

A NEW SPIN

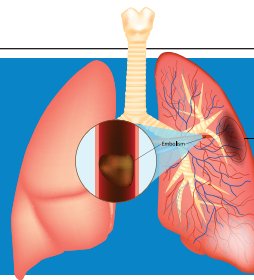
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The Official Voice of Emergency Medicine

JULY 2018

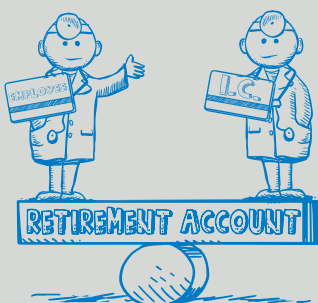
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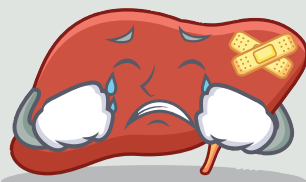


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## THE TWO SIDES OF APAP



Acetaminophen is safe until it's not

by KRISTEN C. PEÑA, DO, AND  
JOHN S. KASHANI, DO

### The Case

The patient is a 17-year-old non-English-speaking Bengali female with no past medical history who presented to the pediatric emergency department at 12:30 a.m. with complaints of abdominal pain, vomiting, and headache that began earlier that evening. She is accompanied by her mother, younger sister, and a male neighbor who was asked to come to help translate. She describes the abdominal pain as diffuse in nature without localization, with more than 15 episodes of non-bloody, non-bilious emesis.

There is no food exposure to account for her symptoms as she has not had anything to eat that day. Her last menstrual period was about 20 days prior to ED visit and was normal. She denies recent travel, fever, chills, urinary symptoms, diarrhea, sick contacts, or taking medications for her symptoms.

On exam, she appears pale and uncomfortable, with dry mucous membranes. However, she is awake, alert, and oriented, with a Glasgow Coma Scale score of 15. The abdominal exam reveals

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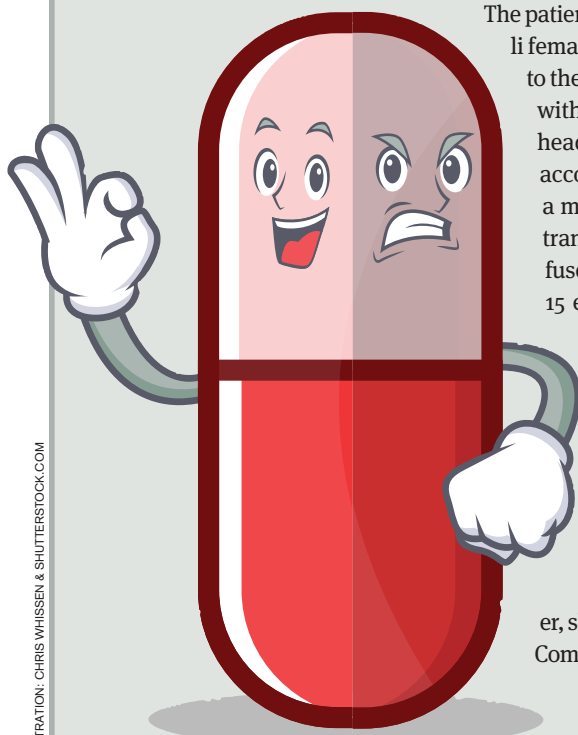


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## Necrotizing Fasciitis

### Recognizing the tip of this ID iceberg

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

Necrotizing fasciitis is a rapidly progressive inflammatory infection of the fascia, with secondary necrosis of the subcutaneous tissues. The spectrum of presentation is wide, ranging from a benign-appearing rash in a well person to obvious skin necrosis with hemodynamic

instability, multi-organ failure, and death. Patients who present early in this spectrum of disease are difficult to diagnose, with an initial misdiagnosis rate of 71.4 percent.<sup>1</sup> However, initiation of treatment in these early stages gives patients



the greatest chance of survival in this otherwise deadly disease. In this early phase, necrotizing fasciitis can be mistaken for simple cellulitis, and while the skin may appear benign, it is often the tip of the ice-

CONTINUED on page 15

## ACEP PRESIDENT-ELECT RESIGNS

Prior to the June Board of Directors meeting, ACEP President-Elect John Rogers, MD, FACEP, resigned his position, despite the Board's attempts to refuse his resignation.

In his resignation, Dr. Rogers, who was elected to be ACEP's next President by the Council in 2017, voiced his desire to unify the specialty. He said he didn't want his lack of emergency medicine board certification to be a distraction to the work of the College.

Dr. Rogers sent a heartfelt and personal note to the Board on June 27:

"This is a time when the residents in the house of emergency medicine should be coming together, and respecting each other as allies in a common cause. Unfortunately, it appears I have become a focal point for divisive-

ness. Not by my words or actions, but by one indisputable fact that neither I nor anyone else can change.

"It became clear that this would not only be a continuous cloud over my term as President, a distraction to the Board and College, but a barrier to unity within our emergency medicine community. I know in my heart this is the right direction and decision."

Dr. Rogers, who has been practicing emergency medicine for more than 30 years, brought a great deal of experience and knowledge, especially on rural EM issues, to ACEP during his seven years as a member of the ACEP Board. Dr. Rogers also served the College as Secretary/Treasurer, Vice President, Chairman of the Board, Chair of EMF, and President of the Georgia chapter.

"While his leadership as President could have advanced the specialty a great deal, we respect his decision and are humbled that he selflessly chose emergency medicine over his personal role—a hallmark of the kind of leader that he is," said ACEP President Paul Kivela, MD, MBA, FACEP.

On June 28, in an election run by the Council officers in accordance with the College bylaws and Council standing rules, the ACEP Board selected Vidor E. Friedman, MD, FACEP, to serve as President-Elect. At the ACEP18 Council meeting, Council members will either ratify that decision or the Council can elect a new President-Elect who would assume the Presidency at the end of the Council meeting. ACEP will update you on the latest information as we receive it.

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# NEWS FROM THE COLLEGE

## UPDATES AND ALERTS FROM ACEP

### Historic Meeting on Unscheduled Sedation Guidelines

ACEP hosted a multidisciplinary group of health care providers who perform unscheduled sedation to create a set of consensus guidelines that benefits our patients. As all emergency physicians know, there are often restrictions placed on the ability of emergency physicians and nurses to provide the best care. The Centers for Medicare and Medicaid Services permits institutions to use specialty guidelines when constructing their own guidelines. However, to date, many guidelines have tried to encompass all sedation. The consensus guidelines will be published in the future in the Annals of Emergency Medicine after other organizations endorse this work. The group welcomes input from other groups with an interest in these guidelines. Interested societies should contact ACEP at [sschneider@acep.org](mailto:sschneider@acep.org), and they will be sent a draft of the guidelines document to comment on.



ACEP President Dr. Paul Kivela addresses participants at the unscheduled sedation guidelines meeting.

