (see Figure 3). This project was driven by nursing leaders Nelson Tuazon, assistant chief nursing officer, and Missam Merchant, director of the central operations management group. Note the dra-

matic increase in early discharges.

The effect of early inpatient discharge on ED boarding is impressive (see Figure 4). By initiating discharge momentum earlier, beds opened up for ED admissions, which begin late in the morning and continue throughout the day.

At UHS, boarding had been difficult to manage. The increased DBN project had an immediate effect. This nursing-led inpatient project had the support of the dean, the med-

ical school chairs, and the hospital leaders. With everyone aligned with the mission, they recovered wasted capacity without spending a penny on new inpatient rooms. The hospital has improved on its boarding problem so effectively that the emergency department has consistently avoided diversion for the past six months.

The take-home message is there are boarding solutions out there if your hospital is willing to Power Through! ☺

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**Caveats**

However, it should be clearly recognized these trials and publications are produced in their entirety by the sponsor, Nabriva Therapeutics. The vast majority of authors are either employees of, consultants for, or members of the board of directors for Nabriva. There are clear professional and corporate financial interests tied to conducting the ideal trial leading to approval and to presenting these data in the best possible light. These biases do not imply misconduct nor misleading factual presentation, but they may limit generalizability of the effectiveness and safety profile to real-world use.

Regardless, lefamulin is likely to become an important antibiotic option in human medicine. Its long, effective use in veterinary medicine supports the findings observed in these trials. As with any new antibiotic, stewardship will be critical. While the trade magazine advertisements for Xenleta are likely to surge, our prescribing should not follow suit. The narrow eligibility of these trials, the drug’s use in low-acuity patients, the relative paucity of safety information, and, of course,

the drug’s increased cost compared with current generic options all reduce its appropriateness. Antibiotics such as this, with unique mechanisms of action, should be held in

reserve for cases in which established resistance limits alternative options. These data portend a welcome advance in our treatment options for otherwise challenging infections but are best restricted to such narrow indications.

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

Lefamulin is likely to become an important antibiotic option in human medicine. ... As with any new antibiotic, stewardship will be critical.

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# CODING WIZARD



NAVIGATE THE  
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YOUR  
REIMBURSEMENT

**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.

## CODING FOR NON-PHYSICIAN PROVIDERS

by JASON ADLER, MD, FACEP

### Question: How can we maximize reimbursement for services provided by advanced practice providers?

"Non-physician provider" (NPP), a term used by Medicare, and "advanced practice provider" (APP) refer to both physician assistants (PAs) and nurse practitioners (NPs). APPs, growing in numbers in the ED space, represent a significant percentage of the labor pool.

The documentation guidelines for the supervision of APPs and reimbursement levels vary by payer and service provided. For Medicare and many Medicaid evaluation and management (E/M) codes, a physician signature alone will result in payment of 85 percent of the physician's

rate. Alternatively, a properly documented split-shared visit should increase the reimbursement to 100 percent of the physician's rate. Proper documentation requires the physician to indicate face-to-face (direct supervision) interaction.

Check with your local payers for APP supervision requirements. Some payers require the supervising physician to document at least one element of the history of present illness, examination, or medical decision making. For other private payers, a cosignature alone may be sufficient to support APP supervision and payment at the physician's rate.

Procedures performed by the APP are typically billed under the APP National Provider Identifier and cannot be shared. Critical care may be billed under the APP as long as the APP satisfies the time and medical necessity requirements. Critical care cannot be a split-shared visit. Combining physician and APP time to meet the 30-minute threshold is not valid.

For more information, check out the FAQ at [www.acep.org/administration/reimbursement/reimbursement-faqs/advanced-practice-provider-faq](http://www.acep.org/administration/reimbursement/reimbursement-faqs/advanced-practice-provider-faq).

**Brought to you by the ACEP Coding and Nomenclature Committee.**

**DR. ADLER** is vice president of practice improvement at Brault in San Dimas, California, and clinical assistant professor of emergency medicine at the University of Maryland School of Medicine in Baltimore.

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This is currently an area of active investigation about which little is known for certain. Here's what we do know.

**Quick Tips: Diagnosis and Treatment**

Available evidence suggests that the predominant form of lung injury is lipoid pneumonia. This may relate largely to the vaping of tetrahydrocannabinol (marijuana-like) products, which are diluted using vitamin E acetate. However, not all patients report a

history of vaping with tetrahydrocannabinol, so other products may be involved as well.

