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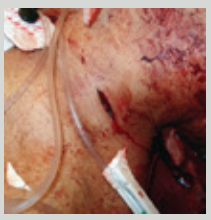

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DIARRHEA: A SYMPTOM, NOT A DIAGNOSIS

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IS THE ONLY ANSWER?

Showing kindness and trying for voluntary admission can make a tense situation easier for everyone

by DINAH MILLER, MD

Eleanor (not her real name) talked to me at length about her experience as a patient who had been committed to a psychiatric unit. Eleanor came to the emergency department in distress. In fact, she was screaming inconsolably when a physician gave her an injection of a sedating medication and filled out a "5150," the California jargon for an involuntary hold. Eleanor's stay on the unit lasted three weeks. During that time, she was repeatedly held down by security guards and injected with medications, and she spent a good deal of

CONTINUED *on page 10*

PHOTO: BENJAMIN THOMAS

'DON'T LET ME DIE'

Treating gunshot wounds, making a plea to stop the violence

by BENJAMIN THOMAS, MD

"Don't let me die," he told me. As I provided supplemental oxygen to him at the head of the bed, I told him, "You are in good hands. Everything will be OK." But everything wasn't OK. He had multiple gunshot wounds to his abdomen and died on the operating room table 30 minutes later. He was only 27 years old, not much younger than I at the time, and his last words were a plea to save his life.

IMAGES IN EM

To his family and friends, this would be a tragic loss that would change their lives

CONTINUED *on page 17*

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by JOHN CORKER, MD; SHAMIE DAS, MD, MBA, MPH; AND ZACH JAROU, MD

Remember the first time you felt "at home" in emergency medicine—like you were in the right place at the right time with the right people? Having a professional home, somewhere you belong, can provide a sense of community and unified purpose that serves as a powerful antidote to physician burnout.

To this end, the Emergency Medicine Residents' Association (EMRA), in partnership with the award-winning talk show Radio Rounds, recently developed an inspirational podcast

CONTINUED *on page 9*

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EXERTIONAL HEAT STROKE DESTROYS FROM THE INSIDE

WHEN THEIR BODY TEMPERATURE RISES TO DANGEROUS LEVELS, IT CAN QUICKLY BECOME A LIFE-THREATENING SITUATION.[1]

Exertional heat stroke (EHS) is a hyperthermic and hypermetabolic crisis that creates an immediate cascade of CNS and other serious complications. If core body temperatures remain elevated, EHS has been shown to cause long-term neurologic damage and death.[1-3]

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THE BREAK ROOM

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"Bandwagon Bias"

[Regarding "Is Bias Affecting You and Your Patients?" April 2017] The IAT does not predict behavior of racial bias whatsoever. Is credible science not important anymore? The bias here is "bandwagon bias." Perhaps we should pause before jumping on board.

It's hard to disagree with the conclusion of Fiedler and his colleagues that it is only "fair and appropriate to treat the IAT with the same scrutiny and scientific rigour as other diagnostic procedures." If that's true, then between Project Implicit and cutting-edge diversity trainings, the IAT has misled potentially millions of people. Over and over and over and over, the IAT, a test whose results don't really mean anything for an individual test-taker, has induced strong emotional responses from people who are told that it is measuring something deep and important in them. This is exactly what the norms of psychology are supposed to protect test subjects against.

—Mark Buettner, DO, FACEP

Dr. Lopez Responds

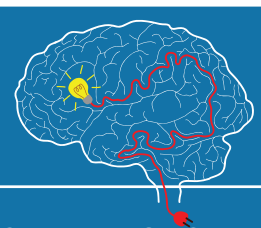
In my article, I never said that the IAT predicts behavior of racial bias. Much research has been done on the IAT since it was first described. Thus, the test has undergone significant scientific scrutiny and raises questions on just exactly what it measures. One school of thought is that the IAT may simply be measuring the association of positive evaluations with the "in" or majority group and negative evaluations with the "out" or minority group and that it may not be a specific attribute effect but rather the manner in which humans behave. In my article, I describe a study that suggests that in-group/out-group membership, and not nationality, was the important factor.

Too often, people are told to take the test on their own. Therein lies the potential harm—they read the results and may assume that they are prejudiced against a group. The test may also be used by diversity educators who may suggest the existence of prejudice. In this regard, I agree with Dr. Buettner that the IAT is misleading. In my article, I gave the opinion that the IAT is a tool that can be used to stimulate thought about one's unconscious biases but should NOT be used to measure one's "prejudices." Having a strong preference for a certain group does not mean that one is prejudiced against another. Knowledge of this preference is useful when dealing with someone from "the other" group as it allows you to consider how your bias may affect certain behaviors and decisions. The use of the IAT needs to be done in a controlled setting that stresses the fact that it does not measure prejudice and that it should simply stimulate thought about one's unconscious biases.

I disagree with Dr. Buettner's statement that the IAT is a test whose results don't really mean anything for an individual test-taker. For the individual, the results suggest a preference. This preference, when used to stimulate thought (not measure prejudice) on potential biases, can be valuable in future interpersonal interactions.

—Bernard L. Lopez, MD, MS, CPE, FACEP, FAAEM
Philadelphia, Pennsylvania

WHAT ARE YOU THINKING?



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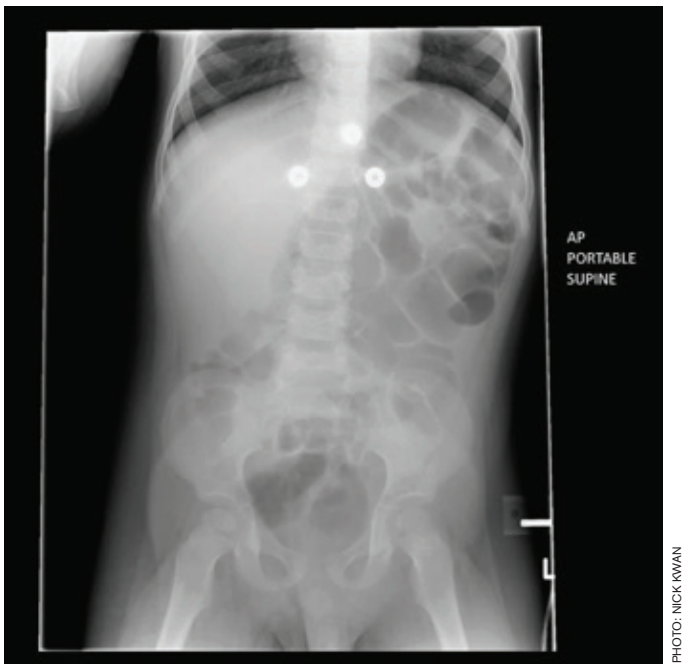

PHOTO: NICK KWAN

FIGURE 1: Abdominal X-ray showing increased bowel gas.

Hemolytic uremic syndrome is a rare but serious complication of E. coli infection

by PINGCHING N. KWAN, MD, FACEP; AND CHANGYOW C. KWAN, BS

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THE CASE

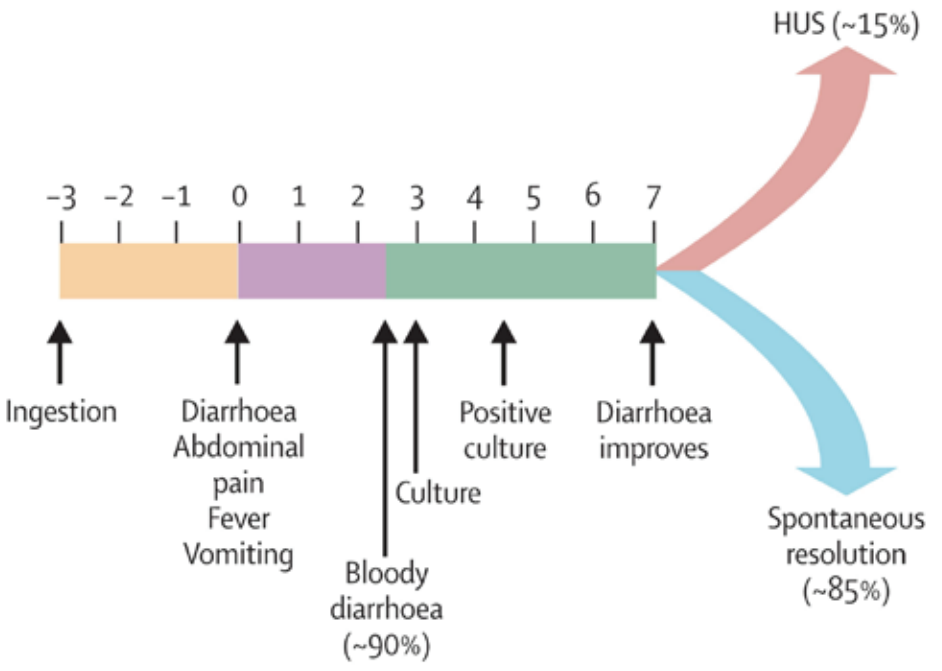
A 3-year-old boy with watery diarrhea for the past three days as well as vomiting and fever that started the day prior is brought to the emergency department by his mother. No recent traveling or antibiotic usage is reported. He has otherwise been in good health. On physical exam, the patient appears well-developed, nourished, alert, and oriented. The vitals are stable, and the abdomen is non-tender and non-distended. At shift change, the patient's condition seems to be improving. He can tolerate apple juice and no longer has fever. The patient is signed out to the incoming physician with pending diagnostic studies.

However, the patient starts to develop tarry black stools shortly after shift change, and on reassessment, the patient's blood pressure is 80/45. He appears to be pale with a rapidly deteriorating clinical status. The initial diagnostic studies are significant for hematuria, metabolic acidosis with elevated creatinine, and C-reactive protein. Abdominal X-ray shows increased bowel gas (see Figure 1), and abdominal ultrasound does not suggest any radiographic evidence of intussusception. Two hours after shift change, the patient becomes more hypotensive, and his abdomen becomes more rigid. Emergent critical care transport is initiated while the patient is placed on vasopressors to maintain a systolic blood pressure above 90. The patient is transported to a tertiary pediatric facility, where his stool culture was positive for *Escherichia coli* 0157, the most common cause of hemolytic uremic syndrome (HUS) in the United States. Fortunately, the patient is diagnosed, treated for HUS, and makes a full recovery.

DISCUSSION

This case highlights the importance of recognizing the symptoms of HUS. HUS is a serious complication resulting from *E. coli* infection, most often with Shiga toxin–producing *E. coli* (STEC). The toxins produced by STEC activate the endothelium, create a prothrombotic state, and lead to inflammation. *E. coli* 0157 is the most common strain of STEC in the United States and accounts for more than 90 percent of HUS cases in children under 5 years of age.

FIGURE 2: Progression of *E. coli* 0157 infection in children.



GRAPHIC: LANCET. *2005;365(9464):1073-1086.*

About 5 percent to 15 percent of people infected with STEC develop HUS. The incidence is about 2–3 per 100,000 children under 5 years of age in the United States.[1,2] HUS can have severe complications, and early recognition and treatment are paramount to preventing morbidity and mortality.

The clinical course of HUS is shown in Figure 2. Diarrhea, abdominal pain, fever, and vomiting develop a few days after inoculation with the pathogen. Within a week, the patient's condition can either resolve or develop to full-blown HUS. HUS is defined by the classic triad of microangiopathic hemolytic anemia, thrombocytopenia, and acute renal injury. Though the long-term prognosis for renal recovery is good, up to 50 percent of patients with HUS may require dialysis during the acute phase. Additionally, HUS can affect many other organ systems, including the central nervous system (CNS), gastrointestinal tract, liver, pancreas, and heart. CNS involvement, including seizures, coma, and stroke, is seen in up to 20 percent of cases and is associated with increased mortality.[3] In this case, the patient was colonized with *E. coli* 0157 and had hematuria, rectal bleeding, hypotension due to significant fluid loss, and early renal injury. Early recognition and treatment resulted in a complete recovery.

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MS. KWAN is a MS2 at Northwestern University Feinberg School of Medicine in Chicago.

