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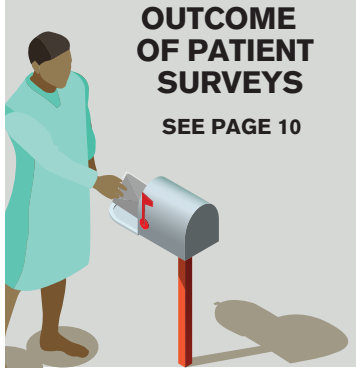
INFLUENCING THE OUTCOME OF PATIENT SURVEYS



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EM bracing Danger: Patients First!

Lessons learned from my California hospital evacuation experience

by SUSAN FITZGERALD, MD

I got the alert on my cellphone at 1:51 a.m the morning of Monday, Oct. 9, 2017. "Please come to the ED if you are available to help with the surge from fire victims and evacuees."

My first thoughts: "What fire? What evacuees? Which ED is this?"

CONTINUED *on page 8*

PHOTO: JITESH VISADIA

HAS THE tPA QUESTION LEFT THE STATION?

Dr. Radecki spins off about tPA and stroke

by RYAN PATRICK RADECKI, MD, MS

A few months ago, possibly while you weren't looking, the debate regarding the utility of tissue plasminogen activator (tPA) in acute ischemic stroke was finally settled. Even if Genentech and the American Stroke Association haven't won over many hearts and minds in the emergency medicine community, the war is effectively over. The forces aligned in favor of tPA fought the battles that mattered by funding the people authoring the guidelines and hospital quality measures, not via sniping in the academic literature. Given the prevailing medicolegal climate in many states, coupled with the institutional interest in stroke center certification and the growing reach of telestroke services, holding out as a conscientious objector

A NEW SPIN

PEARLS FROM THE MEDICAL LITERATURE

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Buprenorphine Explained

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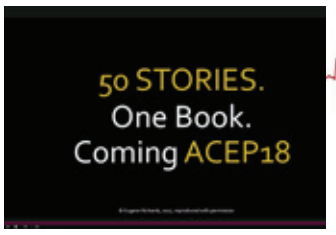

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Get your copy at bookstore.acep.org/bring-em-all-509619.

Advocating for You

ACEP responded to a letter from the Texas insurance commissioner, Kent Sullivan, to Blue Cross and Blue Shield of Texas that expressed his concern with their ED denials program for their out-of-network HMO policyholders. ACEP's letter urged Mr. Sullivan to avoid such policy features.

ACEP recently joined with 80 national medical, public health, and research organizations to send a joint letter to House and Senate leaders asking for $50 million in funding for the Centers for Disease Control and Prevention to conduct public health research on firearms injury prevention.

Two more ACEP emergency physicians testified on opioids in front of congressional committees. Tim Westlake, MD, FACEP, testified before the House Committee on the Judiciary in a hearing titled "Challenges and Solutions in the Opioid Abuse Crisis." Charles Pattavina, MD, FACEP, testified in front of the Senate Special Committee on Aging on the issue of seniors and opioids.

ACEP was invited by the Center for Medicare and Medicaid Innovation to advise its efforts on developing new payment models for rural health. ACEP President-Elect John Rogers, MD, FACEP, attended.

ACEP member Scott Zeller, MD, visited the Center for Medicare and Medicaid Innovation to propose that it consider developing a demonstration project to test a wider implementation of the Alameda Model, a regional dedicated psychiatric emergency service.

ACEP is planning an opioid initiative under its Emergency Quality Network (E-QUAL) program, which will focus on building toolkits, as well as education and training webinars and podcasts. The American Hospital Association (AHA) has keen interest in participating, and ACEP leadership is committed to collaboration with AHA on opioids.

ACEP

Legislative Victory

Debra Perina, MD, FACEP (left), and Jeffrey Goodloe, MD, FACEP, hold up a signed copy of HR 304, Protecting Patient Access to Emergency Medications Act of 2017. This law legalizes the use of standing orders for EMS for using controlled substances and formalizes the process for receipt, storage, and dispensing of controlled substances by EMS services. Craig Manifold, DO, FACEP, Dr. Goodloe, and Dr. Perina were instrumental in working to get this bill signed into law.


ACEP

ACEP President Receives Award

ACEP President Paul Kivela, MD, MBA, FACEP, received a gold medal from the Intercontinental Emergency Medicine Congress at its April meeting.

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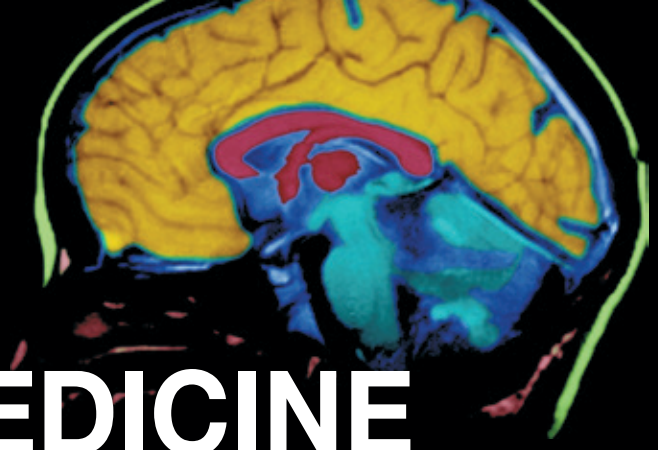

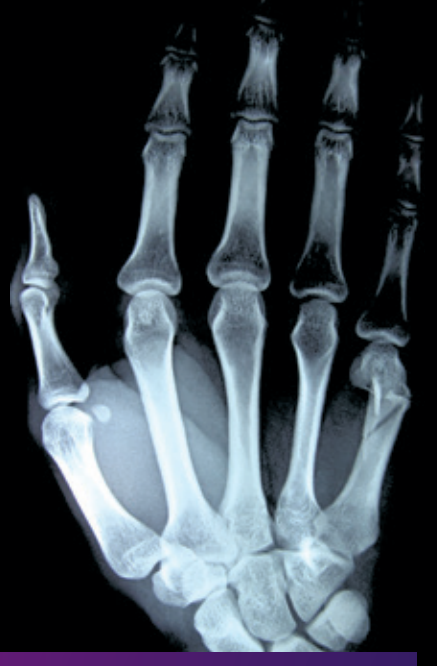

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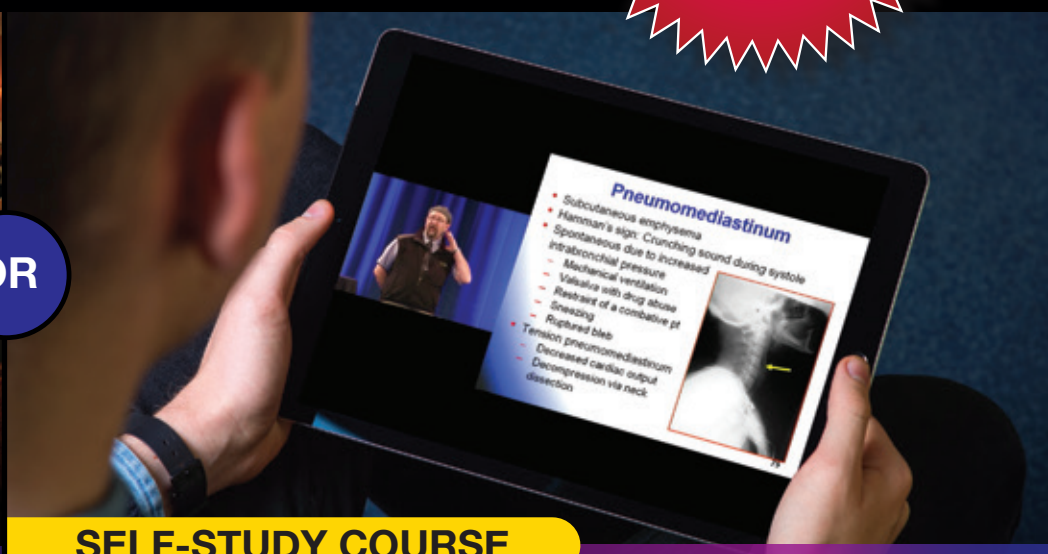

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THE BREAK ROOM

Stroke Treatment Window

In our April issue, we published "Time to Expand Stroke Treatment Window?: Pushing the Envelope for Mechanical Thrombectomy" by Alexei Wagner, MD, MBA; and Sam Shen, MD, MBA, which reviewed Stanford University's novel Stroke Code Extended protocol, and we invited readers to weigh in on the protocol. Here are some of those responses:

While I commend Dr. Wagner and Dr. Shen for their enthusiasm regarding thrombectomy in strokes, I tend to be a "big picture" kind of person, and the lack of perspective in their article is striking.

First, their assertion that many EPs have felt a certain satisfaction in "saving" stroke victims from a lifetime of debilitating deficits is not shared by a large number of my colleagues who have not witnessed such dramatic saves, and in either case, such anecdotes are not data as to the efficacy of thrombolysis. (NINDS has never been repeated).

Second, raising patients' and their families' expectations that there is a "miracle cure" for stroke does no one any good.

Third, the authors fail to point out how few stroke victims are candidates for thrombectomy compared to the total number of strokes. Likewise, data exist that more than half of all patients, thought to be good candidates, transferred for thrombectomy don't get the advanced treatment.

Finally, as a corollary to point three, how do our scarce resources get used for a treatment designed to help just a few people? I'm thinking in particular of rearranging the entire EMS system so that a few patients get routed to the comprehensive stroke centers.

I want the tertiary care centers to continue their research into stroke treatments so that, in the future, we may have a better idea as to who may benefit from advanced therapies. But until we know who benefits and under what circumstances, I suggest we don't get ahead of ourselves.

–Jonathan D. Lawrence, MD, FACEP
Long Beach, California

"...many emergency physicians can attest to the professional satisfaction of successfully administering treatment to a patient who otherwise would have had a lifelong, debilitating neurologic deficit ..."

Many EM docs have also had a patient presenting with significant deficits who got better before thrombolysis could be initiated. If we got the tPA in fast enough, we would have thought we did a wonderful thing. But that's why we have double-blind trials. NINDS didn't show a short-term benefit. The benefit shown was at three months, a time frame beyond the follow-up for most EM docs.

– Joel Pasternack, MD, PhD
Rochester, New York

Good News from Las Vegas

In our February and March issues, we brought you first-person accounts of the October 2017 mass shooting at the Route 91 Harvest country music festival in Las Vegas, one from Scott Scherr, MD, an emergency physician who treated shooting victims at Sunrise Hospital & Medical Center (left), and the other from shooting victim Jeannine Ruggeiro (right). Dr. Scherr recently contacted *ACEP Now* to let us know that Ms. Ruggeiro is doing great and is nine months pregnant. We wish her well!

Inside

ILLUSTRATION: CHRIS WHISSEN PHOTOS: SHUTTERSTOCK.COM

A NEW SPIN

CONTINUED FROM PAGE 1

to the use of tPA grows ever more perilous.

However, all these factors pale in the context of the public-shaming hit job from *The New York Times* titled, "For Many Strokes, There's an Effective Treatment. Why Aren't Some Doctors Offering It?"[1] If you didn't read the article, its general tone should be apparent from the title. The author wades into the debate over tPA by pitting the two sides against each other with a biased portrayal of their positions: the neurologists, beleaguered and confused by the opposition to their sterling evidence, and the emergency physicians, which the author described as being led by shyster figurehead Jerome Hoffman, MD, professor of emergency medicine at the University of California, Los Angeles, and his cadre of disinformation trolls on social media. The author effectively implies only the lunatic fringe would contest the efficacy of tPA, and even the lead subject of the article, Christopher Lewandowski, MD, an emergency physician at Henry Ford Hospital in Detroit, is considered a victim. The pervasive reach of anti-tPA dissent, according to this reporting, prevented his father from receiving the blessed miracle of "clot-busting" therapy.

Hyperbole and exaggeration aside, this obviously is not an appropriate characterization of our specialty nor of some of our most respected leaders in the critical appraisal of medical evidence. Also, it isn't productive to refresh, ad nauseum, the back-and-forth regarding the efficacy of tPA, tweeting out the enrollment imbalances, the effect sizes, or the relative relevance of the trials that did not result in statistically significant positive findings. The most important lessons from this odd article in the *Times* relate to why, 23 years after the National Institute of Neurological Disorders and Stroke tPA clinical trial was published, such uncertainty persists regarding the appropriate treatment of patients suffering acute ischemic stroke and why it remains such a fiery topic.[2]

Persistent Uncertainty

First, the practice of the emergency physician has been dictated by outside specialty societies without proper collaboration and appropriate understanding of our specialty. The management controversy associated with acute ischemic stroke is hardly an outlier in emergency medicine. Over the past decades, we have been subject to implementation mandates for early goal-directed therapy (EGDT) for sepsis, recommendations for early provocative testing for patients with chest pain, and high-dose steroids in spinal cord trauma, among countless others. Many of these treatment pathways and recommendations demand profound reorganization of systems of care in the emergency department.

Second, many of these same external edicts ultimately fell victim to medical reversal. The original EGDT protocol has evolved into an entirely different sepsis hydra. The pendulum is swinging back toward a conservative approach to patients with chest pain. The initial enthusiasm for high-dose steroids in spinal cord trauma has given way to concerns over harm and critically flawed methodology.

The same pervasive syndrome of medical reversal affects ED care, even when looking solely at trials published in such journals as *The New England Journal of Medicine*, *Lancet*, and *JAMA*.[3] It should be clear by now there is great prudence in allowing additional evidence and evaluation to percolate through academic circles prior to adoption. The longer evidence is allowed to accumulate, the better understanding of patient-level factors influencing individual treatment response can be appreciated.