The clinical presentation of VAPI usually begins gradually over several days with gastrointestinal and pulmonary symptoms. Early on, patients may appear to have a viral gastroenteritis or mild pneumonia. Eventually hypoxemic respiratory compromise worsens, with the development of bilateral pulmonary infiltrates. Additional symptoms may include fever, chest pain, and weight loss. CT scans typically show bilateral diffuse ground-glass

opacification. Steroid administration may be associated with clinical improvement, although this remains unproven and speculative. Severity is variable, with some patients requiring intubation or even extracorporeal membrane oxygenation.

The optimal approach to investigation and treatment of this disorder remains unknown. Evaluation is primarily driven toward exclusion of alternative likely possibilities (especially various types of infectious pneumonia). Whether every patient requires a

bronchoscopy is debatable. For critically ill patients at risk of deterioration, the safest approach could be to provide empiric therapy for both pneumonia and VAPI (current approaches are a combination of antibiotics and a steroid).

This is a rapidly evolving topic, and approaches are likely to evolve even as this goes to print. The most important aspect is to be aware that VAPI exists. This awareness should prompt us to take a detailed vaping

CONTINUED on page 54

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The Department of Emergency Medicine at Baylor College of Medicine, a top medical school, is located in the world's largest medical center, in Houston, Texas. The Baylor Emergency Medicine Residency was established in 2010, and we recently received department status in January 2017. Ultrasound specific educational programs exist for our residency (14 residents per year in a 3-year format), ultrasound fellowship, physician assistant fellowship and UME programs. We offer a highly competitive academic salary and benefits commensurate to academic level and experience.

Our academic program is based out of Ben Taub General Hospital and Baylor St. Luke's Medical Center. Ben Taub General Hospital is the largest Level 1 trauma center in southeast Texas with certified stroke and STEMI programs that sees nearly 100,000 emergency visits per year. Baylor St. Luke's Medical Center is home to the Texas Heart Institute and, with freestanding Baylor St. Luke's Emergency Centers, offers multiple additional practice sites for Baylor faculty. BCM has a collaborative affiliation with eight world-class hospitals and clinics in the Texas Medical Center. These affiliations, along with the medical school's preeminence in education and research, help to create one of the strongest emergency medicine experiences in the country. Those interested in a position or further information may contact Dr. Jennifer Carnell via email [carnell@bcm.edu](mailto:carnell@bcm.edu) or by phone at 713-873-7045. Please send a CV and cover letter with your past experience and interests.

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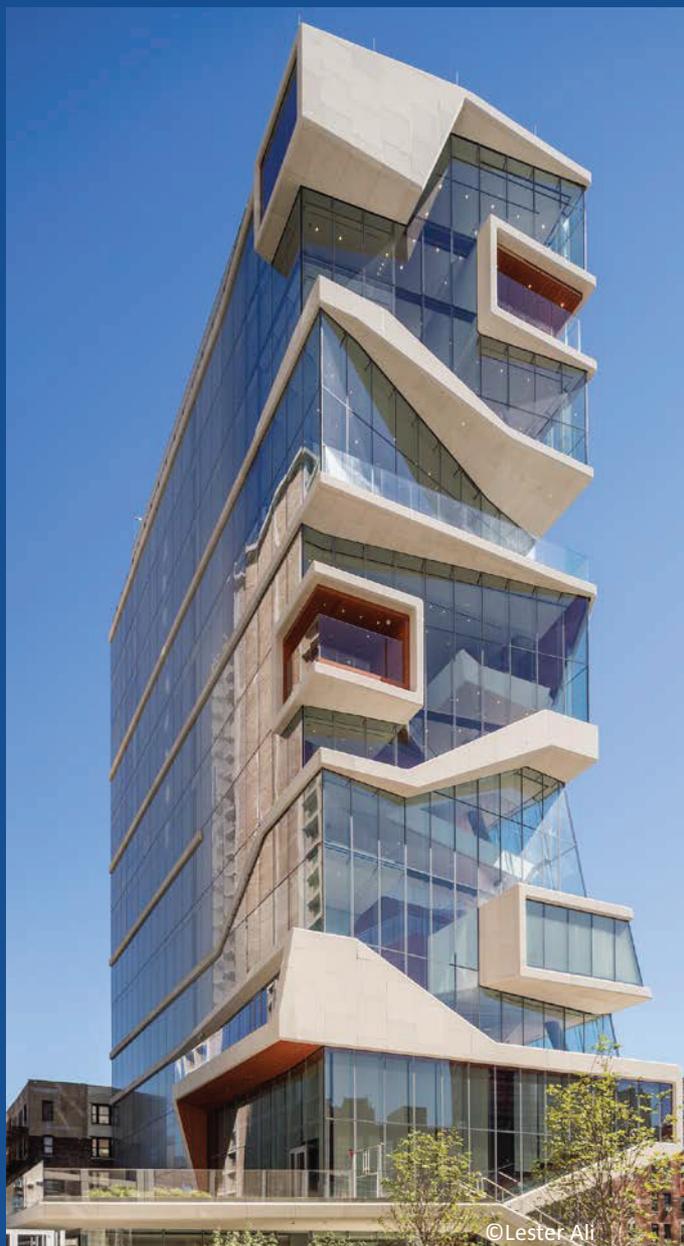
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The Henry JN Taub Department of Emergency Medicine was established in 2017. Baylor College of Medicine is a top medical school located in the world's largest medical center in Houston, Texas. The Baylor Emergency Medicine Residency was established in 2010, and our residency program has grown to 14 residents per year in a 3-year format. We offer a highly competitive academic salary and benefits commensurate to academic level and experience.