No Merit Badges for Emergency Ultrasound

The case against APCA and ARDMS

by J. MATTHEW FIELDS, MD, FACEP

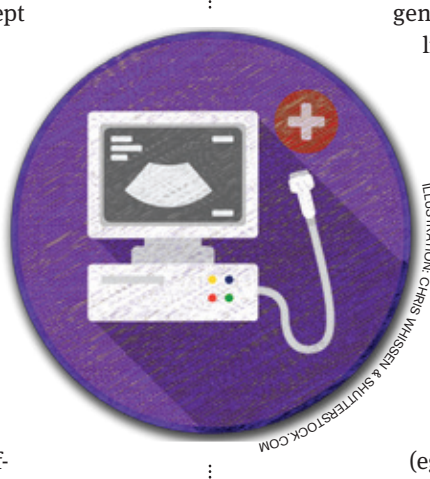
For those of you who haven't been recently barraged by advertisements, a new organization called the Alliance for Physician Certification & Advancement (APCA) is offering a "special opportunity" to be certified in emergency ultrasound.

It sounds awesome, except for a couple things: 1) It costs money, and 2) It's completely unnecessary. The ACEP Emergency Ultrasound Guidelines already outline the pathways for emergency ultrasound training, which are either residency- or practice-based.

So why would a new organization suddenly offer a certificate for emergency ultrasound to emergency physicians? I have two thoughts: money and power. APCA's POCUS Academy is an online program that costs hundreds of dollars to take and must be maintained annually. Since it is virtual, it can be replicated at little cost to APCA.

Who is APCA? APCA is under the umbrella of a larger organization called Inteleos. Inteleos also houses the American Registry for Diagnostic Medical Sonography (ARDMS). If ARDMS sounds familiar to you, it is because many emergency physicians have obtained Registered Diagnostic Medical Sonographer (RDMS) credentials. This past year, Inteleos restructured so that physician certification is done through APCA and technician certification is done through ARDMS. In the past, RDMS wasn't so much a threat as an option for those of us who had done more scans and training. RDMS credentials may have helped many emergency ultrasound directors achieve recognition of ultrasound expertise when emergency ultrasound was in its infancy.

Clinical ultrasound is now a Residency Review Committee requirement and an emergency medicine milestone, so there is no need for any emergency physician to have RDMS credentials. Now that ARDMS has changed its robes to APCA and is attempting to profit from and exert control in our specialty, I feel it is time for emergency medicine and ARDMS to part ways.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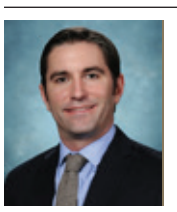
External certification, in general, is bad for our specialty. In 1998, the American Medical Association created Resolution 802, which states that ultrasound is in the scope of practice of appropriately trained physicians and that training and education standards should be developed by each physician's respective specialty. Since 2001, the emergency ultrasound guidelines have become one of the most utilized documents for clinical (point-of-care) ultrasound in the world. By leading the way in emergency ultrasound, we have not only saved lives but also discovered uses for ultrasound that would otherwise never have been realized (eg, extended focused assessment with sonography for trauma [FAST], critical care resuscitation, and procedural guidance). By never allowing external control, emergency medicine has been able to push the frontier of emergency ultrasound in modern medicine. It is incumbent on our specialty that we keep these tools under our supervision and never abdicate this responsibility to external entities.

Emergency medicine is probably just the beginning. APCA will likely expand to other specialties here and abroad. If we were crazy enough to buy into this unnecessary merit badge program, we would put APCA in a prime position to manipulate the set standards for ultrasound training and qualifications. We would essentially be letting a group not based in emergency medicine tell us how to train and practice with one of our most beloved bedside tools.

What can we do? The best thing we can do is ... nothing! Don't sign up for unnecessary merit badge courses in emergency medicine. You are only hurting your peers when credentialing committees see you with a merit badge certificate and then start demanding it of others.



DR. FIELDS is chair of the ACEP Emergency Ultrasound Section and a physician in the department of emergency medicine at Kaiser Permanente San Diego.

"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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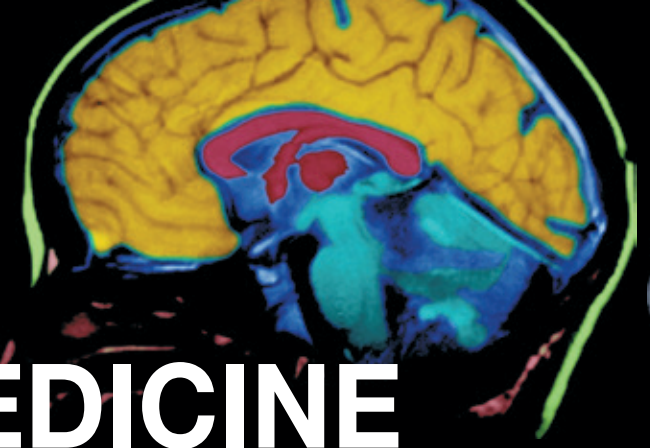

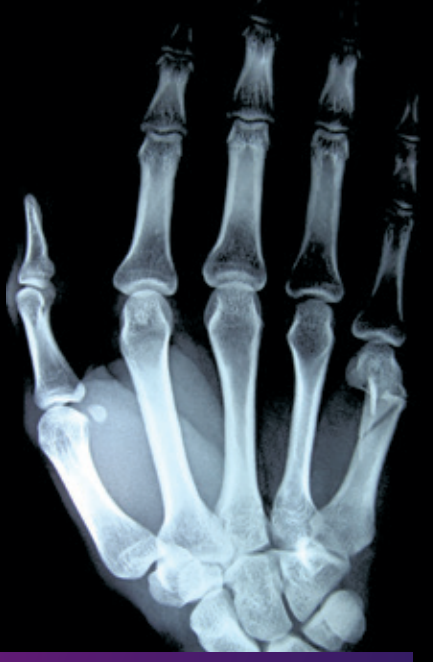

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VENUE SHOPPING: PLAINTIFFS AVOIDING TORT REFORM

Court decision helps ensure patient access to care across state lines

by JAMES WILLIAMS, DO, MS, FACEP

A recent New Mexico Supreme Court decision has huge professional liability ramifications for physicians treating patients from another state. The March 13, 2017, ruling is of importance to emergency physicians who, under EMTALA, are unable to deny a patient care due to illness, injury, inability to pay, or lack of health history.

The issue at stake in *Montaño v. Frezza* was which state's laws claim legal jurisdiction when a patient who resides in one state (New Mexico, in this case) receives care in another (Texas, in this case).

Montaño-Frezza Case Background

More than a half million patients from eastern New Mexico rely on a range of medical care from physicians in Lubbock, Texas. Texas has significant medical liability reforms; New Mexico does not.

In 2003, Texas passed comprehensive reforms regarded nationally as the gold standard in medical liability legislation. These reforms included a $250,000 cap on pain-and-suffering-type damages and a heightened willful and wanton standard of negligence for those providing emergency care.[1] A voter-approved constitutional amendment affirmed the legality of the damage cap.[2] Since 2003, 118 counties have grown their base of emergency physicians, including 53 counties where previously no emergency physicians practiced.[3,4]

Eastern New Mexico is largely rural and has a significant shortage of primary and tertiary care. Patients often drive one to three hours from New Mexico to Texas to receive needed care. Covenant Health, the dominant hospital system in the Texas Panhandle, accepts multiple critically ill patients from New Mexico daily.

In 2004, Kimberly Montaño, a New Mexico resident, traveled to Lubbock to have gastric bypass surgery. The operation was performed in-network by bariatric surgeon Eldo Frezza, MD. At the time, Dr. Frezza was the chief of bariatric surgery at Texas Tech Hospital in Lubbock, a facility owned and operated by Texas Tech University Health Sciences Center. In the ensuing years, Dr. Frezza provided follow-up care for complications related to Ms. Montaño's surgery. All of the care rendered by Dr. Frezza was in Texas. Dr. Frezza's only connection to New Mexico was the fact that he was the only bariatric surgeon on the Lovelace New Mexico Health Plan.

Ms. Montaño sued Dr. Frezza in a New Mexico court. She argued her case should be tried under New Mexico law because her injuries "manifested" in New Mexico.

The Courts' Decisions

The New Mexico appellate court agreed with the plaintiff, concluding the "place of wrong" is the place where the injury manifested and not where the alleged injury occurred.

The court also concluded the "choice of law" favored New Mexico since applying Texas liability law violated New Mexico public policy that provides a greater remedy for plaintiffs. The points of contention—place of the injury and the jurisdiction—affect physicians of every specialty.

The New Mexico Court of Appeals ruled that New Mexico law is controlling, but ultimately, the state's Supreme Court overturned that decision.[5] The Texas College of Emergency Physicians and ACEP joined a "friend of the court" brief challenging the lower court's ruling.[6]

The New Mexico Supreme Court instructed the lower court to dismiss the complaint without prejudice. Writing for the majority, Justice Edward Chavez stated, "The public interest in maintaining access to cross-border medical services is promoted by applying the law where such services were rendered."[5]

The ruling, while not binding in all states, has persuasive authority, according to Alice Lorenz, New Mexico co-counsel for the Texas Alliance for Patient Access, the lead amicus who challenged the lower court's ruling. In all, 31 parties signed on to the brief: 10 from New Mexico, 18 from Texas, and three national organizations, including ACEP and the American Medical Association.

A Win for Emergency Physicians

Had the plaintiff prevailed, Texas doctors would have been twice bitten. They would have lost Texas medical liability protections and yet remained ineligible to buy into and receive the benefits of the New Mexico Patient Compensation Fund. The Patient Compensation Fund provides an excess layer of liability coverage for doctors and hospitals that qualify under New Mexico's Medical Malpractice Act. Dr. Frezza did not qualify to purchase such coverage because he practiced in Texas only.

A loss in the *Montaño* case would likely have caused Texas doctors and hospitals to reconsider their willingness to accept transfers or referrals of New Mexico patients. After all, why would or should doctors agree to assume greater liability risk simply by agreeing to see New Mexican patients in Texas? Additionally, Texas hospitals, such as Covenant, would have had trouble retaining emergency physicians and trauma specialists who are required to meet the obligations of its regional trauma center.

ACEP President-Elect Paul Kivela, MD, MBA, FACEP, describes the court victory as "a win for minimizing venue shopping by plaintiffs' attorneys and, more importantly, maintaining patient access to care."

Because of the victory in *Montaño*, the time-honored patient referral pipeline remains open between New Mexico and Texas.

The outcome is best summarized by one of Covenant Health's patients, Lovington, New Mexico–resident Samuel Murphy. "I'd be dead today if not for the great care I received in Lubbock," he said. "These were doctors and nurses I wanted to work on me. They gave me a fighting chance, and for that I am eternally grateful. Lots of people I know here in Lovington rely on the availability of medical care in Lubbock. I like our local hospital, but Lubbock is our lifeline."[7]

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DR. WILLIAMS is clinical assistant professor of emergency medicine at Covenant Medical Center, Texas Tech University Health Science Center, and medical director of Neighbors HealthCare, both in Lubbock.

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CONTINUED FROM PAGE 1

series, EMpower, as an extension of the EMpower series in *EM Resident* magazine (www.emresident.org/empower).

The goal is to highlight the value of the community EMRA embodies by sharing the incredible stories of former EMRA members and other pioneers in our field who used their early involvement in organized medicine as a launching pad for their careers. These conversations capture the unique perspectives and motivations that have guided emergency medicine trailblazers to enduring and fulfilling professional lives with the hopes of empowering current and future physicians to more effectively navigate the ever-changing landscape of our distinguished profession.

Together, EMRA and Radio Rounds have opened a fascinating window into the lives and careers of the best that emergency medicine has to offer. For example, ACEP President Rebecca Parker, MD, FACEP, talks about emergency medicine's transformative efforts to tackle perceived diversity deficiencies within our profession head on. Kevin Klauer, DO, FACEP, reminds us that simply taking the best care of our patients is the surest form of "risk management." John Rogers, MD, FACEP, remembers some of his career's most tragic losses and how they've formed him into a compassionate, resilient physician, and Jay Kaplan, MD, FACEP, reveals that everything he's ever needed to know he learned from Noah's Ark.