### Notes from the AHA Roundtable

ACEP and the American Hospital Association (AHA) met May 22, 2018. Discussion included:

**Resilience and Well-Being:** Jay Kaplan, MD, FACEP, ACEP Past President provided an update on ACEP's work in the area of well-being, including the 2017 EM Wellness Week initiative and the recent EM Wellness Summit as well as three main activities of a consensus paper to be submitted for publication, a survey on workplace issues contributing to lack of wellness, and the formation of an EM wellness institute.

**Opioids:** Laura Wooster, MPH, ACEP associate executive director for public affairs, provided an update on ACEP's advocacy work in the opioid area and the process for expansion of the Alternatives to Opioids (ALTO) program. Sandra Schneider, MD, FACEP, ACEP associate executive director for academic affairs, talked about training materials and an app ACEP is developing to help expand ALTO. AHA confirmed support of ACEP's federal legislative efforts through the Preventing Overdoses While in Emergency Rooms (POWER) Act. The group discussed how AHA could advocate for fewer burdens on the waiver process to allow for easier prescribing of medication-assisted treatment. ACEP President Paul Kivela, MD, MBA, FACEP, discussed ACEP support of Collective Medical Technologies and the Emergency Department Information Exchange and our work to expand that, but also the limitations on resources because of new ways patients are presenting and seeking medications in the emergency department.

**Drug Shortages:** Ms. Wooster provided an update on ACEP's work to address drug shortages. AHA co-signed two congressional letters asking U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb to convene the FDA's Drug Shortages Task Force along with other key federal departments and stakeholder groups in order to identify the root causes of drug shortages and make recommendations back to Congress on how to

address them. Dr. Schneider discussed efforts to work with the American Society of Health-System Pharmacists to have them disseminate alternatives for drugs in short supply. Dr. Schneider also shared information on ACEP's Emergency Medicine Practice Research Network and offered the resource to AHA to gather information on critical questions.

### Leaders Met with TJC

Topics included our Geriatric ED Accreditation program, freestanding emergency departments, suicide screening, and pediatric readiness. The Joint Commission (TJC) reiterated its standard that universal suicide screening in the emergency department was required for patients with behavioral health chief complaints. Where resources make it feasible, screening of other populations at risk within the population served is encouraged but not a standard. TJC also discussed the issue of inpatient and in-facility suicides. Their data shows that this is actually a rarer event than had been suggested. Nonetheless, they suggest that rooms that house patients with suicidal ideation be free of ligature risks. Among those who kill themselves in a hospital facility, most do so by hanging.

### ACEP-Developed Opioid Bills Pass the House

Two pieces of opioid legislation—the POWER Act and the ALTO Act—that ACEP developed and introduced to Congress have successfully passed the House of Representatives and are moving to the Senate. At LAC18 just last month, ACEP members advocated for the bills to their state representatives. Your advocacy works!

### Emergency Physician Elected to AMA Council

At the 2018 American Medical Association (AMA) Annual Meeting, ACEP member Stephen K. Epstein, MD, MPP, FACEP was elected to the AMA Council on Medical Service. This council studies the social and economic aspects of medical care and recommends policies. Congratulations, Dr. Epstein!

### ACEP Leader on Sickle Cell Care Collaborative

ACEP Board of Directors member Jon Mark Hirshon, MD, PhD, MPH, has been appointed to the Emergency Department Sickle Cell Care Collaborative (EDSC3), a group formed of representatives of governmental and other society groups. The collaborative is organizing a leadership summit on Aug. 16, 2018, with multiple federal agencies, professional organizations, and others to discuss improving emergency department care for sickle cell disease. 📌



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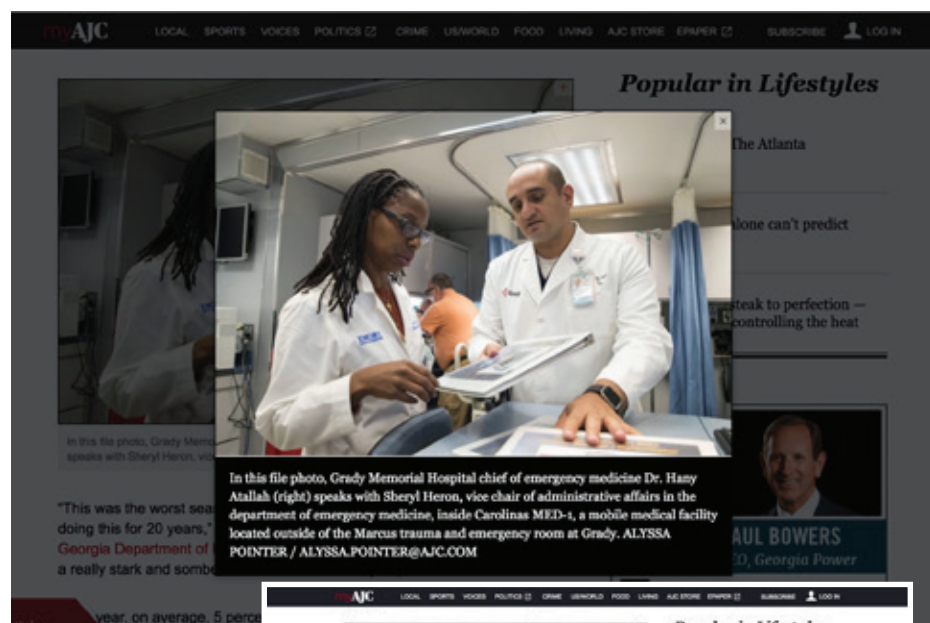


FIGURE 1: The Atlanta Journal Constitution website showing the image of Dr. Hany Atallah and Dr. Sheryl Heron. Note that Dr. Heron was not listed as Dr.

# When Unconscious Bias Hits Home (Again)

A lack of recognition perpetuates the problem

by SHERYL HERON, MD, MPH;  
WITH CONTRIBUTIONS FROM MICHELLE LALL, MD, MHS

It was surprising to receive an email advising me that I had appeared on the front page of the *Atlanta Journal Constitution* (AJC), the local newspaper in Atlanta. Without reading the article, which addressed the end of the flu crisis in Georgia, there I was with my colleague and friend Hany Atallah, MD. There was an image of Dr. Atallah and me. I was advised the image was quite reflective of the seriousness of the flu season and the flu season finally coming to a close. What I didn't see, which my husband immediately brought to my attention, was the verbiage underneath the photo. My husband simply stated, "Now that's unconscious bias right there on the front page." Puzzled, I didn't understand what he meant. However, there it was. My colleague and friend Hany was noted as Dr. Hany Atallah, and I was noted as Sheryl Heron, not Dr. Sheryl Heron (see Figure 1).

As one who has spent a large part of my professional life giving local and national presentations on unconscious bias, there it was staring me in the face. As an African-American woman, full professor in emergency medicine, vice chair as the article noted, and assistant dean, why wasn't I afforded the title of doctor as my male colleague was?

The data are clear on gender and racial bias, with more studies addressing this reality each day. These biases contribute to microaggressions and the continuous need for women and underrepresented minorities (URMs) to feel they have to prove themselves.