Our academic program is based out of Ben Taub Hospital and Baylor St. Luke's Medical Center. Ben Taub Hospital is a Level 1 trauma center with certified stroke and STEMI programs that sees nearly 90,000 emergency visits per year. Baylor St. Luke's Medical Center is home to the Texas Heart Institute and with freestanding Baylor St. Luke's Emergency Centers offers multiple additional practice sites for Baylor faculty. BCM has a collaborative affiliation with eight world-class hospitals and clinics in the Texas Medical Center. These affiliations, along with the medical school's preeminence in education and research, help to create one of the strongest clinical experiences in the country.

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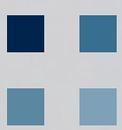
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history among patients with respiratory or gastrointestinal symptoms, especially in otherwise healthy patients not expected to develop acute respiratory illnesses. In suspected cases, specialty consultation may be advisable (most often pulmonology), and local health departments should be notified as they can provide updated clinical guidance and assist in tracking cases.

**The Devil We Don't Know**

Vaping's popularity has been, in part, driven by the medical community, which has viewed the habit as a safer alternative to smoking cigarettes. Unfortunately, the use of vaping as a smoking cessation strategy is scientifically a bit dodgy. Our understanding of the toxicity of cigarettes emerged very slowly. This toxicity wasn't recognized for decades, until long-term epidemiological evidence implicated smoking in lung cancer. Since vaping hasn't been around that long, it's simply impossible to know what its long-term effects will be. Thus, it's impossible to be sure that the long-term effects of vaping will be less severe than those of smoking. Nonetheless, passion to eliminate smoking has promoted this transition away from the devil we know toward a devil we don't yet understand.

Once commercialized, vaping has rapidly expanded to new markets. Companies have aggressively promoted vaping to adolescents, using advertisement campaigns on Instagram and products of various flavors, including fruit and candy flavors. Consequently, vaping has become common among adolescents, who have been led to believe that vaping is a safer alternative to smoking. Currently, more than a third of high school seniors report some use of vaping.

**Trouble Brewing**

The gastrointestinal tract has evolved to take in widely heterogeneous material, absorb nutrients, and excrete the remainder. Overall, the gut is astonishingly successful at coping with foreign materials while remaining healthy. In comparison, the lungs are not well-designed to deal with foreign material. Vaping exposes the lungs to a dizzying array of chemicals (some of which are known to cause lung disease). This is a recipe for potential disaster.

About a dozen case reports over the last several years have described various forms of lung disease that may result from vaping. The most fulminant form is acute eosinophilic pneumonia, a form of respiratory failure, which may also be caused by smoking cigarettes. Other forms of lung disease associated with vaping include lipoid pneumonia and cryptogenic organizing pneumonia. These are more gradual but may nonetheless progress to ventilator-dependent respiratory failure. To simplify matters, these various forms of VAPI share similar features—they cause bilateral pulmonary infiltrates, which generally respond to steroids.

Despite some early signals of harm, most practitioners have remained blissfully unaware of vaping risks, so it is not a part of medical culture to think about it. Vaping wasn't taught to us as something to ask about during a medical history the way other substance use was. It's possible that some cases of VAPI weren't diagnosed simply because we didn't know enough to ask about it.

**MORE ONLINE**



More information is available at the **Centers for Disease Control and Prevention website** ([www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](http://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)) and at the **Internet Book of Critical Care** (<https://emcrit.org/ibcc/vaping-associated-pulmonary-injury>).