Available via free download and streaming audio online at www.emra.org/resources/emra-cast or by podcast subscription in iTunes, EMpower is designed to teach, train, and entertain. Unique in their scope and approach, these positive, forward-thinking, pearl-filled conversations have already garnered thousands of downloads. The short, easy-to-digest podcasts provide helpful tips on how to improve one's practice as well as share myriad incredible accounts of life in one of the most interesting places anyone can work, our emergency departments.

DR. CORKER is an emergency medicine resident at Parkland Hospital, UT Southwestern Medical Center in Dallas. **DR. DAS** is an emergency medicine resident at Emory University School of Medicine in Atlanta. **DR. JAROU** is an emergency medicine resident at Denver Health Medical Center.

time in a seclusion room where she felt she was running out of oxygen. She crouched by the bottom of the door, trying to suck in air, all the while convinced that the staff were trying to kill her. It was a traumatic experience for Eleanor; to this day, she finds it difficult to ride in a car with the windows up, and years after her hospitalization, she continued to visit my psychiatry blog as part of an effort to process an experience she wanted never to repeat, one she readily called traumatizing.

Doorway to Psychiatric Care

The emergency department is the doorway to involuntary psychiatric care, and most emergency departments don't have psychiatrists on-site. The most crucial and controversial decision in psychiatry often falls on the shoulders of an emergency physician, with or without the help of a mental health professional. Patients are involuntarily committed because they are acutely suicidal, acutely psychotic, or both. Someone is worried they might be dangerous.

The forces in play here are considerable. We have patients, who may be too impaired to make decisions or even see that they are ill and who should ideally have the right to autonomy over their medical decisions. We have society, which may worry that people with mental illness pose a danger to others. We have the families, who watch a loved one suffer and miss the wonderful opportunities that life has to offer but who may have their own agendas for wanting a family member to be in the hospital. We have the doctor, who wants to do right by patients while simultaneously serving as the gatekeeper for resources (that rare psychiatric bed) and worrying about the malpractice implications of a bad outcome. We have the taxpayer, who pays for lost productivity, disability benefits, and institutionalization of these patients. Finally, we have the insurer, who wants to pay for as little as possible. All of these agencies are quietly in the background whenever a decision is made to involuntarily hospitalize a patient (or not).

PHOTO: RGNIXON/ISTOCK

The most crucial and controversial decision in psychiatry often falls on the shoulders of an emergency physician, with or without the help of a mental health professional.

If doctors in the emergency department begin with the idea that forced care is a good thing—that it helps people get well at times when they may be too sick to recognize that they are ill, and that treatment enables patients to stay housed, working, connected to their loved ones, and out of jail and institutions—then they do it a lot, sometimes with a "better safe than sorry" approach. However, if doctors start off with the assumption that forced care is potentially traumatizing in a way that leaves some patients with years of distress, then the threshold for committing patients to involuntary treatment is significantly altered, and involuntary hospitalization gets viewed as a last resort.

Sometimes, there is simply no choice but to hospitalize people against their will and to use physical force to keep everyone safe, especially when patients are delusional, disorganized, and agitated. This is not something that should be done lightly. Involuntary treatment initiates a process whereby the treatment team becomes the adversary to the patients they are trying to serve. It makes for long and difficult days for everyone. Furthermore, when it comes to suicidal patients, we don't know if involuntary care prevents suicide. Still, it can be very difficult to let a suicidal patient leave an emergency department if the doctor believes the patient is at risk of dying.

We know very little about involuntary psychiatric treatment. There are no national statistics on how many people are involuntarily hospitalized each year, and there are no statistics on how common it is for people to be traumatized. What we do know is that in the battle over involuntary psychiatric care, there are no organized patient groups lobbying for legislation to make forced care easier. There are, however, organized groups of people who call themselves "psychiatric survivors," who feel they have been injured by what psychiatrists have to offer. There is no doubt that our treatment of those with psychiatric disorders needs to be more thoughtful and respectful. Ultimately, forced care puts us in the very awkward position of being the adversaries to the people we are trying to serve.

Smoothing the Way for Psychiatric Treatment

So what's a doctor in the emergency department to do? I would contend that if, after careful assessment and consideration of less restrictive alternatives, there is no choice but to involuntarily hospitalize a patient, the first action should be to try to convince the patient to sign in voluntarily. This seems obvious, but it doesn't always work out that way. Why would busy doctors expend the effort to convince patients to sign in if they could more easily force care?

Remember that Eleanor came to the emergency department seeking help; she would have signed in to the hospital, but that option was never offered.

Obviously, the use of physical force should be avoided unless absolutely necessary to maintain a safe environment. While restraints, seclusion, and the forcible injection of medication may be necessary to keep everyone safe, the ED setting is one where patients easily escalate. They may have been brought from their homes by the police in handcuffs, and they may be required to wait hours or even days for evaluation and admission. From the point of view of anguished patients, this is embarrassing and difficult. Force should not be used for strict adherence to policy—for example, to force a person in no obvious physical distress to have admission lab work. It didn't serve United Airlines well, and it doesn't serve psychiatry well!

Finally, I would say be nice to involuntary patients. They are some of our sickest and most dangerous patients and will likely benefit from remaining in our care. They may make us angry, and they may be a lot of work, but these patients need us. Like all human beings, those in need of emergency care may well appreciate small acts of kindness.

As difficult as involuntary care may be, the truth is that it's better to have a traumatized patient than a dead patient. Still, there are times when involuntary treatment could be avoided or when the trauma could be mitigated. It's effort worth making.

DR. MILLER is an instructor of psychiatry at Johns Hopkins School of Medicine and has a private psychiatry practice in Baltimore. She is coauthor of *Committed: The Battle Over Involuntary Psychiatric Care and Shrink Rap: Three Psychiatrists Explain Their Work.*

New Policy on Psychiatric Boarding

ACEP clinical policy on adult mental health patients in the emergency department

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

While the number of mental health–related visits to emergency departments has increased steadily, the number of inpatient psychiatric beds has decreased.

by DEVORAH NAZARIAN, MD

In January 2017, the ACEP Board of Directors approved a clinical policy developed by the ACEP Clinical Policies Committee on critical issues in the diagnosis and management of adult psychiatric patients presenting to the emergency department. This policy was published in the April issue of the *Annals of Emergency Medicine*, can be found on the ACEP website, and has been accepted for inclusion in the National Guideline Clearinghouse.

While the number of mental health-related visits to emergency departments has increased steadily, the number of inpatient psychiatric beds has decreased. Substantial declines in mental health resources have additionally burdened emergency departments with increasing numbers of patients with mental health issues. The "boarding" process for mental health patients in emergency departments nationwide averages seven to 11 hours and often takes more than 24 hours when patients require transfer to an outside facility. New systems and resources need to be made available to better serve mental health patients.

Based on input from the ACEP membership, the committee focused on the critical questions regarding the evaluation and management of adult psychiatric patients in the emergency department. A systematic review of the evidence was conducted, and the committee made recommendations (A, B, or C) based on the strength of evidence (see Table 1). This clinical policy underwent internal and external review during a 60-day open-comment period, and responses were used to refine and enhance this clinical policy.

CRITICAL QUESTIONS AND RECOMMENDATIONS

QUESTION 1. In the alert adult patient presenting to the emergency department with acute psychiatric symptoms, should routine laboratory tests be used to identify contributory medical conditions (nonpsychiatric disorders)?

Patient Management Recommendations

Level A: None specified.

Level B: None specified.

Level C: Do not routinely order laboratory testing on patients with acute psychiatric symptoms. Use medical history, previous psychiatric diagnosis, and physician examination to guide testing.

It is important to note that this is a level C recommendation because of the limited amount of data with sufficient quality to support a higher-level recommendation. However, this should not be interpreted to imply that there is strong evidence supporting the use of laboratory diagnostics in most emergency department mental health patients.

In addition, it is likely that subsets of patients with higher rates of disease (eg, elderly, immunosuppressed, new-onset psychosis, substance abuse) may benefit from routine laboratory testing. Routine urine toxicology testing has not been shown to provide benefit in terms of influencing the management or disposition of ED patients, but it may be helpful for an objective understanding of the patient's potential substance abuse on transfer to a psychiatric facility.

Table 1. Translation of Classes of Evidence to Recommendation Levels

Strength of recommendations regarding each critical question were made by subcommittee members using results from strength of evidence grading, expert opinion, and consensus among subcommittee members according to the following guidelines:

- **LEVEL A RECOMMENDATIONS.** **Generally accepted principles for patient care that reflect a high degree of clinical certainty (eg, based on evidence from one or more Class of Evidence I or multiple Class of Evidence II studies).**
- **LEVEL B RECOMMENDATIONS.** **Recommendations for patient care that may identify a particular strategy or range of strategies that reflect moderate clinical certainty (eg, based on evidence from one or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).**
- **LEVEL C RECOMMENDATIONS.** **Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances where consensus recommendations were made, "consensus" is placed in parentheses at the end of the recommendation.**

QUESTION 2. In the patient with new-onset psychosis without focal neurologic deficit, should brain imaging be obtained acutely?

Patient Management Recommendations

Level A: None specified.

Level B: None specified.

Level C: Use individual assessment of risk factors to guide brain imaging in the emergency department for patients with new-onset psychosis without focal neurologic deficit (consensus recommendation).

There were no Class I, II, or III studies to answer this question. In the Class X studies that did categorize imaging abnormalities, the percentage of imaging findings described as being clinically relevant, influencing clinical management, or altering diagnosis ranged from 0 percent to approximately 5 percent.

QUESTION 3. In adult patients presenting to the emergency department with suicidal ideation, can risk-assessment tools in the emergency department identify those who are safe for discharge?

Patient Management Recommendations

Level A: None specified.

Level B: None specified.

Level C: In patients presenting to the emergency department with suicidal ideation, physicians should not use currently available risk-assessment tools in isolation to identify low-risk patients who are safe for discharge. The best approach to determine risk is an appropriate psychiatric assessment and good clinical judgment, taking patient, family, and community factors into account.

Class III studies were identified that investigated whether risk assessment can identify patients who are at risk for future self-harm. The designs of these studies were problematic, and no tool has been demonstrated to accurately predict the risk of suicide among patients in the emergency department.

QUESTION 4. In the adult patient presenting to the emergency department with acute agitation, can ketamine be used safely and effectively?

Patient Management Recommendations

Level A: None specified.

Level B: None specified.

Level C: Ketamine is an option for immediate sedation of the severely agitated patient who may be violent or aggressive (consensus recommendation).

Management of acutely agitated patients in the emergency department remains a critical issue. Most of these patients can be sedated safely with antipsychotics and/or benzodiazepines. However, there remains a subset of extremely agitated patients for whom this approach will not be effective. These patients have a significant effect on the emergency department staff in terms of time and dedicated resources required to maintain a safe environment for patients and others in the emergency department. Although there is a lack of Class I, II, or III studies establishing the safety and efficacy of ketamine to control acute agitation in the emergency department, the skills set of emergency physicians and their familiarity with the use of ketamine make it a reasonable choice when immediate control of the acutely agitated patient is required for patient and/or staff safety.

DR. NAZARIAN is assistant professor of emergency medicine at Icahn School of Medicine at Mount Sinai in New York City.

Clinical Trial Results Matter

Explore the efficacy and safety data at **hcp.eliquis.com**

NVAF

Indicated to reduce the risk of stroke and systemic embolism in patients with NVAF[1]

NVAF: nonvalvular atrial fibrillation.

INDICATIONS

ELIQUIS is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). ELIQUIS is indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE following initial therapy.