My colleague Michelle Lall, MD, MHS, president of the Academy for Women in Academic Emergency Medicine (AWAEM), and I were co-authors on a paper addressing the current status of gender and racial/ethnic disparities in academic emergency medicine physicians.<sup>1</sup> The paper revealed that gender and URM disparities exist and persist as it relates to salary and rank among full-time US academic emergency medicine faculty. There are also gender and URM disparities in rank and leadership positions. Women earn less than men regardless of rank, clinical hours, or training. There

are multiple studies showing that women physicians lag behind their male counterparts in compensation, research funding, leadership opportunities, and achievement.<sup>2-9</sup> These trends have been consistent over the last 15 to 20 years and are not improving.

As we continue to examine unconscious bias, not calling attention to examples such as these when they occur will only serve to perpetuate the problem. We've earned the right, as our male colleagues enjoy, to be addressed as doctor, and we count on the media to help us recognize these biases. We can and must do better. +

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**DR. HERON** is professor and vice chair of administrative affairs in the department of emergency medicine, assistant dean of clinical education and student affairs, and associate director for education and training at the Injury Prevention Research Center at Emory University School of Medicine in Atlanta.



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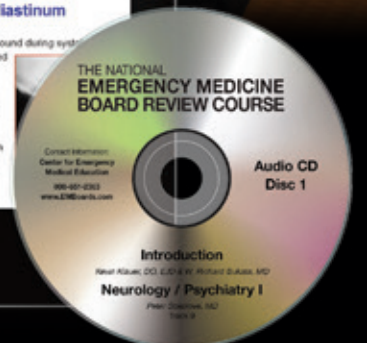
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mild diffuse abdominal tenderness without radiation, rigidity, or guarding. IV access is obtained, and blood work is sent at 1 a.m. Her complete blood count, complete metabolic panel, lipase, urinalysis, and urine human chorionic gonadotropin are all within normal limits. She is treated with a 1 L normal saline bolus, Zofran 4 mg IV, Pepcid 20 mg IV, and ketorolac 30 mg IV, and her symptoms improve.

In the setting of normal blood work and no clear reason for the vomiting, a bedside ultrasound is performed to evaluate the right upper quadrant. The bedside ultrasound is negative for any acute biliary pathology. The patient at this point has changed into a hospital gown and is noted to have self-mutilation marks on her left forearm in the shape of an “M.” When asked about these marks on her arm, she states that she cut herself while cooking. It becomes obvious that there is more to the story. The family and neighbor are asked to step out of the room, and CyraCom translation service is brought to the bedside. The patient is not very cooperative with questioning, but when asked if she took any medications, she admits to taking 27 650 mg Tylenol tablets at 2:30 p.m., about 10 hours prior to arrival. She states she took the pills because she was feeling sad because her boyfriend, whose name begins with “M,” broke up with her.

About one hour into the ED visit, an overdose panel is sent including acetaminophen, aspirin, and alcohol levels, plus a urine toxicology screen. The acetaminophen level is 143.1 ug/mL. A medical toxicologist is consulted, and N-acetylcysteine (NAC) is initiated. Initial aspartate aminotransferase (AST) and

alanine aminotransferase (ALT) are 40 U/L and 37 U/L, respectively. Within 24 hours, her AST and ALT peak at 4,453 U/L and 4,843 U/L, respectively, before starting to trend downward. The repeat acetaminophen level, drawn about eight hours after the initial level, goes from 143.1 ug/mL to 36.5 ug/mL. By hospital day two, the acetaminophen level is <10 ug/mL. The patient remains stable throughout the hospital course and is discharged on hospital day five.

Acetaminophen Overdose

Acetaminophen overdoses are a common cause of hepatotoxicity in both pediatric and adult patients. The availability of the drug and perception of its safety are likely factors in the large number of overdoses, both intentional and unintentional, seen. The metabolism of acetaminophen involves multiple enzymatic pathways. Glucuronidation accounts for the majority of metabolism, with normal dosing accounting for up to 42 percent to 67 percent. A secondary mechanism, sulfonation, is more active in the pediatric population and accounts for up to 20 percent to 46 percent. Both of the aforementioned pathways result in water-soluble metabolites that are renally excreted. Additional mechanisms responsible for the metabolism of acetaminophen are the cytochrome P-450 (CYP) hepatic isoenzymes. Of particular importance is hepatic isoenzyme 2E1, which results in the formation of a reactive metabolite NAPQI. When an overdose is taken, glucuronidation and sulfonation are saturated, resulting in increased metabolic activity of hepatic isoenzyme 2E1. The increased generation of

NAPQI would normally be conjugated to glutathione to form an adduct. However, when glutathione levels decrease to approximately 30 percent, hepatotoxicity occurs, evidenced by an elevation in AST and ALT.

During stage I of the clinical course of toxicity, hepatic injury has not yet occurred, and even patients who will go on to develop hepatotoxicity may be asymptomatic, highlighting the importance of getting an acetaminophen level. Mild symptoms such as nausea, vomiting, pallor, and malaise may be present. A latent period may follow where the patient may have fewer symptoms or even appear clinically well. However, as glutathione stores deplete and NAPQI builds, hepatotoxicity ensues. Stage II represents the onset of hepatic injury, and signs and symptoms may vary with severity of hepatic injury. Most patients will develop elevations of AST and ALT within 24 hours of ingestion. By convention, acetaminophen-induced hepatotoxicity is defined as a peak ALT concentration above 1,000 IU/L.

Stage III represents the time of maximal hepatotoxicity occurring between 72 and 96 hours after ingestion. Patients can progress to fulminant hepatic failure, which clinically manifests as development of encephalopathy, coma, cerebral edema, coagulopathy, and gastrointestinal bleeding. Most deaths occurring from hepatic failure occur three to five days following acetaminophen overdose.<sup>1</sup>

Patients who survive this period reach stage IV, defined as the recovery phase. Survivors have complete hepatic regeneration, and the rate of recovery varies, but in most cases, most lab values normalize within seven days.<sup>2</sup>

Acetaminophen level, for those who present within 24 hours of a single acute ingestion, can be plotted on the Rumack-Matthew nomogram to determine the patient’s risk of hepatotoxicity (see Figure 1). For single ingestions, indications to treat with NAC include a four-hour level of ≥150 mg/L for a witnessed ingestion or a level of >10 mg/L in an unwitnessed event with unknown time of ingestion. NAC can be administered via the oral or intravenous routes.