**Public Health Considerations**

The current epidemic has cast a harsh light on the lack of regulation of vaping products.

Vaping is now a billion-dollar industry in the United States and may already be influenced by substantial political contributions. The U.S.

Food and Drug Administration (FDA) was given authority to oversee vaping in 2016. However, companies have been given until 2022 before they must submit products for review. Overall, the industry has remained largely unregulated.

Vaping itself may turn out to be safer than smoking, as it takes oncogenic tobacco and smoke out of the equation. In fact, the current epidemic of VAPI most likely relates to adulterants (eg, vitamin E acetate), which, once discovered and banned from e-cigarettes, will likely render VAPI a rare entity. However, this outbreak is doubtless facilitated by the

**Indication and Usage**

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

Limitations of Use

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

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

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

**Important Safety Information**

**For infiltration and intramuscular use only.**

Severe hypersensitivity reactions may occur with HYPERRAB. Patients with a history of prior systemic allergic reactions to human immunoglobulin preparations are at a greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available for treatment of acute allergic symptoms, should they occur.

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

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

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

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

**Please see brief summary of Prescribing Information on adjacent page or visit [HyperRAB.com](http://HyperRAB.com) for full Prescribing Information.**



use of vaping products that are designed to be modifiable. And so one of e-cigarettes' appeals—the diversity in product it can deliver—may be a setup for other hazards we have yet to discover.

Given a lack of regulation from the federal government, some local governments have stepped in. Gov. Gretchen Whitmer recently outlawed the sale of flavored electronic cigarettes in Michigan (see “Vaping & Public Health Policy” sidebar). This announcement was lauded by officials from the American Heart Association and the American Thoracic Society. In Vermont, a state law was recently passed increasing the age required to buy e-cigarettes to 21.

### Harm Avoidance

Aside from identifying patients with VAPI, we can begin to educate patients about the potential harms from vaping. If patients are unwilling or unable to abstain from vaping, they should avoid using adulterated vaping liquid or products containing tetrahydrocannabinol. For patients seeking to stop smoking, vaping should not be viewed as an aid; cessation strategies that have definitively been proven to be less dangerous should be tried first. 🍎

**DR. FARKAS** is assistant professor of pulmonary and critical care medicine at the University of Vermont in Burlington.

# Vaping and Public Health Policy

In early September, Michigan became the first state to ban the sale of e-cigarette products under emergency rules ordered by Gov. Gretchen Whitmer. Early news reports indicated the directive could spark legal challenges but would be implemented under a “finding of emergency” issued by the Michigan Department of Health and Human Services on Aug. 30.

The vaping issue is one of many public

health concerns being tackled by emergency physicians who hold influential roles, including Joneigh Khaldun, MD, FACEP, chief deputy director for health for Michigan. Dr. Khaldun will be talking about her role as one of panelists for the ACEP19 Opening General Session at 8 a.m. on Oct. 27 in Denver. Learn more about the session at [www.acep.org/acep19/experience/opening-general-session](http://www.acep.org/acep19/experience/opening-general-session). 🍎

## HyperRAB<sup>®</sup> Rabies Immune Globulin (Human)

### HIGHLIGHTS OF PRESCRIBING INFORMATION

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

#### INDICATIONS AND USAGE

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

#### Limitations of Use:

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

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

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

#### DOSAGE AND ADMINISTRATION

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

Postexposure prophylaxis, along with rabies vaccine, after suspected exposure to rabies	HYPERRAB 20 IU/kg body weight OR 0.0665 mL/kg body weight Single dose	<ul style="list-style-type: none"> <li>Administer as soon as possible after exposure, preferably at the time of the first rabies vaccine dose.</li> <li>Infiltrate the full dose of HYPERRAB thoroughly in the area around and into the wound(s), if anatomically feasible.</li> <li>Inject the remainder, if any, intramuscularly.</li> </ul>
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#### DOSAGE FORMS AND STRENGTHS

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

#### CONTRAINDICATIONS

None.

#### WARNINGS AND PRECAUTIONS

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

#### ADVERSE REACTIONS

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

**To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

#### DRUG INTERACTIONS

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

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Please see Important Safety Information and brief summary of Prescribing Information for HyperRAB on adjacent pages, or visit [www.HyperRAB.com](http://www.HyperRAB.com) for full Prescribing Information.

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

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

**GRIFOLS**

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**HyperRAB<sup>®</sup>**

Rabies Immune Globulin (Human)

**300 IU/mL**