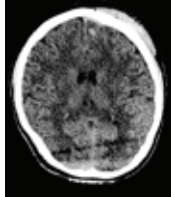


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The Official Voice of Emergency Medicine

DECEMBER 2019

Volume 38 Number 12

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END OF THE  
RAINBOW

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PRESIDENTIAL  
CANDIDATES

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## The Search for the Holy Grail of Syncope Risk Stratification

THE NEWLY DERIVED "FAINT"  
SCORE APPEARS PROMISING  
BUT NEEDS VALIDATION

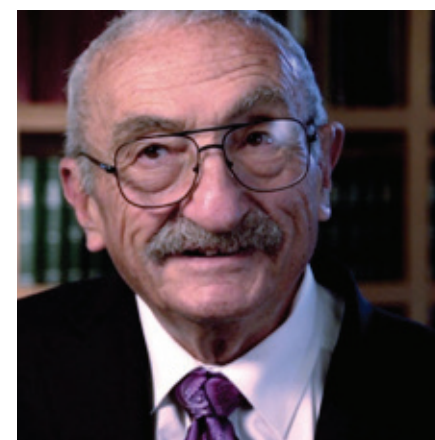
by MARC A. PROBST, MD, MS, FACEP;  
AND BENJAMIN C. SUN, MD, MPP



THE CASE

A 62-year-old female with a history of anemia and hypertension presents following an episode of syncope that morning while making her coffee. She felt light-headed. As she reached for the wall, the room "went dark." The next thing she remembers is waking up on the floor. She denies headache, chest pain, shortness of breath, or palpitations. She has been feeling well recently and eating and drinking

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## IN MEMORY OF PETER ROSEN

One of the founders of  
the field of emergency  
medicine has died, his  
legacy intact

by RICHARD WOLFE, MD

Foreword by Jeremy Samuel Faust, MD, MS,  
FACEP

Peter Rosen, MD, a giant in the field of emergency medicine, died on Nov. 11, 2019, in Tucson, Arizona, from complications of long-standing cardiac and renal disease. He was 84 years old. Dr. Rosen's professional life and legacy were defined by a decades-long campaign to legitimize emergency medicine as a discipline, a field of study, and a vital academic specialty. In these efforts, he was largely successful. He was the author of hundreds of academic articles, he founded the *Journal of Emergency Medicine*, and he was the first emergency physician elected to the Institute of Medicine of the National Academy of Sciences. He founded two prestigious emergency medicine residency programs and taught at several others in a career that spanned six decades. The recipient of droves of awards and accolades as a medical educator, he will perhaps best be remembered as the founding editor of the first definitive textbook for the field of emergency medicine, *Rosen's Emergency Medicine: Concepts and Clinical Practice*, known today simply as "Rosen's."

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## BRINGING EMERGENCY CARE TO THE WORLD

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# NEWS FROM THE COLLEGE

## UPDATES AND ALERTS FROM ACEP

### Applications Now Being Accepted for ACEP Executive Director Position

ACEP's Executive Director, Dean Wilkerson, announced in September that he will retire in the summer of 2020. The Board has retained a search firm and established a Search Committee that created a position description, which is now available at [www.assnstrategies.com/active-searches](http://www.assnstrategies.com/active-searches). Applications are being accepted through Jan. 17, 2020.

### CMS Releases Major Final Regulation: 2020 Medicare Physician Fee Schedule

Recently, the Centers for Medicare and Medicaid Services (CMS) released its final 2020 Medicare Physician Fee Schedule rule, which includes changes that will affect Medicare physician payments and the Merit-based Incentive Payment System starting Jan. 1, 2020.

CMS finalized an increase in these payments in line with the American Medical Association Relative Value Scale Update Committee recommendation for 2020. However, CMS also finalized a proposal to increase the office and outpatient evaluation and management (E/M) services rate in 2021. Medicare requires that overall changes to Medicare physician payments be budget-neutral, so this adjustment to the office and outpatient E/M codes is likely to reduce reimbursement to emergency medicine. So while emergency physician services will be more appropriately valued in 2020, payments for these same services may be significantly reduced the following year. Fortunately, CMS is leaving the door open to re-evaluate this policy in next year's regulation, and ACEP will be working hard to ensure that these payment reductions do not become a reality in 2021.

ACEP has broken down the rule on the Regs & Eggs blog, emphasizing seven key policies that apply to emergency medicine and ACEP's stance on each policy. View the blog at [www.acep.org/federal-advocacy/federal-advocacy-overview/regs-eggs/regs--eggs21](http://www.acep.org/federal-advocacy/federal-advocacy-overview/regs-eggs/regs--eggs21). Want to subscribe to Regs & Eggs to stay abreast of the regulatory updates affecting emergency medicine? Sign up to receive email updates at [www.acep.org/regsandeggs](http://www.acep.org/regsandeggs).

### ACEP Applauds Federal Court Rejection of HHS Conscience Rule

On Nov. 7, 2020, ACEP put out a statement applauding the United States District Court for the Southern District of New York for rejecting a Department of Health and Human Services (HHS) rule that would shield health professionals who refuse to deliver care or services based on religious belief or moral conviction. ACEP looks forward to additional states acting to invalidate this flawed regulation because denying emergency care or delaying emergency services based on the religious or moral beliefs of a medical provider is unethical, dangerous, and could violate EMTALA.

The HHS regulation fails to recognize the unique and vital nature of emergency medicine and opens the door to discrimination by institutions or individuals who are expected

to prioritize patient care and safety ahead of personal beliefs.

### New Member Benefit Offers Counseling, Legal Assistance

ACEP's new Wellness & Assistance Program was launched during ACEP19 in Denver. It offers ACEP members exclusive access to three free counseling or wellness sessions. Support is available 24-7, and you can conduct your sessions over the phone, face to face, via text message, or through an online chat service—whatever works best for you. The service also offers 30-minute consultations for individual legal/financial matters. Learn more about this new benefit at [www.acep.org/support](http://www.acep.org/support).

### FDA Drug Shortage Task Force Releases Long-Awaited Report

The U.S. Food and Drug Administration (FDA) recently released its long-awaited Drug Shortages Task Force report, "Drug Shortages: Root Causes and Potential Solutions." ACEP has been involved in this effort from the beginning, including calling for the creation of this task force, urging the FDA to find solutions to the drug shortage crisis, and working with congressional partners. In its report, the task force identifies three root causes of drug shortages: 1) lack of incentives to produce less profitable drugs; 2) the market's failure to recognize or reward manufacturers for mature quality management systems; and 3) logistical and regulatory challenges that make it difficult for the market to recover after a disruption.

The report also provides three potential solutions: 1) create a shared understanding of the impact of drug shortages and the contracting practices that may contribute to them; 2) create a rating system to incentivize drug manufacturers to invest in achieving quality management system maturity; and 3) promote sustainable private sector contracts. The report includes several ACEP priorities, including the need to enhance transparency to ensure adequate competition in the marketplace and better supply chain monitoring and response so as to guarantee the availability of lifesaving emergency medications.

ACEP President William Jaquis, MD, FACEP, had a call with the nominee for FDA commissioner, Stephen Hahn, MD, FASTRO, on Nov. 15 to discuss the report and the impact drug shortages have had on emergency medicine. ACEP will continue to work alongside Congress and the FDA on this issue. Stay apprised of our progress at [www.acep.org/drugshortages](http://www.acep.org/drugshortages).

### Congratulations to the ACEP Section Award Winners

Every year, ACEP recognizes its membership sections that excel with the Service to Section, Service to College, Promoting Section Membership, and Outstanding Newsletter Awards. Congratulations to 2019 section award winners:

**Service to Section:** Social Emergency Medicine Section

**Service to College:** Young Physicians Section

**Promoting Section Membership:** Ameri-

can Association of Women Emergency Physicians (AAWEP), Careers in EM

**Outstanding Newsletter:** Young Physicians Section

Learn more about the section awards at [www.acep.org/how-we-serve/sections/section-awards](http://www.acep.org/how-we-serve/sections/section-awards).



**JACEP Open Now Accepting Submissions**

ACEP's new peer-reviewed, open-access journal is officially open for business! As a companion journal to *Annals of Emergency Medicine*, the focus of *JACEP Open* is to publish high-quality original peer-reviewed research, across the spectrum of basic and clinical research, in an open-access format to the worldwide community. *JACEP Open* will publish contributions in the form of original research, clinical reports, opinion, and educational information related to the practice, teaching, and research of emergency medicine. *JACEP Open* is welcoming submissions at <https://onlinelibrary.wiley.com/journal/26881152>. 📍

**TOXICOLOGY Q&A**

**Psychedelic Bloom?**



by JASON HACK, MD, FACEP, FACMT

**QUESTION:** What flower with varietal names including Heavenly Blue, Flying Saucers, and Blue Star might have felt at home in a Beatles song?

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# THE BREAK ROOM



## Team Approach to Compartment Syndrome

I read the October *ACEP Now* article “Spot and Treat Compartment Syndrome” by Dr. Long and Dr. Koyfman with interest. I found the article to have a number of very good points, including the inaccuracy of the history and physical examination. As someone who has been actively involved in this topic for many years, I have several observations.

The article implies that obtaining the intracompartmental pressure is expected when entertaining the diagnosis and that it has a great sensitivity and specificity. The test characteristics of pressure measurement are probably excellent in the hands of someone who uses the technique frequently and acts upon those results. I would propose that person is not an emergency physician.

The problems with the emergency physician measuring the intracompartmental pressure are several.

1) You must measure the pressure in each compartment. There are four compartments in the leg, two in the forearm, and nine (!) in the foot. Being sure that you have measured the pressure in each compartment and using the measurement tool properly are not a given. Then, what would you do with the result? I can’t imagine any surgeon will operate based solely on your measurements or say-so. They will insist on their own evaluation and/or measurements as the authors suggest in the article. Seemingly, this is a redundant and painful procedure for the patient. I have performed pressure measurements several times with an orthopedist, and they are not as straightforward as: Just do it.

2) There will surely be an emergency physician who will avoid (consciously or subconsciously) entertaining the diagnosis if it requires an infrequently used and somewhat cumbersome procedure. Suggesting that intracompartmental pressure is an integral part of the diagnostic workup paints an imprecise and perhaps unnecessarily tortuous path for the emergency physician to make the diagnosis of compartment syndrome.

3) Lastly, fasciotomy is the definitive treatment for compartment syndrome. This is a procedure that no emergency physician should be performing (or has delineated in their staff privileges to perform) regardless of the pressure results (except under the rarest of circumstances). The surgeon will be charged with acting based on their own evaluation that may or may not include pressure measurements.

Emergency physician intracompartmental pressure monitoring has a number of shortcomings. Consequently, let’s not make the process of diagnosing compartment syndrome more onerous than it really is by suggesting that the emergency physician should be performing a procedure that should be more appropriately performed by the person who will be the interventionist. Keep it simple.

So, how should emergency physicians handle cases where they are concerned about compartment syndrome? Call the surgeon and discuss the case.

*Jim Webley, MD, FACEP  
Pontiac, Michigan*

### The Authors Respond

We thank Dr. Webley for his insightful comments on the article. He brings to light several important considerations, including the

## 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.

### LAURA HELFMAN, MD, FACEP



**Laura Helfman, MD, FACEP**, is an emergency physician in in Chattanooga and Johnson City, Tennessee. After discovering white-water sports while in medical school, she has spent the majority of her career as a locums so she can work as a white-water river guide in the Southeast and Colorado during the spring and summer. She even guided while receiving chemotherapy for uterine cancer. She enjoys white-water guiding for both its similarities and differences from her life in the emergency department. “You never know what might come in the door or what type of procedure or situation you might encounter...,” she says. “In both instances, you are gearing up for the worst while usually experiencing the best.” And while working in the emergency department often means supporting people during their worst moments, working as a river guide lets her ride beside people who are having exciting, once-in-a-lifetime experiences on the water. “It’s nice to see happy people and push them to their limits,” she says.

### PUNEET GUPTA, MD, FACEP



**Puneet Gupta, MD, FACEP**, is an emergency physician in Los Angeles. He was working at a Level I trauma center in Flint, Michigan, when he started contemplating living a minimalist life. He ran into some people who lived out of a van and thought, “That’s pretty cool. I think I’ll try it out.” He found the perfect van—an affordable 2008 Ford Econoline E-350—and gave away everything he had (except his rare vinyl records, of course). He spent his free time making his van livable, knowing it needed to be ready to survive cold Michigan winters. “The coolest moment was when I jerry-rigged a way to power the batteries off the van and solar panels, and then I connected the lights for the first time,” he said. “While I was an engineer in the past, I had never done anything on this scale.” Dr. Gupta doesn’t have any long-term plans for his van because, in his words, “the van is all about being in the moment and appreciating the beauty of life and little moments.” As for now, he takes his van on long road trips and spends his time “making [the van] more awesome.”

### MARA WINDSOR, DO, FACEP



**Mara Windsor, DO, FACEP**, is the EM clinical site director, CME and education director, and chief wellness officer for HonorHealth John C. Lincoln Hospitals in Arizona. She founded Living in Fulfilled Enlightenment (LIFE), a wellness nonprofit. Her own wellness journey started with a very traumatic pregnancy during which she miscarried one twin and found out the other had severe health issues. When her son had to go on a feeding tube at six months old, she found herself working non-stop to subsidize her baby’s expensive medical care. She was hardly eating and sleeping and realized she was, she said, “no good to anyone else” if she didn’t focus on self-care. That led her to found LIFE, and now she provides monthly community education focused on three pillars: communication, philanthropy, and mentorship. As a facilitator for Empowering Steps Movement Therapy, she also teaches resiliency courses, mindfulness yoga, and emotional intelligence to elementary children. “I find fulfillment, purpose, and meaning in my life through this work,” Dr. Windsor explained. “This is what sustains me and keeps me well.”

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need for early orthopedic involvement if compartment syndrome is suspected. Measurement of a compartment pressure is not necessary prior to orthopedic surgeon consultation. If the compartment pressure is assessed, the clinician obtaining the measurement must be familiar with the anatomy due to the differing compartments dependent on the specific location.