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

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

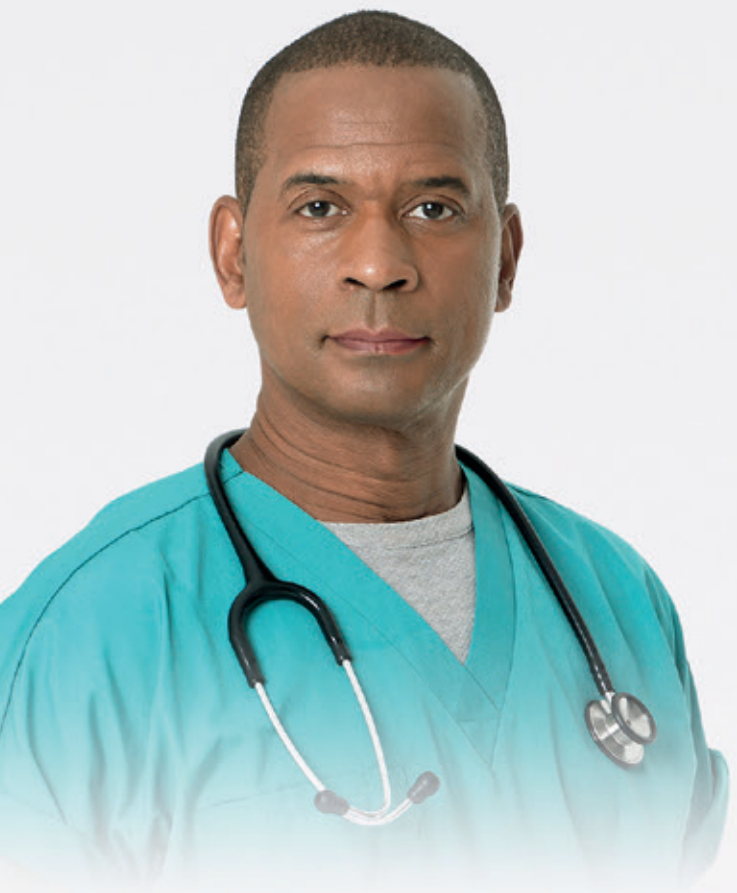
CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events after Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including ELIQUIS, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in atrial fibrillation patients. If ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Bleeding Risk:** ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding.
  - Concomitant use of drugs affecting hemostasis increases the risk of bleeding, including aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs.
  - Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.
  - There is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for at least 24 hours after the last dose (i.e., about two half-lives). A specific antidote for ELIQUIS is not available.
- **Spinal/Epidural Anesthesia or Puncture:** Patients treated with ELIQUIS undergoing spinal/epidural anesthesia or puncture may develop an epidural or spinal hematoma which can result in long-term or permanent paralysis.

  The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS.



Eliquis®
(apixaban) tablets 5mg 2.5mg

DVT/PE

Indicated for the treatment of DVT and PE, and to reduce the risk of recurrent DVT and PE following initial therapy[1]

DVT: deep vein thrombosis;
PE: pulmonary embolism.

WARNINGS AND PRECAUTIONS (cont'd)

The next dose of ELIQUIS should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of ELIQUIS for 48 hours.

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

- **Prosthetic Heart Valves:** The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves and is not recommended in these patients.
- **Acute PE in Hemodynamically Unstable Patients or Patients who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of ELIQUIS is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

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

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

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

DRUG INTERACTIONS

- **Strong Dual Inhibitors of CYP3A4 and P-gp:** Inhibitors of cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are strong dual inhibitors of CYP3A4 and P-gp (e.g., ketoconazole, itraconazole, ritonavir, or clarithromycin). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with strong dual inhibitors of CYP3A4 and P-gp.
- **Strong Dual Inducers of CYP3A4 and P-gp:** Avoid concomitant use of ELIQUIS with strong dual inducers of CYP3A4 and P-gp (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban and increase the risk of stroke and other thromboembolic events.
- **Anticoagulants and Antiplatelet Agents:** Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

PREGNANCY CATEGORY B

- There are no adequate and well-controlled studies of ELIQUIS in pregnant women. Treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. ELIQUIS should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.

Reference: 1. ELIQUIS® Package Insert. Bristol-Myers Squibb Company, Princeton, NJ, and Pfizer Inc, New York, NY.

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

Bristol-Myers Squibb Pfizer

ELIQUIS® (apixaban) tablets, for oral use

℞ ONLY

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

WARNING: (A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS

(B) SPINAL/EPIDURAL HEMATOMA

(A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any oral anticoagulant, including ELIQUIS, increases the risk of thrombotic events. If anticoagulation with ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant *[see Dosage and Administration, Warnings and Precautions, and Clinical Studies (14.1) in full Prescribing Information]*.

(B) SPINAL/EPIDURAL HEMATOMA

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

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

[see Warnings and Precautions]

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 *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

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

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

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

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

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

DOSAGE AND ADMINISTRATION (Selected information)

Temporary Interruption for Surgery and Other Interventions

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

CONTRAINDICATIONS

ELIQUIS is contraindicated in patients with the following conditions:

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

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation

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

Bleeding

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

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

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

Reversal of Anticoagulant Effect

A specific antidote for ELIQUIS is not available, and there is no established way to reverse the bleeding in patients taking ELIQUIS. The pharmacodynamic effect of ELIQUIS can be expected to persist for at least 24 hours after the last dose, i.e., for about two drug half-lives. Use of procoagulant reversal agents, such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa, may be considered but has not been evaluated in clinical studies *[see Clinical Pharmacology (12.2) in full Prescribing Information]*. When PCCs are used, monitoring for the anticoagulation effect of apixaban using a clotting test (PT, INR, or aPTT) or anti-factor Xa (FXa) activity is not useful and is not recommended. Activated oral charcoal reduces absorption of apixaban, thereby lowering apixaban plasma concentration *[see Overdosage]*.

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

Spinal/Epidural Anesthesia or Puncture

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

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

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

Patients with Prosthetic Heart Valves

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

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

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

ADVERSE REACTIONS

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

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

Clinical Trials Experience

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

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

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

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

Bleeding in Patients with Nonvalvular Atrial Fibrillation in ARISTOTLE and AVERROES

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

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

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

* Bleeding events within each subcategory were counted once per subject, but subjects may have contributed events to multiple endpoints. Bleeding events were counted during treatment or within 2 days of stopping study treatment (on-treatment period).
† Defined as clinically overt bleeding accompanied by one or more of the following: a decrease in hemoglobin of ≥2 g/dL, a transfusion of 2 or more units of packed red blood cells, bleeding at a critical site: intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, retroperitoneal or with fatal outcome.
‡ Intracranial bleed includes intracerebral, intraventricular, subdural, and subarachnoid bleeding. Any type of hemorrhagic stroke was adjudicated and counted as an intracranial major bleed.
§ On-treatment analysis based on the safety population, compared to ITT analysis presented in Section 14.
¶ GI bleed includes upper GI, lower GI, and rectal bleeding.
** Fatal bleeding is an adjudicated death with the primary cause of death as intracranial bleeding or non-intracranial bleeding during the on-treatment period.

In ARISTOTLE, the results for major bleeding were generally consistent across most major subgroups including age, weight, $CHADS_2$ score (a scale from 0 to 6 used to estimate risk of stroke, with higher scores predicting greater risk), prior warfarin use, geographic region, and aspirin use at randomization (Figure 1). Subjects treated with apixaban with diabetes bled more (3.0% per year) than did subjects without diabetes (1.9% per year).

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

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

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

Other Adverse Reactions

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

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

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

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

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

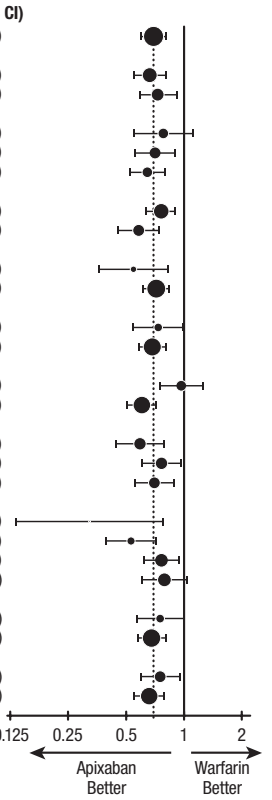
Table 3: Bleeding During the Treatment Period in Patients Undergoing Elective Hip or Knee Replacement Surgery

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

* All bleeding criteria included surgical site bleeding.
† Includes 13 subjects with major bleeding events that occurred before the first dose of apixaban (administered 12 to 24 hours post surgery).
‡ Includes 5 subjects with major bleeding events that occurred before the first dose of apixaban (administered 12 to 24 hours post surgery).
§ Intracranial, intraspinal, intraocular, pericardial, an operated joint requiring re-operation or intervention, intramuscular with compartment syndrome, or retroperitoneal. Bleeding into an operated joint requiring re-operation or intervention was present in all patients with this category of bleeding. Events and event rates include one enoxaparin-treated patient in ADVANCE-1 who also had intracranial hemorrhage.
¶ CRNM = clinically relevant nonmajor.

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

Subgroup	n of Events / N of Patients (% per year) Apixaban	Warfarin	Hazard Ratio (95% CI)
All Patients	327 / 9088 (2.1)	462 / 9052 (3.1)	0.69 (0.60, 0.80)
Prior Warfarin/VKA Status			
Experienced (57%)	185 / 5196 (2.1)	274 / 5180 (3.2)	0.66 (0.55, 0.80)
Naive (43%)	142 / 3892 (2.2)	188 / 3872 (3.0)	0.73 (0.59, 0.91)
Age			
<65 (30%)	56 / 2723 (1.2)	72 / 2732 (1.5)	0.78 (0.55, 1.11)
≥65 and <75 (39%)	120 / 3529 (2.0)	166 / 3501 (2.8)	0.71 (0.56, 0.89)
≥75 (31%)	151 / 2836 (3.3)	224 / 2819 (5.2)	0.64 (0.52, 0.79)
Sex			
Male (65%)	225 / 5868 (2.3)	294 / 5879 (3.0)	0.76 (0.64, 0.90)
Female (35%)	102 / 3220 (1.9)	168 / 3173 (3.3)	0.58 (0.45, 0.74)
Weight			
≤60 kg (11%)	36 / 1013 (2.3)	62 / 965 (4.3)	0.55 (0.36, 0.83)
>60 kg (89%)	290 / 8043 (2.1)	398 / 8059 (3.0)	0.72 (0.62, 0.83)
Prior Stroke or TIA			
Yes (19%)	77 / 1687 (2.8)	106 / 1735 (3.9)	0.73 (0.54, 0.98)
No (81%)	250 / 7401 (2.0)	356 / 7317 (2.9)	0.68 (0.58, 0.80)
Diabetes Mellitus			
Yes (25%)	112 / 2276 (3.0)	114 / 2250 (3.1)	0.96 (0.74, 1.25)
No (75%)	215 / 6812 (1.9)	348 / 6802 (3.1)	0.60 (0.51, 0.71)
$CHADS_2$ Score			
≤1 (34%)	76 / 3093 (1.4)	126 / 3076 (2.3)	0.59 (0.44, 0.78)
2 (36%)	125 / 3246 (2.3)	163 / 3246 (3.0)	0.76 (0.60, 0.96)
≥3 (30%)	126 / 2749 (2.9)	173 / 2730 (4.1)	0.70 (0.56, 0.88)
Creatinine Clearance			
<30 mL/min (1%)	7 / 136 (3.7)	19 / 132 (11.9)	0.32 (0.13, 0.78)
30-50 mL/min (15%)	66 / 1357 (3.2)	123 / 1380 (6.0)	0.53 (0.39, 0.71)
>50-80 mL/min (42%)	157 / 3807 (2.5)	199 / 3758 (3.2)	0.76 (0.62, 0.94)
>80 mL/min (41%)	96 / 3750 (1.5)	119 / 3746 (1.8)	0.79 (0.61, 1.04)
Geographic Region			
US (19%)	83 / 1716 (2.8)	109 / 1693 (3.8)	0.75 (0.56, 1.00)
Non-US (81%)	244 / 7372 (2.0)	353 / 7359 (2.9)	0.68 (0.57, 0.80)
Aspirin at Randomization			
Yes (31%)	129 / 2846 (2.7)	164 / 2762 (3.7)	0.75 (0.60, 0.95)
No (69%)	198 / 6242 (1.9)	298 / 6290 (2.8)	0.66 (0.55, 0.79)



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

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

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

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

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

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

Vascular disorders: hypotension (including procedural hypotension)

Respiratory, thoracic, and mediastinal disorders: epistaxis

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

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

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

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

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

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

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

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

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

AMPLIFY Study

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

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

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

Table 5: Bleeding Results in the AMPLIFY Study

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

* CRNM = clinically relevant nonmajor bleeding.
Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

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

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

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

AMPLIFY-EXT Study

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

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

Table 7: Bleeding Results in the AMPLIFY-EXT Study

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

* CRNM = clinically relevant nonmajor bleeding.
Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

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

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

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

Other Adverse Reactions

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

Blood and lymphatic system disorders: hemorrhagic anemia

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

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

Musculoskeletal and connective tissue disorders: muscle hemorrhage

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

Vascular disorders: hemorrhage

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

Eye disorders: conjunctival hemorrhage, retinal hemorrhage, eye hemorrhage

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

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

DRUG INTERACTIONS

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

Strong Dual Inhibitors of CYP3A4 and P-gp

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

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

Strong Dual Inducers of CYP3A4 and P-gp

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

Anticoagulants and Antiplatelet Agents

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

There are no adequate and well-controlled studies of ELIQUIS in pregnant women. Treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. ELIQUIS should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.