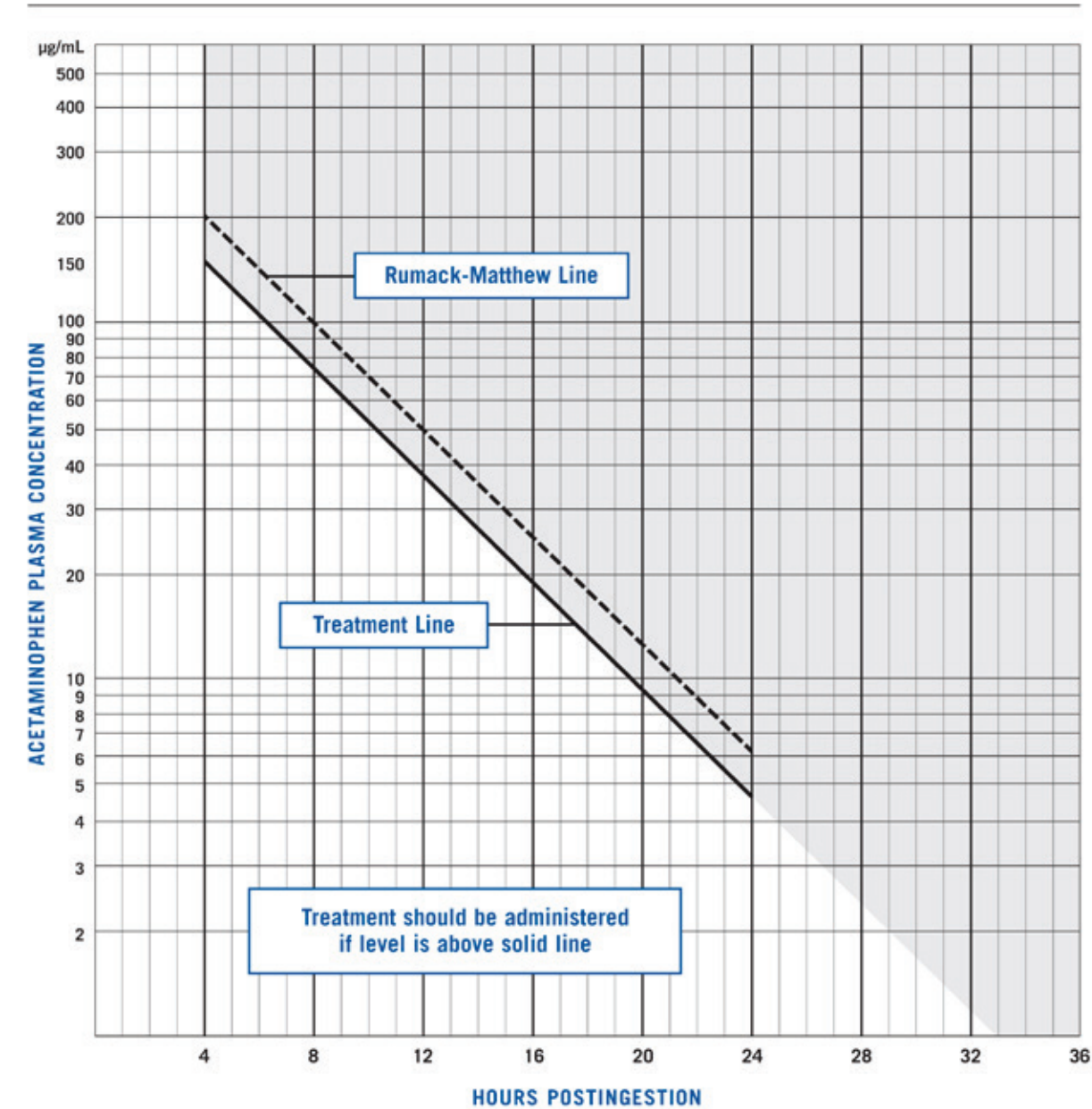
There are several variations in treatment protocols; however, the most common are a 21-hour intravenous infusion and a 72-hour oral-dosing protocol. The variation in treatment exists because treatment theoretically should be initiated when the patient is suspected to be at risk for hepatotoxicity, continue while the patient remains at risk, and cease once the risk or toxicity is gone. Studies have shown equal efficacy in preventing toxicity between the intravenous and oral routes.<sup>2</sup> The recommended dose of intravenous NAC is 150 mg/kg IV x 1 over 60 minutes followed by 50 mg/kg IV x 1 over four hours followed by 100 mg /kg IV x 1 over 16 hours for both pediatrics and adults.

Specific indications for intravenous NAC include fulminant hepatic failure, inability to tolerate oral NAC, and acetaminophen poisoning in pregnancy. The major adverse effect associated with intravenous NAC can be a severe anaphylactoid reaction; however, this is rare. The recommended dose of oral NAC is a 140 mg/kg loading dose either orally or via enteral tube. Starting four hours after the loading dose, 70 mg/kg should be given every four hours for an additional 17 doses. The main disadvantage of oral NAC is the high incidence of vomiting, which, in turn, can delay care.<sup>2</sup> This is most beneficial if treatment is initiated within eight hours after ingestion.<sup>1</sup> Therefore, it is important to assess the patient’s risk for hepatotoxicity, and at times, it may be necessary to initiate treatment with NAC prior to laboratory studies in order not to delay care.

The effects of delaying care are far worse than initiating treatment that may ultimately not be needed, in which case therapy can be stopped. Additional elimination techniques exist, including hemodialysis. Indications for hemodialysis include patients with exceedingly high acetaminophen levels (greater than 500 ug/mL) who are at high risk for hepatotoxicity despite NAC therapy as well as those with elevated lactic acid levels and metabolic acidosis. Hemodialysis also removes NAC, and subsequently, NAC infusion rates need to be doubled during dialysis.<sup>2</sup>

Patients can also present with chronic acetaminophen toxicity from repeated supratherapeutic doses. However, the incidence of serious acetaminophen toxicity is small following

Single Acute Acetaminophen Overdose Nomogram



**Nomogram:** acetaminophen plasma concentration vs time after acetaminophen ingestion (adapted with permission from Rumack and Matthew. *Pediatrics*. 1975;55:871-876). The nomogram has been developed to estimate the probability of whether a plasma acetaminophen concentration in relation to the interval post-ingestion will result in hepatotoxicity and, therefore, whether acetylcysteine therapy should be administered.

- CAUTIONS FOR USE OF THIS CHART:**
- 1. Time coordinates refer to time post-ingestion.
  - 2. Graph relates only to plasma concentrations following a single, acute overdose ingestion.
  - 3. The Treatment Line is plotted 25% below the Rumack-Matthew Line to allow for potential errors in plasma acetaminophen assays and estimated time from ingestion of an overdose (Rumack et al. *Arch Intern Med*. 1981;141(suppl):380-385).