It's Not a Slam Dunk

This circles back to tPA. We know tPA administration does not help every patient who receives it. A variety of factors influence whether the clot buster even lyses the clot. A variety of factors influence whether there is actually any surviving tissue behind the clot. Even proponents of tPA cite statistics in which the number needed to treat represents benefit for only the gross minority of patients.

That said, in the ED and in medicine in general, we provide many treatments in which only a small handful are expected to realize substantial benefit. We must treat 10 to 15 patients complaining of sore throat with dexamethasone for one to enjoy a clinically meaningful difference in symptomatic improvement. A similar number of antibiotic exposures would be needed to prevent a single case of recurrence after abscess drainage. The list is virtually endless, but many of these treatments remain commonplace because the costs and harms are considered relatively small.

This is not the case for tPA in acute ischemic stroke. A subset of patients will likely experience some benefit, but there is also known significant risk for intracranial hemorrhage, not to mention the profound financial costs associated with both the acute evaluation and subsequent hospitalization relating to tPA administration. However, the guidelines and certifications forced upon us offer little or no flexibility in narrowing the treatment population. Surprisingly, in 23 years little evidence or guidance has been offered to clarify the individual balance between risks and benefits.

This is where the opportunity for change exists and where ACEP leadership may play an important role. External guidelines affecting ED care must have representation from experts within our specialty to ensure their impact on our practice is not unreasonable. Additional efforts should be made to downgrade evidence produced solely by sponsored entities and to elevate the opinions of those without the voice and platform afforded to those with industry ties. Further, given the pervasiveness of medical reversal for novel treatments and pathways, it would be of great value for our leaders to firmly oppose a perceived standard of care until further independent confirmatory evidence may be accrued.

Our patients may have already lost the battle for additional evidence to help tailor optimal risks and benefits with ischemic stroke. We can, however, help ensure added protections for future innovations by taking a more active but cautious role in the process of translating external guidance to the emergency department.

"A New Spin" is the personal perspective of the author and does not represent an official position of *ACEP Now* or ACEP.

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DR. RADECKI is assistant professor of emergency medicine at The University of Texas Medical School at Houston. He blogs at Emergency Medicine Literature of Note (emlitofnote.com) and can be found on Twitter @emlitofnote.

I was sound asleep, and it took a while to figure it out. I'd transferred from Kaiser Permanente (KP) Walnut Creek Medical Center in Walnut Creek, California, to KP Santa Rosa two years prior, and I still received the occasional alert from Walnut Creek.

I finally woke up enough to realize I could log onto the ED track board. KP Santa Rosa didn't look unusually busy. I called my friend and colleague Josh Weil, MD, who was on the overnight shift.

"Josh, I got the page. Was that you guys? Do you need help?"

His voice was uncharacteristically strained.

"I think my house is gone. Claire and Sophie just evacuated. They literally ran through a wall of flames to get out." Claire is his wife, and Sophie is his 15-year-old daughter.

"What do you need?" I asked. It was hard to take in; our entire emergency department just had an end-of-summer barbecue at their house a few weeks before.

"I don't know what I need."

"I'm coming in," I said. I hung up the phone. This was real.

My partner, Fred, came in through the back door. I hadn't even noticed he was gone. He'd been driving around our small neighborhood to see if he could locate a fire.

"I can't see any fire, but the smoke is bad," he said. I stepped outside. The wind was brisk, and the smell of smoke was pervasive. The Tubbs Fire, which had started around 9 p.m. the previous day, was raging.

"I have to go into work," I told him. "Josh's house is on fire. Claire and Sophie barely got out." Fred's face fell.

He turned on the TV. I threw on some scrubs. "There are fires everywhere," he said.

Realizing I might be gone for a while and Fred might need to evacuate, I gathered some things for him to take just in case—papers, pictures, and cherished family items. My hands were shaking as I packed.

I'm an emergency physician, and I also spend half my work time in disaster planning and training for KP Northern California. I've worked both domestically and internationally in disaster response, including New York after Superstorm Sandy in 2012 and Haiti after the 2010 earthquake. I'd like to say all I had to do was grab my prepacked evacuation bag and head out the door in five minutes, but I didn't. Although we have a home disaster kit with supplies, food, and water for our family and an evacuation bag for our dog, I hadn't compiled the important documents and family items I now found myself stuffing into boxes and bags.

After what felt like an eternity, I found myself hurtling east down Guerneville Road toward the hospital. There was a large orange glow on the horizon, and the smell of smoke was growing stronger. I couldn't help but notice the steady stream of cars driving west, away from the fire.

There weren't many cars going in my direction, toward the fire.

Entering the Fire Zone

My normal route was blocked. The exit was blocked; there was a police car stationed there with lights flashing.

I showed my ID, and the officer let me through. I thought back to all the times I'd taught staff to keep their IDs with them. I always promise it will get folks through a roadblock, and it had. I later learned many of our hospital administrators were not so lucky. It didn't matter what they showed or said, they were turned away at other entry points because they were in active fire zones.

PHOTO: WES MCBRIDE

The Tubbs Fire rages behind KP Santa Rosa hospital.

I kept driving. A sea of flashing lights and emergency vehicles appeared before me only a half block from the hospital. I turned left into the parking lot, wound my way around the buildings, and parked in the garage.

The smoke was incredibly thick when I got out of the car, and a security guard was controlling access to the emergency department.

That's when things get fuzzy. My brain didn't register the people carrying their belongings walking the other way or the embers flying through the air. And although I walked right past the Journey's End mobile home park on my left, only yards away from the hospital's property line, my brain didn't register anything unusual there either, despite the fact it was almost completely engulfed in flames.

Here's what I do remember: the smoke in the emergency department and hospital hallways; the calm, focused intensity in the hospital command center; and the decision to evacuate the hospital when the fire department told us it was making "a last stand." I remember the cadre of police officers who showed up when we needed to step up the evacuation even further and how we went floor to floor in teams to clear out the bed-bound patients. My brain finally registered the fire as I passed a fourth-floor window and saw the flames at our hospital's property edge.

Evacuation

We staged patients by the freight elevators and took them down one by one. Once downstairs, we lined them up in the hallway to await transport. We assigned one staff member, from MDs to RNs to environmental service workers, to every patient and documented each patient as they went through the lobby doors onto the ambulances and city buses waiting to take them to safety. The patients and staff were amazing; there was no panic and very little noise.

Here's what I remember most: watching the last bus pull away from the KP Santa Rosa Medical Center at 6 a.m. and realizing we safely evacuated 122 patients in two and a half hours.

Not a bad night's work.

Our work didn't end there, of course. It would take more than three weeks until the hospital and clinics were fully back up and running. Even now, things are not back to normal, given that more than 200 of our staff and physicians lost homes and entire neighborhoods in our community are gone.

Things will never be back to normal. Instead, we have a new normal, one that is wiser, stronger, more realistic, and, most of all, kinder and more cooperative.

DR. FITZGERALD is an emergency physician at Kaiser Permanente Santa Rosa in Santa Rosa, California.

LESSONS LEARNED

- Not all disasters happen at 10 a.m. on Monday. A disaster that occurs at 3 a.m. on Sunday presents increased challenges in terms of personnel availability and functionality.
- Keep your medical ID with you at all times.
- Some of your key responders may not be able to get to the hospital in a disaster event.
- Evacuation is a parallel process. The resources needed to evacuate the adult ICU and NICU patients are different from those needed to evacuate the patients on the floor. For those who can walk, buses and private cars are your new best friends if the situation is urgent. If you even think you might have to evacuate, start preparation immediately, including making plans for how you will track your patients and the supplies, patient care information, and medical personnel you will send along with them. You can determine and practice much of this in advance.
- When evacuating patients or when handling a patient surge, assign one staff member to each patient to monitor, track, and help transport. Having direct eyes on every patient, whether by someone medically trained or not, is invaluable during chaotic disaster events.
- Practice makes perfect when it comes to disaster response and infrequently used plans such as evacuation plans. Talk through and drill your plans as often as you can. Muscle memory will prove extremely helpful when the time comes.
- The concept of the "disaster brain" is real, though the extent to which it dictates behavior in a disaster varies. We may not even realize our brains are not 100 percent until much later. It's like they used to teach us for codes, "Take your own pulse first." Call a huddle; do a quick time-out. Make sure everyone is on the same page. If the situation gets worse or more chaotic, repeat this sequence, just like you would repeat the ABC's in a difficult or extended code. Drill under time pressure to grow more resilient.

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African-American soldiers of the US Army 93rd Infantry Division traveling along the Numa Numa Trail, Bougainville, Solomon Islands, May 1, 1944.

Stories from a Soldier

EM allows you to meet amazing people, and great rewards come from "knowing" your patients

by JOHN QUEEN, MD, FACEP

I remember why I decided to apply to medical school when I was young. I also remember the reasons that I chose to be an emergency physician. Recently, I found another reason to be thankful for the career I've chosen after having the opportunity to care for a 92-year-old man.

It was one of those days that was not crazy busy and one of those times when, for some unknown reason, I chose to take a few extra moments to be a bit more social. The patient in room 3 was having mild chest discomfort and fatigue, but his vitals were normal, and as I signed the ECG with normal sinus rhythm that was more normal than those of many patients half his age, I walked into the room to meet Walter.

After a typical history and physical examination, I was impressed with how healthy and talkative Walter was as a nonagenarian. Continuing on, I asked him the usual: where he lived, what he had done for a living, how long he had worked for the city, and if he started that job after high school. His answers were not the usual, and I was in for a treat.

Walter told me that he went into the army in 1943, and only after the war did he get his job with the city. Yes, he was in World War II. He told me several stories about the war. As an African American, he fought in the Pacific alongside four other men from Cleveland as part of the segregated 93rd Infantry Division, seeing action on Bougainville Island in 1944. As a rifleman, the most common designation at that time, Walter saw his share of action. He recalled an early battle he was in, and he could hear the bullets from the machine gun cutting through the leaves overhead. "I will never forget that sound," he said and then told me that one of those men from Cleveland stood up and immediately fell back to the ground, shot in the head. This was the first of those in his company from his hometown of Cleveland who was killed in action.

Walter's chest X-ray revealed pneumonia, and he spiked a fever in the emergency department, so antibiotics and an admission to medicine were in order. Before Walter went upstairs, he shared more stories about his unit. Though treated differently than the white units, he was proud to be a soldier. There was no hint of resentment or regret, only pride about his service. He told stories about the way the United States and the rest of the world reacted while the war continued, the difficulties fighting in the islands, and how daily casualties numbered in the thousands. He remembered the hope that he would not be in that number but that someday he would come home to his girlfriend, whom he had known since high school. He was going to ask her to marry him when he returned.

The most surprising response was to my question of how it felt when he heard the Japanese surrendered. His answer was "lonely." Not what I expected to hear. He explained that he felt lonely because his job was done and "I just wanted to go home to be with my girlfriend." Walter proposed, and they did get married, raising five children and living their lives in Cleveland together until he lost his wife several years ago.

I went to sleep that night feeling fortunate, humbled, and honored. I am fortunate to have met this former soldier, humbled by his service and selflessness in going to war for his country, and honored to be able to care for him. When I went to work that morning, I had no idea that I would meet this World War II veteran and hear his stories. What an amazing reminder that as emergency physicians not only do we have the greatest job in the world, but we often have opportunities to find hidden treasures like Walter as long as we take the time to look for them.

DR. QUEEN is an emergency physician at the Cleveland Clinic in Cleveland and assistant residency program director for the Cleveland Clinic/MetroHealth emergency medicine residency program. He is the chapter President of Ohio ACEP and a former member of its Board of Directors.

PATIENT SATISFACTION SURVEYS

Influencing the outcome of the ED Patient Experience of Care survey

by JAY KAPLAN, MD, FACEP

It is no secret that emergency physicians have been unhappy about patient satisfaction surveys. While there is much evidence in the medical literature that the patient experience and patient clinical outcomes are interdependent, the surveys that have measured "patient satisfaction" have suffered from significant methodological flaws including:

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

- Too many questions leading to a poor response rate (anywhere from 3 to 17 percent, averaging around 10 to 11 percent).
- Inappropriate questions such as, "During your ER visit, did the doctors and nurses do everything they could to help you with your pain?" while in the midst of an opioid epidemic.
- An inappropriately small sample size leading to wide variation in scores and questions regarding statistical validity.
- A delay of six to eight weeks in the survey results, making the response to patient perception difficult in terms of performance improvement.
- The inability to give individual physicians actionable feedback unless the sample is gathered over six to 12 months, with too long a lapse by the time the physician receives feedback.

On top of those issues, use of the survey results by hospitals and physician employers has been problematic due to their decisions to implement:

- Physician credentialing based on patient experience as one of the criteria, when the sample size is far too small.
- Payment incentives based on ED patient satisfaction when physician communication and behavior is one of a multitude of factors, over most of which the emergency physician has little or no control.

History of Hospital Satisfaction Surveys

Patient satisfaction surveys have been in existence since the mid 1980s, and many physicians who were practicing at that time remember that even back then there was intense pressure from senior hospital leaders to improve patient satisfaction as a way to grow market share and build the financial bottom line.

More than 10 years ago, the Centers for Medicare and Medicaid Services (CMS) implemented the Hospital Consumer Assessment of Health Care Providers and Systems (HCAHPS) survey. This survey, on inpatients age 18 and older who are discharged home, has been the foundation on which other surveys, such as the Clinician and Group CAHPS survey (which measures patients seen in the outpatient clinic/physician office setting), have been built.