Treatment of pregnant rats, rabbits, and mice after implantation until the end of gestation resulted in fetal exposure to apixaban, but was not associated with increased risk for fetal malformations or toxicity. No maternal or fetal deaths were attributed to bleeding. Increased incidence of maternal bleeding was observed in mice, rats, and rabbits at maternal exposures that were 19, 4, and 1 times, respectively, the human exposure of unbound drug, based on area under plasma-concentration time curve (AUC) comparisons at the maximum recommended human dose (MRHD) of 10 mg (5 mg twice daily).

Labor and Delivery

Safety and effectiveness of ELIQUIS during labor and delivery have not been studied in clinical trials. Consider the risks of bleeding and of stroke in using ELIQUIS in this setting *[see Warnings and Precautions]*.

Treatment of pregnant rats from implantation (gestation Day 7) to weaning (lactation Day 21) with apixaban at a dose of 1000 mg/kg (about 5 times the human exposure based on unbound apixaban) did not result in death of offspring or death of mother rats during labor in association with uterine bleeding. However, increased incidence of maternal bleeding, primarily during gestation, occurred at apixaban doses of ≥25 mg/kg, a dose corresponding to ≥1.3 times the human exposure.

Nursing Mothers

It is unknown whether apixaban or its metabolites are excreted in human milk. Rats excrete apixaban in milk (12% of the maternal dose).

Women should be instructed either to discontinue breastfeeding or to discontinue ELIQUIS (apixaban) therapy, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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

Renal Impairment

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

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

- age ≥80 years
- body weight ≤60 kg
- serum creatinine ≥1.5 mg/dL

Patients with End-Stage Renal Disease on Dialysis

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

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

No dose adjustment is recommended for patients with renal impairment, including those with ESRD on dialysis *[see Dosage and Administration (2.1) in full Prescribing Information]*.

Clinical efficacy and safety studies with ELIQUIS did not enroll patients with ESRD on dialysis or patients with a CrCl <15 mL/min; therefore, dosing recommendations are based on pharmacokinetic and pharmacodynamic (anti-FXa activity) data in subjects with ESRD maintained on dialysis *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Hepatic Impairment

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

OVERDOSAGE

There is no antidote to ELIQUIS. Overdose of ELIQUIS increases the risk of bleeding *[see Warnings and Precautions]*.

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

In healthy subjects, administration of activated charcoal 2 and 6 hours after ingestion of a 20-mg dose of apixaban reduced mean apixaban AUC by 50% and 27%, respectively. Thus, administration of activated charcoal may be useful in the management of apixaban overdose or accidental ingestion.

PATIENT COUNSELING INFORMATION

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

Advise patients of the following:

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

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All Charged Up & No Place To Go

Proposed algorithm for shock-resistant ventricular fibrillation

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

The Case

You get a call that a 50-year-old woman collapsed while running a marathon. Bystanders started CPR immediately. Nearby paramedics found her to be in ventricular fibrillation (VF). She was shocked three times and given 3 amps of epinephrine. She is still in VF when she arrives at your emergency department.

Advanced cardiac life support (ACLS) was originally designed to give us a common language and help us avoid paralysis in a crisis situation. However, with each year that passes, it seems like ACLS has become more and more simplified to appeal to a broader scope of rescuers, including those who rarely run codes. Yet cardiac arrest physiology just isn't that simple. Managing these patients requires a lot more finesse. Practitioners working in settings where they manage codes regularly (eg, the emergency department) should be expected to have a more sophisticated approach when standard ACLS algorithms aren't effective. In this month's column, I'll suggest four strategies to improve the chances of return of spontaneous circulation (ROSC) in shock-resistant VF and, perhaps, survival to hospital discharge. Shock-resistant VF, or electrical storm, is defined as three or more sustained episodes of VF in a 24-hour period.

1. Prepare Your Team

Team-based preparation prior to patient arrival is essential to optimizing cardiac arrest care and takes fewer than five minutes. It can be broken down into three points to be discussed in a team huddle:

- What do we **know**? What do we expect to see? What are the possibilities? Run through the most likely immediate life-threatening issues.
- What do we **do**? What actions will you take, and what contingency plans will you have in place if those actions fail? Teams respond more efficiently and decidedly if they have anticipated failure rather than having failure of a plan surprise them.
- **Role assignment**: Assign logistical tasks to team members, including definitive airway management, chest compressions, medication administration, and defibrillation.

In this case, consider premixing amiodarone 300 mg and esmolol 500 mcg/kg and setting up for dual-shock therapy.

2. Consider Stopping Epinephrine

Epinephrine is associated with increased myocardial oxygen consumption and ventricular dysrhythmias and has never been shown to improve survival to hospital discharge in cardiac arrest.[1] Epinephrine, in the doses used in cardiac arrest, causes cerebral vasoconstriction that may impair tissue oxygenation and brain perfusion and compromise neurological recovery.[2] There is an argument to be made that epinephrine should be decreased or eliminated in all patients with shock-refractory VF because of its catecholamine effects. It makes little physiologic sense to add catecholamine fuel, like epinephrine, to the catecholamine firestorm of refractory VF. In fact, we want to achieve the opposite: Block the catecholamine surge so that the VF breaks.

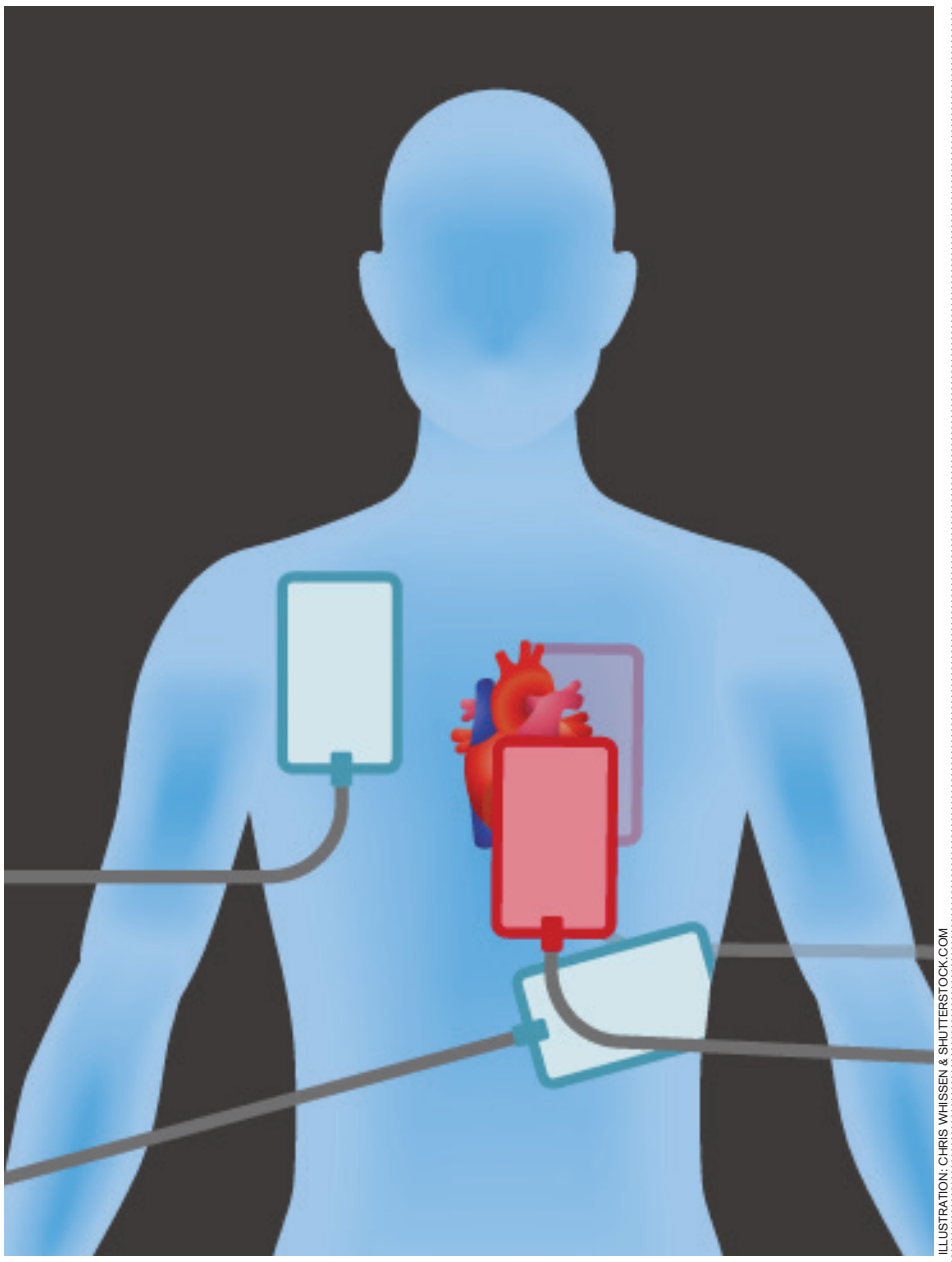

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

To perform dual-shock defibrillation, place one set of defibrillator pads in the traditional positions on the chest (blue pads) and attach a second set of pads from a second defibrillator in the anterior-posterior "sandwich" position (red pads).

3. Block Sympathetic Tone

Shock-resistant VF increases sympathetic tone, which leads to a vicious cycle of fibrillation and increased sympathetic tone.[3] Esmolol decreases sympathetic tone and counteracts the endogenous and exogenous catecholamine surge theorized to occur during refractory VF arrest. Esmolol is the only drug in the management of cardiac arrest that has shown an increased rate of survival to hospital discharge with favorable neurologic outcomes. Albeit in a small study, patients who received esmolol after three defibrillations and 3 mg of epinephrine had a 50 percent survival to hospital discharge with a favorable neurologic outcome compared to 11 percent of patients who did not receive esmolol.[4] Larger randomized controlled trials are needed. However, in the meantime, there is little downside to giving esmolol in this setting.

If you have the point-of-care ultrasound skills necessary, a second method to block sympathetic tone is to administer a stellate ganglion block.[5] Case studies and one small randomized trial suggest reduced mortality in refractory VF with this method. The stellate ganglion at the level of C7 conducts sympathetic activity to the heart.

Directly blocking sympathetic outflow to the heart may decrease the sensitivity of the myocardium to arrhythmias.[6]

4. Consider Dual-Shock Defibrillation

If standard defibrillation isn't working, consider double defibrillation. Animal studies show that most failed shocks are actually successful shocks but that the patient goes back into VF in less than one second. Eighty percent of patients who are resistant to a single shock will respond to dual shock.[7] The idea is that you need to depolarize 90 percent of the myocardium to achieve effective defibrillation. If the patient has defibrillator pads in the traditional positions on the chest, attach a second set of pads from a second defibrillator in the anterior-posterior "sandwich" position (see image). At the time of defibrillation, both shock buttons are depressed simultaneously.