We also agree that fasciotomy is a difficult procedure, and most emergency clinicians are not trained to perform it. However, as Dr. Stuart Swadron says, “we need to know what we need to know, and one step further.” While rare, there are circumstances where an emergency clinician may need to perform this procedure, such as in an austere military setting with no surgical backup.

As Dr. Webley discusses, the key to diagnosis is clinical suspicion in the ED, as failure to consider the condition is why we often miss it. A patient with severe pain, recurrent need for analgesia, or objective evidence of neurovascular compromise warrants emergent discussion with the surgeon. Keep in mind that severe pain, which may be out of proportion to the exam or increase with passive stretch of the compartment, is often the only finding in acute compartment syndrome.

*Brit Long, MD, FACEP; and Alex Koyfman, MD, FACEP, FAAEM*

## Toxicology Q&A Answer

QUESTION ON PAGE 3

### ANSWER: Morning glory.

Morning glory is often referred to by its variety—including Heavenly Blue, Pearly Gates, Flying Saucers, Blue Star, Summer Skies, and Wedding Bells. This hardy annual climbing vine has single-colored funnel-shaped flowers spaced along its course, with deep green heart-shaped leaves. It blooms in early summer until the first frost.

“Morning” references that the flowers roll themselves closed every evening and unfurl in the morning.

The seeds of many species of morning glory contain a naturally occurring tryptamine, lysergic acid amide (LSA), which is chemically similar to LSD and has similar effects. Seeds are used for their strong psychedelic or hallucinogenic mental effects.

Often, the seeds are crushed and swallowed or made into teas to induce intentional intoxication.

Apart from the desired hallucinogenic effects, patients often exhibit dilated pupils, increased heart rate, nausea, vomiting, diarrhea, numbness of the limbs, and muscle spasms.

Culturally, the hallucinogenic effects have been ceremonially used by the Aztec people in various rituals, and they referred to the plant as “Rivea corymbosa” or “ololiuqui.”



PHOTOS: JASON HACK (OLEANDER PHOTOGRAPHY)

### MORNING GLORY

*Ipomoea tricolor, violacea, and others*

**COMMON NAMES:** Heavenly Blue, Flying Saucers, Blue Star

Other South American cultures have used the seeds to diagnose illnesses and foretell various future events.

#### Interesting Facts

- The Victorian language of flowers uses the morning glory blossom to represent “love in vain.”
- Although morning glory seeds for sale are often coated with methylmercury (an antifungal) to stop abuse, many online retailers will sell them in bulk specifically as “untreated.” Online comment sections are an interesting read for these items.

- There is some evidence that the LSA alkaloid present in morning glory seeds may originate in fungi that grew with the seeds, which became symbiotically entwined with the plant life cycle. +



**DR. HACK (OLEANDER PHOTOGRAPHY)** is professor of emergency medicine and director of the division of medical toxicology at Brown University in Providence, Rhode Island. Contact him via [ToxinRI@gmail.com](mailto:ToxinRI@gmail.com), online at [www.toxinRI.com](http://www.toxinRI.com), or on Instagram at [oleanderphotography](https://www.instagram.com/oleanderphotography).

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## 10%

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as a specialty in terms of overall number of physicians with a DEA-X waiver

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Compiled by Alister Martin, MD, instructor in emergency medicine, Massachusetts General Hospital, Boston

Visit [ACEPNow.com](http://ACEPNow.com) for the sources of these statistics.

# Providing a Path Home

Homeless navigators in the emergency department can help connect high utilizers to housing

by ALISTER MARTIN, MD, MPP; SAJEN PLEVYAK; AND DAVID VELASQUEZ

**In** 2018, the U.S. Department of Housing and Urban Development estimated that more than half a million people experience homelessness on any given night. Many find shelter in our emergency departments.

City governments across the country—such as Los Angeles, New York City, and Boston—have mobilized significant resources to address homelessness by creating housing units meant for the homeless and implementing greater supportive services. The problem with this approach is that these city and statewide efforts don't coordinate with the most crucial partner in the ecosystem of services that care for the homeless: hospitals.

The result is a cycle of missed opportunities that plays out nightly in emergency departments across the country.

Could the implementation of housing navigators—specially trained experts in housing placement who have been traditionally used outside of the hospital setting—as ED staff be the answer?

In the absence of more robust, permanent supportive housing units, I propose that there is no other intervention that could have a more significant impact on ED care for the homeless than implementation of ED-based housing navigators. Consider the recent case of a patient in our emergency department.

### Terry's Story

It was 2 a.m. and 2°F outside in Boston. We were about to discharge Terry (whose name was changed for this story) from our department for the second time in 24 hours. Terry was homeless, and this was our routine all winter last year, especially when it was too cold for him to sleep under a highway overpass or in shop doorways downtown. Many times, he was drunk, and so we monitored him until he was sober enough to walk out. Other times, he concocted medical issues that needed to be urgently evaluated, excuses that he (and we) knew would keep him in our emergency department safe and warm, at least for a few hours.

That night, my colleague was the provider caring for Terry. I showed her a list I'd been given of high utilizers of emergency services (and yes, the term "frequent flier" is derogatory). This list contained the top 50 homeless utilizers of the city's emergency services, their housing status, and where they were on the path to being placed in city housing.

It is remarkable that the city even has such a list. But the city's major problem? Due to the nature of homelessness, it has trouble simply locating these patients. A colleague who worked for the Department of Public Health thought that, as an emergency physician, I might be able to keep an eye out for patients on this list who presented to the emergency department. This particular list is one of nearly a dozen distinct housing lists that create a disconnected and complex patchwork of resources that weaves together the housing system in Boston.

My colleague's eyes fixed on the screen. There was Terry's name. Not only did he already have a housing voucher assigned to him, he also had a city-owned apartment waiting for his arrival. He had never checked in.

Later during that shift, we contacted Terry's

## MORE IDEAS FOR HELPING HOMELESS PATIENTS

Want more on social determinants of health? Check out the special *Annals of Emergency Medicine* supplement "Inventing Social Emergency Medicine: A Consensus Conference to Establish the Intellectual Underpinnings of Social Emergency Medicine" online. You'll find a repository of work that will help you improve the health and lives of your patients by incorporating social context into your practice. Read the supplement at [www.annemergmed.com/issue/S0196-0644\(19\)X0013-X](http://www.annemergmed.com/issue/S0196-0644(19)X0013-X).

case manager, and while he was in the hospital, preparations were made for him to move in. He was later discharged. To his new home.

Terry's case was exceptional in that the stars aligned. He happened to have available housing and an effective outpatient case manager. But his case is not unique. There are patients who are in the same situation as Terry. Sadly, hospitals that see these patients are often kept in the dark.

Usually, hospitals simply discharge patients like Terry back to the streets with a list of shelters. We don't fundamentally advance them on the pathway toward housing. I hear you asking, should we? My answer is yes.

### What We Can Do

After caring for Terry, I've often wondered how many cases like his I had come across in my practice. How many of these individuals whom I had seen actually had city and state housing opportunities simply waiting to be utilized?

Recently, analyses of the interplay between housing and health have prompted hospital systems to institute programs that address homelessness. Through these programs, successful institutions often find ways to identify homeless patients and then connect them to appropriate housing and ancillary services.

The methods vary. Some institutions rely on case managers to tack on extra workflows of basic housing navigation to their already overflowing list of responsibilities, while others use inundated social workers to perform these tasks. Data show that social workers or case managers combined with intensive housing assistance may be effective. But unfortunately, most social workers and case managers can't or don't solely focus on housing their patients. Thus, these benefits are often not sustainable. This fact, combined with the complexities of the housing sector, has pushed hospitals to introduce a new field of hospital staff: housing navigators.

Housing navigators are workers trained in helping advance the housing status of the homeless. They have been effective in contributing to higher rates of long-term housing permanency for the homeless. Traditionally, housing navigators have only existed outside

of hospitals and only work in shelters or community outreach programs that address homelessness.

That is beginning to change as a growing number of hospitals and emergency departments are employing housing navigators who are helping to advance the housing status of our nation's homeless.

In Minnesota, Hennepin Healthcare System created a program that leverages housing navigators. Its preliminary results? Emergency department visits fell 35 percent among their homeless high-utilizer population, and nearly 50 percent of their highest utilizers became stably housed. Similarly, in California, Hospital Harbor Interfaith Services partnered with South Bay Hospitals to create a housing navigator position that helps hospital social workers navigate the complex housing system for their patients. The results were so substantial that after only one year of implementation, partnering hospitals funded the program for an additional three years.

Minnesota and California are not alone in these endeavors. In New York, Mount Sinai Health System recently hired a housing navigator to help homeless patients transition to permanent housing, and Vanderbilt University Medical Center in Nashville also introduced a housing navigator in 2016.

What about the finances? The good news is that even payers have identified the utility of implementing housing navigators. UnitedHealthcare is employing housing navigators to work with emergency departments in Texas, Washington, and throughout the Midwest. For obvious reasons, they see the value.

Introducing emergency departments to housing navigators means that patients such as Terry will no longer have to rely on a slim chance of clinicians glancing at housing lists to claim the resources available to them.

Instead, homeless patients unaware of the resources available to them would be assessed by housing navigators and transitioned into housing opportunities at the city and state level or be triaged to transitional care, such as shelters, respite care, and adult foster care, when longer-term solutions are not immediately available. These housing navigators act as additional specialists who can help unburden busy ED providers who are not well-versed or trained in navigating their community's housing ecosystem, let alone doing so at 2 a.m.

With the increasing administrative focus on social determinants of health, I strongly believe that hospital-based housing navigators can serve as powerful resources, not only to reduce health care costs but also, more important, to house people who frequently present to our emergency departments in search of temporary shelter.

Emergency departments have an opportunity to treat homelessness like any other medical problem by connecting homeless patients to the specialists they need most. The implementation of housing navigators is the first crucial step in doing so. 📍

**DR. MARTIN** is an emergency physician at the Center for Social Justice and Health Equity at Massachusetts General Hospital and Harvard Medical School in Boston. **MR. PLEVYAK** is an anthropology student and **MR. VELASQUEZ** is a medical student at Harvard.

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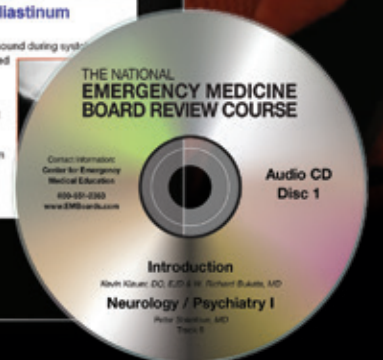
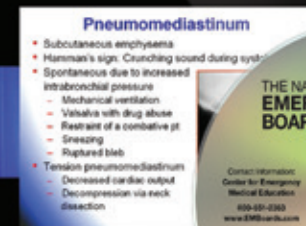
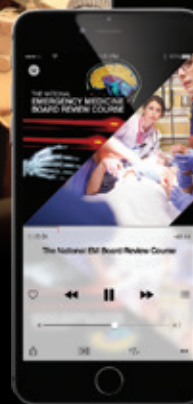
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The team that worked on the resolution from World Health Organization and Ethiopia. Dr. TSION FIREW is fourth from the left.

# BRINGING EMERGENCY CARE TO THE WORLD

by TSION FIREW, MD, MPH

Here in the United States, we take emergency medicine and emergency services for granted. Having an emergency? Help is just a 911 call away.

The same isn't true around the world. But now, with the help of the World Health Organization (WHO), things are starting to change.

Imagine what would happen if you needed immediate emergency medical care while traveling in a low- or middle-income country? Is there a system analogous to our 911 system? Even if so, would trained providers in well-equipped ambulances be dispatched? Would you be taken to an emergency department and evaluated by an emergency medicine-trained clinician?

Naturally, people have medical and surgical emergencies in every part of the world. And yet the quality and manner of emergency care delivery vary greatly among countries, even among nations with similar economic resources.

How can we raise standards everywhere so we might ensure timely, high-quality emergency care in nations of all levels of income?

The first step is awareness. From there, implementation can occur.

Fortunately, there is good news to report. Theory is starting to become reality, thanks to efforts by the governments in the nations of Ethiopia and Eswatini (a small landlocked nation in southeast Africa) and their work within the WHO structure.

Most physicians in America and around the world do not know how WHO works. I hope an inside look on how emergency medicine is making waves of change there will shed some light on it.

## Resolution 72.16

The World Health Assembly (WHA) is composed of health ministers from 194 member states (countries). The assembly meets annually in Geneva, Switzerland, and makes recommendations, driving policy and funding priorities for WHO. This past May, the 72nd WHA convened under the theme "Universal Health Coverage: Leaving No-one Behind."



The World Health Assembly deliberates and discusses the new emergency care resolution.

Emergency care is often overlooked internationally, which leaves a significant gap in care for patients who need it the most. The governments of Ethiopia and Eswatini saw this year's theme as an opportunity to change that.

They argued that emergency care is an essential component of universal health coverage (UHC) and a crucial gateway toward the attainment of several United Nations Sustainable Development Goal targets. Capitalizing on the moment, delegates from Ethiopia and Eswatini proposed a new resolution at the 72nd WHA titled "Emergency Care Systems for Universal Health Coverage: Ensuring Timely Care for the Acutely Ill and Injured."

During the executive board deliberations in the five months leading up to the assembly, delegates from Ethiopia and Eswatini proposed that emergency care be added as a provisional agenda item. The WHO secretariat prepared a report outlining the state of access to emergency care worldwide and the key actions needed to strengthen emergency care systems.

Simultaneously, technical experts from the aforementioned countries developed a draft resolution and distributed it to all WHO/WHA member states. Country representatives then deliberated over the language of the draft, word by word, line by line. The Ethiopian Ministry of Health chaired these sessions, which continued until all countries agreed on the text. The result became known as Resolution

72.16.

In what many of us feel was a historic moment, Resolution 72.16 went to the floor of the assembly on May 25, 2019. During the discussions, member states and representatives of professional societies spoke from the floor in support of the resolution, frequently commending the sponsoring countries for bringing attention to this area. In the end, the resolution was officially co-sponsored by more than 30 member states, and it was passed unanimously, a triumphant moment for emergency medicine.