For the past four to five years, CMS, utilizing the RAND Corporation, has been working on the government-sponsored ED survey, which now has a new name, the ED Patient Experience of Care (EDPEC) survey. While initial development included versions to be used for admitted as well as discharged patients, the survey in current development is only for patients "discharged to community" (DTC).

Physician leaders of ACEP have been active in the ongoing transformation of that survey. In October 2014, we wrote to CMS: "On behalf of more than 33,000 members and the 136 million patients seen annually in the nation's emergency departments, the American College of Emergency Physicians (ACEP) appreciates the opportunity to provide comments on the latest revision to the draft survey instrument, now titled 'Emergency Department Patient Experience of Care' (EDPEC). Overall, we urge CMS to rethink the objectives of gathering this information (aside from fulfilling the ACA mandate) and articulate how the information will advance and improve patient care."

The original draft survey had 53 questions, of which 32 were about care and 21 were demographics. The questions on physicians included the following:

- "During this emergency room visit, how often did doctors treat you with courtesy and respect?"
- "During this emergency room visit, how often did doctors listen carefully to you?"
- "During this emergency room visit, how often did doctors explain things in a way you could understand?"
- "During this emergency room visit, how often did doctors spend enough time with you?"

There were four possible answers: Never, Sometimes, Usually, and Always. However, the only answer that counted as positive was "Always."

The questions on pain were:

- "During this emergency room visit, did you have any pain?"
- "During this emergency room visit, did you get medicine for pain?"
- "During this emergency room visit, did the doctors and nurses do everything they could to help you with your pain?"

Patients could choose one of three responses: Yes, definitely; Yes, somewhat; and No. The only response that counted as positive was "Yes, definitely."

ACEP's Response

CMS asked for comments from the medical community. William Sullivan, DO, JD, FACEP, a member of ACEP's Medical Legal Committee, clinical assistant professor emergency medicine at the University of Illinois at Chicago, attending physician at St. Margaret's Hospital in Spring Valley, Illinois, and owner of Sullivan Law Office in Frankfort,

Illinois, and I, in conjunction with Barbara Tomar, ACEP's former director of regulatory affairs who is now retired, and ACEP's Washington, D.C., office, did not just make comments but rewrote the survey for CMS. We suggested that 53 questions were too many, some were duplicative, and some were poorly worded.

We suggested a maximum of 15 questions. We recommended that the pain questions be removed entirely, as we were seeing the effects of the opioid epidemic and the pressure we had received for many years to treat "pain as the fifth vital sign." We advised that "emergency room" should be changed to "emergency department" and that all of the questions should have the three-response option of "Yes, definitely; Yes, somewhat and No," in view of the ED visit being a one-time event unlike the multiday inpatient experience.

CMS accepted some of our suggestions. It reduced the number of questions from 53 to 43, and it removed the question, "How often did doctors spend enough time with you?" It refused to change "emergency room" to "emergency department," but it did change the pain questions to the following:

- "During this emergency room visit, did you have any pain?"
- "During this emergency room visit, did the doctors and nurses try to help reduce your pain?"
- "During this emergency room visit, did you get medicine for pain?"
- "Before giving you pain medicine, did the doctors and nurses describe possible side effects in a way you could understand?"

Physician leaders of ACEP have been active in the ongoing transformation of [the EDPEC] survey.

Testing and Revision

Then CMS field-tested its draft survey on a selected number of emergency departments.

In 2017, CMS convened a technical expert panel on the EDPEC survey. Thom Mayer, MD, FACEP, executive vice president of EmCare, founder and CEO of Best Practices, Inc., and clinical professor of emergency medicine at George Washington University in Washington, D.C., and I served on that panel. We had a several-hour conference call and follow-up communication. The newest draft published in August 2017 has a total of 39 questions (29 questions about the care, 10 demographic), and these are the pain questions:

- "During this emergency room visit, did you have any pain?"
- "During this emergency room visit, did the doctors or nurses talk with you about how much pain you had?"

In a later section under "Leaving the Emergency Room," there are additional questions regarding pain:

- "Before you left the emergency room, did the doctors or nurses give you as much information as you wanted about how to treat your pain at home?"
- "Before you left the emergency room, did the doctors or nurses talk with you about things you could do at home to reduce your pain other than take medicine?"

Response options include the three "Yes, definitely; Yes, somewhat; and No" and also a fourth option, "I did not need to reduce pain after I got home from the emergency room."

We hope that emergency physicians will view this as a major win for us. While the pain questions are not completely gone, they are much improved, and there is a question on the nonpharmaceutical treatment of pain.

CMS and the RAND EDPEC team have been working with us to make the survey appropriate and meaningful. The second round of feasibility testing for the EDPEC DTC survey is now being completed. The testing has a push-to-web focus. This round of feasibility testing is examining issues such as:

- Survey response rates and differences by survey administration arm
- Email and mobile phone coverage rates
- Feasibility of email and text invitations to a web survey
- Testing of the use of a QR code in a mailed invitation
- Paradata, such as how long the surveys (and individual items) take, what type of device individuals use to respond to web surveys, whether people are changing their answers, etc.

CMS and the RAND EDPEC team have asked us to not share the current draft of the survey, as the survey will continue to evolve in response to results from feasibility testing. They will be holding another round of technical expert panels this summer once preliminary data from the field testing are available, and we will again serve on that panel to represent the views of emergency physicians and the patients we serve.

There is currently no defined timeline for implementation of the CMS EDPEC survey, but it will likely happen within the next year. If we can move in the direction of more rapid information feedback and a more representative sample of our patient population, both emergency physicians and our patients will benefit. The entire purpose of the survey should be to give emergency physicians and nurses information they can act upon to improve the ED patient experience and, by doing so, increase patient compliance with recommended therapies and improve clinical outcomes. Stay tuned; we will keep you informed.

DR. KAPLAN is medical director of care transformation at LCMC Health in New Orleans, clinical associate professor of medicine in the section of emergency medicine at Louisiana State University Health Sciences Center, University Medical Center New Orleans, and a Past President of ACEP.

RETIREMENT TIPS

ACEP members weigh in on how they got ready for retirement and how they're spending their "leisure" time

In a recent letter to ACEP Now, an ACEP member raised some important questions about career transitions:

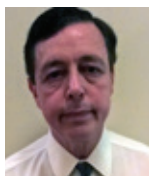
I am 66 years old and ready to retire, but I am not sure how to go about it.

I've had a great career so far. After working 12 years as a registered nurse (part of it in the Alaskan bush), my family (wonderful husband and three super kids) and I started medical school in 1986 (when I was 34). I was hooked by emergency medicine and decided to make it my life's work. I did what so many had done—worked two and three jobs for years and years, taking every course I could until I could "grandfather" into becoming FACEP. I served a year as Washington ACEP's President and two years as a national Councillor for ACEP. After working at a 45,000-per-year emergency department, I "semi-retired" after nearly 20 years and have worked in a rural,10,000-per-year emergency department over the last seven years.

How will life with my husband of 44 years look and how will my career look in retirement? Should I retire active for licensure? What should I do about my DEA? Once I close the door, so to speak, is it irrevocable? What would a "minimum practice" look like? It's a little daunting to give up my clinical "life," so to speak. I know many of us baby-boomers face similar life decisions.

—Merry Alto, MD, FACEP
Spokane, Washington

ACEP Now *polled several retired and semi-retired ACEP members for their words of wisdom on how to transition from a full-time clinical career and how to keep doing what you love in retirement. Here are their tips.*



First and foremost, during your formative practicing years, don't neglect your family and health. Once you retire, your family often assumes primary focus. A lifelong exercise program will put you in great position to take full advantage of family and leisure time.

Second, actively engage in professional activities outside of clinical practice. Emergency physicians have demonstrated that they have all the right attributes in fields as diverse as hospital administration, entrepreneurship, and quality assurance. Seek out administrative opportunities within your ED practice that will allow professional growth as your clinical activities wind down.

—Jeffrey Bettinger, MD, FACEP
Managing member,
Bettinger, Stimler & Associates, LLC
Pinecrest, Florida

Start planning your well-thought-out retirement program early, perhaps a decade in advance. Do not just "retire" at a specific date without a well-developed plan. Do not underestimate that a significant portion of a physician's sense of self-worth is the physician-patient relationship; it's what makes us a "doctor." Consider fading out of clinical practice gradually, because it is very difficult for most physicians to suddenly and completely cease patient interactions. Gradually reducing clinical shifts while ramping up potential new considerations, or a just gradual increase in desired nonclinical activities, will smooth your transition.

Consider your best-loved personal interests beyond clinical practice, and investigate alternative future activities both within and outside of medicine. There are only so many days you can sit on a beach, read a book, play golf, travel, etc., and continuing medical and nonmedical intellectual pursuits will substantially maintain your physician-developed sense of self-respect and enhance your retirement enjoyment. With a well-developed and gradually implemented plan, you'll be surprised at how enjoyably active your retirement from clinical practice can become!

—David E. Wilcox, MD, FACEP
Medical director consultant
South Glastonbury, Connecticut

Early in my career, a mentor encouraged me to read and to and to reflect upon the poem, "The Road Not Taken" by Robert Frost. Just as Frost's traveler did, "I kept the first for another day." I encourage colleagues not to lose sight of the other road and to ask themselves frequently, "What would I have studied if I had not chosen medicine? What mysteries of life would I like to understand?" When one often reflects on such questions, it will be easy to identify an opportunity to choose "the other path" in retirement.

— Susan Nedza, MD, MBA, FACEP
Candidate, Masters in Liberal Arts
University of Chicago

Retirement is not about stopping anything! It is about pursuing activities you enjoy, including those work activities you enjoy most. So sharpen your focus to make room for interests you've long deferred. Be more physically active than you had time for previously. Take care of yourself to stay healthy. Keep in touch, or reconnect, with those you love. If you've planned your finances, live that financial plan and enjoy the freedom of not having to work solely to pay bills. Achieve real work-life balance and make your trade-offs wisely. Only so many hours exist in each busy retirement day, and only so many days remain in each retirement life. Be genuinely grateful for every one!

Although I've never thought so, perhaps, I **am** "retired" already ... just not under a more traditional definition. Cheers!

—Randall B. Case, MD, MBA, MSE, FACEP
President, Healthrecord Solutions, LLC
Dallas/Fort Worth, Texas

Find something that you can do in retirement that allows you to put to good use some of the knowledge you gained in your practice, to keep your hand in the game, for several years after you retire from clinical practice. In order to have a niche, you need to start working toward that goal about 10 years prior to retirement, gaining expertise and experience in the medical niche you think might be interesting. Unless you plan to do part-time clinic or urgent care work, don't expect to actively use your clinical skills in this post-retirement arena, as they will deteriorate with lack of use, but keep your "special knowledge" honed in the niche area you hope to become expert in. If you can earn some money at it, this keeps you from having to tap your IRA for your entire post-retirement income. There's nothing like a little fresh money coming in. Take some courses first to find your niche if you are uncertain, then bone up and begin using these skills or knowledge base while you are still practicing, substituting this time for a couple of shifts a month if you have that flexibility. If you wait until you retire to acquire these niche skills or this knowledge base, you will have blown it. For example, if you want to write medical mystery novels in retirement, start writing years before you retire from ED practice.

—M. Myles Riner, MD, FACEP
Health care consultant, reimbursement expert witness, and author of The Fickle Finger *blog*
Incline Village, Nevada

I gave up practicing medicine for the third and final time at age 70. I was always convinced I would die seeing patients in a Maine emergency department, but financial preparation made elective retirement possible. Arthritic knees forced my ED retirement in 2001. I missed practicing so much that, three years later, I found shorter shifts in an urgent care center.

Tip #1: Do not give up your licenses, boards, or CME yet; reassess each renewal and consider alternative clinical work.

Tip #2: If you want to keep "working" turn your nonclinical expertise into a paying/part-time "job." My husband and I left Maine, where I knew "everyone," after 30 years. I did urgent care, attended state and national ACEP meetings and went to local medical CME, but did not integrate well. I knew no one in the emergency department when my husband had his myocardial infarctions and cerebrovascular accident, couldn't recommend a surgeon when my son ruptured his appendix, didn't know the orthopod who casted my granddaughter, and allowed strangers to remove my cancer and perform my endarterectomy. I have experienced medical isolation.

Tip #3: If you like what you are doing, keep doing it. Don't tell anyone you are retired—they might stop calling you to work.

—Pamela P. Bensen, MD, MS, FACEP
President, Medical Education Programs
Buffalo Junction, Virginia

PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

TOXICOLOGY Q&A

Pretty in Pink

QUESTION: Is this pretty sunflower deadly, useful, or just eye candy?

ANSWER *on page 15*

Buprenorphine Explained

Solving the pharmacological mystery of this opioid treatment tool

by R. COREY WALLER MD, MS FACEP, DFASAM

Editor's Note: This is the third part of an ongoing series on what emergency physicians can do to combat the opioid epidemic. The series will continue in the August issue.

I feel cheated! After all that time in pharmacology classes and the tests in undergraduate, graduate school, medical school, and residency all oversimplify the concept of the difference between a partial agonist and full agonist. When you dig deep into the pharmacology literature, you find only one true full agonist, DAMGO (ie, [D-Ala2, N-MePhe4, Gly-ol]-enkephalin), which is not even a medication used in humans.

In fact, all the opioid pain medications we give patients are only partial agonists to varying degrees. And as if that wasn't enough, the ceiling effect of buprenorphine seems to be a myth regarding pain control.

Partial or Full?

As a quick review, we conventionally determine if a medication has partial agonist or full agonist activity based on its intrinsic activity Kappa (Ki). The Ki tells us how much an opioid, or any drug for that matter, activates a receptor when it binds. The strict definition of a full agonist would be any substance that binds to the receptor and activates it 100 percent.