Adding a second set of pads changes the energy vectors through the myocardium, which helps achieve that 90 percent threshold. A few small studies have shown promising results for ROSC, with one showing 70 percent conversion with dual shock and 30 percent achieving ROSC in the field.[8] It is important to note that the largest study to date on dual defibrillation in refractory VF did not show any benefit for neurologically intact survival.[7]

Don't forget that since many patients with shock-resistant VF have an underlying cardiac ischemic event as the primary cause, cardiac arrest experts recommend consulting an interventional cardiologist for consideration of immediate transfer to the cath lab for *all* VF patients who have achieved ROSC.

Thanks to Jordan Chenkin, Paul Dorian, Laurie Morrison, and Steve Lin for their contributions to the podcasts that inspired this article.

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RESOURCES ONLINE

Episode 71 ACLS Guidelines 2015–Cardiac Arrest Controversies Part 1: emergencymedicinecases.com/acls-guidelines-2015-cardiac-arrest/

Journal Jam 7–Amiodarone vs Lidocaine vs Placebo in Cardiac Arrest: The ALPS Trial: emergencymedicinecases.com/amiodarone-vs-lidocaine-vs-placebo-alps-trial/

IMAGES IN EM | CONTINUED FROM PAGE 1

forever. To the greater world around him, he is sadly another unfortunate statistic of inner-city gun violence. The photos shown this month are not of this particular patient but of those who shared the same fear, pain, and stress of being a victim of violence.

This topic of inner-city violence strikes a chord with me. Being an African-American physician, I cannot help but lament over the loss of life in the community I serve. Normally, I try to place some mental and emotional distance between myself and the tragic events that I frequently encounter in the emergency department to preserve my humanity. However, that distance becomes hard to place when you are continually treating peers who look like you and come from a similar background as you. I cannot help but feel something. Despair? Anger? Guilt? Maybe all of the above? Whatever the feeling is, it drives the question of how we, as a society, can stop the violence.

Injuries from gun violence account for nearly 37,000 emergency department visits annually. Firearms are the second leading cause of death among youths (14–24 years of age) in the United States and disproportionately affect youth and adult populations in minority communities stricken by poverty and neglect.[1] Individuals victimized by firearms are at higher risk to be reinjured and rehospitalized, especially within the first year after their injury. They experience higher rates of functional disability, PTSD, and depression.[2] Furthermore, the societal costs associated with firearm violence, injury, and death are not trivial. Every year, an estimated $630 million is spent on acute medical care alone, and there is approximately $32 billion in lost wages and productivity.[3]

A handful of interventions such as blight remediation and therapist-delivered interventions have been shown to decrease firearm and non-firearm violence.[3,4] However, there is still a paucity of medical literature and validated interventions on how we as a medical community can ameliorate the effects of gun violence. As emergency physicians, we are on the front lines of this epidemic and have a unique but powerful capacity to make change. I am by no means advocating for the infringement on people's Second Amendment rights. My plea is that we do more in curtailing this epidemic by supporting more research around this issue, investing in community-based interventions, and advocating for future victims who may become nameless statistics.

PHOTO: BENJAMIN THOMAS

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BE A MEDICAL DETECTIVE—BONE UP ON YOUR FORENSIC SKILLS

FORENSIC FACTS

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DR. ROZZI is an emergency physician, director of the Forensic Examiner Team at WellSpan York Hospital in York, Pennsylvania, and chair of the Forensic Section of ACEP.

Stab Wound Taxonomy

Listen carefully, wounds have a story to tell

by RALPH J. RIVIELLO, MD, MS, FACEP; AND HEATHER V. ROZZI, MD, FACEP

THE CASE: A 58-year-old male presents to the emergency department in cardiac arrest after sustaining a stab wound to the left neck (zone 1). The patient was apneic with a faint pulse at the scene but arrested en route to the emergency department. Medics have the patient intubated, and two large-bore IVs have been initiated with crystalloids infusing. He is still pulseless in the emergency department. A focused assessment with sonography for trauma (FAST) exam is negative. After brief resuscitative efforts in the trauma bay, the patient is pronounced dead.

Forensic Pearls

A stab wound is a form of sharp-force trauma caused by a thrusting action whose injury length on the body surface is less than its depth of penetration into the body. The force is delivered along the long axis of a narrow, sharply pointed object. The impact force is concentrated at the tip of the object—and the sharper the tip, the more easily it can penetrate the skin. Stab wounds can be homicidal, self-inflicted, or accidental. Internal and external hemorrhage are of concern when treating stabbing victims. Knives tend to make up the majority of weapons used in stabbings. However, any pointed object can be a weapon (eg, pencil, screwdriver, barbecue fork, scissors, awl, etc.).

The skin edges of a stab wound are called the wound's margins, and the ends or tips are the wound's angles. The length of the wound is measured from one angle to the other. A line drawn between the two angles is the long/longitudinal axis. The longitudinal axis can be described as vertical, horizontal, or angled. The width is the widest measurement between the two margins.

Several factors should be considered when determining the characteristics of a stab wound. These include motion used, force applied, sharpness/dullness of the tip, type/nature of the weapon, and type/nature of tissue encountered.

There are several things that can be learned about the weapon from looking at the wound itself. However, determining the dimensions of the weapon and depth of penetration are not among them. This is due to the effect of elasticity of skin shrinking slightly on withdrawal of the object (by up to 2 mm). Also, when the blade has entered the skin at an oblique angle, the length of the entry slit may be longer than expected. Skin elasticity and Langer's lines (orientation of collagen fibers in the dermis) can cause wounds to gape, contributing to miscalculations. If the weapon has not fully entered the skin, the wound depth will correspond to the part that has penetrated the skin and will not represent the maximum length of the weapon. In addition, objects are rarely pushed into the body and withdrawn at exactly the same angle, and rocking of the knife distorts a wound's appearance. Finally, compressible body parts, like the abdomen or chest wall, often indent during the stabbing, and thus the area penetrated can be at a depth greater than the weapon.

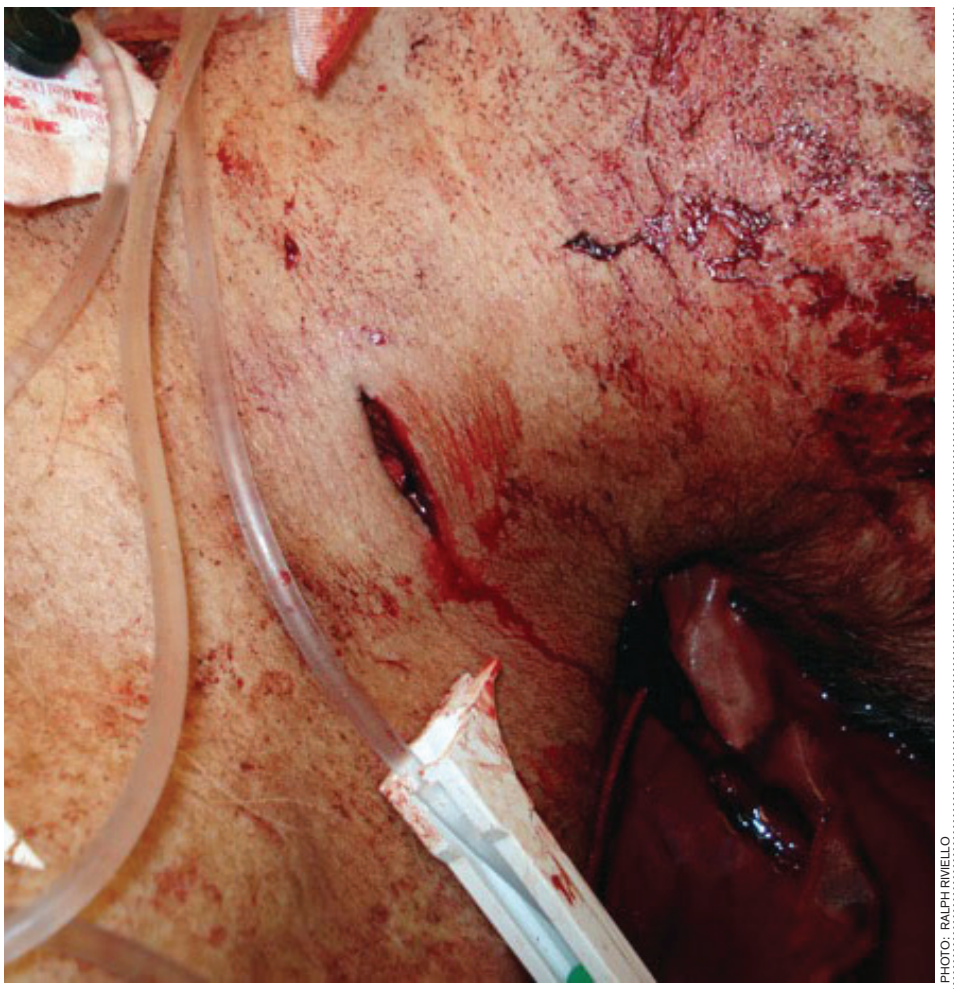

PHOTO: RALPH RIVIELLO

A 58-year-old male with a stab wound to the left neck (zone 1).

Characteristics of Stab Wounds

- Stab wounds have clean-cut edges.
- Single-edge knives (like kitchen knives) cause wounds that have a clearly pointed edge.
- Serrated knives may leave serrations when the knife has been drawn over the skin surface. This is, however, not a consistent feature of serrated knife stab wounds, and they are usually indistinguishable from wounds caused by other single-edge knives.
- Knives or weapons with two sharp edges (double-edge blades), such as military knives, bayonets, and ceremonial daggers, show pointed edges on both sides of the wound or a spindle-shaped entry slit tapered at both ends.
- Knives with blade guards (at the handle end closest to the blade) can produce distinctive bruising/abrasions to the side of one of the wound angles.
- Bruising may also be present where the assailant's fist impacts against the skin during the stabbing, depending on the amount of force used and depth of weapon penetration.
- Wounds caused by other implements may cause patterned wounds characteristic of the sharp end of the weapon, such as an X-shaped wound from a Phillips head screwdriver.
- Traditional screwdrivers and chisels usually produce rectangular wounds with abraded margins.
- Ice picks and awls produce wounds that can be mistaken for small caliber gunshot wounds (rounded defect surrounded by thin rimmed abrasion).
- Scissors may produce different wounds depending upon their design and position (open or closed) at the time of the injury. Closed scissor wounds are single and Z-shaped. Open scissor wounds are paired, with varying distances between the pair.
- Barbecue forks will produce paired stab wounds with a fixed distance between the pair. Forks should produce wounds that match the number of tines, maintaining a fixed distance between the wounds.

Forensic Documentation

When caring for a stabbing victim, there are several forensically important considerations. Stab wounds should be documented in terms of their anatomic position and their relative position to fixed anatomical landmarks. The overall wound length, width, and directionality should be documented and the appearance of the wound's margins and angles described. If the wound is gaping, the margins can be held together to better evaluate the wound angles. This can be done by simply holding the margins together or using clear tape over the wound. If there are multiple stab wounds, each needs to be documented separately. Preprinted body diagrams/drawings can be used for documentation, and of course, photographic documentation should be used whenever possible.

The hands and arms should be inspected for the presence of defensive wounds. If the patient presents with the weapon, care should be taken to handle the weapon as little as possible; gloves should be worn. The weapon should be placed in a protective covering or commercial storage device and turned over to law enforcement.

The treating physician should never guess the directionality of the wound tract and the degree or depth of penetration. The weapon could have entered directly perpendicular to the body or at upward or downward angles, drastically changing the possibility of structures injured. The depth of penetration can be shorter than, equal to, or longer than the weapon's length. The physician should rely on computed tomography or direct surgical exploration to determine wound tract direction, penetration depth, and injury.

Case Resolution

Based on the wound angle characteristics, it is suspected the weapon was a double-edge knife. A suspect is apprehended carrying a military knife that has the victim's blood on it. At autopsy, it is determined that the blade entered at a downward angle and severed his proximal subclavian artery.