## What Does This Mean for International Emergency Medicine?

A WHA resolution is a compelling directive to WHO and its member states. It functions as a mandate to prioritize the resolution's subject. It is a powerful guide for advocacy for a neglected area such as frontline emergency care.

Resolution 72.16 has the potential to be incredibly transformative in strengthening health systems globally. If member states and other partners heed the call, it provides an opportunity for coordinated action in a high-impact area, and to raise awareness of the enormous potential contribution of emergency care to a range of related agendas.

Resolution 72.16 specifically urges member states to promote emergency care as a pillar of UHC. It asks the member states to incorporate dedicated, equipped prehospital and hospital

## The World Health Assembly adopts Resolution 72.16

emergency unit care into their health strategies and to integrate facility-based and prehospital care systems. It also urges member states to establish a toll-free universal access number similar to the 911 system in the United States. It also encourages each member state to provide training programs for all levels of clinicians and to incorporate emergency care into national disaster and outbreak response plans.

You can find the full text of the adopted resolution at [https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R16-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R16-en.pdf).

## How Can You Advocate for Emergency Medicine?

The unanimous adoption of Resolution 72.16 comes at a crucial time. Currently, all world leaders are being encouraged to work toward UHC as part of the United Nations' Sustainable Developmental Goals. We, as emergency care providers, have the opportunity to advocate for emergency care as an essential component of UHC. Ensuring timely and high-quality care forms the core of this advocacy.

The next step is to engage the public and gain their support. In this age in which social media is an advocacy tool and means of vital communication, it was exciting to see the director-general of WHO tweet about the importance of emergency care:

"Emergency care is the first point of contact with the health system for many people and the delivery of definitive care for many others," tweeted WHO Director-General Tedros Adhanom Ghebreyesus, MSc, PhD. "WHO is ready to support countries with the evidence and tools to provide high-quality emergency care, as part of its journey towards #healthforall."

As individuals, we, too, should use social media to disseminate our efforts in emergency care and implementation of the resolution by tagging @WHO and @drtedros, as well as local, regional, and national leaders and ministers of health.

Member states can utilize resources from WHO to determine where gaps in care exist in order to aid implementation. These resources can also be used to spread awareness for inter-

CONTINUED on page 15



# 2020 Course Topics

- Unusual Antibiotic Side Effects
- MRI vs. CT in the ED Setting
- Challenges of Managing Pediatric UTIs
- Emerging Issues in Anticoagulation
- Chest X-Ray, Ultrasonography or CT?
- Myths in Emergency Medicine - Part 1
- Myths in Emergency Medicine - Part 2
- Headache – New ACEP Guidelines
- LPs in Febrile Infants 29-60 Days Old?
- Pearls From *Risk Management Monthly*
- Pearls From *ED Leadership Monthly*
- Assessing Suicide Risk
- Cardiovascular Pearls, 2019
- Hyperglycemia and DKA Update
- Sore Throat: Still Trying to Get It Right
- Sexual / Racial / Ethnic Disparities in the ED
- ACS & PE – New ACEP Guidelines
- Psychiatric Patients: Medical Evaluation
- Challenges of Atrial Fibrillation - Part 1
- Challenges of Atrial Fibrillation - Part 2
- Pediatric Vomiting and Diarrhea
- Sepsis 2019: Hot Off the Press
- Otitis Media Doesn't Cause Fever
- Pneumonia: IDSA Guidelines
- Urologic Imaging Guidelines
- Trauma 2019: Hot Off the Press
- Visual Diagnosis Challenges - Part 1
- Visual Diagnosis Challenges - Part 2
- Important Recent EM Literature - Part 1\*
- Important Recent EM Literature - Part 2\*
- Optimizing ED Operations\*
- Diagnostic and Therapeutic Controversies\*

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

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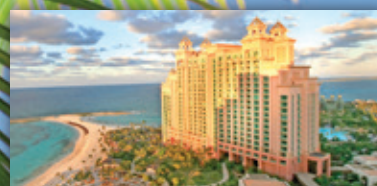
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# ACEP4U: Supporting Physician Mental Health

YOUR MENTAL HEALTH IS IMPORTANT—  
WE'RE MAKING IT EASIER FOR YOU TO  
GET THE SUPPORT YOU NEED



by JORDAN GRANTHAM

**W**e continue to hear the sobering statistics surrounding physician mental health, and we know your job isn't getting any easier. Emergency physicians work compassionately with patients and their families during their worst moments, but the emotional and physical burdens eventually take their toll. While there's no easy fix, ACEP is dedicated to developing resources and providing support that can help you weather the storm.

During ACEP19 in Denver, we rolled out the ACEP Wellness & Assistance Program, which offers ACEP members exclusive access to three free counseling or wellness sessions in partnership with Mines & Associates. Sessions are available 24-7 by phone, text, or online messaging, or you can schedule a face-to-face appointment near your office, home, or school.

What's the difference between a counseling session and a wellness session? Counseling sessions can cover everyday issues including stress, anxiety, depression, family issues, drug and alcohol abuse, relationships, death and grief, and more. When you call in for a referral, the clinical staff will assess your situation, discuss plans for resolving your issues, advise you of available resources, and refer you to a local counselor.

Wellness sessions are 30-minute phone calls to help you reach your personal wellness goals. National Board of Medical Examiners-certified wellness coaches can help you set specific wellness goals and plan for progress checks along the way to help you reach your objectives. Areas of focus can include weight control, nutrition, healthy habits, stress, caffeine reduction, injury recovery, relationships, sleep, smoking cessation, and more.

Participation in this new program is strictly confidential and free with your ACEP membership. For an additional \$15 per year, ACEP members can also access additional benefits, including legal and financial support services and access to the Mines & Associates' Personal Advantage Online Resource Library, which has thousands of helpful resources related to finances, personal development, child care and elder care, mental health, and more. Legal and financial support services include unlimited 30-minute in-person or phone consultations per legal or financial issue, plus a 25 percent discount on select legal and financial services with the Mines professional network.

Learn more about this new program at [www.acep.org/support](http://www.acep.org/support). 📍

**MS. GRANTHAM** is ACEP communications manager.

## Here to Help

The ACEP Wellness & Assistance Program is our newest program available to support physician mental health, but many other resources are available.

### State Support

ACEP's state and chapter services department provided all chapters with a template letter to send to state medical boards urging them to utilize the Federation of State Medical Boards' language related to what mental health treatment needs to be disclosed on licensing applications. Chapters also received specific talking points to support their advocacy efforts in this area, along with a templated letter for hospital administrators regarding questions on credentialing applications.

### Wellness Section

ACEP's Wellness Section provides an opportunity to learn what you can do to avoid burnout, enjoy a balanced life, and keep the vitality necessary to be a healthy emergency physician. Section members are involved in research on a variety of wellness issues and, in addition, have an opportunity to volunteer for peer-to-peer support on career issues and litigation stress. The Wellness Section has a compilation of mental health resources for emergency physicians, residents, and medical students. Learn more at [www.acep.org/how-we-serve/sections/wellness/](http://www.acep.org/how-we-serve/sections/wellness/).

### Wellness Guide Book

Visit [www.acep.org/wellness](http://www.acep.org/wellness) to download the free guide book *Being Well in Emergency Medicine: ACEP's Guide to Investing in Yourself*. Written by Rita A. Manfredi, MD, FACEP, and Julia M. Huber, MD, FACEP, the book presents the emotional, physical, financial, spiritual, social, and intellectual well-being spokes of life in emergency medicine. This page is also home to more resources on a variety of topics that contribute to physician mental health: litigation stress, burnout, posttraumatic stress disorder, work schedules, and more.

## We Need Your Input

Many of these member benefits and resources, including the "Let's Eat" clarification, originated from member suggestions. One way we can help lighten your mental load is by working to eliminate onerous regulations that add to your administrative burden, but we need your help to identify those thorns in your side. We recently conducted an all-member survey asking you to identify the regulations that are most frustrating, and we received 952 responses. We sent your feedback to The Joint Commission to identify more ways we can work together to reduce your burden.

If you have additional suggestions, your input is always welcome at [membership@acep.org](mailto:membership@acep.org).



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### Let's Eat:

Your mental health can be affected by physical issues, including hospital policies that make it difficult for you to eat and drink during your shift. ("Hangry" is a real emotion.) Earlier this year, ACEP worked with The Joint Commission to clarify its policies related to eating and drinking in the emergency department. Need to convince your administrators? We've provided resources to make your case at [www.acep.org/letseat](http://www.acep.org/letseat).



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- Arthrocentesis
- Intra-osseous cannulation
- Wound care: I & D abscesses, suture repair
- Peripheral nerve blocks (facial, rib, wrist, ankle, femoral)

### Non-Cadaver Lab - 7.0 hours of CME

- Ultrasound Techniques, including vascular access, peripheral nerve blocks, and FAST exams for physicians – taught by EMsono
- EZ-IO demonstration station

### Airway Lab – Optional – 6.0 hours of CME

- Airway station with manikin intubation using adult and pediatric models (including King Vision, LMA, Combitube, SALT and others as available)

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# Where Do the Candidates Stand?

A review of the Democratic front-runners' health care plans

by ADAM LIEBER AND TREVOR POUR, MD

MR. LIEBER is a medical student at the Icahn School of Medicine at Mount Sinai in New York City. DR. POUR is an assistant professor of emergency medicine at Mount Sinai.



## Joe Biden

Former U.S. Vice President

Establish a "public option" that would compete in the marketplace with private insurance.

Increase tax credits by eliminating 400 percent income cap on eligibility and lowering cost of coverage from 9.8 percent to 8.5 percent.

End "surprise billing" by barring hospitals from charging out-of-network rates when patients do not have control over which providers they see.

Allow Medicare to directly negotiate with drug companies over prices, limit drug price increase to inflation rate, and allow consumers to import prescription drugs from other countries.

Reverse President Donald Trump's policies on women's health.



## Pete Buttigieg

Mayor of South Bend, Indiana

"Medicare-for-all who want it."

Allow private insurers to compete with Medicare-type plan.

Expand Public Service Loan Forgiveness Program to include employees of rural hospitals.

Increase Medicare reimbursement rates in underserved areas.

Expand community paramedicine programs in rural areas to include preventative care.

Expand telehealth services by increasing coverage of high-speed internet and help providers purchase technology by doubling Federal Communications Commission Rural Health Care Program budget.

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## Bernie Sanders

*U.S. Senator from Vermont*

Guarantee health care to all people through a Medicare-for-all, single-payer program.

Proposal includes hospital and primary care, emergency services prescription drugs, mental health, maternity care, dental, audiology, and vision services.

Finance via a 4 percent increase in income tax for families earning more than \$29,000, 7.5 percent tax on employers above \$2 million in payroll, and increasing progressive income and estate tax and/or wealth tax.

Peg prescription drug prices to the median drug prices of other major countries and allow consumers to buy prescription drugs from other countries.

Allow Medicare to directly negotiate with drug companies over prices.



## Elizabeth Warren

*U.S. Senator from Massachusetts*

Supports Medicare-for-all, single-payer program.

Lower cost of prescription drugs by allowing the Department of Health and Human Services to manufacture generic drugs when individual drugs have little or no competition, are in shortage, or when prices are high.

Hold insurers accountable for providing adequate mental health benefits.

Invest \$100 billion in federal funding over 10 years to fight the opioid crisis.

Create new Medicare designation to reimburse rural hospitals at a higher rate.

Increase funding for community health centers by 15 percent per year; create a \$25 billion capital fund for rural health.



## STAY UP TO DATE ON FEDERAL REGULATIONS

Want to keep up with regulations and policy changes in Washington, D.C., that affect your practice and your patients? Check out Regs & Eggs, a weekly breakfast blog by Jeffrey Davis, ACEP director of regulatory affairs.

Mr. Davis provides a heads-up about new proposed or final regulations, demonstrations, grant opportunities, or other announcements from federal agencies like the Centers for Medicare and Medicaid Services and the Department of Veterans Affairs. Recent blog topics include drug shortages, price transparency regulations, 2020 Medicare Physician Fee Schedule and President Trump's response to "Medicare-for-All."

You can view the archives or have your Regs & Eggs delivered fresh to your inbox at [www.acep.org/regsandeggs](http://www.acep.org/regsandeggs).

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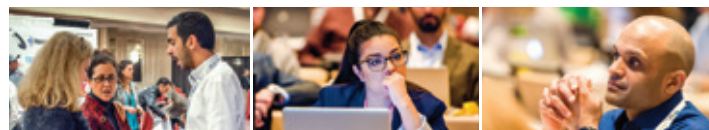


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**Table 1: FAINT Score<sup>1</sup>**

LETTER	PREDICTOR	SCORE
<b>F</b>	history of heart <b>F</b> ailure	<b>1</b>
<b>A</b>	history of <b>A</b> rrhythmia	<b>1</b>
<b>I</b>	abnormal <b>I</b> nitial ECG	<b>1</b>
<b>N</b>	elevated <b>N</b> -terminal-prohormone BNP (NT-ProBNP)	<b>2</b>
<b>T</b>	elevated high-sensitivity <b>T</b> roponin T	<b>1</b>

as usual. She has been taking her antihypertensives as prescribed. She is now back to her neurological baseline but feels fatigued.

In the emergency department, she appears tired but well. Her vital signs and physical exam are unremarkable. She has no signs of head trauma, no cardiac murmurs, and no signs of heart failure. Her initial ECG is normal. Bloodwork has been sent to the lab. What is the utility of cardiac biomarkers in this patient? What will her ultimate ED disposition be if her workup is unremarkable?

**The Tricky Problem of Syncope**

In many ways, syncope management is a microcosm of emergency medicine. The differential diagnosis is broad, and the etiology is typically benign but rarely can also be serious or life-threatening. Safe medical decision-making requires a mixture of diagnostic acumen and risk stratification. Which patients can be safely discharged from the emergency department? Which require a stay in the observation unit or hospital? This question has vexed emergency clinicians for years.

Over the last 20 years, researchers have attempted to identify risk factors for adverse events after syncope. The usual suspects emerged: advanced age, history of heart disease, abnormal vital signs, abnormal ECG.