CONTINUED on page 8



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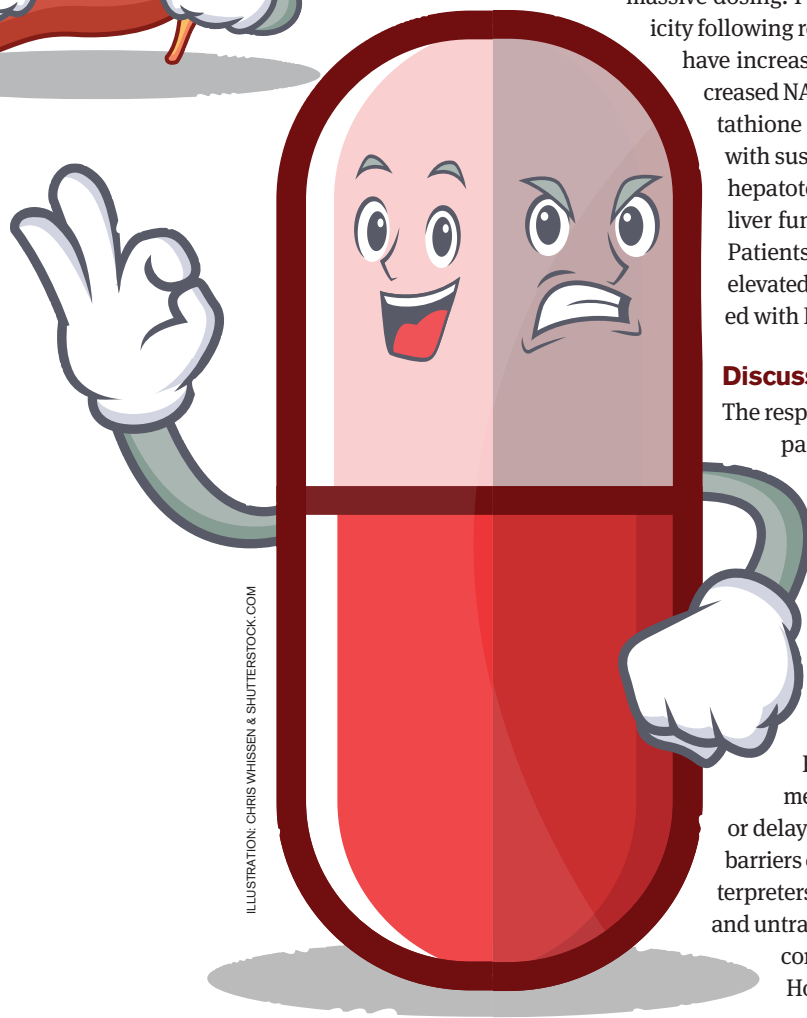
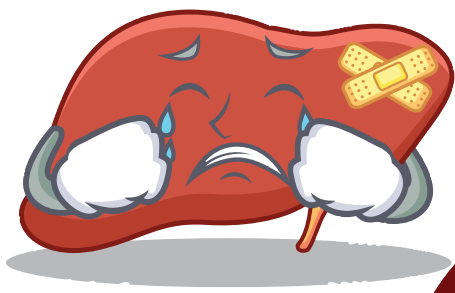


ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

chronic ingestion and much more common in acute, massive dosing. Patients at greater risk for hepatotoxicity following repeated supratherapeutic ingestions have increased activity of CYP 2E1 leading to increased NAPQI formation or have decreased glutathione stores and turnover rate. In patients with suspected chronic ingestion with risk of hepatotoxicity, an acetaminophen level and liver function enzymes should be obtained. Patients with elevated liver enzymes and/or elevated acetaminophen level should be treated with NAC to prevent further liver damage.<sup>2</sup>

#### Discussion

The responsibility to provide the best care for patients is incumbent on emergency physicians, and they may have to overcome numerous barriers to fulfill that responsibility. Language barriers can have deleterious effects, and patients who face such barriers are less likely than others to have a usual source of medical care. In 1998, the Office for Civil Rights of the Department of Health and Human Services issued a memorandum that states that the denial or delay of medical care because of language barriers constitutes discrimination. Ad hoc interpreters including family members, friends, and untrained members of the support staff are commonly used in clinical encounters. However, they are more likely to com-

mit errors that may have adverse consequences. Ad hoc interpreters are unlikely to have had training in medical terminology and confidentiality. Their presence may inhibit discussions regarding sensitive issues such as domestic violence, substance abuse, or mental illness, as illustrated in this case.<sup>3</sup> Barriers such as these leave emergency physicians more vulnerable to medical error that could be harmful to their patients. For this reason, it is important to be knowledgeable about the potential pitfalls and to approach each patient with the same objectivity. +

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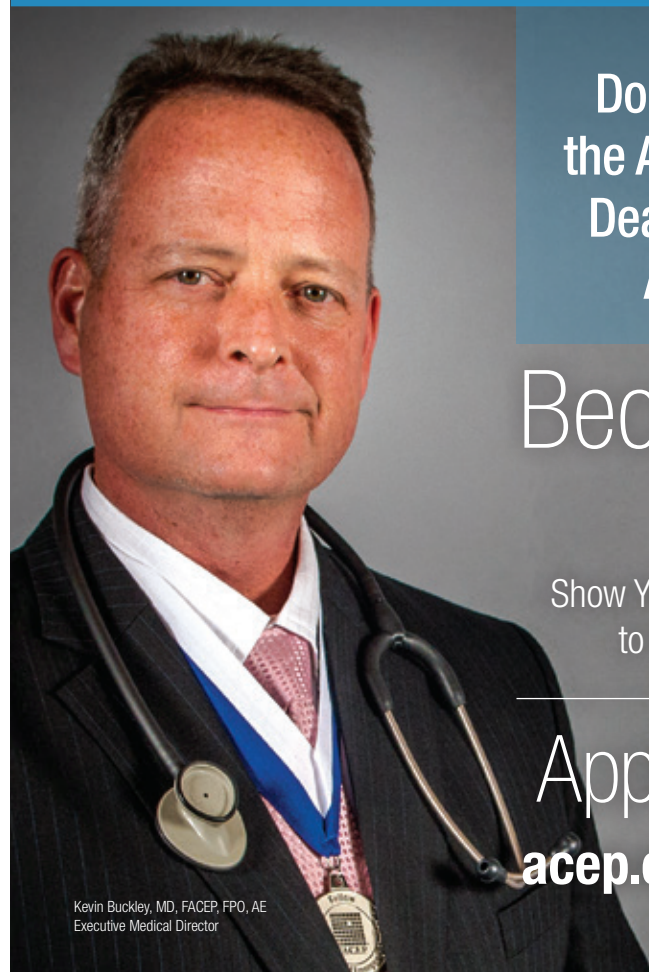
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**In this article, members of the ACEP Human Trafficking Work Group respond to our interview with Cynthia M. Deitle, JD, on the topic of human trafficking published in April and May, and offer additional insights from the perspective of emergency medicine.**



# Complexities of Helping Trafficked Patients in the ED

Additional perspectives on recognizing and responding to human trafficking from ACEP Work Group

by WENDY MACIAS-KONSTANTOPOULOS, MD, MPH,  
on behalf of the ACEP Human Trafficking Work Group

**L**abor and sex trafficking are the two major forms of human trafficking occurring in the United States. Although U.S. discourse on human trafficking is excessively focused on forced commercial sexual exploitation, this should not be interpreted to mean that sex trafficking is more prevalent than labor trafficking. Indeed, accurate prevalence estimates elude our epidemiological understanding of the problem in the United States, though global research suggests that labor trafficking is the more prevalent form.