RESOURCES FOR FURTHER READING

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Q&A ABOUT OUR LITTLEST PATIENTS

KIDS KORNER

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DR. CANTOR is professor of emergency medicine and pediatrics, director of the pediatric emergency department, and medical director of the Central New York Poison Control Center at Upstate Medical University in Syracuse, New York.

1. Sepsis & 2. Near Drowning

Serum lactate screening for sepsis and prophylactic antibiotics in near drowning called into question. You decide!

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

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

Question 1: Are serum lactate levels good screening tools for sepsis in pediatric patients?

In adults, a screening serum lactate ≥4 mmol/L identifies patients at significantly higher risk of death from sepsis, serving as a valuable risk stratification tool.[1] For this reason, it is common practice to obtain this test in adult patients suspected of having sepsis. However, in children, there are considerably less data on this topic.

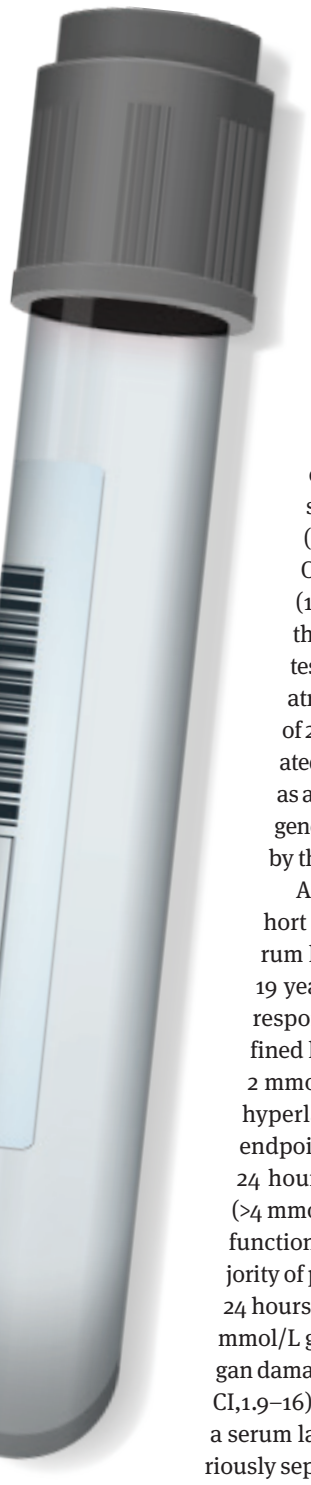

ILLUSTRATION: SHUTTERSTOCK.COM

The literature on this topic has typically been limited to pediatric ICU patients. One early study was a very small (n=11) prospective pediatric ICU study.[2] The authors evaluated children ages 1 to 18 years in septic shock who required mechanical ventilation. In these 11 children, they drew 53 serum lactate samples—an initial sample in each, plus six-hour trending follow-up samples. In these patients, only 15 of 53 (29 percent) samples were >1.8 mmol/L. Of the initial lactates drawn, only 2 of 11 (18 percent) were >4 mmol/L, suggesting that serum lactates are not good screening tests for severe sepsis/septic shock in pediatric patients. Another retrospective study of 289 children younger than 18 years evaluated screening serum lactate measurements as an outcome predictor in a pediatric emergency department.[3] Death was not predicted by the serum lactate in that study.

A later prospective observational cohort study (n=239) evaluated screening serum lactate levels in children younger than 19 years if they met systemic inflammatory response syndrome (SIRS) criteria.[4] Predefined levels of serum lactates were normal (< 2 mmol/L), intermediate (2–4 mmol/L), and hyperlactatemia (>4 mmol/L). The primary endpoint was end-organ dysfunction within 24 hours. For patients with hyperlactatemia (>4 mmol/L), the sensitivity for end-organ dysfunction was only 31 percent (4 of 13); the majority of patients with end-organ damage within 24 hours of ED presentation presented in the <4 mmol/L group. While the relative risk of end-organ damage within 24 hours was higher (5.5; 95% CI,1.9–16) in the hyperlactatemia group, having a serum lactate <4 mmol/L did not rule out a seriously septic child, suggesting that practitioners should not use screening serum lactates alone to risk-stratify pediatric patients suspected of having sepsis.

A recent pediatric prospective, observational, cohort study (n=1,299), similar to previous adult studies, evaluated whether an elevated screening serum lactate >36 mg/dL (>4 mmol/L) was associated with increased mortality in pediatric patients.[5] The primary outcome was in-hospital, all-cause mortality within 30 days. The overall mortality was 1.9 percent (25 of 1,299). In patients with lactates >36 mg/dL, the mortality was 4.8 percent (5 of 103) versus 1.7 percent (20 of 1,196) in the group <36 mg/dL. While the mortality in the hyperlactatemia group (>36 mg/dL) was higher, the difference in mortality was not nearly as robust as in the adult literature. For this reason, screening serum lactates in children should not be routine. More important, a serum lactate in the 18–36 mg/dL group (2–4 mmol/L) should not falsely reassure the practitioner that a child is not sick, as there were a number of deaths in this group.

While screening pediatric patients for sepsis with serum lactates is not routine, there are data to suggest that trending lactates for clearance is associated with less persistent organ dysfunction at 48 hours.[6]

Conclusion: Serum lactate measurements in children do not provide the robust sepsis risk stratification demonstrated in the adult literature. While hyperlactatemia (>4 mmol/L) may suggest a sicker patient, it is very important to recognize that a normal or intermediate lactate level should not falsely reassure you that a child is not sick.

Question 2: Do prophylactic antibiotics decrease the likelihood of drowning-associated pneumonias in children?

In general, the data are scarce and based on a mixture of adult and pediatric patients. One of the earliest studies on this topic was a retrospective study of 91 consecutive children and adults (ages 1 to 79).[7] Of these patients, 81 of 91 (89 percent) survived, and they appeared to have a variety of presentations, with 33 patients requiring intubation. The data are very limited, and the authors noted, "More patients died who received prophylactic antibiotic therapy [7 of 54 (13.0 percent)] than did those from whom such therapy was withheld until gram staining, culture, and the clinical course suggested the presence of active infection [2 of 36 (5.6 percent)]." There was one patient unaccounted for and no mention of statistical significance. They did not mention the patients' ages or the severity of illness for patients who received prophylactic antibiotics.

An older retrospective study of 40 patients, with 33 of the patients younger than 17 years, found that prophylactic antibiotics given to 31 of 40 patients "had no apparent benefit" in the patient population.[8] An additional retrospective study of 125 submersion victims included an unspecified breakdown of children versus adults and found no significant benefit from prophylactic antibiotics.[9]

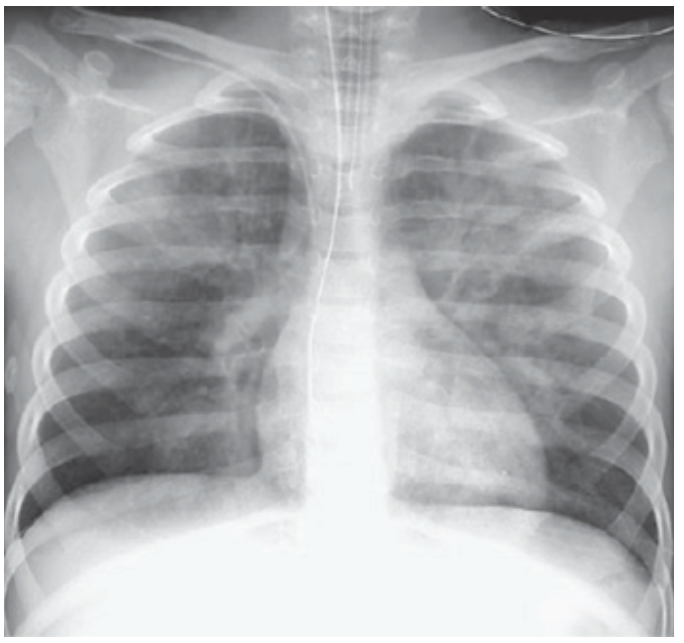

PHOTO: WELLS RG. DIAGNOSTIC IMAGING OF INFANTS AND CHILDREN; 2015. © 2017 MCGRAW-HILL EDUCATION. ALL RIGHTS RESERVED. MCGRAW-HILL EDUCATION MAKES NO REPRESENTATIONS OR WARRANTIES AS TO THE ACCURACY OF ANY INFORMATION RELATED TO THIS IMAGE. IN NO EVENT SHALL MCGRAW-HILL EDUCATION HAVE ANY LIABILITY TO ANY PARTY FOR SPECIAL, INCIDENTAL, TORT, OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH IT.

There is a patchy distribution of pulmonary edema in this 6-year-old near-drowning patient.

Conclusion: While there has been no reported benefit from prophylactic antibiotics in cases of near drowning, there have been no prospective trials assessing this topic. Current expert consensus on this very limited topic by the Wilderness Medical Society recommends that "there is no evidence to support empiric antibiotic therapy in the treatment of drowning patients."[10] Thus, the use of prophylactic antibiotics remains at the discretion of the treating physician .

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DOGMA FEELS RIGHT UNTIL YOU STEP IN IT

SKEPTICS' GUIDE TO EMERGENCY MEDICINE

DR. MILNE is chief of emergency medicine and chief of staff at South Huron Hospital, Ontario, Canada. He is on the Best Evidence in Emergency Medicine faculty and is creator of the knowledge translation project the Skeptics' Guide to Emergency Medicine (www.TheSGEM.com).

Appendicitis? NOT a Problem!

Nonoperative treatment of *pediatric* appendicitis

by KEN MILNE, MD, MSC, CCFP-EM, FCFP, FRRMS

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

The Case

Johnny is a 10-year-old boy who presents to the emergency department after a 24-hour history of abdominal pain. It started in the periumbilical region and is located in the right lower quadrant. The pain is increasing in severity. His mother knew something was wrong when he did not want to eat dinner or play soccer with friends after school. He was nauseated and developed a low-grade fever. On examination, he is maximally tender over McBurney's point. An ultrasound confirms acute, uncomplicated appendicitis.

Background

One of the most common pediatric surgical emergencies is appendicitis. The peak incident is in the second decade of life, with a lifetime risk of 7 percent to 8 percent.[1]

The standard treatment for acute appendicitis, ever since Dr. Charles McBurney described it in 1889, has been appendectomy.[2] This surgical approach has been highly successful for more than a century.

There have been a number of recent publications suggesting a nonoperative treatment (NOT) of appendicitis in adults.[3,4] They propose using antibiotics rather than surgery to manage this common condition.

Clinical Question

Is NOT safe and effective in pediatric patients with acute, uncomplicated appendicitis?

Reference

Georgiou R, Eaton S, Stanton MP, et al. Efficacy and safety of nonoperative treatment for acute appendicitis: a meta-analysis [published online ahead of print Feb. 17, 2017]. *Pediatrics*. 2017:139(3).

- **Population:** Patients under 18 years of age with acute, uncomplicated appendicitis.
- **Exclusions:** Complicated appendicitis (ie, perforation, rupture, abscess, or appendix mass), studies of mixed adults and children, or studies of acute appendicitis only in children with malignancy.
- **Intervention:** Intravenous antibiotics.
- **Comparison:** Primary appendectomy.
- **Outcomes:**
- **Primary:** Discharge from hospital without appendectomy.
- **Secondary:** Serious adverse effects of NOT, complications, long-term efficacy (no appendectomy at final reported follow-up), recurrent appendicitis (confirmed by histology or treated with second course of NOT), and hospital length of stay.

Authors' Conclusion

"Current data suggest that NOT is safe. It appears effective as initial treatment in 97 percent of children with acute, uncomplicated appendicitis, and the rate of recurrent appendicitis is 14 percent. Longer-term clinical outcomes and cost-effectiveness of NOT compared with appendectomy require further evaluation, preferably in large randomized trials, to reliably inform decision-making."

Key Results

Ten studies were included that had a total of 413 pediatric patients selected or randomized to NOT.

Primary Outcome: NOT was successful in 97 percent of cases (95% CI, 95–99%).