More recently, researchers have attempted to create simple, objective risk scores to help clinicians deliver sensible care to syncope patients—care that matches their risk profile.

The San Francisco Syncope Rule gained early acceptance but has gradually faded away after attempts to validate the score were unsuccessful.

**Developing a New Metric**

We wanted to know if we could improve clinical outcomes and reduce low-yield admissions by developing a more accurate and reliable syncope risk score. So with funding from the National Institutes of Health, we conducted a five-year multicenter study to enroll a large enough sample size. We included patients ages 60 years and older with an ED complaint of syncope or near syncope. We excluded patients with other causes of loss of consciousness (eg, concussion, hypoglycemia, seizure) and those with a serious diagnosis identified in the emergency department (eg, myocardial infarction, pulmonary embolism, gastrointestinal bleed).

After six years of hard work, and with the help of about a dozen collaborators, our syncope risk score, the aptly named “FAINT Score, was finally published in the *Annals of Emergency Medicine*.<sup>1</sup> In the end, we had enrolled more than 3,100 older adults with unexplained syncope or near syncope across 11 emergency departments in the United States. The primary outcome was death or serious cardiac event at 30 days.

The FAINT Score consists of five variables (see Table 1). A FAINT Score of zero had a sensitivity of over 96 percent and specificity of 22 percent for predicting death or serious cardiac event at 30 days (see Table 1).

The negative predictive value of a FAINT Score of zero was over 99 percent, a promising finding that should satisfy those clinicians who believe that 1 percent is generally an acceptable miss rate for patients presenting with cardiovascular complaints. However, this risk score has not been externally validated and thus is not ready for clinical use in isolation.

The FAINT Score now joins its Canadian cousin from Ottawa, the Canadian Syncope Risk Score. The latter has a greater number of variables (nine), some of which are subjective (ED diagnosis of cardiac syncope, for example), and is designed for use in patients ages 16 and older. Not surprisingly, both scores use the ECG and troponin as important predictive variables.

What’s next? Both scores are pending ex-

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ternal validation to confirm that their test characteristics are, in fact, consistent with those in the initial derivation studies. Meanwhile, the formal external validation of the Canadian score is expected to be published soon.

The validation of the FAIN'T Score is likely a few years away. Until then, we cannot formally endorse the use of it for widespread implementation. However, these scores are an exciting new development in the field of syncope risk stratification and may offer clinicians a useful tool to help determine which patients can be safely discharged directly from the emergency department. Ultimately, we believe these scores should be used in conjunction with, and not instead of, clinical gestalt, as is true for all clinical decision instruments. Consideration of other factors—such as the so-

cial circumstances, patient values, and preferences—is always warranted.

### Case Resolution

Since the FAIN'T Score has not yet been externally validated, you cannot rely solely upon it. But its components may still be useful. You aptly order a high-sensitivity troponin and elevated N-terminal-prohormone BNP (NT-ProBNP), both of which come back normal. Calculating the patient's FAIN'T Score to be zero, you believe that her risk of a serious cardiac event within 30 days is likely to be less than 1 percent. You return to the bedside and engage in shared decision-making with the patient. She understands that her risk is probably low but not zero. Although she lives alone, she agrees that discharge home with

close outpatient follow-up this week is appropriate. The etiology of the syncope is never determined, but months later she is doing well, safely drinking coffee in her living room. +

### Reference

1. Probst MA, Gibson T, Weiss RE, et al. Risk stratification of older adults who present to the emergency department with syncope: the FAIN'T score [published online ahead of print Oct. 23, 2019]. *Ann Emerg Med*.

**DR. PROBST** is associate professor in the department of emergency medicine at Mount Sinai Hospital and Icahn School of Medicine at Mount Sinai in New York City.

**DR. SUN** is Perelman Professor and Chair in the department of emergency medicine at the University of Pennsylvania in Philadelphia.

**Table 2: Estimated Risk of Serious Clinical Outcome at 30 Days<sup>1</sup>**

FAINT SCORE	ESTIMATED RISK
0	0.9%
1	3.1%
2	3.6%
3	6.6%
4	10.5%
5	8.1%
6	24.1%

## WHO RESOLUTION

CONTINUED FROM PAGE 8

national and domestic resource mobilization.

Whenever you are using your voice as an advocate for emergency care, reinforce your efforts by reminding your officials about Resolution 72.16 or by citing the resolution text in funding applications. In addition, this resolution also enhances your capacity to persuade your audience in the importance and relevance of your particular areas of expertise and interest on a global scale. For example:

- As an educator, you can use WHO resources such as the Basic Emergency Care (BEC) course to teach frontline providers in emergency care. This five-day course covers basic approaches to life-threatening conditions and is available open-access on the WHO website. A standardized facilitator training process developed by the International Federation for Emergency Medicine consists of a Training of Trainers course as well as participation in a BEC course. ACEP facilitated those efforts by sponsoring a WHO BEC Training of Trainers course at ACPE19.
- As a researcher, you can support local researchers by working with them to develop implementation and process outcomes utilizing WHO's data collection tools.
- As part of a nongovernmental organization, you can support countries by coordinating and mobilizing resources to implement the actions outlined in the resolution using tools described in the WHO Essential Resources for Emergency Care.
- As an administrator, you can use WHO quality improvement tools and the Emergency Unit Management Course to help train local staff in best practices in emergency unit administration.

Our success in 2019 is not the capstone but rather the cornerstone of the rise of emergency care around the world. With your help, we will see growth in 2020 and beyond. +

**DR. FIREW** is special advisor to the Minister on Emergency Care and Strategic Partnerships for the Federal Ministry of Health in Ethiopia and assistant professor in the department of emergency medicine at Columbia University Medical Center in New York City.

## WHO EM Resources

For more WHO resources for countries and organizations, visit [www.who.int/emergencycare/en](http://www.who.int/emergencycare/en).

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His landmark 1979 essay, “The Biology of Emergency Medicine,” largely defined the landscape of a field still in its infancy, laying out the dueling responsibilities of the well-trained emergency physician: the identification and treatment of life- and limb-threatening conditions on one hand, and the cognitive discipline of confidently reassuring and discharging the well on the other. He argued convincingly that the unique skills of the emergency physician could not be adequately performed by physicians from other specialties, who typically had expertise in only one particular facet of emergency medicine.

Dr. Rosen mentored hundreds of emergency physicians and had many more thousands of admirers. Equal parts intellectual and indelicate, he furnished his colleagues and disciples with a lifetime of memorable quo-

tations, both amusing and poignant. His insights, quips, and bon mots are often repeated, passed down from one generation to the next, making him a kind of modern-day Osler.

I have asked Dr. Richard Wolfe to provide some personal recollections.

—Dr. Faust, ACEP Now Medical Editor in Chief

**P**eter Rosen died on the evening of Nov. 11, 2019, slipping off quietly, his wife and best friend, Ann, at his side, as she had been throughout their 60-year marriage.

Medically, his death came as no surprise. He had long suffered from coronary artery disease and ischemic cardiomyopathy. In the last year of his life, he was on dialysis, had become frail, and used a wheelchair to get around. But until the end, his mind remained brilliant, incisive, and iconoclastic. To all of us who knew

him, his death still feels untimely.

Peter Rosen was larger than life, extraordinary in vision, language, and character. His work inspired, guided, and shaped our specialty through lectures and writing, and more directly as a mentor to countless students, residents, and practicing physicians who carry on his passion and vision for emergency medicine. His productivity—books, articles, editorials, lectures, and national leadership—defined the specialty of our field as we know it, and many justly consider him to have been the “father of emergency medicine.” His appointment as the first emergency physician to the Institute of Medicine of the National Academy of Sciences was an appropriate recognition of a life devoted to our specialty.

I knew Peter—as he always insisted on being called, never “Dr. Rosen” except with pa-

tients—my entire life. He was my uncle and became a father figure to me. Later, he was my mentor, as a student and during residency, and finally a colleague.

I am lucky to have visited Peter a week before his passing. Over steaks and Diet Cokes, we shared stories about the early days of emergency medicine. We worried over threats to our specialty: ED crowding and the commoditization of our physician colleagues by large corporate groups. He cared deeply for emergency medicine and felt that his mission was not over. At the time of his death, he had recently decided to record podcasts that would have covered the history of emergency medicine and also tried to help guide its future.

Peter Rosen was born to Jewish parents on Aug. 3, 1935, in Brooklyn, New York, where he was raised. He described tearing through the Italian neighborhoods on his bike, armed with a bicycle chain to fight off kids in from other neighborhoods, and lying on the subway tracks while the trains rolled over as a dare with his friends. Perhaps fittingly, he was a devoted fan of the Brooklyn Dodgers. He was particularly fond of Nathan’s hot dogs in Coney Island and steaks at Peter Luger’s.

Peter obtained his B.A. at the age of 20 at the University of Chicago. He was accepted into medical school—on his second attempt, he always pointed out with his usual modesty—at Washington University in St. Louis. After graduating in 1960, he returned to Chicago for an internship in surgery. He completed surgical training at Highland County Hospital in Oakland, California, perhaps the youngest surgeon in the country to graduate that year.

The Vietnam War was raging, and he was drafted into the Army. But as an attending surgeon with the U.S. forces in Germany, he was not enamored by Army rules or its hierarchy. “Captain Rosen’s” sense of humor and rebellious nature were frequently at odds with military expectations. One evening in particular, in annoyance over some banality, he picked up a “hot mic” and announced to the entire base, “Now hear this! The Army sucks. That is all.” As a result of this, he was relegated to a small first-aid station where his “punishment” was to play tennis and chess, thereby reinforcing a life-long strategy of breaking rules he deemed wrong.

After an honorable discharge, he, his wife, and three sons moved to Thermopolis, Wyoming, where he joined a surgical practice (a fourth son was later born there). From 1968 to 1971, he was the only board-certified surgeon in the state. The demand for his skills, combined with his exceptional work ethic, resulted in exceedingly long hours, often causing him to forgo adequate sleep. He would drive back and forth over hundreds of miles from town to town, surgery to surgery.

On the road one night, he developed substernal chest pain. At 35 years old, he was having a myocardial infarction from coronary artery spasm that would end his career as a surgeon and help launch a new academic specialty.

#### A Career Shift

He later told me that he survived stunningly poor care in a local emergency department. At the time, care was provided in emergency rooms staffed by physicians without formal training. Emergency care was viewed by hospitals as a necessary evil, assigned in academic



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US-NUA-0193 08/19



centers to the most junior house staff, usually without supervision.

Peter's experience with the death of his father from poor emergency treatment and his own as a patient helped form his vision and conviction that patients in their most vulnerable stage of disease need the most-, not the least-, trained doctors.

After his recovery, he was told to cease surgical practice and find a less stressful occupation. He considered basic science, but the dean at the University of Chicago instead found him a restful, nonstressful position as the director of the division of emergency medicine. When he took the job, he imagined he would simply continue to practice as a surgeon and that emergency medicine would be an administrative duty. However, the responsibilities to his patients and his department soon led to adversarial relations with other specialties, including the chair of surgery, to whom he reported.

Peter perceived that there was a different way to think when managing emergency patients and a different set of responsibilities. As few others had at that time, he saw the need for a new specialty and began to advocate for it. Despite years neglecting emergency patients writ large, physicians from other disciplines who frequently staffed emergency rooms were suddenly threatened by the loss of turf and income that the shift of emergency care to these new-fangled "emergency physicians" seemed to represent.

Peter was joining a movement still in its early stages. He served as a member of the American Board of Emergency Medicine's original

Board of Directors (from 1976 to 1986), which created the certification process in place today. Only a few years earlier, James Mills had written about one of the first EM practices, the "Alexandria Plan." Community practitioners were just beginning to identify as emergency physicians. The nation's first EM residency had recently been inaugurated in Cincinnati.

What was lacking, however, was a vision of emergency medicine as an academic specialty with a core fund of knowledge, a biology, and an organizational structure like the traditional specialties had.

Peter Rosen had become a visionary advocate for the specialty of emergency medicine at the perfect time.

### Transforming Emergency Care

From his position, he began his lifelong mission of transforming emergency care in this country. He started a residency in Chicago and then another one in Denver, when he moved there in 1977 to become director of the department at what was then Denver General Hospital (today Denver Health Medical Center).

Sensing the need for a formalized curriculum, he spearheaded the first textbook written by and for emergency physicians, *Rosen's Emergency Medicine: Concepts and Clinical Practice*. At the helm of this large undertaking, Peter in essence defined the parameters and the body of knowledge of our specialty. The book is now in its ninth edition, and the 10th is well under way.

After Denver, he built the residency in San Diego and guided the development of the aca-

demical departments at the Harvard-affiliated hospitals. He also served as faculty at the University of Arizona in Tucson, completing his career as the senior mentor for three vibrant academic departments.

In 1979, he wrote an influential paper published in the *Journal of the American College of Emergency Physicians* (today known as the *Annals of Emergency Medicine*) outlining "the biology" of emergency medicine and defining ownership of an area of basic science that would define emergency medicine. He founded the *Journal of Emergency Medicine* to further enrich and support academic work in the new specialty.

Despite his academic and educational achievements, however, Peter's first loyalty was always to the patient.

Peter was also interested in some of the legal implications of practicing emergency medicine and believed that our legal tort system had, in part, triggered the creation of our specialty by compelling hospitals to staff emergency departments with trained providers. In 1990, he wrote about the importance of being a plaintiff expert witness, saying that "physicians who work as an expert for just the defense may appear to a jury to be less objective than physicians who are willing to testify that another physician was negligent." He believed that impartial experts evaluating cases for plaintiffs' attorneys would invisibly stop many lawsuits before they were ever filed. But he also felt that validating legitimate claims by injured patients was important as well. "The last guarantee of fairness in the system is to

have available the testimony of honest physicians," he said. "In the long run, this will prove the strongest defense against nonobjective partisan testimony proffered only to further the financial gain of the dishonest expert." In pursuit of this, he testified for patients and physicians for 40 years and earned a reputation of uncompromising honesty. However, Peter's testimony against another physician in a case several years ago was criticized, turning his long-held beliefs into a surprisingly public issue. While he was officially censured by ACEP, Peter always maintained that his testimony had been medically justified and that he was simply acting upon the beliefs that he had voiced and practiced for years.