But as stated earlier, there are no clinically available opioids that activate the mu receptor 100 percent. Some get close, such as fentanyl and sufentanil, which activate at about 90 percent. However, others such as hydromorphone and morphine only activate the receptor in the high 80 percent or high 70 percent range, respectively. Buprenorphine effectively reduces the receptor activation to 50 percent. Relatively speaking, opioids have the hierarchy of intrinsic activity shown below in Figure 1.

Why does all of this matter? It matters because buprenorphine is possibly the most important medication in the fight against opioid-use disorder and its close cousin, overdose death. Think about a patient who is physically dependent on opioids, either morphine or hydromorphone. If you give this patient a dose of buprenorphine, you may be called to the bedside and read the

CONTINUED *on page 14*

DR P. MARAZZI/SCIENCE SOURCE

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BUPRENORPHINE FOR TREATING OPIOID ADDICTION IN THE EMERGENCY DEPARTMENT

1. If we just go back to the basic pharmacology of buprenorphine, we should realize this medication can safely stop acute withdrawal after naloxone.
2. Buprenorphine comes in parenteral, sublingual, buccal mucosal, transdermal, implantable, and depo-injectable forms.
3. The black-and-white labels of full agonist versus partial agonist are more myth than truth.
4. Buprenorphine should be first-line therapy to stabilize a patient post opioid-overdose reversal with naloxone.
5. Given the still increasing numbers of people suffering opioid overdoses, we must use an FDA-approved, available, safe treatment for a disease that's the number-one killer of people younger than 50 years old.
6. You do not need a special license to prescribe buprenorphine for opioid withdrawal treatment.
7. If the patient is to be discharged, you do not need a special license to prescribe 72 hours of buprenorphine to stabilize the patient in order to get them to follow up for outpatient opioid-use disorder treatment.

FIGURE 1: Hierarchy of Intrinsic Activity

FENTANYL > HYDROMORPHONE > MORPHINE > BUPRENORPHINE > BUTORPHANOL > NALBUPHINE

riot act because they're now in acute precipitated withdrawal!

It turns out this is not just about the IA of buprenorphine, but also the strength in which buprenorphine binds to the mu receptor, or what's known as its affinity. For all you molecular biologists out there, we know the receptor affinity data are based on cell culture experiments and mostly in Chinese hamster ovary (CHO) cells at that, not human cells. We therefore must take the absolute numbers of both IA and affinity with a grain of salt.

However, there is a very real clinical issue that comes up when we give buprenorphine to a patient whose mu receptors are inhabited by a more potent opioid that has a lower affinity (see Figure 2).

For example, if I have a patient who's been on oxycodone and took their last dose right before showing up to the emergency department, and I give them naloxone, this person would go into immediate withdrawal. If I gave that same person a dose of buprenorphine, they would also go into withdrawal. So what's happening?

Conjure up the image of a dimmer switch on the wall. If we turn it clockwise the light goes up, counterclockwise the light goes down. This brightness of the light is the IA and how tightly we hold the dimmer switch is the affinity. If naloxone is given to a patient dependent on opioids, it is like taking the dimmer switch away from the oxycodone and turning it all the way off, predictably causing acute withdrawal. The mechanism is the same for buprenorphine, but instead of turning that dimmer switch from 85 to 0, it turns it from 85 to 50. Clinically, the end result looks similar, a patient in acute opioid withdrawal.

This dimmer switch can also work in the opposite direction. If we have a patient who's physically dependent on opioids and they overdose—that is, they turned the power up so high it kicked off and they caused respiratory arrest—we would give them naloxone. This turns the dimmer switch to 0, allowing the power to come back on.

In this all too common situation, we then could follow with a dose of buprenorphine and turn the dimmer up to 50 percent so the patient is no longer in acute withdrawal *and* still not at risk for respiratory depression. This by itself is pretty cool because now we have a medication we can give 8 mg of sublingually or 0.3 mg of subcutaneously or via IV that will alleviate withdrawal immediately, and we have a patient who is cognitively stable, allowing us to hold a conversation with them about the next steps of their treatment.

Now let me totally blow your minds: What about the patient who's just overdosed on heroin? If I have no naloxone because I just used it all on the previous carfentanil overdose, could I use buprenorphine?

Theoretically, if there is a low-affinity, high-potency opioid onboard such as heroin causing the overdose, I could give them buprenorphine, a higher-affinity, lower-potency opioid, and instead of causing precipitated withdrawal, it would cause precipitated breathing.

Let's be clear: I am not telling you to start giving all your opioid overdose patients buprenorphine to wake them up. However, taking into account our newly understood pharmacology, this is a very plausible pathway that would allow a patient to be reversed from respiratory depression caused by heroin with the same medication that would stabilize and treat them.

As we continue to see more and more patients in the emergency department after an opioid overdose, we need to start thinking about issues other than reversal and discharge of these patients. We should be focusing on the stabilization and treatment of these patients, given the high mortality rate of continued utilization of illicit opioids.

It is incumbent upon us to start to use the basic forms of treatment that already exist, are in every hospital pharmacy in the country (or should be), and are a U.S. Food and Drug Administration-approved first-line treatment for this disease. Making a patient suffer from precipitated withdrawal from the naloxone is not teaching them a lesson, it is just mean!

Editor's Note: Want to learn more about buprenorphine? Visit ACEPNow.com to view some resources for further reading

FIGURE 2: Relative Affinity to the mu Receptor

BUPRENORPHINE > FENTANYL > HYDROMORPHONE > MORPHINE

DR. WALLER is a fellow at the National Center for Complex Health and Social Needs and managing partner at Complex Care Consulting LLC.

SEND US YOUR QUESTIONS!

In future articles in this series, we will delineate the best practices for treatment and approach in the emergency department. If you have questions or ideas, feel free to send them our way at schwarze@wustl.edu.

Toxicology Q&A Answer

QUESTION ON PAGE 12

ANSWER: Eye Candy

Three species, *Echinacea angustifolia*, *Echinacea pallida*, and *Echinacea purpurea*, are used medicinally.[1]

Toxins

Like most unrefined drugs from plant origin, the content and composition of chemicals contained within Echinacea are complex. These consist of a wide variety of chemicals of variable effect and potency that have been explored for antiviral, antibacterial, antifungal, mosquitocidal, antioxidant, and antianxiety effects with mixed results.

It is generally thought that no single constituent or group of constituents is responsible for its activities but that these groups and their interaction contribute to beneficial activity. These include alkamides, caffeic acid derivatives, polysaccharides, and alkenes.

The amount of these complexes in different commercially available Echinacea products is variable as the preparation of the plant differs greatly among products. Different parts of the plant are used, different manufacturing methods (drying, alcoholic extraction, or pressing) are employed, and sometimes other herbs are added.

Traditional/Historical Use

Echinacea has a long history of medicinal use, mainly recommended as a broad-base, nonspecific "anti-infective" because of its purported immune-stimulator effects. Indications for its use have included syphilis, septic wounds, and "blood infections" from bacterial and viral sources. Other traditional uses include for nasopharyngeal congestion/infection and tonsillitis and as a supportive treatment for influenza-like infections and recurrent infections of the lungs or urinary tract.

It has been recommended for skin conditions including boils, carbuncles, and abscesses and also as a snakebite treatment and a laxative.

Effectiveness for Upper Respiratory Infections

A 2007 meta-analysis in *The Lancet Infectious Diseases* reported a positive effect. However, most studies before and after, including a Cochrane review from 2014, did not show significant or consistent improvement of illness.[3] Without credible scientific evidence to the contrary, this plant probably should not be promoted to cure colds or upper respiratory infections. It looks like this pretty sunflower falls short on its medicinal value, making it nothing more than horticultural eye candy.

Other Facts

- Some people are allergic to Echinacea (like ragweed).
- As with upper respiratory infections, there are no objective data to show that Echinacea has any effect on avoidance of or efficacy for the treatment of urinary tract infections.

PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

CONEFLOWER

Echinacea purpurea

COMMON NAMES: **Eastern purple coneflower or purple coneflower**

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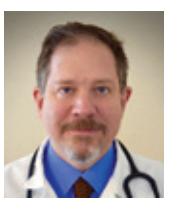

DR. HACK (Oleander Photography) is an emergency physician and medical toxicologist who enjoys taking photographs of beautiful toxic, medicinal, and benign flowers that he stumbles upon or grows in his garden. Contact him at ToxInRI@gmail.com.

THE *History* OF ABEM

A TIMELINE OF PROGRESS

by KEVIN KLAUER, DO, EJD, FACEP, AND FRANCIS L. COUNSELMAN, MD, FACEP

1960

☆ The United States public began to demand improved quality in emergency departments. Thus, hospitals developed full-time emergency services, and a number of physicians began developing the training and practice of EM. New organizations were formed, such as ACEP and the University Association for Emergency Medical Services (UA/EMS), which is now the Society for Academic Emergency Medicine (SAEM).

1973

☆ The American Medical Association (AMA) sponsored a conference on physician education in emergency medical care.

1975

☆ The AMA approved a formal section on EM.

1976

☆ The American Board of Emergency Medicine (ABEM) was incorporated. During this same period, there was increased interest in providing EM graduate training programs. The UA/EMS and ACEP established the Liaison Residency Endorsement Committee for the endorsement of graduate training programs.

☆ ABEM submitted an application to the American Board of Medical Specialties (ABMS) seeking primary board status. This application was referred to the Liaison Committee for Specialty Boards (LCSB), a committee comprised of AMA and ABMS representatives. The LCSB recommended primary board approval and sent the recommendation to its parent bodies. The AMA Council on Medical Education approved this recommendation, but the ABMS defeated it. At the suggestion of various ABMS members, representatives from other specialty boards held a lengthy series of discussions from which a recommendation emerged for a second application, this time seeking approval for a conjoint board (modified). The AMA Council on Medical Education and the ABMS approved this application (see Figure 1).

1979

☆ **SEPTEMBER:** EM became the 23rd recognized medical specialty (see Figure 2).

1980

☆ ABEM offered the first EM certification examinations.

1987

☆ **MAY:** ABEM submitted an application to ABMS for conversion to primary board status. The ABMS Assembly defeated this application.

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IT HAPPENED! THE AMERICAN BOARD OF EMERGENCY MEDICINE WAS APPROVED TODAY BY AN OVERWHELMING VOTE OF THE AMERICAN BOARD OF MEDICAL SPECIALTIES. THIS WAS THE RESULT OF YOUR DEDICATED EFFORTS AND IS A PROUD DAY FOR EMERGENCY MEDICINE AND ACEP.

SINCERELY,

GEORGE PODGORNY, M.D.
PRESIDENT

Figure 1. A Mailgram announcing the approval of the ABEM.

1989

☆ **SEPTEMBER 21:** The ABMS Assembly voted unanimously to approve the ABEM application (see Figure 3). Ten years after the 1979 original vote, ABEM took its place as an ABMS Member Board with full primary board status.

1990

☆ Guidelines for five-year combined training programs were approved for emergency medicine/internal medicine (IM) and emergency medicine/pediatrics. Upon completion, physicians can access the certification examinations in EM and IM or EM and pediatrics.

1991

☆ ABMS approved subspecialty certification in pediatric emergency medicine, with ABEM and the American Board of Pediatrics (ABP) as co-sponsors.

1992

☆ ABMS approved sports medicine as a subspecialty, with by ABEM, the American Board of Family Practice, the American Board of Internal Medicine (ABIM), and ABP as co-sponsors.

1994

☆ ABMS approved medical toxicology as a subspecialty, with ABEM, ABP, and the American Board of Preventive Medicine (ABPM) as co-sponsors.

1997

☆ A task force was appointed to define the context and processes by which a new core content for emergency medicine could be created. The task force included ABEM, ACEP, SAEM, and the Council of Emergency Medicine Residency Directors. Representatives of the Resident Review Committee for Emergency Medicine (RRC-EM) and the Emergency Medicine Residents' Association (EMRA) were later included. ABEM was the administrative organization for the project.

1999

☆ **FEBRUARY:** ABEM and ABIM approved guidelines for a six-year combined training program for triple certification in EM, IM, and critical care medicine (CCM).

☆ The Board of Directors commissioned the Maintenance of Certification (MOC) Task Force. From the work of the task force, ABEM developed the Emergency Medicine Continuous Certification (EMCC) program. The EMCC (professional standing, Lifelong Learning Self-Assessment [LLSA], ConCert, and Assessment of Practice Performance [APP]) program is anchored in the ABMS MOC guidelines for all member boards.

2000

☆ ABMS approved undersea and hyperbaric medicine as a subspecialty, with ABEM and ABPM as co-sponsors.

2001

☆ **FEBRUARY:** The Model of the Clinical Practice of Emergency Medicine (EM Model) was approved. ABEM adapted the EM Model as an examination blueprint for all of the ABEM examinations.

2003

☆ ABEM and ABIM approved the first six-year combined training program for EM/IM/CCM.

2004

☆ **JANUARY:** ABEM implemented the first three components of EMCC. APP was scheduled to begin in 2010.

2005

☆ **JANUARY:** The bylaws were changed to create a board of directors comprised entirely of emergency physicians.

☆ ABEM administered the last paper-and-pencil written certification examination and for the first time began development of a computer-delivered examination to be administered in testing centers in November 2006.

2006

☆ **JANUARY:** The following boards withdrew as sponsors: ABIM, American Board of Obstetrics and Gynecology, ABP, American Board of Psychiatry and Neurology, American Board of Surgery.

☆ **JANUARY:** An MOC program in medical toxicology began.