Notwithstanding the frequently invoked image of women and girls trafficked for commercial sex by predatory males, the truth is that victims and perpetrators of this crime exist in all combinations. Indeed, labor- and sex-trafficked persons can be male, female, transgender, and gender-nonconforming children and adults, much like the traffickers who exploit them. Despite human traffickers being typically thought of as ruthless, unscrupulous adults, it is important to recognize contexts in which the youth themselves engage, either under duress or of their own accord, in the trafficking of other youth. Examples include peer recruitment out of schools and residential homes, homeless youth “street families” (formed out of convenience and necessity) internally exploiting labor and sex, and youth gang leaders trafficking weaker youth for labor related to criminal activities and commercial sex. Thus, to broaden our conceptualization of human trafficking and maximize detection, clinicians must refrain from relying only on the recognition of sex trafficking and male perpetrator–female victim combinations.

Although the crime of human trafficking doesn’t discriminate based on age, gender, race, ethnicity, and immigration status, traffickers strategically exploit specific personal, social, and economic vulnerabilities that may disproportionately place certain demographic groups at higher risk for labor trafficking, sex trafficking, or both. For example, youth who are abused, are homeless, or identify as lesbian, gay, bisexual, transgender, and queer (LGBTQ) are at greater risk for trafficking than their non-abused, non-homeless, and non-LGBTQ counterparts. Linguistically, educationally, economically, and otherwise systematically disadvantaged adults and

minors, such as immigrants and racial/ethnic minorities, are likewise at elevated risk. Understanding risk factors can help clinicians recognize at-risk and potentially trafficked persons while avoiding victim (and perpetrator) profiling that is based solely on visual cues and can result in missed opportunities to assist.

Due to the inherently abusive and violent nature of these crimes, trafficked persons suffer a wide range of physical, reproductive, and mental health morbidity. (Visit ACEPNow.com to view a table of these morbidities, as well as a list of resources for further reading on the topic of trafficking). Studies suggest that trafficked persons are accessing medical care during their exploitation and emergency departments serve as a primary health care access point. In one study of sex-trafficking survivors, nearly 88 percent of survivors surveyed reported accessing care at least once while trafficked, and 63 percent of them reported doing so in a hospital emergency department. Survivors present with the same injuries and illnesses as other emergency departments patients. However, delayed presentations (eg, walking on a fractured ankle for a week before seeking care) should raise concern for something amiss.

For patients who are accompanied to the emergency department, potential red flags include accompanying persons who appear overbearing, attempt to answer all questions, insist on translating, and seem to want to control access to the patient. As accompanying persons can be traffickers or their associates, clinicians should be aware that these individuals can either pose as or be the patient’s parent, legal guardian, family member, family friend, spouse, romantic partner, roommate, friend, coworker, or manager/boss. To avoid missed opportunities, clinicians should always use professional language-interpretation services when needed and should always evaluate the patient in private at some point during the visit without seeking the patient’s permission to do so in the presence of the accompanying person and potentially placing the patient in a precarious position. Clinicians can accomplish this by simply stating it’s their policy to involve professional interpreters and/or evaluate the patient alone for a certain portion of the exam, or by resorting to less conspicuous, more creative ways to separate them or meet with the patient alone. Other potential indicators include patient responses that seem rehearsed

or restricted, explanations that don’t match injury patterns, apparent and stated age discrepancies, patients who appear subordinate or fearful of an accompanying person, and patients who do not know their whereabouts (city) or their own address but are otherwise oriented and unaltered.

Trafficking survivors are threatened, coerced, and forced into submission and silence. Rarely will survivors volunteer any information or want to answer questions about their exploitation for fear of retribution, harm to loved ones (including children), deportation, or criminal charges. As with intimate partner violence, the person being trafficked is in the best position to determine the risk behind attempting an escape or seeking or receiving help. They possess firsthand knowledge of the threats made, the ease with which they or their loved ones can be harmed, and the degree of violence and lethality displayed by the trafficker. Trafficking survivors who believe their silence is protecting loved ones from harm may fear “losing control” of the situation by the involvement of immigration or police officers and the ensuing cascade of events. If, given the circumstances of the situation, the maximum response allowed by law is not definitive or forceful enough and cannot guarantee their protection, then victims may end up in potentially worse or even lethal situations. Clinicians should also be aware that victims may end up punished under the same anti-trafficking laws designed to protect them if they were forced or coerced to engage in recruitment or other trafficking activities.

Unless clinicians have good reason to believe that the patient’s life is in imminent danger, clinicians should always engage the patient in discussion, seek their consent before involving law enforcement, and avoid promising safety. In cases where involvement of outside authorities is mandated by law (ie, state mandatory reporting laws), clinicians should work closely with colleagues from other disciplines (eg, social work, child protection) to ensure the process is as transparent, predictable, and non-retraumatizing as possible.

In some situations, despite the abuse and violence, trafficked persons may not recognize their own exploitation and therefore may not identify with the victim narrative. This is most often the case in sex trafficking when the exploitation is achieved under the guise of romantic seduction rather than more overtly non-relational forms of victimization. In these



cases, trafficking can have the appearance of intimate partner violence and may be initially understood as that alone by the exploited person. In addition to mandated reporting when applicable, clinicians should offer to consult social services for a lethality assessment, safety planning, and referral to resources. If a patient declines social work involvement, the clinician should be prepared to perform some of these tasks and recommend the patient returns to the emergency department when they're ready to receive assistance or go to the nearest police station if the level of danger escalates.

One important resource for clinicians and patients is the 1-888-373-7888 National Human Trafficking Hotline. A patient can be offered a private space in the emergency department to call the hotline, and the clinician can offer to accompany them while making the call. If the patient asks the clinician to make the call on their behalf, the purpose of the call and how much personal information the patient wants revealed should be established first (eg, request for local resources versus assistance). The hotline number can also be provided to the patient for later use, or if a patient fears it being found in their possession, the clinician can help the patient memorize it by noting it may be more easily recalled as 888-3737-888. Patients can also text "HELP" or "INFO" to BeFree (233-733) to reach the hotline, but clinicians should remind patients that smartphones provided to them by the trafficker may be monitored. For greater effectiveness, emergency physicians should become familiar with the local anti-trafficking resources and partner with local law enforcement and other hospital disciplines (eg, addiction, child protection, forensic nurse examiners, social work, security, risk management, legal counsel) in developing a multidisciplinary protocol to facilitate and streamline a trauma-informed, victim-centered response. +

**DR. MACIAS-KONSTANTOPOULOS** is founding chair of the ACEP Trauma and Injury Prevention Section Human Trafficking Work Group. She is a physician in the department of emergency medicine at Massachusetts General Hospital and assistant professor of emergency medicine at Harvard Medical School, both in Boston.

## HIGHLIGHTS FROM ANNALS OF EMERGENCY MEDICINE

### The Role of Restrictive Covenants in Emergency Medicine Employment Contracts

by WILLIAM B. MILLARD, PHD

*This month we introduce a new feature in ACEP Now that will highlight key research studies published in this month's issue of Annals of Emergency Medicine. The following is a summary of "Breaking Up Is Hard to Do: Restrictive Covenants in Emergency Medical Practice" from the July issue of Annals of Emergency Medicine. Visit [www.annemergmed.com](http://www.annemergmed.com) to read the complete article.*

Unlike with other highly salaried professions such as law, many states permit physicians to enter into employment contracts that include restrictive covenants (RCs), including noncompete clauses. These can prohibit a physician from working within a defined geographic area for a predetermined period of time after the end of an employment contract. Currently, only eight states have bans or restrictions on RCs. However, both ACEP and the American Academy of Emergency Medicine (AAEM) oppose them to varying degrees.