Peter is now gone. And yet he will live on in each of us—those who knew him and those who did not—for as long as emergency physicians value our responsibilities as specialists and fight to protect them and our patients.

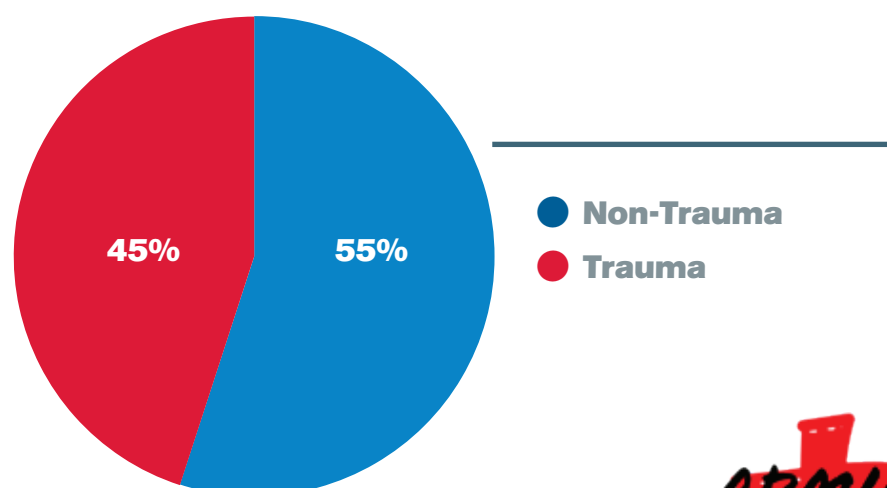
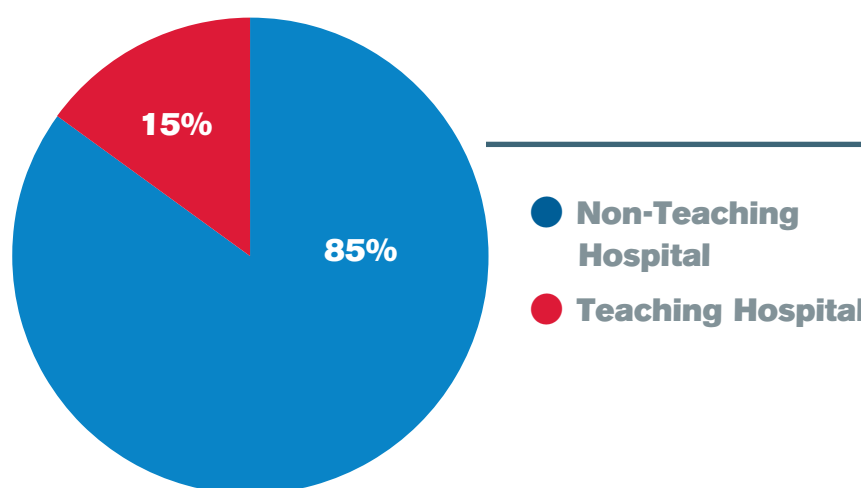
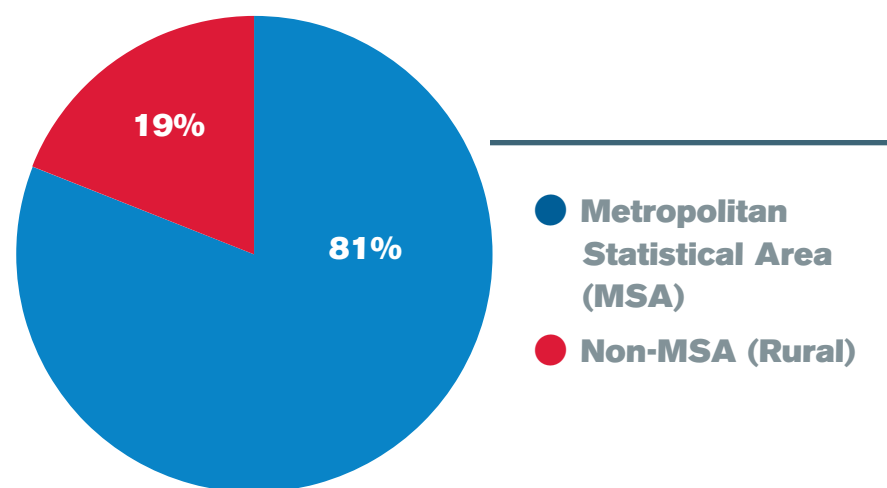
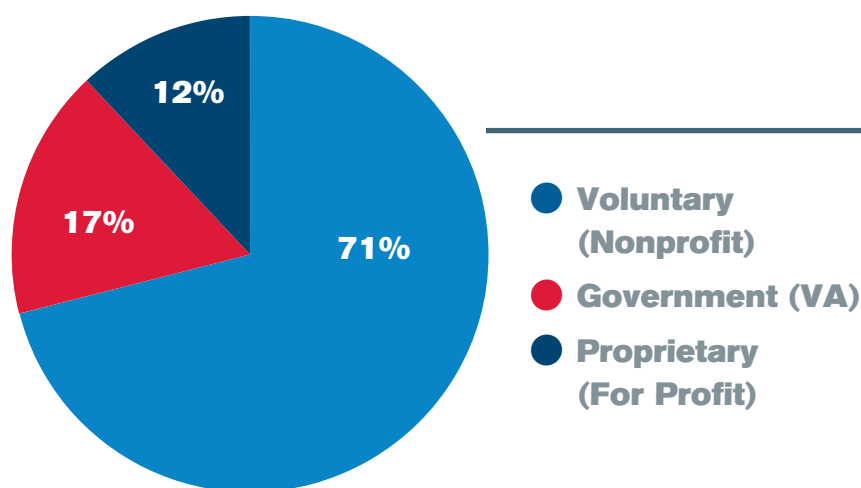
Peter would ask and expect us to care and protect our vulnerable patients, to expand and transfer our knowledge to the next generation of specialists, and to demand excellence in all of these endeavors. And he would do so with the same rigor, affection, and humor for which he was so widely admired during his long and productive life. This is how we will honor the prodigious legacy of Peter Rosen, MD, 1935–2019. ☺

**DR. WOLFE** is chief of emergency medicine at Beth Israel Deaconess Medical Center in Boston.

## Data Snapshots

QUICK STATS FROM THE ED

# Who Are the Hospitals?



by **SAM ASHOO, MD, FACEP**, founder and CEO of Admin EM. More at [admin-em.com](http://admin-em.com).





**DR. FUNK** is a practicing emergency medicine physician in Springfield, Missouri, and owner of Med Mal Reviewer, LLC. He writes about medical malpractice at [www.medmalreviewer.com](http://www.medmalreviewer.com).

# When Delayed Diagnosis = Malpractice Lawsuit

This case report illustrates the perils of vague, nonspecific symptoms

by ERIC FUNK, MD

Patients presenting to the emergency department with multiple vague and nonspecific symptoms pose a particular diagnostic challenge. Generally, these presentations do not result in discovery of any severe issues, but periodically, they herald the onset of a sinister and hidden emergency disease.



Multiple return visits give the emergency physician an opportunity to rethink the situation with the benefit of further information.

The below medical malpractice lawsuit highlights a patient presenting with vague complaints over multiple visits, leading to a bad outcome from a diagnosis that is a well-known medicolegal risk.

## The Case

A 36-year-old man presented to an urgent care with a dry cough, body aches, and general malaise. He was seen by a physician, who did not order any testing and discharged him with generic instructions to take Tylenol and ibuprofen.

Two days later, the patient's symptoms persisted, and he presented to a local emergency department. The documentation from this visit notes he was also complaining of back pain and neck stiffness. An aggressive workup was ordered, including a complete blood count, a comprehensive metabolic panel, mononucleosis testing, urinalysis, an ECG, and a chest X-ray.

The results showed thrombocytopenia of 61,000 and a glucose of 245. Given the patient's neck stiffness, a lumbar puncture was recommended. The cerebrospinal fluid results did not show any abnormal findings. The patient was ultimately discharged with a diagnosis of viral meningitis, thrombocytopenia, and hyperglycemia (see Figure 1).

Over the next few days, the patient continued to feel worse. His malaise progressed, and his back pain also worsened. He presented back to the emergency department. His platelet count had improved to 120,000. A lactate was in the normal range. He was prescribed Percocet and Soma, then discharged again.

Following his third discharge, he began to experience weakness and numbness in his legs. He returned to the emergency department for a fourth time. The emergency physician reviewed his case and appropriately recognized the patient was showing signs of a spinal cord syndrome. Therefore, an MRI of his lumbar spine was ordered.

The results of the lumbar spine MRI did not show any acute abnormalities. Given the patient's objective neurological deficits, he was admitted to the hospital. Eventually, a thoracic MRI was ordered as well. The results showed

**IMPRESSION:** Viral meningitis and thrombocytopenia. He is to follow up with Dr. [REDACTED] and primary care here locally. I did discuss with him his hyperglycemia as well and he is followup with concerning this, which he has arranged.

**DISPOSITION:** Discharged home, routine.

**CONDITION:** Stable.

**IMPRESSION:** Viral meningitis, thrombocytopenia, hyperglycemia.

**FIGURE 1:** The physician's notes following the patient's first ED visit.

### IMPRESSION:

1. Ventral and left lateral thoracic spinal cord lesion, either intramedullary or intradural extramedullary at level of T9 and T10. Lesion is incompletely characterized but demonstrates mass affect on cord.
2. Equivocal lesion of dorsal extramedullary, intradural lesion at T7 level
3. Recommend repeat MRI Cervical and Thoracic spine with and without IV contrast to further assess.
4. Consider neurosurgical consult.
5. Dr. [REDACTED] was notified by phone at 5:29 am MST on [REDACTED]

**FIGURE 2:** The physician's notes following the patient's fourth ED visit.

[REDACTED] and [REDACTED]  
Husband and Wife,  
Plaintiffs,  
vs.  
[REDACTED] corporation, [REDACTED]  
[REDACTED] MD, [REDACTED] MD, AND  
DOE DEFENDANTS I THROUGH V,  
Defendants.

Case No. [REDACTED]

STIPULATION FOR DISMISSAL  
WITH PREJUDICE

The parties stipulate and agree that the above-captioned matter be dismissed on the merits with prejudice, each party to bear its own costs and attorney fees.

**FIGURE 3:** The newly paraplegic patient sued each of his emergency physicians as well as the hospital.

a spinal epidural abscess (SEA) at T9/T10 (see Figure 2).

A neurosurgeon was promptly consulted, and they took the patient to the operating room for surgical decompression. The patient did not recover use of his legs and is paraplegic.

## Off to the Courts

The patient contacted a plaintiff's attorney. A lawsuit was filed against each of the emergency physicians as well as the hospital. Extensive negotiations were held as the lawsuit progressed, and three days before the case was scheduled to go to a jury trial, a settlement was reached. The settlement is confidential but generally would be expected to be at least several million dollars (see Figure 3).

This case represents an unfortunately common malpractice theme in emergency medicine. A patient is seen multiple times with vague symptoms and eventually develops neurological symptoms. The patient is ultimately diagnosed with SEA and suffers permanent disability.

These cases are why plaintiff's attorneys exist. A delay in care that leaves a patient with severe disability that will require a lifetime of care is a reasonable trigger for a legal remedy, even if

those delays in care would have been extremely hard for a physician to predict on the initial visits. But based on the devastating outcomes, it is easy to see why juries are enormously sympathetic to such plaintiffs and why these cases often lead to large settlements or awards.

What went wrong here? A critical issue in the diagnosis of SEA is the availability of MRI. There is wide variation in how easily an emergency medicine physician can order an MRI, ranging from clicking a few buttons to arguing with an on-call specialist to transferring a patient to another facility. Obtaining an MRI can be a lengthy endeavor in hospitals that do not have clear and easy protocols to allow for rapid imaging, further delaying their definitive care.

Unfortunately, individual physicians may be left to bear the liability in these situations, despite the reality that such systems-level problems are not of their own making.

## Right Diagnosis, Wrong Location

In this case, the diagnosis was considered early in the patient's fourth ED visit, once neurological symptoms had developed. However, even then imaging at the wrong level of the spine was ordered, further delaying his care. This is a mistake that has occurred in multiple SEA

malpractice cases I have read. In these cases, the most common mistake is ordering imaging of the lumbar spine, missing the true location of the lesion in the thoracic or cervical spine.

There are two key tips emergency physicians can use to avoid similar situations, both centered around the physical exam. Although a screening neurological exam is appropriate for many ED patients, a cursory exam is not acceptable if the physician is concerned enough about SEA to order an MRI.

The easiest way to address this and not miss key findings is to perform a thorough sensory exam. Although the exact anatomy of the myotome and associated nerves may prove challenging to remember, the dermatome level is easily testable and can be compared to a chart you can find rapidly with a Google search.

Localizing a suspected lesion based on the dermatome will lead the clinician to the appropriate anatomical segment of the spine to image. Many physicians feel an MRI to rule out SEA should always include the entire spine, though this is not evidence-based and there are downsides to this approach (see below). It is not always possible to predict the anatomical region of the lesion based on exam alone.

When the physical exam does not clearly localize the lesion, that may suggest a lesion close to the border between two anatomical segments (or the patient may be providing conflicting information). In these cases, it is certainly best to image the entire spine. This is also important given that patients may have multiple abscesses. Multilevel disease is most common in patients who have a hematogenous spread of infection as the cause of their abscess.

That said, obtaining an MRI with contrast of the patient's entire cervical, thoracic, and lumbar spine will take hours and likely be met by pushback from MRI staff. Calling staff before placing the order and giving a brief explanation will save time and help stave off antagonism.