☆ The medical toxicology certification examination and the MOC cognitive expertise examination were changed to be computer delivered.

☆ ABEM and the American Board of Family Medicine approved guidelines for a five-year combined training program in both EM and family medicine.

Growth
IN THE NUMBER OF ABEM DIPLOMATES
FROM
26,394
IN 209
↓
TO MORE THAN
35,500
IN 2018
(ACEP membership has grown to almost 38,000 in 2018)

Figure 3. (Below) The ABMS Assembly unanimously approved the ABEM application for primary board status on Sept. 22, 1989. Top row (left to right): Ronald L. Krome, MD; G. RIchard Braen, MD; Gail V. Anderson, MD; Benson S. Munger, PhD; Joseph E. Clinton, MD; George Podgorny, MD; David K. Wagner, MD; Harvey W. Meislin, MD. Bottom row (left to right): Judith E. Tintinalli, MD; Mary Ann Reinhart, PhD; Michael V. Vance, MD; Susan K. Adsit.

Figure 2. The 1979–1981 ABEM Board.

★ **SEPTEMBER:** In conjunction with the American Board of Hospice and Palliative Medicine, ABEM joined nine other ABMS member boards in sponsoring the newly approved ABMS subspecialty of hospice and palliative medicine. The first certification examination was given in 2008.

2009

★ **JUNE 1:** The first Medical Toxicology LLSA test became available.

2010

★ **JANUARY:** APP, the fourth component of EMCC, began for some diplomates.

★ **SEPTEMBER 1:** The AMA increased the number of AMA PRA Category 1 Credits from 25 to 60 credits for successfully attaining board certification by passing the oral examination or successfully maintaining certification by passing the ConCert Examination. Diplomates are given up to six years from the effective date on their certificate to apply for the credits.

★ **SEPTEMBER 28:** The ABMS, at its General Assembly meeting, approved EMS as its 112th subspecialty, making it the sixth subspecialty available to ABEM diplomates.

2011

★ **FEBRUARY:** An EMS Examination Task Force, composed of 12 EMS physicians, was appointed by ABEM. The first examination was administered in the fall of 2013.

★ ABEM introduced the next phase of EMCC by changing the requirements and frequency of the EMCC activities required to continue certification.

★ **APRIL 1:** CME for completing the 2011 LLSA CME activity became available. This opportunity was the result of an unprecedented collaboration between ABEM, ACEP, and the American Academy of Emergency Medicine (AAEM). Diplomates can apply for credit for this activity through either AAEM or ACEP. CME is available for all EM LLSAs since 2011, all EMS LLSAs since 2014, and all medical toxicology LLSAs since 2015.

★ **SEPTEMBER 21:** The subspecialty of Internal Medicine-Critical Care Medicine (IM-CCM) was unanimously approved. Emergency physicians can now participate in IM–sponsored CCM fellowships and are eligible to seek board certification. IM-CCM became the seventh subspecialty certification available to ABEM diplomates.

2012

★ **JUNE:** ABEM was approved by the Centers for Medicare and Medicaid Services (CMS) to participate in the Physician Quality Reporting System (PQRS) MOC incentive program. An additional 0.5 percent reimbursement on Medicare billings is available for meeting their basic PQRS reporting requirements. ABEM was approved again in 2013 and 2014. More than 4,100 ABEM diplomates applied for the 2013 bonus, receiving an estimated $2.3 million for participating. EM participated in the PQRS MOC to a greater extent than any other specialty.

★ **SEPTEMBER:** The Emergency Medicine Milestones were approved. The EM Milestones are a matrix of the knowledge, skills, abilities, attitudes, and experiences that should be acquired at different points during EM training. The EM Milestones Project was a joint initiative of the Accreditation Council for Graduate Medical Education (ACGME) and ABEM, and was supported by representatives of the Association of Academic Chairs of Emergency Medicine (AACEM), AAEM, ACEP, Council of Emergency Medicine Residency Directors, EMRA, RRC-EM, and SAEM.

2013

★ The ConCert examination was no longer the final step in renewing certification, delinking the four parts of MOC. Diplomates can, therefore, register for and take the ConCert examination in any of the last five years of certification, even if they have not completed all of their MOC requirements. However, at the end of a diplomate's ten-year certification, any outstanding MOC requirements will result in loss of certification.

★ **MAY:** ACGME's Board of Directors approved allowing emergency physicians to formally enter surgical critical care (SCC) fellowships, providing a pathway for EM diplomates to train for and take the subspecialty certification examination. Certification in SCC is through the American Board of Surgery.

★ **OCTOBER:** The first certification examination in EMS took place. The first EMS LLSA reading list was posted in July 2013, and the first test is in June 2014.

SUBSPECIALTY	ABMS APPROVAL	FIRST EXAMINATION
Anesthesiology Critical Care Medicine	2013	2014*
Emergency Medical Services	2010	2013 and 2014
Hospice and Palliative Medicine	2006	2008
Internal Medicine–Critical Care Medicine	2011	2012*
Medical Toxicology	1992	1994
Pain Medicine	2014	2014
Pediatric Emergency Medicine	1991	1992
Sports Medicine	1992	1992
Undersea and Hyperbaric Medicine	2000	2000

*First examination available to ABEM candidates.

★ **FALL:** The first certification examination in clinical informatics, which is open to diplomates of all ABMS Member Boards, took place, and 44 ABEM diplomates took the exam.

2014

★ **APRIL:** ABEM was approved by the ABMS to become a cosponsor of the subspecialty certification in pain medicine. Subspecialty certification in pain medicine, which had been open to diplomates of any ABMS member board, will be soon available only to diplomates of a cosponsoring board, so this allows ABEM diplomates to continue to have access to the examination.

★ **SPRING:** ABEM launched a patient safety LLSA, jointly developed by ABEM and ACEP. A CME activity worth 20 credits was also available with the Patient Safety LLSA.

★ **JUNE:** ABMS approved anesthesiology critical care medicine subspecialty certification co-sponsored by the American Board of Anesthesiology and ABEM.

2015

★ The enhanced oral exam was launched. The new format more closely resembles the manner in which physicians receive and integrate Information Into emergency care.

2016

★ **FEBRUARY:** The In-training exam was offered in an online format for the first time.

★ **MARCH:** Addiction medicine was approved as a subspecialty by the ABMS, open to any physician certified by an ABMS member board.

★ The ABA and ABEM approved combined training in anesthesiology and emergency medicine. Upon completion of these training programs, physicians can access the certification examinations in both specialties.

2017

★ ABEM and the American Board of Osteopathic Emergency Medicine (AOBEM) joined other EM organizations to form the Coalition on Medical Merit Badges (COMMB). COMMB maintains that participation in either ABEM MOC or AOBEM OCC programs supersedes the need for additional "merit badge" training (eg, advanced cardiac life support). COMMB works to educate other organizations and credentialers about the content of continuing certification programs in order to reduce such requirements for emergency physicians.

DR. KLAUER is an ACEP Board member; CMO–hospital-based services, chief risk officer, and executive director–patient safety organization at TeamHealth; *ACEP Now* medical Editor in Chief; and clinical assistant professor, University of Tennessee and Michigan State University College of Osteopathic Medicine.

DR. COUNSELMAN was President of ABEM in 2014, and is distinguished professor of emergency medicine and chair of the department of emergency medicine at Eastern Virginia Medical School in Norfolk, and member of the Emergency Physicians of Tidewater.

Xarelto®
rivaroxaban tablets

Choose the only NOAC with...

Extensive safety and efficacy data in the most patients studied with ***NVAF*** at a higher risk* of stroke[1-5]

AND

A major bleeding rate as low as aspirin with superior efficacy in recurrent ***DVT/PE*** risk reduction†[6]

†After 6 months initial treatment.

*$CHADS_2$ scores 3 to 6 in pivotal NOAC phase 3 trials: ROCKET AF (N=12,402), ARISTOTLE (N=5502), ENGAGE-AF (N=~11,200), and RE-LY (N=5882).

INDICATIONS

XARELTO® is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF). There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled.

XARELTO® is indicated for the treatment of deep vein thrombosis (DVT). XARELTO® is indicated for the treatment of pulmonary embolism (PE). XARELTO® is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

IMPORTANT SAFETY INFORMATION

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

A. Premature discontinuation of XARELTO® increases the risk of thrombotic events

Premature discontinuation of any oral anticoagulant, including XARELTO®, increases the risk of thrombotic events. If anticoagulation with XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. Spinal/epidural hematoma

Epidural or spinal hematomas have occurred in patients treated with XARELTO® 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 non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, *see* Drug Interactions**
- **A history of traumatic or repeated epidural or spinal punctures**
- **A history of spinal deformity or spinal surgery**
- **Optimal timing between the administration of XARELTO® 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 for thromboprophylaxis.

DVT = deep vein thrombosis; NOAC = non-vitamin K antagonist oral anticoagulant; NVAF = nonvalvular atrial fibrillation; PE = pulmonary embolism.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Active pathological bleeding
- Severe hypersensitivity reaction to XARELTO® (eg, anaphylactic reactions)

WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events After Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Risk of Bleeding:** XARELTO® increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO® in patients with active pathological hemorrhage.
  - A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable.
  - Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, NSAIDs, selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs).
- **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant 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. To reduce the potential risk of bleeding associated with the concurrent use of XARELTO® and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO®. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO® is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (ie, 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO®. The next XARELTO® dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO® for 24 hours. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.
- **Use in Patients With Renal Impairment:**
  - **Nonvalvular Atrial Fibrillation:** Periodically assess renal function as clinically indicated (ie, more frequently in situations in which renal function may decline) and adjust therapy accordingly. Consider dose adjustment or discontinuation of XARELTO® in patients who develop acute renal failure while on XARELTO®.
  - **Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population.
  - **Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue the treatment.
- **Use in Patients With Hepatic Impairment:** No clinical data are available for patients with severe hepatic impairment. Avoid use of XARELTO® in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.
- **Use With P-gp and Strong CYP3A4 Inhibitors or Inducers:** Avoid concomitant use of XARELTO® with known combined P-gp and strong CYP3A4 inhibitors. Avoid concomitant use of XARELTO® with drugs that are known combined P-gp and strong CYP3A4 inducers.
- **Risk of Pregnancy-Related Hemorrhage:** In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).
- **Patients With Prosthetic Heart Valves:** The safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO® is not recommended in these patients.
- **Acute PE in Hemodynamically Unstable Patients/Patients Who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

DRUG INTERACTIONS

- Combined P-gp and strong CYP3A4 inhibitors increase exposure to rivaroxaban and may increase the risk of bleeding.
- Combined P-gp and strong CYP3A4 inducers decrease exposure to rivaroxaban and may increase the risk of thromboembolic events.
- XARELTO® should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (eg, erythromycin) unless the potential benefit justifies the potential risk.
- Coadministration of enoxaparin, warfarin, aspirin, clopidogrel, and chronic NSAID use may increase the risk of bleeding.
- Avoid concurrent use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** The limited available data on XARELTO® in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO® for the mother and possible risks to the fetus when prescribing XARELTO® to a pregnant woman.
  - Fetal/Neonatal adverse reactions: Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.
  - Labor or delivery: The risk of bleeding should be balanced with the risk of thrombotic events when considering the use of XARELTO® in this setting.
  - There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage.
- **Lactation:** Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XARELTO® and any potential adverse effects on the breastfed infant from XARELTO® or from the underlying maternal condition.
- **Females and Males of Reproductive Potential:** Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.
- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

OVERDOSAGE

- Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. The use of activated charcoal to reduce absorption in case of XARELTO® overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable.

ADVERSE REACTIONS IN CLINICAL STUDIES

- The most common adverse reactions with XARELTO® were bleeding complications.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.

References: 1. Patel MR, Mahaffey KW, Garg J, et al; and the ROCKET AF Steering Committee, for the ROCKET AF Investigators. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med*. 2011;365(10):883-891. **2.** Granger CB, Alexander JH, McMurray JJV, et al; for the ARISTOTLE Committees and Investigators. Apixaban versus warfarin in patients with atrial fibrillation. *N Engl J Med*. 2011;365(11):981-992. **3.** Connolly SJ, Ezekowitz MD, Yusuf S, et al; and the RE-LY Steering Committee and Investigators. Dabigatran versus warfarin in patients with atrial fibrillation. *N Engl J Med*. 2009;361(12):1139-1151. **4.** Giugliano RP, Ruff CT, Braunwald E, et al; for the ENGAGE AF-TIMI 48 Investigators. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med*. 2013;369(22):2093-2104. **5.** Savaysa® [prescribing information]. Parsippany, NJ: Daiichi Sankyo, Inc. 2015. **6.** Weitz JI, Lensing AWA, Prins MH, et al; for the EINSTEIN CHOICE Investigators. Rivaroxaban or aspirin for extended treatment of venous thromboembolism. *N Engl J Med*. 2017;376(13):1211-1222.

083074-171026

Xarelto® rivaroxaban tablets

Janssen Pharmaceuticals, Inc.

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Brief Summary of Prescribing Information for XARELTO® (rivaroxaban)

XARELTO® (rivaroxaban) tablets, for oral use
See package insert for full Prescribing Information

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

A. Premature discontinuation of XARELTO increases the risk of thrombotic events

Premature discontinuation of any oral anticoagulant, including XARELTO, increases the risk of thrombotic events. If anticoagulation with XARELTO 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 (2.3, 2.8), in full Prescribing Information, Warnings and Precautions, and Clinical Studies (14.1) in full Prescribing Information]*.