In some areas and practice environments, RCs appear to be common, but recently, some emergency physicians have fought them in court, finding success in some cases and failure in others. Experts such as Larry Weiss, MD, JD, professor of emergency medicine at the University of Maryland School of Medicine in Baltimore and former president of AAEM, be-

lieve that RCs are both widespread and onerous. He and others are worried that RCs might harm both physicians, who might literally have to uproot their families and move away if they were to leave their current jobs, and the communities they serve, which might face doctor shortages, should these contracts be strictly enforced.

Both ACEP and AAEM have supported some physicians in their legal struggles in some instances. For its part, ACEP opposes RCs with some exceptions, such as for individuals who have particularly strong business interests, including owners or partners of an independent physician group. AAEM has taken a harder line against RCs.

Ironically, RCs may not provide nearly as much economic benefit for employers as was previously believed. Therefore, observers such as ACEP President Paul Kivela, MD, MBA, FACEP, believe that physicians should be aware of RCs and discuss them openly at

the time of employment so that bilateral expectations are clear from the beginning of any employment relationship. It may simply be that RCs fade away from common practice as their lack of practical usefulness (and, in some areas, their unenforceability) becomes more widely understood. +

**DR. MILLARD**, a frequent contributor to the *Annals of Emergency Medicine* "News and Perspective" section, is an independent journalist covering health, the built environment, culture, and other topics and is based in New York City.



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# VTE Clinical Policy Revised

Recommendations for evaluation and management of adult ED patients with suspected acute venous thromboembolic disease

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.

by STEPHEN J. WOLF, MD, FACEP

In February 2018, the ACEP Board of Directors approved a revised clinical policy on the evaluation and management of adult patients presenting with suspected acute venous thromboembolic disease.<sup>1</sup> The policy is available at [www.acep.org/patient-care/clinical-policies](http://www.acep.org/patient-care/clinical-policies).

Venous thromboembolism (VTE), including both deep venous thrombosis (DVT) and pulmonary embolism (PE), is a major public health problem. Undiagnosed, untreated patients are believed to be at substantial risk for progressive disease and sudden death typically because of worsening right-sided heart strain and ultimately cardiovascular collapse. Treated patients are at risk for chronic sequelae (ie, vein scarring, leg swelling, and pulmonary hypertension) and adverse events from ongoing anticoagulation (ie, hemorrhage and other medication adverse effects).

One significant challenge for health care providers evaluating patients for VTE lies in the variability of signs and symptoms of the disease that are related to clot burden, location, and the individual patient's cardiopulmonary reserve. Without perfect, cost-effective tests for the diagnosis of VTE, providers have come to rely on Bayesian decision making to guide their workup, using pretest probability to interpret diagnostic evaluations and generate posttest probability of disease. Doing this allows providers to maximize diagnostic accuracy while minimizing over-testing and patient harm from the risks associated with unnecessary evaluation and treatment.

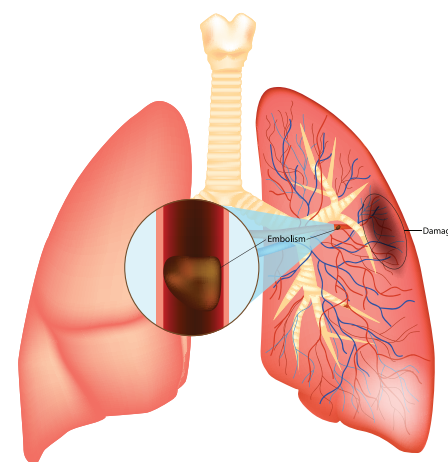
Efforts to refine this Bayesian approach in emergency medicine have been ongoing. Original studies to determine pretest probability and the accuracy of various screening tests have been validated, and the limits of their efficacy are being explored. Additionally, substantial efforts are being made to advance the treatment of VTE by balancing outcomes, anticoagulation risks to patients, and patient preferences. Novel (non-vitamin K antagonist) oral anticoagulants (NOACs) are particularly appealing for long-term anticoagulation because of their simple oral dosing regimens with no need for routine laboratory monitoring.

This most recent revision investigates five areas of interest or controversy in the evaluation and management of VTE. The first two critical questions address the role of unique clinical prediction rules and age-adjusted D-dimer testing in the diagnosis of PE, and the remaining three questions focus on optimal treatment and disposition for individuals receiving a diagnosis of venous thromboembolic disease.

For each critical question, a structured literature review was performed, evidence was systematically graded (see Table 1), and evidence-based recommendations are presented.

## CRITICAL QUESTIONS

**QUESTION 1.** In adult patients with suspected acute PE, can a clinical prediction rule be used to identify a



group of patients at very low risk for the diagnosis of PE for whom no additional diagnostic workup is required?

## Patient Management Recommendations

- **Level A:** None specified.
- **Level B:** For patients who are at low risk for acute PE, use the Pulmonary Embolism Rule-out Criteria (PERC) to exclude the diagnosis without further diagnostic testing.
- **Level C:** None specified.

**QUESTION 2.** In adult patients with low to intermediate pretest probability for acute PE, does a negative age-adjusted D-dimer result identify a group of patients at very low risk for the diagnosis of PE for whom no additional diagnostic workup is required?

## Patient Management Recommendations

- **Level A recommendations:** None specified.
- **Level B recommendations:** In patients older than 50 years deemed to be at low or intermediate risk for acute PE, clinicians may use a negative age-adjusted D-dimer result to exclude the diagnosis of PE. For highly sensitive D-dimer assays using fibrin equivalent units (FEUs), use a cutoff of age  $\times$  10  $\mu$ g/L; for highly sensitive D-dimer assays using D-dimer units (DDUs), use a cutoff of age  $\times$  5  $\mu$ g/L.
- **Level C recommendations:** None specified.

**QUESTION 3.** In adult patients with subsegmental PE, is it safe to withhold anticoagulation?

## Patient Management Recommendations

- **Level A recommendations:** None specified.
- **Level B recommendations:** None specified.
- **Level C recommendations:** Given the lack of evidence, anticoagulation treatment decisions for patients with subsegmental PE without associated DVT should be guided by individual patient risk profiles and preferences (consensus recommendation).

**QUESTION 4.** In adult patients diagnosed with acute PE, is initiation of anticoagulation and discharge from the emergency department safe?