Spinal epidural abscesses can be very difficult for clinicians to diagnose and can lead to devastating patient outcomes. In the early stages of the disease, nonspecific symptoms predominate. During the later course of the disease, when physicians likely have a high suspicion for SEA, careful attention should be given to obtaining a thorough exam to guide imaging decisions. Use of the sensory exam dermatome level or imaging the entire spine will help avoid the heartbreaking situation of making the right diagnosis at the wrong location. 📌

## SEE THE RECORDS FROM THIS CASE

To read the entire medical record from this case and see additional legal documents, visit [www.medmalreviewer.com/case-2-fever-visit-1/](http://www.medmalreviewer.com/case-2-fever-visit-1/).



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

# Is TXA as Good as They Say?

What the data say about benefits and adverse events

by RYAN PATRICK RADECKI, MD, MS

**T**ranexamic acid (TXA) seems to have many uses. But where do we stand on the evidence?

The last time we visited the breaking literature regarding TXA, it was to examine the World Maternal Antifibrinolytic (WOMAN) trial.<sup>1</sup> That trial generated newspaper headlines, such as “Inexpensive Drug Prevents Deaths in New Mothers, Study Finds” in *The New York Times*.<sup>2</sup> On cursory glance, however, the WOMAN trial was actually a negative trial with regard to the primary outcome.

TXA recently made the news again as the results of the Clinical Randomization of an Antifibrinolytic in Significant Head Injury (CRASH-3) trial were revealed.<sup>3</sup> With headlines in *The Guardian* stating “Drug Could Prevent Thousands of Head Injury Deaths,” surely this couldn’t be yet another negative trial, could it?<sup>4</sup>

Amazingly enough, it is.

## Background

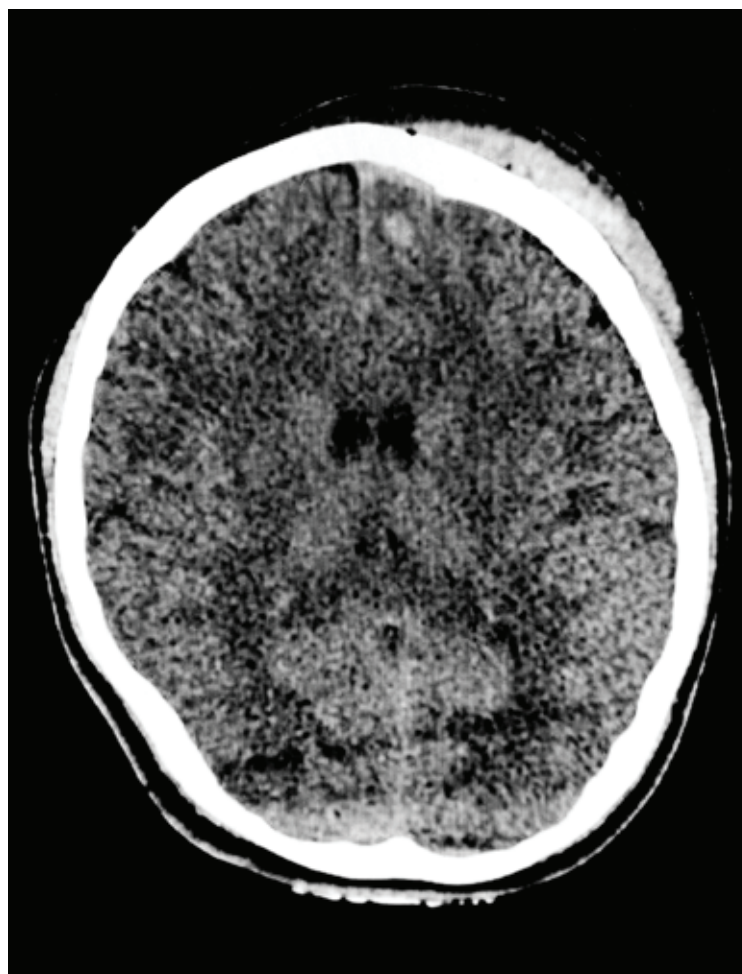
Tranexamic acid is a staple of traumatology. It is on the World Health Organization’s list of essential medicines. It has been around since the 1960s, initially designed as treatment for menorrhagia. It can be bought over the counter for this purpose in Europe.

A synthetic analogue of the amino acid lysine, TXA binds to plasminogen, preventing conversion to plasmin and subsequent fibrin degradation. TXA became prominently used in many clinical practices following the CRASH-2 trial, which tested its efficacy in trauma patients with either significant hemorrhage or risk for significant hemorrhage.<sup>5</sup>

CRASH-2 randomized more than 20,000 patients to TXA infusion or placebo. In that trial, a small overall mortality difference was observed—all-cause mortality at four weeks post-injury was 14.5 percent in those treated with TXA compared to 16.0 percent of those treated with placebo. Subgroup analyses of the results indicated a mortality benefit was only observed in the two-thirds of the trial cohort treated within three hours of injury. Thus, the common practice of timely administration of TXA in trauma was born—early administration in suspected or confirmed hemorrhage.

Implementation has been varied. Some institutions limit its use to patients exhibiting objective evidence of excessive fibrinolysis on thromboelastography (TEG) testing. Overall, TXA is considered safe and efficacious.

Since CRASH-2, a variety of further applications for TXA have been investigated, ranging from melasma to epistaxis to angioedema. However, the most prominent investigations remain in the realm of life-threatening hemorrhage. Two years ago, the WOMAN trial was published, investigating its use in postpartum hemorrhage. This trial was conducted primarily in sub-Saharan Africa and south Asia, representative of the resource-scarce settings in which 99 percent of deaths from postpartum hemorrhage occur. In another massive undertaking, more than 20,000 participants were enrolled. The primary outcome was a composite of death from any cause or hysterectomy within six weeks. Unfortunately, neither this composite primary outcome nor the overall risk of death were decreased



CT scan of subdural hematoma and intracranial hemorrhage.

SHUTTERSTOCK/ANDAPHOTO

by administration of TXA, with an absolute difference in both endpoints of 0.3 percent.

Adventuring through subgroup analyses, again in those treated within three hours, the authors teased out and highlighted a favorable secondary outcome: death due to bleeding. In this analysis, the absolute difference in endpoints expanded to 0.5 percent, favoring TXA administration. This effect size finally attained the Holy Grail of statistical significance and became the focus of the authors’ discussion and subsequent media spin.

## CRASH-3 Results

The presentation of CRASH-3 is perplexingly more of the same. Although CRASH-2 investigated TXA’s use for major trauma and extracranial bleeding, CRASH-3 evaluated its use for intracranial hemorrhage. Originally designed to detect overall mortality within 28 days, the study was changed following publication of CRASH-2 to focus on head injury–related death, and then was expanded to ensure an adequate sample could be enrolled and treated within the crucial first three hours. However, like the WOMAN trial before it, neither the results for the original primary outcome nor the modified primary outcome reached statistical significance.

Again, however, the authors expend but a few words acknowledging their original primary outcome. Nor do they pour much mention upon the observed *increase* in non-head injury–related deaths associated with TXA treatment. Instead, as with the WOMAN trial, the authors dive into the subgroups for head injury–related death, further stratifying those results by Glasgow Coma Scale (CGS).

Within the 12,000 patients randomized, only 4,500 had GCS scores of 9–15 and were treated within three hours. In this subgroup alone, the authors report beneficial effects from TXA administration, with a reduction in head injury–related death

from 7.5 percent to 5.8 percent. This subgroup alone forms the foundation of the authors’ discussion and the subsequent coverage in the popular press.

And what of adverse events? In all these studies, the authors confidently state no differences were observed between TXA and placebo. Although technically true, these trials were not specifically powered to detect differences in many infrequent outcomes. For example, in both the WOMAN and CRASH-2 trials, there were more deaths in the group of patients treated with TXA after the three-hour time window, indicating there are clearly some difficult-to-detect harms associated with the use of TXA. When only small benefits in a subgroup are touted as the positive outcome, even a handful of excess adverse events may be important signals.

CRASH-3 is not the only recent trial that assessed the utility of TXA for intracerebral hemorrhage. A smaller trial, Tranexamic Acid for Hyperacute Primary Intracerebral Hemorrhage (TICH-2), randomized 2,325 patients with spontaneous intracerebral hemorrhage to either TXA or placebo.<sup>6</sup> This trial was unable to reliably detect a difference favoring TXA. However, as with WOMAN and CRASH-3, overall trends and secondary outcome measures generally favored the TXA cohort, albeit the true absolute difference is likely to remain vanishingly small.

So clearly the data do not fully jibe with the findings promoted in the lay press. Where does that leave us when making a bedside decision on TXA use? The overall effect of TXA administration in a subset of patients with head injury is most likely to be positive with respect to head injury–related mortality. This is not inconsequential. However, there are wide confidence intervals and uncertainty resulting from the overall survival observations, and the number of patients needed to treat to save one life may be hundreds of patients or more. Meanwhile, the points the various authors of these studies make are true: This treatment is relatively inexpensive, and the rate of serious adverse events is low enough as to be challenging to detect.

The bottom line, unsatisfyingly enough, is uncertainty. There is clearly room for individual practice variation with no obviously right answer. When considering the use of TXA for intracerebral hemorrhage, at the least it must be given as early as possible and within three hours, targeted at those with mild to moderate head injury, and only after the other higher-yield clinical interventions have been performed.

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

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# 10 Tax-Free Investments to Consider

With a little planning, you can grow your money and minimize taxes

by JAMES M. DAHLE, MD, FACEP

**Q. I am tired of paying taxes and I hear there are tax-free investments out there. What are they, and should I use them?**

**A.** Many physicians are heavily taxed, so it is no surprise you are looking for ways to invest that do not increase your tax burden. However, it is critical that you pay attention not just to the taxes paid but to the after-tax return on the investments. Sometimes it makes sense to pay more in taxes “now” if it leaves you with more later.

In this column, I’m going to discuss 10 ways to invest without paying any taxes at all. Naturally, with each method there is a way you could owe taxes if you are not careful, but for the most part, these investments are tax-free, at least at the time of deposit.

## 1. Municipal Bonds

Municipal bonds are a loan to a state or municipality. Municipal bond interest is federal income tax-free (although some bonds do produce interest subject to the Alternative Minimum Tax). A municipal bond from your state is also often state income tax-free. Of course, if you sell a bond or bond mutual fund for a gain, capital gains taxes would apply.

## 2. Treasury Bonds

Treasury bonds are a loan to the federal government. While not free from federal income tax, they are free from state income tax. This is one reason their yields are generally lower than those of corporate bonds. Like a municipal bond or bond fund, if sold for a gain, capital gains taxes apply.

## 3. Savings Bonds

Savings bonds, whether the standard type EE or inflation-adjusted, are like treasury bonds in that they are always free of state and local income tax. Federal income taxes are deferred until the bond is redeemed, perhaps decades later. If the proceeds are used for education, they are free from federal income tax, too.

## 4. Anything in a Roth Account

The dollars you contribute to a Roth IRA, Roth 401(k), Roth 403(b), or Roth 457(b) have already been taxed, but all earnings from these accounts, no matter the investment, are free from federal, state, and local income taxes. There are two notable exceptions: First, income from leveraged real estate in a self-directed Roth IRA may be subject to Unrelated Business Income Tax. Second, if you withdraw money from the account prior to age 59½ and do not have a viable exception such as disability, a first home, or early retirement under the Substantially Equal Periodic Payments Rule, there will be a 10 percent penalty on earnings.

## 5. Anything in a 529 Account

529 contributions may provide a state tax credit or deduction at the time of contribution, but if the proceeds are used for approved educational expenses, there are also no federal, state, or local income taxes due on the earnings.

## 6. Anything in a Health Savings Account

Contributions to a health savings account (HSA) also provide a federal and state income tax deduction. If used to pay for ap-

proved health care expenses, there are no federal, state, or local income taxes due on withdrawals from the account. Note that New Jersey and California do not recognize HSAs, so contributions there are not state income tax deductions and earnings are not free from state income tax.

## 7. Basis

Many people forget that you never owe income taxes on your “basis” (ie, the purchase price, excluding commissions and other expenses) since it has already been taxed when you earned it. Basis is the amount the IRS considers you to have paid into an investment. For example, if you paid \$10,000 for stock and then sell it when it is worth \$15,000, you only owe capital gains taxes on \$5,000. The initial basis is income tax-free. This characteristic allows many retirees to dramatically lower their tax bill in retirement.

## 8. Equity Real Estate Covered by Depreciation

Depreciation can be an important tax break, and the bonus depreciation enabled by the Tax Cuts and Jobs Act, which went into effect in 2018, offers significant savings. The income from equity real estate is often completely offset by this deduction, providing tax-free income. If you or your spouse qualifies for real estate professional status, that depreciation can even be used to offset your earned income. While depreciation is recaptured when you sell a house, it is recaptured at a maximum of 25 percent and can be deferred by doing “1031 tax-free exchange” of a property instead of selling it. If you do not sell prior to death, the depreciation recapture is eliminated for your heirs by the step up in basis at death (ie, when the basis of an appreciated asset is adjusted to current market value when it is inherited).

## 9. Non-Dividend-Paying Stocks

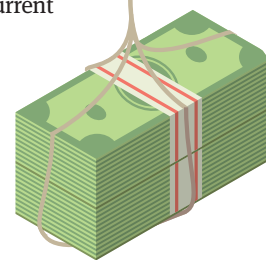
Qualified stock dividends are eligible for lower tax rates, but if the stock does not pay dividends at all and you do not sell the stock, then the investment grows tax-free. If left to your heirs, the heirs will also benefit from the step up in basis at death and receive an income tax-free inheritance. Of course, the risks and lack of diversification with picking individual stocks may outweigh this benefit, but a growth stock index fund with a yield under 1 percent is still tax-efficient.