B. Spinal/epidural hematoma

Epidural or spinal hematomas have occurred in patients treated with XARELTO 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 non-steroidal 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 XARELTO and neuraxial procedures is not known**

***[see Warnings and Precautions and Adverse Reactions]*.**

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary *[see Warnings and Precautions]*.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thrombo-prophylaxis *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation: XARELTO is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

There are limited data on the relative effectiveness of XARELTO and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled *[see Clinical Studies (14.1) in full Prescribing Information]*.

Treatment of Deep Vein Thrombosis: XARELTO is indicated for the treatment of deep vein thrombosis (DVT).

Treatment of Pulmonary Embolism: XARELTO is indicated for the treatment of pulmonary embolism (PE).

Reduction in the Risk of Recurrence of Deep Vein Thrombosis and/or Pulmonary Embolism: XARELTO is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: XARELTO is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

CONTRAINDICATIONS

XARELTO is contraindicated in patients with:

- active pathological bleeding *[see Warnings and Precautions]*
- severe hypersensitivity reaction to XARELTO (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 XARELTO, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO to warfarin in clinical trials in atrial fibrillation patients. If XARELTO 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 (2.3, 2.8) and Clinical Studies (14.1) in full Prescribing Information]*.

Risk of Bleeding: XARELTO increases the risk of bleeding and can cause serious or fatal bleeding. In deciding whether to prescribe XARELTO to patients at increased risk of bleeding, the risk of thrombotic events should be weighed against the risk of bleeding.

Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO in patients with active pathological hemorrhage. The terminal elimination half-life of rivaroxaban is 5 to 9 hours in healthy subjects aged 20 to 45 years.

Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) *[see Drug Interactions]*, selective serotonin reuptake inhibitors, and serotonin norepinephrine reuptake inhibitors.

Concomitant use of drugs that are known combined P-gp and strong CYP3A4 inhibitors increases rivaroxaban exposure and may increase bleeding risk *[see Drug Interactions]*.

Reversal of Anticoagulant Effect: A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of rivaroxaban. Partial reversal of prothrombin time prolongation has been seen after administration of prothrombin complex concentrates (PCCs) in healthy volunteers. The use of other procoagulant reversal agents like activated prothrombin complex concentrate (APCC) or recombinant factor VIIa (rFVIIa) has not been evaluated.

Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant 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 *[see Boxed Warning]*.

To reduce the potential risk of bleeding associated with the concurrent use of XARELTO and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known.

An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (i.e., 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. The next XARELTO dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO for 24 hours.

Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.

Use in Patients with Renal Impairment: Nonvalvular Atrial Fibrillation: Periodically assess renal function as clinically indicated (i.e., more frequently in situations in which renal function may decline) and adjust therapy accordingly *[see Dosage and Administration (2.4) in full Prescribing Information]*. Consider dose adjustment or discontinuation of XARELTO in patients who develop acute renal failure while on XARELTO *[see Use in Specific Populations]*.

Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population *[see Use in Specific Populations]*.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO should discontinue the treatment *[see Use in Specific Populations]*.

Use in Patients with Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment.

Avoid use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy since drug exposure and bleeding risk may be increased *[see Use in Specific Populations]*.

Use with P-gp and Strong CYP3A4 Inhibitors or Inducers: Avoid concomitant use of XARELTO with known combined P-gp and strong CYP3A4 inhibitors *[see Drug Interactions]*.

Avoid concomitant use of XARELTO with drugs that are known combined P-gp and strong CYP3A4 inducers *[see Drug Interactions]*.

Risk of Pregnancy-Related Hemorrhage: In pregnant women, XARELTO should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (e.g., a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

Patients with Prosthetic Heart Valves: The safety and efficacy of XARELTO have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients or Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of XARELTO is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the labeling:

- Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation *[see Boxed Warning and Warnings and Precautions]*
- Bleeding risk *[see Warnings and Precautions]*
- Spinal/epidural hematoma *[see Boxed Warning and 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 clinical practice.

During clinical development for the approved indications, 18560 patients were exposed to XARELTO. These included 7111 patients who received XARELTO 15 mg or 20 mg orally once daily for a mean of 19 months (5558 for 12 months and 2512 for 24 months) to reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (ROCKET AF); 6962 patients who received XARELTO 15 mg orally twice daily for three weeks followed by 20 mg orally once daily to treat DVT or PE (EINSTEIN DVT, EINSTEIN PE), 10 mg or 20 mg orally once daily (EINSTEIN Extension, EINSTEIN CHOICE) to reduce the risk of recurrence of DVT and/or PE; and 4487 patients who received XARELTO 10 mg orally once daily for prophylaxis of DVT following hip or knee replacement surgery (RECORD 1-3).

Hemorrhage: The most common adverse reactions with XARELTO were bleeding complications *[see Warnings and Precautions]*.

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 4.3% for XARELTO vs. 3.1% for warfarin. The incidence of discontinuations for non-bleeding adverse events was similar in both treatment groups.

Table 1 shows the number of patients experiencing various types of bleeding events in the ROCKET AF trial.

Table 1: Bleeding Events in ROCKET AF*- On Treatment Plus 2 Days

Parameter	XARELTO N=7111 n (%/year)	Warfarin N=7125 n (%/year)	XARELTO vs. Warfarin HR (95% CI)
Major Bleeding†	395 (3.6)	386 (3.5)	1.04 (0.90, 1.20)
Intracranial Hemorrhage (ICH)‡	55 (0.5)	84 (0.7)	0.67 (0.47, 0.93)
Hemorrhagic Stroke§	36 (0.3)	58 (0.5)	0.63 (0.42, 0.96)
Other ICH	19 (0.2)	26 (0.2)	0.74 (0.41, 1.34)
Gastrointestinal (GI)¶	221 (2.0)	140 (1.2)	1.61 (1.30, 1.99)
Fatal Bleeding#	27 (0.2)	55 (0.5)	0.50 (0.31, 0.79)
ICH	24 (0.2)	42 (0.4)	0.58 (0.35, 0.96)
Non-intracranial	3 (0.0)	13 (0.1)	0.23 (0.07, 0.82)

Abbreviations: HR = Hazard Ratio, CI = Confidence interval, CRNM = Clinically Relevant Non-Major.

* Major bleeding events within each subcategory were counted once per patient, but patients may have contributed events to multiple subcategories. These events occurred during treatment or within 2 days of stopping treatment.

† Defined as clinically overt bleeding associated with a decrease in hemoglobin of ≥2 g/dL, a transfusion of ≥2 units of packed red blood cells or whole blood, bleeding at a critical site, or with a fatal outcome.

‡ Intracranial bleeding events included intraparenchymal, intraventricular, subdural, subarachnoid and/or epidural hematoma.

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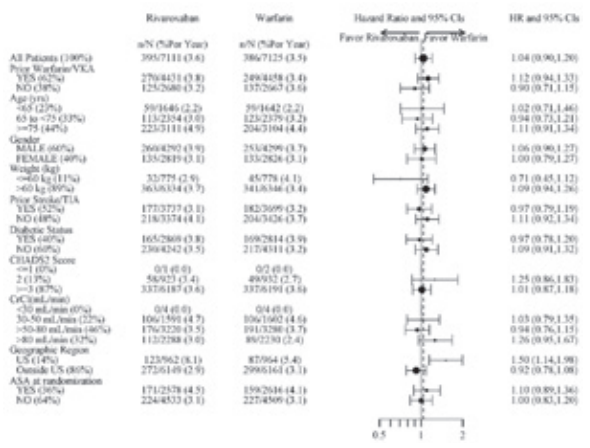
§ Hemorrhagic stroke in this table specifically refers to non-traumatic intraparenchymal and/or intraventricular hematoma in patients on treatment plus 2 days.

¶ Gastrointestinal bleeding events included upper GI, lower GI, and rectal bleeding.

Fatal bleeding is adjudicated death with the primary cause of death from bleeding.

Figure 1 shows the risk of major bleeding events across major subgroups.

Figure 1: Risk of Major Bleeding Events by Baseline Characteristics in ROCKET AF – On Treatment Plus 2 Days



Note: The figure above presents effects in various subgroups all of which are baseline characteristics and all of which were pre-specified (diabetic status was not pre-specified in the subgroup, but was a criterion for the CHADS2 score). 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.

Treatment of Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE): EINSTEIN DVT and EINSTEIN PE Studies: In the pooled analysis of the EINSTEIN DVT and EINSTEIN PE clinical studies, the most frequent adverse reactions leading to permanent drug discontinuation were bleeding events, with XARELTO vs. enoxaparin/Vitamin K antagonist (VKA) incidence rates of 1.7% vs. 1.5%, respectively. The mean duration of treatment was 208 days for XARELTO-treated patients and 204 days for enoxaparin/VKA-treated patients.

Table 2 shows the number of patients experiencing major bleeding events in the pooled analysis of the EINSTEIN DVT and EINSTEIN PE studies.

Table 2: Bleeding Events* in the Pooled Analysis of EINSTEIN DVT and EINSTEIN PE Studies

Parameter	XARELTO† N=4130 n (%)	Enoxaparin/ VKA† N=4116 n (%)
Major bleeding event	40 (1.0)	72 (1.7)
Fatal bleeding	3 (<0.1)	8 (0.2)
Intracranial	2 (<0.1)	4 (<0.1)
Non-fatal critical organ bleeding	10 (0.2)	29 (0.7)
Intracranial‡	3 (<0.1)	10 (0.2)
Retroperitoneal‡	1 (<0.1)	8 (0.2)
Intraocular‡	3 (<0.1)	2 (<0.1)
Intra-articular‡	0	4 (<0.1)
Non-fatal non-critical organ bleeding§	27 (0.7)	37 (0.9)
Decrease in Hb ≥ 2 g/dL	28 (0.7)	42 (1.0)
Transfusion of ≥2 units of whole blood or packed red blood cells	18 (0.4)	25 (0.6)
Clinically relevant non-major bleeding	357 (8.6)	357 (8.7)
Any bleeding	1169 (28.3)	1153 (28.0)

* Bleeding event occurred after randomization and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule in EINSTEIN DVT and EINSTEIN PE studies: XARELTO 15 mg twice daily for 3 weeks followed by 20 mg once daily; enoxaparin/VKA [enoxaparin: 1 mg/kg twice daily, VKA: individually titrated doses to achieve a target INR of 2.5 (range: 2.0-3.0)]

‡ Treatment-emergent major bleeding events with at least >2 subjects in any pooled treatment group

§ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥2 units of whole blood or packed red blood cells

Reduction in the Risk of Recurrence of DVT and/or PE: EINSTEIN CHOICE Study: In the EINSTEIN CHOICE clinical study, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 1% for XARELTO 10 mg, 2% for XARELTO 20 mg, and 1% for acetylsalicylic acid (aspirin) 100 mg. The mean duration of treatment was 293 days for XARELTO 10 mg-treated patients and 286 days for aspirin 100 mg-treated patients.

Table 3 shows the number of patients experiencing bleeding events in the EINSTEIN CHOICE study.

Table 3: Bleeding Events* in EINSTEIN CHOICE

Parameter	XARELTO† 10 mg N=1127 n (%)	Acetylsalicylic Acid (aspirin)† 100 mg N=1131 n (%)
Major bleeding event	5 (0.4)	3 (0.3)
Fatal bleeding	0	1 (<0.1)
Non-fatal critical organ bleeding	2 (0.2)	1 (<0.1)
Non-fatal non-critical organ bleeding§	3 (0.3)	1 (<0.1)
Clinically relevant non-major (CRNM) bleeding¶	22 (2.0)	20 (1.8)
Any bleeding	151 (13.4)	138 (12.2)

* Bleeding event occurred after the first dose and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule: XARELTO 10 mg once daily or aspirin 100 mg once daily.

§ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥ 2 units of whole blood or packed red blood cells.

¶ Bleeding which was clinically overt, did not meet the criteria for major bleeding, but was associated with medical intervention, unscheduled contact with a physician, temporary cessation of treatment, discomfort for the patient, or impairment of activities of daily life.

In the EINSTEIN CHOICE study, there was an increased incidence of bleeding, including major and CRNM bleeding in the XARELTO 20 mg group compared to the XARELTO 10 mg or aspirin 100 mg groups.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: In the RECORD clinical trials, the overall incidence rate of adverse reactions leading to permanent treatment discontinuation was 3.7% with XARELTO.

The rates of major bleeding events and any bleeding events observed in patients in the RECORD clinical trials are shown in Table 4.

Table 4: Bleeding Events* in Patients Undergoing Hip or Knee Replacement Surgeries (RECORD 1-3)

	XARELTO 10 mg	Enoxaparin†
Total treated patients	**N=4487 n (%)**	**N=4524 n (%)**
Major bleeding event	14 (0.3)	9 (0.2)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	2 (<0.1)	3 (0.1)
Bleeding that required re-operation	7 (0.2)	5 (0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	4 (0.1)	1 (<0.1)
Any bleeding event‡	261 (5.8)	251 (5.6)
Hip Surgery Studies	**N=3281 n (%)**	**N=3298 n (%)**
Major bleeding event	7 (0.2)	3 (0.1)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	1 (<0.1)	1 (<0.1)
Bleeding that required re-operation	2 (0.1)	1 (<0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	3 (0.1)	1 (<0.1)
Any bleeding event‡	201 (6.1)	191 (5.8)
Knee Surgery Study	**N=1206 n (%)**	**N=1226 n (%)**
Major bleeding event	7 (0.6)	6 (0.5)
Fatal bleeding	0	0
Bleeding into a critical organ	1 (0.1)	2 (0.2)
Bleeding that required re-operation	5 (0.4)	4 (0.3)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	1 (0.1)	0
Any bleeding event‡	60 (5.0)	60 (4.9)

* Bleeding events occurring any time following the first dose of double-blind study medication (which may have been prior to administration of active drug) until two days after the last dose of double-blind study medication. Patients may have more than one event.