Secondary Outcome:

Serious Adverse Events: None reported.

Long-Term Efficacy of NOT: 82 percent (95% CI, 77–87%).

Recurrent Appendicitis: 14 percent (95% CI, 7–21%).

Hospital Length of Stay: Mean difference 0.5 days fewer with appendectomy (95% CI, 0.2–0.8; *P*=0.002).

Evidence-Based Medicine Commentary

Quality of Studies: Nine of the 10 studies were observational studies. This is a low level of evidence. Only associations can be concluded, not cause and effect. Four of these studies had no comparison group. Only one small randomized pilot study of 50 patients was included.

Lack of Blinding: There was no blinding in any of the studies. It would be difficult to conduct a study with a sham surgery group to address this bias.

Antibiotic Regimes: There was no standard antibiotic protocol. While this may be pragmatic, it makes it difficult to know what would be the best antibiotic regimen for acute,

CONTINUED *on page 23*

AVOID THE HAZARDS OF EM PRACTICE: FAQs FROM YOUNG PHYSICIANS

WHAT I WISH I KNEW...

DR. KLAUER is an ACEP Board member; chief medical officer–emergency medicine, 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.

Tips for Negotiating Employment Contracts

Focus on the end of the relationship, not the beginning

by KEVIN M. KLAUER, DO, EJD, FACEP

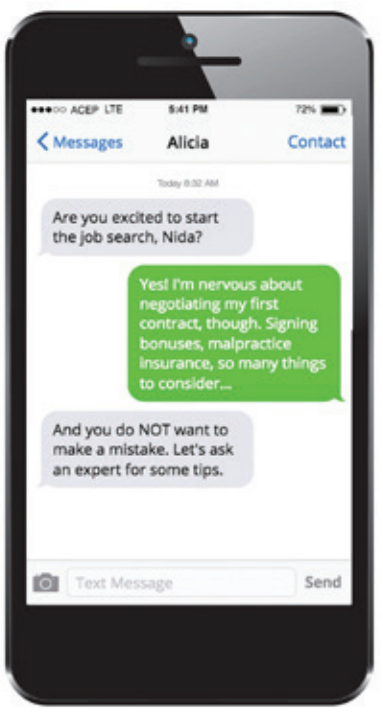
QUESTION: I'm getting ready to look for my first job as an emergency physician. What should I know about negotiating my first employment contract?

ANSWER: This is a great question. My response is fairly brief and not intended to give adequate treatment to employment or independent contractor agreements but merely to provide some practical tips that every emergency physician should be aware of regarding employment or independent contractor agreements.

1. Contracts should be written in plain English. The concept of writing contracts with the overly laborious use of the Queen's English has long since passed. Although you shouldn't be expected to fully understand the legal effect of every legal term, you should be able to read the contract and come away with a general understanding of the intent. If you don't understand it, don't sign it. It's not a sign of weakness to ask for clarification. There's a pretty good chance that the person who obtained it from an attorney—or, worse, from the Internet—can't explain it either.

2. Professional liability coverage should be expected but not assumed. You should either have occurrence-based medical malpractice coverage or claims-made coverage with a tail. Basically, occurrence-based coverage provides you coverage for any occurrence during the policy duration regardless of when the claim is filed. So if you work for a group in 2017, leave in 2018, and are sued in 2020, you will be covered by an occurrence-based policy that was for the coverage year 2017. However, if you had a claims-made policy and didn't have a tail, the claim would not be covered. Claims-made is a face-value term. When a claim is made, the claim is covered if your policy is in force. However, when the policy ends, no prior acts are covered. So if you work for a group in 2017 and leave in 2018, any claims filed after the coverage year 2017 would not be covered unless you have tail coverage, which covers those prior acts. These terms must be clear in your agreement.

3. Integration is a very important concept in contract law. An integrated agreement is the entire agreement. When you sign your employment or independent contractor agreement, integration ensures that both parties understand they are bound by the terms in the contract and of that agreement only. In other words, if someone promised you something but it's not in the integrated agreement, they have no legal obligation to perform to that promise.



Nida F. Degesys, MD, is an EM resident at the University of California, San Francisco–San Francisco General Hospital and the Emergency Medicine Residents' Association (EMRA) representative to the ACEP Board of Directors. Alicia Kurtz, MD, is an EM resident at the University of California, San Francisco–Fresno and President of EMRA.

4. Outside activities can be limited by a future employer. This is seen more often in academic contracts. A clause may exist limiting time spent on outside pursuits or discouraging such conduct by requiring that earnings for such activities be remitted to the employer. At some places, this may be required. However, if you are uncomfortable, ask to have that clause removed or amended. For instance, if you are already engaged in writing a book or teaching advanced cardiac life support, the compromise could be to have those activities excluded.

5. Sign-on (signing) bonuses can be tricky. Don't focus on the cash; focus on the terms. Spending money is generally pretty easy, but paying money back that you don't have isn't. Pay close attention to the repayment terms. How do you fulfill your obligations, and what happens if you leave prior to the fulfillment date? Chances are, if you bail early, they are going to want their money back. My advice is to save that money until you have fulfilled that portion of your agreement. You don't want to finance the repayment of your sign-on bonus if you decide you want to leave prematurely. If you do spend it, make certain you save enough to cover your tax liability the following year.

6. Noncompete clauses and restrictive covenants are very common. They are not unique to health care and certainly not to emergency medicine. The intended goal is to protect a business interest. I think most would agree that if a group, big or small, spends time, money, and other

CONTINUED *on page 22*

resources to obtain an ED contract, staff and manage that department, and develop a long-standing relationship with the hospital, they are entitled to protect their investment from one of their employees.

However, the extent of that business interest and that of the restrictions placed on the physician are the greatest points of contention. Many would agree that the business interest, in most cases, begins and ends at the front door of that hospital. In other words, a noncompete that disallows a physician to work anywhere in the state would be far beyond a reasonable business interest. The enforceability of such clauses varies from state to state and with the specific circumstances of a given case. It isn't right or wrong to have noncompete clauses, to sign them, or to not sign them. Just make certain that you can live with whatever restrictions are listed when and if you choose to separate.

7. Contract reviews are worth the relatively minimal amount you'll pay for them. Although you are likely to spend $500 to $1,000 for a contract review, this will ensure that the rights and obligations of both parties are thoroughly understood by you and that your interests are met. I have heard from many residents that their attendings have offered to perform such reviews. That certainly may be of value but shouldn't be your only source of input. If attendings have no formal education in contract law, what would qualify them to opine on such matters? Just because someone has been around the block a few times and has read many contracts does not qualify them to interpret a legal document and its full impact on the parties. When you have a leaky faucet, who do you call?

Chances are, you call a plumber. When you need legal advice, call a lawyer.

Philosophers have said that funerals are for the living, not the dead. Contracts are similar in that they are most important when you're leaving, not when you're staying. Early in your employment, the relationship is often at its best, so it's easy not to become overly worried about the details of an agreement. However, you should read your agreement from the perspective you'll have if and when you leave. If you can't live with the terms, don't sign the agreement.

CLASSIFIEDS

SKEPTICS' GUIDE | CONTINUED FROM PAGE 20

While NOT of acute, uncomplicated pediatric appendicitis is interesting, there is not enough high-quality evidence to recommend it at this time.

uncomplicated pediatric appendicitis.

Safety: While researchers did not report any serious adverse events with NOT, the total number of patients managed nonoperatively is too small to claim safety.

Diagnosis of Acute, Uncomplicated Appendicitis: It is much easier to diagnose complicated appendicitis than uncomplicated appendicitis. In addition, the diagnostic accuracy of ultrasound and CT are not 100 percent.

Bottom Line

While NOT of acute, uncomplicated pediatric appendicitis is interesting, there is not enough high-quality evidence to recommend it at this time.

Case Resolution

The surgeon is called, obtains informed consent from Johnny's parents, and successfully performs an appendectomy.

Thank you to Dr. Ross Fisher from www.ffolliet.com his help with this review. Dr. Fisher is a pediatric surgeon working at Sheffield Children's Hospital in Sheffield, UK.

Remember to be skeptical of anything you learn, even if you heard it on the Skeptics' Guide to Emergency Medicine.

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The successful candidate would be interested in joining a lively, energetic and committed group of ED physicians providing quality emergency care to our patients and solid evidence-based education to our residents, medical students and PA trainees. We welcome ED physicians interested in being involved in all aspects of Emergency Medicine, including trauma, pediatric care, toxicology, EMS, education, ultrasonography, research, quality and safety, simulation and observation medicine.

EHN offers a competitive salary, sign-on bonus, relocation assistance, CME allowance, defined benefit pension plan, excellent health insurance and other benefits. Academic appointments are through the Sidney Kimmel Medical School of the Thomas Jefferson University and are commensurate with candidate experience.

Philadelphia is an affordable, walkable, large city with a diverse population and world-class educational institutions, medical facilities, museums, entertainment/sports venues and restaurants.

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Einstein HEALTHCARE NETWORK

Please send curriculum vitae to: Kim Hannan, Physician Recruiter, Einstein Healthcare Network, Recruitment and Placement Center, Phone: 267-421-7435, HannanKi@einstein.edu

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The Department of Emergency Medicine at Baylor College of Medicine, a top medical school, is located in the world's largest medical center, in Houston, Texas. The Baylor Emergency Medicine Residency was established in 2010, and we recently received department status in Jan 2017. Our residency program has grown to 14 residents per year in a 3-year format. We offer a highly competitive academic salary and benefits commiserate to academic level and experience.

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Those interested in a position or further information may contact Dr. Dick Kuo via email dckuo@bcm.edu or by phone at 713-873-7044. Please send a CV and cover letter with your past experience and interests.

Assistant/Associate Program Director Opening

The Department of Emergency Medicine at Baylor College of Medicine in Houston, TX is seeking outstanding candidates for the **position of Assistant/Associate Program Director**.

Applicants should have a strong background in medical education with a career path directed towards graduate medical education. Duties of this position will include a focus on developing and implementing innovative educational strategies in the CLER pathways (Patient Safety, Health Care Quality, etc.) that meet and exceed the ACGME accreditation standards. In addition, we are searching for applicants who will contribute to our missions of promoting academic excellence, diversity, and teamwork in service to our patients.

Interested applicants should submit a CV, letter of intent, and 1 letter of recommendation to the Program Director, Dr. Tyson Pillow (pillow@bcm.edu).

TEG

Honolulu, Hawaii

The Emergency Group, Inc. (TEG) is a growing, independent, democratic group that has been providing emergency services at The Queen's Medical Center (QMC) in Honolulu, Hawaii since 1973. QMC is the largest and only trauma hospital in the state and cares for more than 65,000 ED patients per year. QMC opened an additional medical center in the community of West Oahu in 2014, which currently sees 50,000 ED patients annually.

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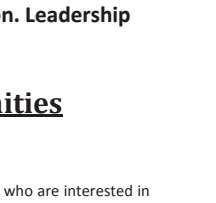

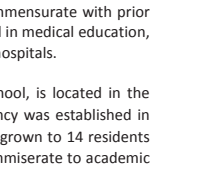

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Contact: Thomas Lee, MD,
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We offer salaries commensurate with qualifications, sign-on bonus, relocation assistance, physician incentive program and a CME allowance. Our comprehensive benefit package includes health insurance, education assistance, retirement options, on-campus fitness center, day care, credit union and so much more! For your health, Hershey Medical Center is a smoke-free campus.

Applicants must have graduated from an accredited Emergency Medicine Residency Program and be board eligible or board certified by ABEM or AOBEM. We seek candidates with strong interpersonal skills and the ability to work collaboratively within diverse academic and clinical environments. Observation experience is a plus.

For additional information, please contact:
Susan B. Promes, Professor and Chair, Department of Emergency Medicine, c/o Heather Peffley, Physician Recruiter, Penn State Hershey Medical Center, Mail Code A590, P.O. Box 850, 90 Hope Drive, Hershey PA 17033-0850, Email: hpeffley@hmc.psu.edu OR apply online at www.pennstatehersheycareers.com/EDPhysicians

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