## 10. Whole Life Insurance

Cash-value life insurance policies such as “whole life” grow in a tax-deferred manner. Partial surrenders of the policy allow you to access your basis first, which is tax-free. The death benefit is also always income tax-free. In addition, you can borrow against the value of your policy tax-free (just like you can borrow against your house, car, and investment portfolio tax-free), albeit not interest-free. Even with that tax treat-

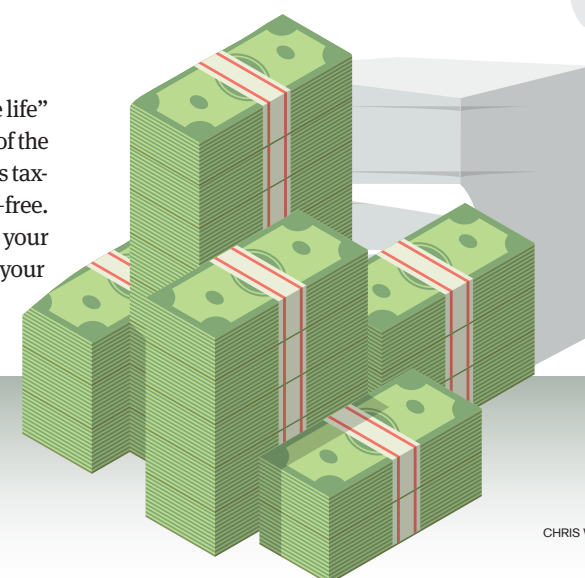
ment, it is hard to recommend whole life insurance to someone who doesn’t have the permanent need to have a benefit paid upon their death. The low returns (negative for the first five to 15 years) and high insurance costs make this a niche product that is appropriate for only a few physicians.

Do not be afraid to pay more taxes if it means you come out ahead after tax. For example, if a municipal bond fund yields 1.5 percent and a taxable bond fund yields 2.1 percent and you are in the 24 percent federal tax bracket, you can quickly see that  $2.1\text{ percent} - (24\text{ percent} \times 2.1) = 1.6\text{ percent}$ . In that case, you would be better off with the taxable bond fund than the municipal bond fund. Minimizing taxes is an important part of being an investor, but do not let the tax tail wag the investment dog. +



**BOND**

**STOCK  
CERTIFICATE**



**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

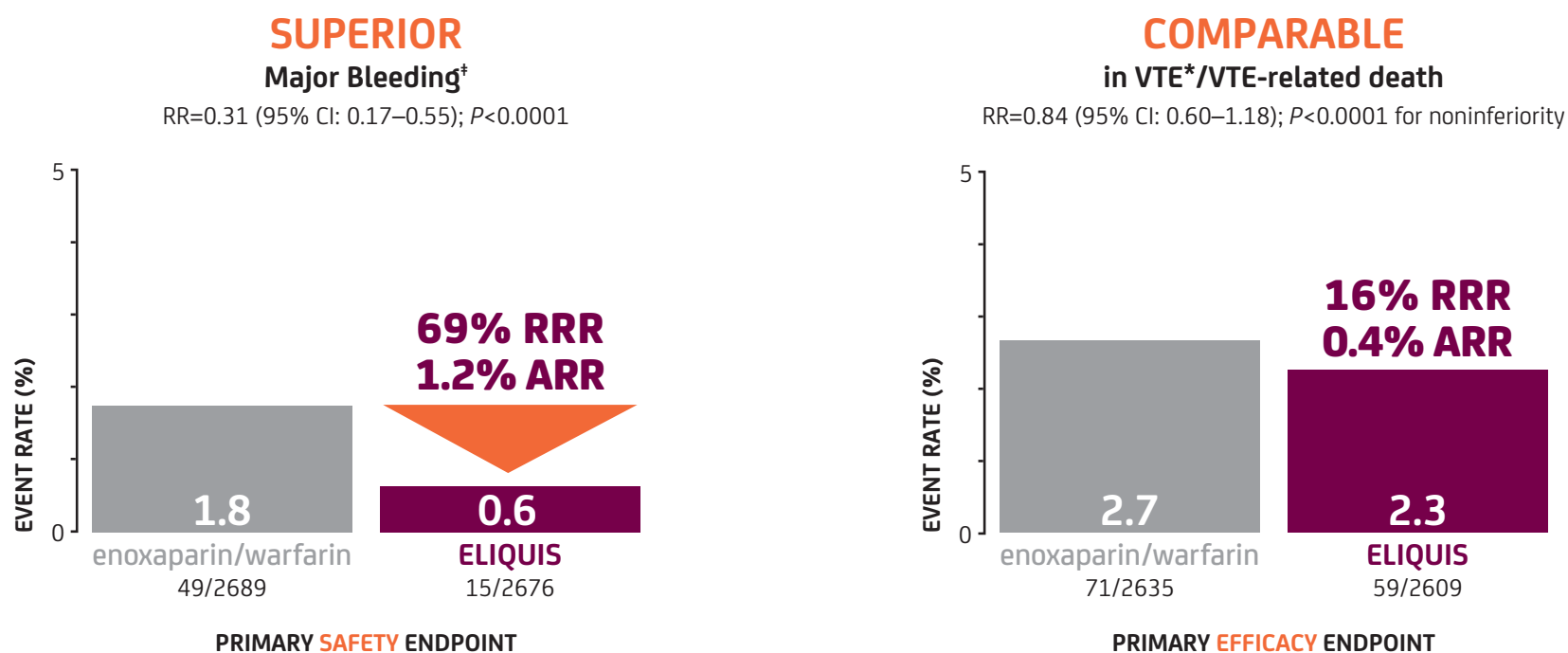
- **Combined P-gp and Strong CYP3A4 Inhibitors:** Inhibitors of P-glycoprotein (P-gp) and cytochrome P450 3A4 (CYP3A4) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is 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 Dosage and Administration, Warnings and Precautions, and Clinical Studies (14.1) 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 Warnings and Precautions]</p> <p>Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary [see Warnings and Precautions].</p> <p>Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated [see Warnings and Precautions].</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.

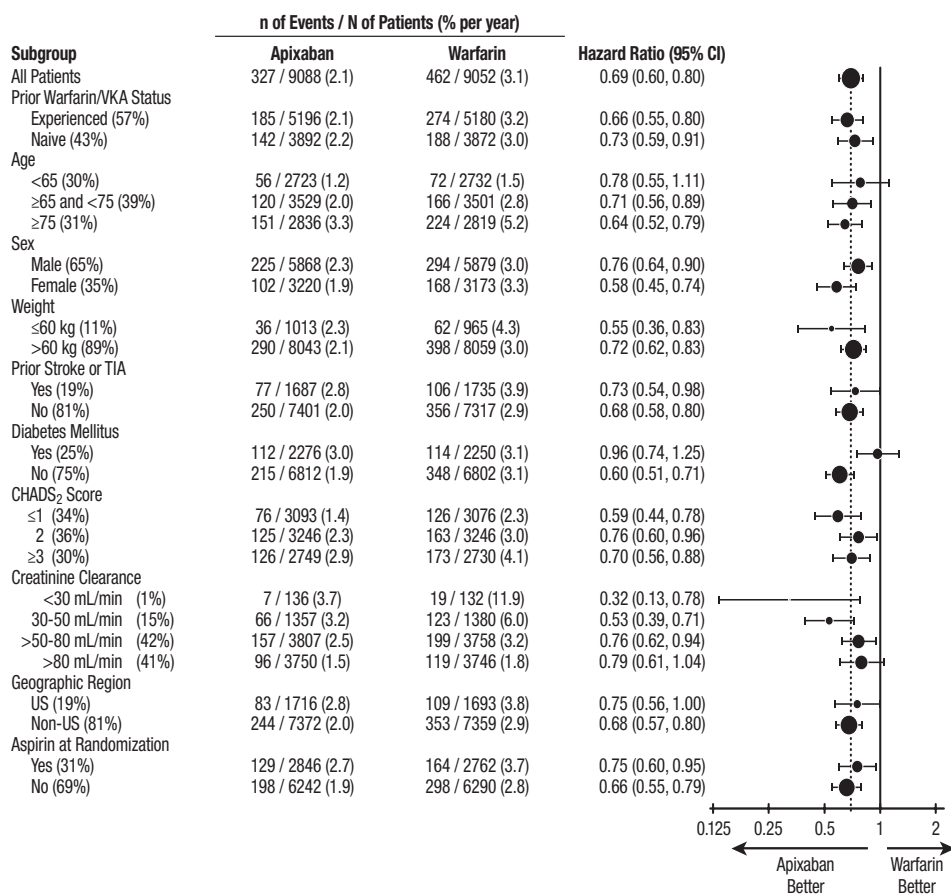
‡ Intracranial bleed includes intracerebral, intraventricular, subdural, and subarachnoid bleeding. Any type of hemorrhagic stroke was adjudicated and counted as an intracranial major bleed.

§ 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.
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**JAMES J. AUGUSTINE, MD, FACEP**, is a clinical professor of emergency medicine at Wright State University in Dayton, Ohio; on the Board of Directors of ACEP; vice president of EDBA; chair of the National Clinical Governance Board for US Acute Care Solutions; and a medical director for fire EMS agencies in Atlanta; Naples, Florida; and Dayton, Ohio.

# The Trip Down Admission Lane

The latest data reveal our important role as gatekeepers

by JAMES AUGUSTINE, MD, FACEP

Emergency departments have become the nucleus of the hospitals they serve. Emergency physicians not only provide lifesaving treatment, they also serve as gatekeepers to their hospital's inpatient services.

Every day, emergency physicians in U.S. emergency departments manage about 411,000 patients and decide that about 74,000 would benefit from inpatient services. Those 74,000 patients represent about 70 percent of the 106,000 patients admitted to hospitals each day.

New data give us a clear view of our role.

## The EDBA and NHAMCS Data

The Emergency Department Benchmarking Alliance (EDBA) studies and reports on the operations required to manage our evolving patient group. The 2018 EDBA Performance Measures annual survey includes almost 2,000 emergency departments that served about 76 million patients.

Admissions and transfers account for roughly 20 percent of all patient dispositions across the United States.

The "admission percentage" is the percentage of patients seen in the emergency department and then placed in an inpatient area of the hospital. This percentage includes the total number of admitted patients taken to an inpatient area, including those defined as observation patients by hospital processes. This is important for hospital administrators to know because ED patients who need inpatient services require a disproportionate amount of time and energy from emergency physicians and ED staff.

The "transfer percentage" is the percent of patients seen in the emergency department and then transferred from the emergency department to another emergency department or hospital. This group has uniform requirements under EMTALA for management, documentation, patient consent, and records maintenance. Small-volume emergency departments have the highest transfer rates, at about 5 percent.

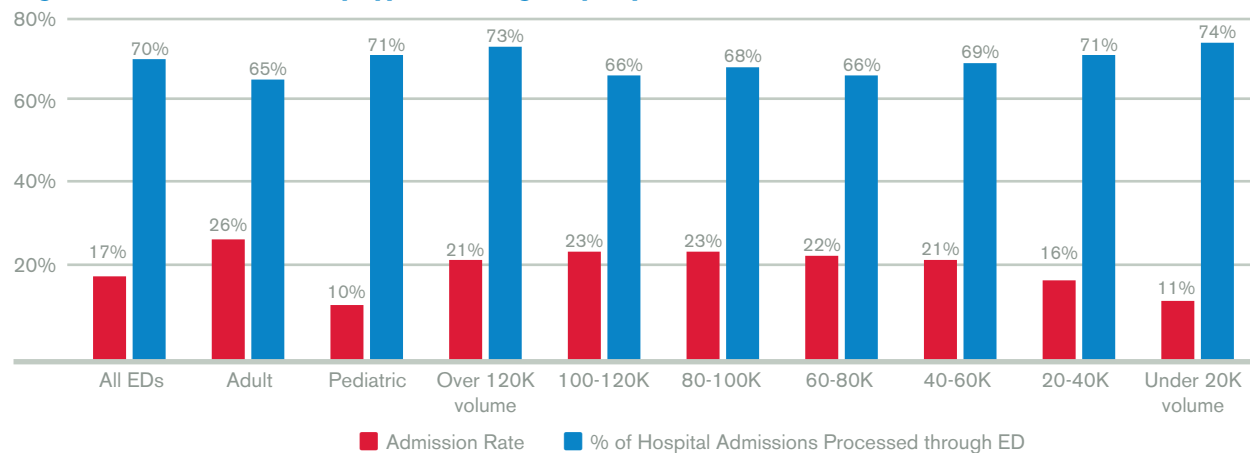
The "percentage of hospital admissions processed through the emergency department" is calculated by measuring the total number of patients admitted from the emergency department and dividing it by the total number of general admissions to the hospital.

In 2018, inpatient units were the site of disposition of emergency patients in about 17 percent of visits. The emergency department remains the dominant source of hospital admissions in the United States with about 70 percent of hospital inpatients processed through it. In addition, about 2.8 percent of patients were transferred to another hospital, typically for admission, too.

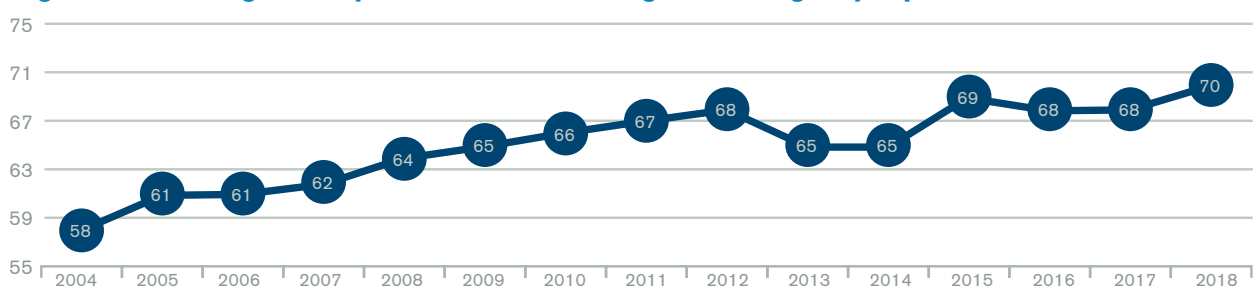
In 2018, the EDBA data survey also measured critical time intervals of admitted patients. The median length of time from the moment the patient arrived in the ED until the decision was made to admit the patient for inpatient services was 188 minutes. The second critical time interval was from the time of an admission decision to when the patient was moved out of the emergency department to the inpatient unit. Nationally, that median time interval was 116 minutes.