† Includes the placebo-controlled period for RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

‡ Includes major bleeding events

Following XARELTO treatment, the majority of major bleeding complications (≥60%) occurred during the first week after surgery.

Other Adverse Reactions: Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in the EINSTEIN DVT and EINSTEIN PE studies are shown in Table 5.

Table 5: Other Adverse Reactions* Reported by ≥1% of XARELTO-Treated Patients in EINSTEIN DVT and EINSTEIN PE Studies

Body System Adverse Reaction		
EINSTEIN DVT Study	**XARELTO 20 mg N=1718 n (%)**	**Enoxaparin/VKA N=1711 n (%)**
Gastrointestinal disorders		
Abdominal pain	46 (2.7)	25 (1.5)
General disorders and administration site conditions		
Fatigue	24 (1.4)	15 (0.9)
Musculoskeletal and connective tissue disorders		
Back pain	50 (2.9)	31 (1.8)
Muscle spasm	23 (1.3)	13 (0.8)
Nervous system disorders		
Dizziness	38 (2.2)	22 (1.3)
Psychiatric disorders		
Anxiety	24 (1.4)	11 (0.6)
Depression	20 (1.2)	10 (0.6)
Insomnia	28 (1.6)	18 (1.1)
EINSTEIN PE Study	**XARELTO 20 mg N=2412 n (%)**	**Enoxaparin/VKA N=2405 n (%)**
Skin and subcutaneous tissue disorders		
Pruritus	53 (2.2)	27 (1.1)

* Adverse reaction with Relative Risk >1.5 for XARELTO versus comparator

Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in RECORD 1-3 studies are shown in Table 6.

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Table 6: Other Adverse Drug Reactions* Reported by ≥1% of XARELTO-Treated Patients in RECORD 1-3 Studies

Body System Adverse Reaction	XARELTO 10 mg N=4487 n (%)	Enoxaparin† N=4524 n (%)
Injury, poisoning and procedural complications		
Wound secretion	125 (2.8)	89 (2.0)
Musculoskeletal and connective tissue disorders		
Pain in extremity	74 (1.7)	55 (1.2)
Muscle spasm	52 (1.2)	32 (0.7)
Nervous system disorders		
Syncope	55 (1.2)	32 (0.7)
Skin and subcutaneous tissue disorders		
Pruritus	96 (2.1)	79 (1.8)
Blister	63 (1.4)	40 (0.9)

* Adverse reaction occurring any time following the first dose of double-blind medication, which may have been prior to administration of active drug, until two days after the last dose of double-blind study medication

† Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

Other clinical trial experience: In an investigational study of acute medically ill patients being treated with XARELTO 10 mg tablets, cases of pulmonary hemorrhage and pulmonary hemorrhage with bronchiectasis were observed.

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of XARELTO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders: agranulocytosis, thrombocytopenia

Gastrointestinal disorders: retroperitoneal hemorrhage

Hepatobiliary disorders: jaundice, cholestasis, hepatitis (including hepatocellular injury)

Immune system disorders: hypersensitivity, anaphylactic reaction, anaphylactic shock, angioedema

Nervous system disorders: cerebral hemorrhage, subdural hematoma, epidural hematoma, hemiparesis

Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome

DRUG INTERACTIONS

General Inhibition and Induction Properties: Rivaroxaban is a substrate of CYP3A4/5, CYP2J2, and the P-gp and ATP-binding cassette G2 (ABCG2) transporters. Combined P-gp and strong CYP3A4 inhibitors increase exposure to rivaroxaban and may increase the risk of bleeding. Combined P-gp and strong CYP3A4 inducers decrease exposure to rivaroxaban and may increase the risk of thromboembolic events.

Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Interaction with Combined P-gp and Strong CYP3A4 Inhibitors: Avoid concomitant administration of XARELTO with known combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole and ritonavir) *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Although clarithromycin is a combined P-gp and strong CYP3A4 inhibitor, pharmacokinetic data suggests that no precautions are necessary with concomitant administration with XARELTO as the change in exposure is unlikely to affect the bleeding risk *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Interaction with Combined P-gp and Moderate CYP3A4 Inhibitors in Patients with Renal Impairment: XARELTO should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (e.g., erythromycin) unless the potential benefit justifies the potential risk *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Drugs that Induce Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Anticoagulants and NSAIDs/Aspirin: Coadministration of enoxaparin, warfarin, aspirin, clopidogrel and chronic NSAID use may increase the risk of bleeding *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Avoid concurrent use of XARELTO with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: The limited available data on XARELTO in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO for the mother and possible risks to the fetus when prescribing XARELTO to a pregnant woman *[see Warnings and Precautions]*.

Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Clinical Considerations: *Disease-Associated Maternal and/or Embryo/Fetal Risk:* Pregnancy is a risk factor for venous thromboembolism and that risk is increased in women with inherited or acquired thrombophilias. Pregnant women with thromboembolic disease have an increased risk of maternal complications including pre-eclampsia. Maternal thromboembolic disease increases the risk for intrauterine growth restriction, placental abruption and early and late pregnancy loss.

Fetal/Neonatal Adverse Reactions: Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.

Labor or Delivery: All patients receiving anticoagulants, including pregnant women, are at risk for bleeding and this risk may be increased during labor or delivery *[see Warnings and Precautions]*. The risk of bleeding should be balanced with the risk of thrombotic events when considering the use of XARELTO in this setting.

Data: *Human Data:* There are no adequate or well-controlled studies of XARELTO in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage. In an *in vitro* placenta perfusion model, unbound rivaroxaban was rapidly transferred across the human placenta.

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Animal Data: Rivaroxaban crosses the placenta in animals. Rivaroxaban increased fetal toxicity (increased resorptions, decreased number of live fetuses, and decreased fetal body weight) when pregnant rabbits were given oral doses of ≥10 mg/kg rivaroxaban during the period of organogenesis. This dose corresponds to about 4 times the human exposure of unbound drug, based on AUC comparisons at the highest recommended human dose of 20 mg/day. Fetal body weights decreased when pregnant rats were given oral doses of 120 mg/kg during the period of organogenesis. This dose corresponds to about 14 times the human exposure of unbound drug. In rats, peripartal maternal bleeding and maternal and fetal death occurred at the rivaroxaban dose of 40 mg/kg (about 6 times maximum human exposure of the unbound drug at the human dose of 20 mg/day).

Lactation: Risk Summary: Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. Rivaroxaban and/or its metabolites were present in the milk of rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XARELTO and any potential adverse effects on the breastfed infant from XARELTO or from the underlying maternal condition *(see Data)*.

Data: *Animal data:* Following a single oral administration of 3 mg/kg of radioactive [^{14}C]-rivaroxaban to lactating rats between Day 8 to 10 postpartum, the concentration of total radioactivity was determined in milk samples collected up to 32 hours post-dose. The estimated amount of radioactivity excreted with milk within 32 hours after administration was 2.1% of the maternal dose.

Females and Males of Reproductive Potential: Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in the RECORD 1-3 clinical studies evaluating XARELTO, about 54% were 65 years and over, while about 15% were >75 years. In ROCKET AF, approximately 77% were 65 years and over and about 38% were >75 years. In the EINSTEIN DVT, PE and Extension clinical studies approximately 37% were 65 years and over and about 16% were >75 years. In EINSTEIN CHOICE, approximately 39% were 65 years and over and about 12% were >75 years. In clinical trials the efficacy of XARELTO in the elderly (65 years or older) was similar to that seen in patients younger than 65 years. Both thrombotic and bleeding event rates were higher in these older patients, but the risk-benefit profile was favorable in all age groups *[see Clinical Pharmacology (12.3) and Clinical Studies (14) in full Prescribing Information]*.

Renal Impairment: In pharmacokinetic studies, compared to healthy subjects with normal creatinine clearance, rivaroxaban exposure increased by approximately 44 to 64% in subjects with renal impairment. Increases in pharmacodynamic effects were also observed *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, patients with CrCl 30 to 50 mL/min were administered XARELTO 15 mg once daily resulting in serum concentrations of rivaroxaban and clinical outcomes similar to those in patients with better renal function administered XARELTO 20 mg once daily. Patients with CrCl 15 to 30 mL/min were not studied, but administration of XARELTO 15 mg once daily is also expected to result in serum concentrations of rivaroxaban similar to those in patients with normal renal function *[see Dosage and Administration (2.4) and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Patients with End-Stage Renal Disease on Dialysis: Clinical efficacy and safety studies with XARELTO did not enroll patients with end-stage renal disease (ESRD) on dialysis. In patients with ESRD maintained on intermittent hemodialysis, administration of XARELTO 15 mg once daily will result in concentrations of rivaroxaban and pharmacodynamic activity similar to those observed in the ROCKET AF study *[see Clinical Pharmacology (12.2, 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 ROCKET AF.

Treatment of DVT and/or PE and Reduction in the Risk of Recurrence of DVT and/or PE : In the EINSTEIN trials, patients with CrCl values <30 mL/min at screening were excluded from the studies. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Prophylaxis of DVT Following Hip or Knee Replacement Surgery: The combined analysis of the RECORD 1-3 clinical efficacy studies did not show an increase in bleeding risk for patients with CrCl 30 to 50 mL/min and reported a possible increase in total venous thromboemboli in this population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Hepatic Impairment: In a pharmacokinetic study, compared to healthy subjects with normal liver function, AUC increases of 127% were observed in subjects with moderate hepatic impairment (Child-Pugh B).

The safety or PK of XARELTO in patients with severe hepatic impairment (Child-Pugh C) has not been evaluated *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Avoid the use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy.

OVERDOSAGE

Overdose of XARELTO may lead to hemorrhage. Discontinue XARELTO and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. The use of activated charcoal to reduce absorption in case of XARELTO overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information]*. Partial reversal of laboratory anticoagulation parameters may be achieved with use of plasma products.

Active Ingredient Made in Germany

Finished Product Manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778
or
Bayer AG
51368 Leverkusen, Germany

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Licensed from:
Bayer HealthCare AG
51368 Leverkusen, Germany

 cp-49791

ABEM Continuing Innovations for MOC

Preserving the integrity of MOC, while addressing concerns of the high-stakes ConCert, cost, and testing format

by TERRY KOWALENKO, MD

The American Board of Emergency Medicine (ABEM) is working to create a new process for continuing certification by offering an alternative to the ConCert Examination. The ConCert will remain an option for physicians who wish to take it, and many likely will. However, there will soon be a way to opt out of taking the 10-year exam.

ABEM just completed a year-long listening program where we sought the opinions of leaders in our specialty. ABEM has had extensive conversations with the ACEP Board of Directors, the leadership of the American Academy of Emergency Medicine, and about half of the state ACEP chapters. We've also reviewed thousands of survey responses from last year. One of the most helpful conversations we had was at the ConCert Summit, a national summit we convened last October that included representatives from every major emergency medicine organization. What we heard was a desire to focus on three areas: cost, convenience, and clinical relevance.

The Three Cs

Despite Maintenance of Certification (MOC) fees averaging only $265 per year, those costs are not evenly distributed, and they do not include additional costs that a physician might spend. Discussions about cost are complicated. We know that 32 percent of physicians take an off-site board prep course, which adds an additional expense. However, there is usually a substantial amount of continuing medical education (CME) awarded, and the course's expense is tax deductible. We also know that being board-certified is associated with higher financial compensation. Still, the costs feel considerable. ABEM also realizes that there is a significant cost in time. We know that 98 percent of physicians study for the ConCert because the consequences of failing are substantial. The amount of preparation by physicians is also why the pass rate is so high, and more than 90 percent of physicians report a learning benefit to preparing for and taking the ConCert.

Convenience is a challenge. When ABEM changed from offering the recertification examination on a single date in only a handful of sites to offering the examination at Pearson VUE testing centers, ABEM-certified physicians were very pleased. Times have changed. We heard a strong request to add flexibility into the process and expand when and where tests can be taken. For the existing ConCert, starting in 2019, ABEM will offer the test twice yearly to provide an extra opportunity to pass the examination so that physicians have greater opportunities to maintain certification. We are looking at additional ways to optimize the convenience of completing the ConCert alternative.

Improving the clinical relevance of the continuing certification process was a key request. A message we received loud and clear was that emergency physicians remain committed to a rigorous program of continuing certification, as long as it helps them become better clinicians. What a remarkable statement! The bottom line for emergency physicians is improved patient care, not self-interest. ABEM is committed to a revised process that helps physicians find learning opportunities and involves assessment that is more clinically focused. This could even involve looking up material much like we do when working in the emergency department.

Communicating

Many of the details of the ConCert alternative are not yet defined, but ABEM wanted to let physicians know the importance of what they told us and how we are responding. We envision that the alternative assessments will be shorter (possibly taking an hour or less to complete) and will target one or more content areas (such as trauma). Because relevance was a key issue for physicians, we will attempt to integrate more recent and timely topics into the alternative more quickly. Another consideration is the ability to use of some form of reference material(s). Finally, the feasibility of remote access to the assessment is being explored. ABEM will begin phasing in the alternative assessment in 2020. Over the next year, more and more details will be forthcoming. We also want to hear from ABEM-certified physicians about their ideas and thoughts on improvements.

Maintaining Credential Strength

ABEM is committed to maintaining the integrity and strength of ABEM certification as a credential. Emergency medicine faces many challenges, and those challenges are best addressed by skilled and talented physicians leveraging the strong credential of ABEM certification. ABEM supports using continuing certification as an indicator of quality and patient safety in our struggles surrounding scope of practice. ABEM strongly believes that continuing certification eliminates the need for medical merit badges and state-based CME requirements. We believe that the alternative assessment to the ConCert must ensure the continuing strength of ABEM certification so that emergency physicians can use the credential to their professional benefit and to optimize patient care. We think the ConCert alternative, as well as administering the ConCert more frequently, can address the issues of cost, convenience, and clinical relevance while maintaining the potency of ABEM certification.