There are significant variations in admission and transfer rates by type of emergency department and by patient group served (see Figure 1). In adult emergency departments, the admission rates are the highest at about 26 percent, with adults accounting for about 65 percent of all hospital admissions. In pediatric emergency departments, the admission rate is only 10 percent, but that patient group accounts for 71 percent of all hospital admissions in those facilities. Low-volume emergency departments (ie, those that see fewer than 20,000 patients per year) have the lowest admission rate of any volume cohort at

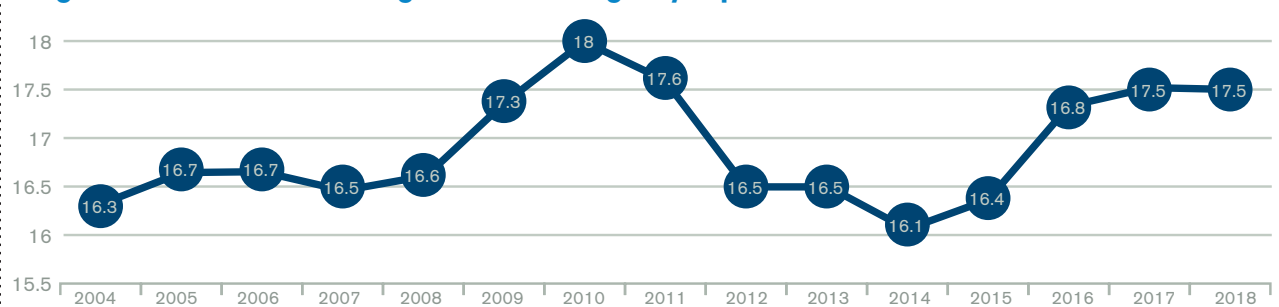
**Figure 1: Admission Rate by Type of Emergency Department**



**Figure 2: Percentage of Hospital Admissions Through the Emergency Department**



**Figure 3: Admission Percentage Rates of Emergency Department Patients Over 14 Years**



11 percent.

Another data set, provided by the National Hospital Ambulatory Medical Care Survey (NHAMCS) from the Centers for Disease Control and Prevention (CDC), provides a different statistical estimate of emergency department patients, treatment, and disposition based on federal demographic data and a statistical sampling of visits to American emergency departments. The latest data tables published reflect patient visits from 2016.

The NHAMCS report finds about 11 percent of ED visits resulted in admission and about 2.7 percent resulted in patient transfer. The NHAMCS report typically finds a lower-acuity population than is reported in the EDBA data surveys, likely due to its sampling methodology—its surveys may contain more low-volume and low-acuity emergency departments. Meanwhile, the EDBA report is based on ED data of actual patient outcomes and does not use sampling methods.

Admission and transfer rates impact the overall flow of the emergency department. Effective inpatient movement is associated with efficient ED flow and should be a priority for emergency physicians and hospital leaders.<sup>1,2</sup>

## ED Admissions Data Trends

A core competence of emergency medicine practice is determining which patients would benefit from inpatient care and which can be safely managed as outpatients. Various guides purport to define which patients qualify for inpatient services and further attempt to divvy those patients among those who will benefit from full admission versus observation. The reality

is that a complex mix of factors determines the safety of outpatient care for a patient undergoing evaluation in the emergency department.

Emergency physicians deliver great value to the health system by making those determinations in about three hours from the time a patient arrives in the emergency department. Trend data indicate the medical community entrusts emergency physicians to determine which patients will benefit from inpatient care after the patient receives diagnostic workup and initial treatment in the emergency department. Indeed, the use of emergency departments as a processing center for hospital admissions has increased over the last 14 years, from 58 percent to about 70 percent (see Figure 2).

Systemically, admission needs for patients over the past 14 years have remained relatively consistent (see Figure 3), varying in a narrow range between 16 percent and 18 percent. Despite improvements in outpatient services, there have been no reductions in overall average admission rates.

Emergency physicians should appreciate the role of the emergency department as the intake center for patients who will require inpatient services. This role has increased over time and is unlikely to change as more diagnostic and treatment services are offered through emergency departments. +

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**DR. DAS** is director of undergraduate point-of-care ultrasound medical education and assistant professor of emergency medicine at Columbia University Vagelos College of Physicians and Surgeons in New York City.

# Networks of Support

The importance of women-focused groups in academic medicine

by DEVJANI DAS, MD, RDMS, FACEP

For the first time in history, women accounted for the majority of medical school matriculants in 2017.<sup>1</sup> Gender-equity problem solved, right? Not quite.

Although this reflects progress for women in medicine, many studies have demonstrated that gender inequity becomes increasingly apparent as women progress through their careers. Increasing the number of women in medicine will not adequately address or magically fix this.

Both within the United States and beyond, women are much less likely than men to become full professors, even after taking into account



age, experience, specialty, and independent measures of research and clinical productivity.<sup>2</sup>

Women of color are particularly affected, accounting for 7.5 percent of all full-time faculty in the United States and, even more alarmingly, only 0.9 percent of professors in the United Kingdom.<sup>3</sup>

In emergency medicine, a 2017 study by Madsen et al revealed a salary gap of \$19,462 in academic emergency medicine, with women earning less than men regardless of rank, clinical hours, or training.<sup>4</sup>

Course correction is needed. A multi-pronged approach is necessary and will include some temporary stopgap solutions as well as lasting systemic reforms. In 2016, Choo et al published best-practice recommendations to support the recruitment, retention, and promotion of women within academic emergency medicine through specific and feasible recommendations.<sup>5</sup> Mentorship and networking opportunities are the core strategies, in essence mirroring successful paths that men have used. A more organized approach can be found in gender-specific groups created specifically to propel success for women in academia. Until recently, though, there was little evidence to validate the utility of such groups in advancing the career objectives of female physicians.

A small recent qualitative study utilized semistructured interviews of female physicians at various career stages who have been a part of a national women-focused group.<sup>6</sup> Most participants found many reasons that membership had helped further their careers. Several dominant themes, both objective and subjective, emerged.

## Mentorship and Sponsorship

In a recent systematic review, mentoring was seen as a central component in almost all formal programs that were created to support the careers of women in academic medicine.<sup>3</sup> Although no generalizable method for mentor-



The ACEP19 opening session "Perspectives from Female Physicians on Leadership, the Ascent of Women in Medicine and Women at the Forefront of Change" focused on empowering the audience to become change makers in health care. It featured five women emergency physicians speakers (from left): Resa Lewiss, MD, FACEP; Joneigh Khaldun, MD, FACEP; Megan Ranney, MD, MPH, FACEP; Hiral Tipirneni, MD; and Dara Kass, MD, FACEP.

ship or formalized program was universally implemented, those undergoing such mentorship noted improvement in perceived skills and self-esteem.<sup>7</sup> In particular, Lin et al found that junior female faculty often felt mentorship increased their sense of confidence. Sponsorship, an entity distinct from mentorship, was also highlighted as a benefit, as it led to senior members nominating junior members for leadership, awards, and research opportunities.<sup>6</sup>

## Facilitating Peer Support and Collaborations

Opportunities for research collaboration were deemed a major benefit of being part of a women-focused group. Not only was participating in such a group conducive to formulating pertinent avenues of research to pursue, it was also a method by which women felt that they were able to acquire new skills and gain confidence in their writing.<sup>6</sup>

## Facilitating Nonacademic Opportunities and Collaboration

Separate from purely academic pursuits, Lin et al found that participation in a women-focused group also allows for networking opportunities that eventually can lead to enhanced employment options.<sup>6</sup> In addition, several women commented on how they were inspired to pursue careers outside of purely academic medicine, including founding organizations and businesses to promote the advancement of women.

## Enhancing Negotiating Skills

Research has shown women have undue difficulty when negotiating. Even when attempting to negotiate, women are viewed more negatively by their peers and supervisors than their male counterparts.<sup>8</sup> Members of women-focused groups are acutely aware of such issues and, whether formally through workshops or informally through mentorship networks, are able to address this important topic.

## Navigating Bias and Harassment

The rates of gender-based harassment are staggering and contribute to the long list of gender-based inequities. As a National Academies of Sciences, Engineering, and Medicine report described, harassment includes a mix of verbal and nonverbal behaviors that "convey hostility, objectification, exclusion or second-class

status about members of one gender."<sup>9</sup> Members of women-focused groups are able to band together and put forth best-practice standards that call for institutional reforms that may be key to the recruitment, retention, and advancement of female physicians.

CONTINUED on page 28

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**Navigating Work-Life Demands**

For many, the initial impetus for creating or joining a women-focused group was to bring attention to the precarious balance that many women face when attempting to balance professional duties with family/personal life demands. The old adage of work-life balance has been largely supplanted by the concept of work-life integration. Nevertheless, many well-known issues remain. For example, a report from the Association of American Medical Colleges found that 40 percent of women

physicians scale back their medical practice, whether going part-time or leaving medicine entirely, within six years of completing residency.<sup>10</sup> Among the reasons women leave full-time medical careers so soon after completing training are family-specific concerns.<sup>10</sup> Women-focused groups allow female physicians to find camaraderie while working together in calling for institutional reforms to accommodate different life phases. Without the explicit and implicit support offered by such organizations, many women may feel

isolated and find reasons to leave the medical field entirely.

**Reduced Professional Isolation**

Though largely attributed to work-life-family conflict, it is likely that women feel isolated for many reasons and suffer from a lack of support at their home institutions. Becoming part of a women-focused group is a way for women to decrease professional isolation and increase their sense of belonging within a community of individuals who have dealt and continue to

deal with similar issues.

Here, the digital age offers potential avenues for improvement by making it possible for women to easily communicate on a larger scale than what was previously possible. Women from a variety of different racial and ethnic backgrounds, upbringings, experiences, and perspectives are now able to communicate instantaneously and form communities that were once inconceivable. Grassroots efforts have formed powerful networks of women, such as FemInEM, that have

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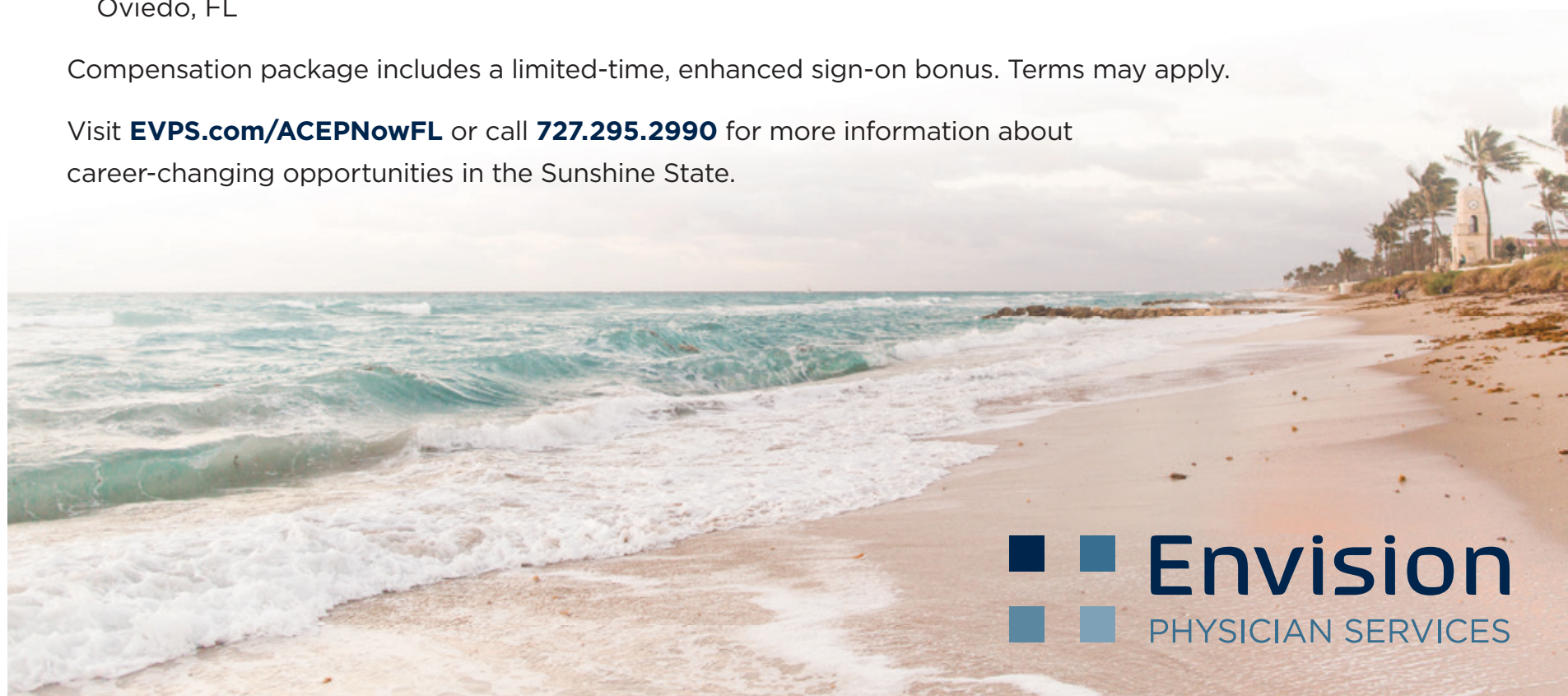


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used their online footprint to spread important messages to a global arena. Social media campaigns, such as #TimesUpHealthcare, #WomenInMedicine, and #GirlMedTwitter, have been able to spread their messages and bring together a global community of women who face similar issues, though they may be separated by time and distance.

### Conclusion

Women today are entering the sciences, particularly the medical field, in record numbers. However, it is clear that we are losing great numbers of these women (and women-hours of productivity) as they advance through their careers. We must find ways to curb this prob-

lem so we retain the diversity and value that female physicians provide to medicine. Research is now shedding light on the tangible benefits of joining women-focused organizations. The potential improvements span across multiple domains, including creating opportunities for mentorship, promotion, scholarly productivity, and advocacy for gender-specific issues. But this is only the beginning. With the advent of so many different avenues to create a network of women with similarly focused goals, we are just now sensing how much can be accomplished.

*"The Equity Equation" is curated by Dara Kass, MD, and Uché Blackstock, MD. 📌*

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