DR. KOWALENKO is President of ABEM.

The bottom line for emergency physicians is improved patient care, not self-interest. ABEM is committed to a revised process that helps physicians find learning opportunities and involves assessment that is more clinically focused.

ACS Trauma CME Dropped for MOC Participants

The American College of Surgeons (ACS) recently revised the criteria for trauma-related CME credits for ABEM-certified physicians working in ACS-designated trauma centers. Effective immediately, ABEM-certified physicians participating in MOC no longer need to acquire trauma-related CME credits to fulfill ACS trauma center verification requirements. This change applies only to CME requirements housed under the ACS designation. As a result, it is possible that you may have other CME requirements depending on state or local mandates. ABEM encourages you to speak with your administrator for further clarification. ABEM will continue to seek opportunities like this to add value to your certification.

EM PICS WORTH A THOUSAND WORD

IMAGES IN EM

DR. THOMAS is an emergency medicine resident at Highland Hospital in Oakland, California.

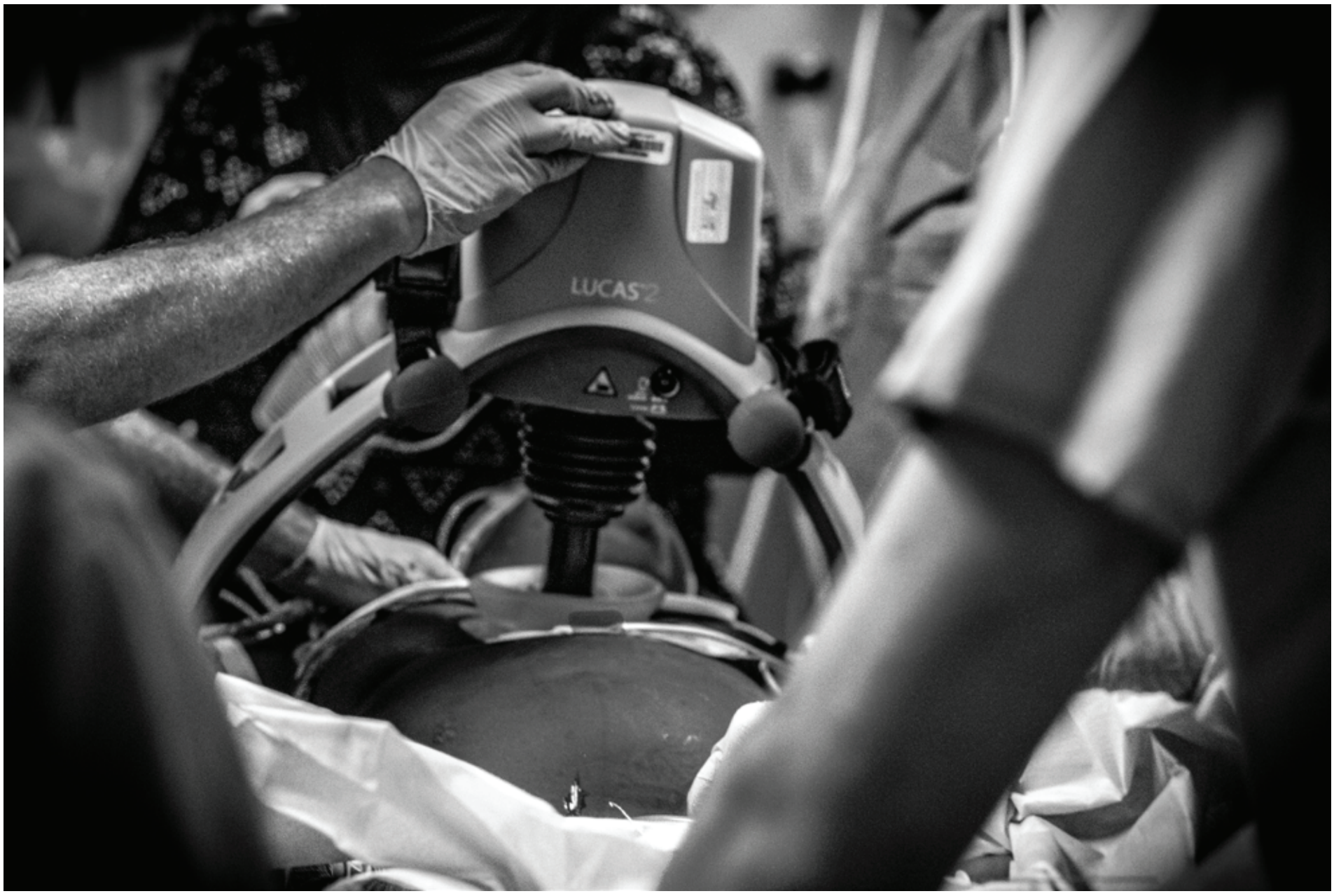

PHOTO: BENJAMIN THOMAS

The Burden of Mortality

Dealing with an emotionally difficult case

by BENJAMIN THOMAS, MD

Beep! Beep! Beep! "This is EMS bringing in a code three cardiac arrest. We have a toddler who was found unresponsive by parents. CPR is in progress. ETA five minutes."

The hairs on the back of my neck jumped as I listened to the ring down. A wave of anxiety and fear coursed through my body in anticipation of what would soon roll through the ED doors. No matter how many times I mentally prepare myself, organize my team, and establish the tools necessary for resuscitation, nothing truly prepares me for the emotional toll that ensues after it's all done.

The child was barely a year old. The paramedics rushed this small, lifeless body into our resuscitation bay, and we immediately descended upon her with full force and hope to bring her back. After an hour of throwing the kitchen sink (and then some) to revive this child, our efforts were ultimately futile. I called the code. Time of death 10:56 a.m.

After the adrenaline wore off, an air of sorrow and lament settled among everyone in the room, including me. I asked everyone if we could share in a moment of silence for this life that was taken too soon. I felt defeated and hollow inside. My emotions were frenetic, but I knew I had to compose myself to do something more difficult than calling the code.

I walked out of the room and immediately met the eyes of the father, who had already been peeking through the door to know whether his child was going to make it. Upon seeing my face, he knew. He collapsed to the floor and sent out a wail of anguish that shook the entire emergency department. Fighting tears myself, I picked him up and walked him to a private room to tell the rest of his family the news. I remember slowly staggering out of that room, thinking to myself, "You can't gas out now. This is only the first hour of a very long shift."

Three Tactics

As emergency physicians, all of us have had, or will have, cases like this in our career. Over the few years I've been in training, I've learned some tactics that help keep me mentally and emotionally intact after a difficult case:

1. **A moment of silence:** Consider taking a moment to recognize the life that was lost. As emergency providers, we love to highlight our saves, but we should also take time to acknowledge the lives we can't save.
2. **A team debrief:** After long resuscitations, gather everyone involved in the case to share what went well or didn't go well and to share how they are feeling. I find it provides an emotional release and serves as a powerful platform for the team members to provide feedback to one another.
3. **A moment for yourself:** I find it emotionally difficult to walk away from an intense code and directly move on to see another patient with a minor chief complaint. I know I can't provide the best care to my next patient if my mind and emotions are still wrapped up in another. Take a moment to reflect on what has happened and find time to compose yourself. This will not only benefit you but also the next set of patients you care for.

I entered medicine to save lives, yet my experience in training has provided the harsh lesson that they can't all be saved.

As physicians, we serve as beacons of hope during times of crisis for patients and their families. That honor also comes with the burden of delivering the sobering messages of death and dying. In my humble opinion, this is the most difficult part of being a doctor.

Despite what you may think or may have learned in training, there is never a perfect way to deliver bad news. The only thing you can hope for is that you communicate with respect and empathy, dignifying the life that was lost.

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

Combat Pharma Price Gouging

Drug costs are one of the fastest-growing health care expenses, but there are things you can do to help reduce costs

by CEDRIC DARK, MD, MPH

Half of all Americans in a recent Gallup Poll had a somewhat negative or very negative view of the pharmaceutical industry.[1] With the actions of executives like Martin Shkreli (the founder of Turing Pharmaceuticals who drew heavy criticism for instituting large prince increases on Daraprim), drug shortages ranging from atropine to vecuronium, and the unacceptably high prices of older medications such as colchicine, who can blame them?[2] Large majorities of Americans agree that the pharmaceutical industry's prices are too high, that their profits are too large, and that there are many ways to curb these costs.[3]

Some of these broader solutions that are supported by a majority of Americans include allowing the federal government to negotiate pharmaceutical prices for Medicare Part D beneficiaries, making it easier for generics to enter the market, allowing importation of less-expensive drugs from Canada, and eliminating some pharmaceutical advertising, such as the direct-to-consumer ads, which arguably increase patient demand for medications they may not even need.

Even though pharmaceuticals make up only about 10 percent of overall health care costs, they represent one of the most rapidly rising sectors for health care cost growth. Thus, it is imperative that we act now before drug costs swallow the remaining slices of the health care pie. Unlike physician Medicare costs, which arbitrarily could come crashing down due to price controls via sequestration rules and/or payment reform, there is no immediate check to the rise of pharmaceutical prices. Historically, drug companies have only been subject to what the market will bear.

A recent article on the Emergency Medicine Residents' Association website, reprinted below with permission, discusses why pharmaceutical prices are so high and offers solutions that even the clinician at the bedside can undertake to fight the war on drug prices.

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EMRA+POLICYRx HEALTH POLICY JOURNAL CLUB

Physicians Can Take Steps to Limit Pharma Price-Gouging

by DEMETRIO AN MUNOZ

The cost of prescription drugs in the United States is constantly in the news, with the public becoming aware of increasing prices for off-patent drugs from the obscure Daraprim (up almost 5500 percent overnight from $13.50 to $700 per capsule) to the universally known epinephrine (up almost 550 percent from $94 in 2007 to $609 in 2016 for a set of two EpiPens).[1,2]

A recent study in *JAMA* reviewed medical and health policy literature to uncover the reasons prescription drug prices in the United States are so much higher than in other highly developed nations, and discussed possible solutions.[3]

The main reasons for higher prices in the United States are a permissive patent system that extends patents for minor changes in a drug's formulation with no improved outcome and the inability of one of our nation's largest health

care systems to negotiate drug prices with pharmaceutical companies.

Drug patents give pharmaceutical companies time to recoup the cost of their investment in a new drug by being a monopoly provider, usually for six to eight years after U.S Food and Drug Administration (FDA) approval of the drug. However, pharmaceutical companies have extended their period of exclusive coverage by many maneuvers, such as by getting a new patent on a stereoisomer of their drug and then withdrawing their original drug before it becomes generic or by refusing to provide samples of their drug to potential generic manufacturers to delay their competitors' FDA bioequivalence approval studies.[4]

Medicare, which accounted for 29 percent of national retail prescription drug spending in 2014, is prohibited by federal law from using its market power to negotiate lower drug prices while being required to cover all FDA-approved drugs.[5] Essentially, manufacturers are allowed to name their price in America.

By contrast, in England and Wales, the National Institute for Health and Care Excellence considers whether a new drug passes a cost-utility threshold before recommending it for coverage by the National Health Service. If a drug is rejected, the manufacturer might decide to offer it at a lower price. The authors propose reforms that individual physicians can do, such as educating themselves about drug costs and efficacy, limiting dispense-as-written prescriptions, and not using samples of branded products that ultimately increase demand.

Editor's note: The U.S. Department of Health and Human Services recently released a blueprint for reducing drug costs. It includes a number of proposals, including increasing Medicare's ability to negotiate drug prices, supporting the development and approval of generics and biosimilars, value-based purchasing, increasing drug price transparency, and reforms of drug rebate and discount programs.

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MR. MUNOZ is a medical student at SUNY Upstate Medical University in Syracuse, New York.

CODING WIZARD

NAVIGATE THE CPT MAZE, OPTIMIZING YOUR REIMBURSEMENT

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

WHAT YOU NEED TO KNOW WHEN WORKING WITH RESIDENTS

by **MICHAEL LEMANSKI, MD, FACEP, FAAFP**

Question: How should my residents and I document examinations they perform?

Answer: Residents are supported in part by graduate medical education funds paid to hospitals by the Centers for Medicare & Medicaid Services (CMS). Teaching physicians (TPs) who work with residents should understand the care provided by residents has essentially been paid for by CMS. Only the care that is personally provided by TPs is payable. TPs should see the patient, confirm the history and examination, and actively participate in the medical decision making.

The good news is TPs do not have to write a separate note. TPs can review, confirm, and correct the resident note and may choose to expand on the medical decision making and treatment provided. TPs may see the patient concomitantly with the resident or separately. When incorporating the resident note, TPs must include an attestation that reflects the care they delivered and meets CMS requirements, such as, "I personally evaluated and examined the patient and discussed the care with the resident. I agree with the resident's written findings and plan, except as noted."

If residents perform a procedure that takes more than five minutes, TPs must document that they were present for the "key or critical" portion of the procedure. See the ACEP Teaching Physician at www.acep.org/administration/reimbursement/reimbursement-faqs/teaching-physician-guidelines-faq for further details.

Brought to you by the ACEP Coding and Nomenclature Committee.

DR. LEMANSKI is associate professor of emergency medicine at Baystate Medical Center/Tufts University School of Medicine in Springfield, Massachusetts.

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[1] Data on file at BioFire Diagnostics

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