## Patient Management Recommendations

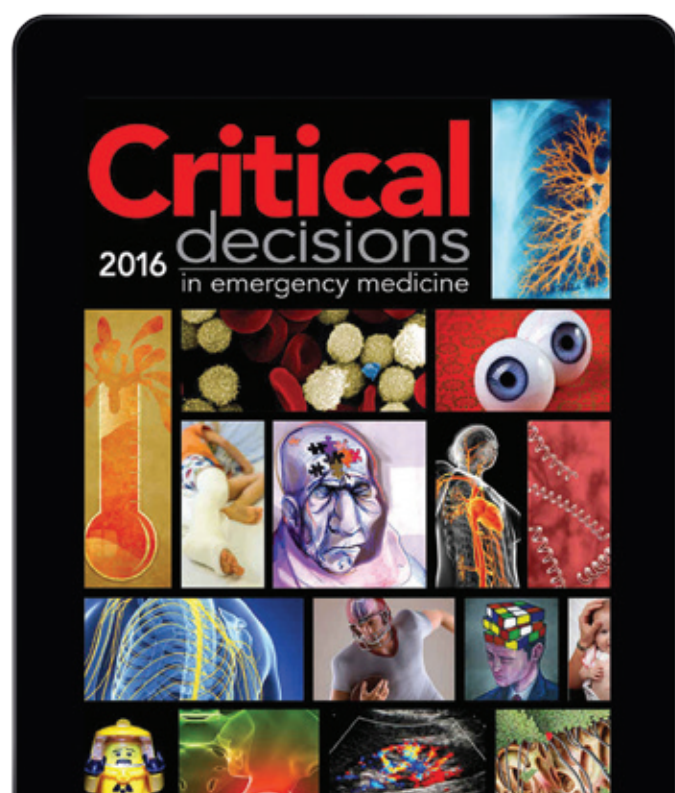
- **Level A recommendations:** None specified.
- **Level B recommendations:** None specified.
- **Level C recommendations:** Selected patients with acute PE who are at low

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# THE FORCES THAT SHAPED OUR SPECIALTY

Key public policy decisions that have influenced today's emergency medicine

by RICARDO MARTINEZ, MD, FACEP



**A**s emergency physicians look back on the growth of the specialty, we have the opportunity to note significant internal milestones along that path, such as the establishment of dedicated emergency department coverage by physicians in Alexandria, Virginia, in 1961; the formation of the American College of Emergency Physicians in 1968; the first emergency medicine residency at the University of Cincinnati in 1970; and the recognition as a specialty by the American Medical Association and American Board of Medical Specialties in 1979.

Just as important is understanding the external social, political, and financial policies that created the need for emergency medicine and have shaped our profession over the decades. As these forces continue to evolve, so will emergency medicine. Knowing how we got here is as essential as knowing where we need to go.

## Genesis of Emergency Departments

In the mid 1940s, with Americans returning from World War II, President Harry Truman signed the Hill-Burton Act, which provided grants and loans for the construction of hospitals and other health facilities, dramatically expanding the U.S. health care infrastructure. This era saw a huge boost in the U.S. population (the baby boom), which continued for a decade. The Hill-Burton Act also placed hospitals in a new area of growth, the suburbs, as growing families moved out from city centers. By 1960, one-third of American families lived in suburban areas.

This act, lasting until the late 1990s, was partially motivated to address lack of access to care in many communities and is responsible for many of the hospitals in which emergency physicians practice today. The Hill-Burton Act stated that funded hospitals would provide care to patients who were unable to pay for free or at reduced cost, making the hospital an access point for all.

As the population boomed, so did the need for unscheduled and acute care, but the medical community could not meet those demands. As a result, the local hospital's small emergency room became the community access point and a physician on call was assigned to respond. A 1958 *New England Journal of Medicine* article reported survey responses from 63 hospitals in the Midwest and Atlantic seaboard.<sup>1</sup> It found a nearly 400 percent increase in emergency room visits in the 15-year period of 1940–1955, with a 16.2 percent admission rate.

The driving force for patient visits to the emergency department was limited access to their physicians on nights and weekends, as well as physicians' concerns that the patients' needs were more than could be provided for in their offices. The authors noted that, "The study reflects an apparent change in thinking upon the part of physicians and the public and suggests that physicians and hospitals should plan for the future by increasing emergency

room facilities. It is believed that this trend is dictated by the public." The study recommended expansion of dedicated floor space to the emergency room.

A tripling of emergency room visits nationwide occurred between the 1940s and the 1960s. The decade of the 1960s represents a confluence of policy and social changes that lit the match for the creation of emergency medicine and the transformation of the emergency room into the emergency department. By 1961, the first groups of physicians dedicated to providing care in the emergency department started.

Several major events in the 1960s converged to change social thinking and the health care landscape. In 1966, the National Academy of Sciences and National Research Council published the landmark report, "Accidental Death and Disability: The Neglected Disease of Modern Society," which highlighted the magnitude of the injury problem in America and the poor state of ambulance and emergency services.<sup>2</sup> Motor vehicle injuries, during a time in which automobiles and highways were also booming, were a matter of particular concern. The report noted that soldiers injured in the Korean War on the front lines were systematically moved to emergency care better and faster than Americans at home injured in motor vehicle crashes. This white paper had a huge impact on EMS and emergency services in hospitals.

## Health Care Goes National

In 1965, health care became a national issue. About half of Americans age 65 or older (called "the aged") lived in poverty and had no insurance. In response to growing public concerns, Medicare and Medicaid were enacted to provide insurance for the aged and money to the states to provide Medicaid to the poor. This was overseen by the Bureau of Health Insurance, which became the Health Care Financing Administration, and then became the Centers for Medicare and Medicaid Services. Hill-Burton–financed hospitals were obligated to accept these new insurances.

The resulting expansion of patients with insurance caused greater demand for care that existing doctors' offices and clinics could not meet, so people turned to the emergency department for care, often sicker than if they had had routine care.

In 1966, President Lyndon Johnson, responding to a March report from the Presi-

dent's Committee for Traffic Safety, made it a priority in his State of the Union address. He championed legislation, the Highway Safety Act, that included driver education, law enforcement, crash prevention, engineering standards, and medical care and transportation of the injured. The Department of Transportation was formed, and within it, the National Highway Traffic Safety Bureau was formed, later becoming the National Highway Traffic Safety Administration (NHTSA). EMS was expanded federally due to the death toll from motor vehicle crashes, which is why NHTSA has always played a large role in EMS and still does today. In 1971, NHTSA's Office of EMS published the first guidelines for training emergency medical technicians.

In the 1970s, Congress enacted the Emergency Medical Services Systems Act of 1973 to authorize the Department of Health, Education, and Welfare to provide funding for

planning and development of EMS systems throughout the United States. The act identified 15 specific components of EMS systems including manpower, training, communications, and data collection and led to the development of more than 300 regional EMS systems across the United States, both extending emergency care to the community and

delivering higher-acuity patients to the emergency department.

In 1996, NHTSA brought the various participants in EMS together to create a common vision, The EMS Agenda for the Future, which helped modernize EMS and better integrate it with today's complex health systems. That vision is currently being revised toward 2050, building upon the remarkable progress of the last few decades.

All of these have collectively placed a greater focus on emergency response and care and became a tipping point for emergency medicine, which began to grow as a specialty in response to needs of the increasingly complex patients arriving to emergency departments.

## EMTALA, ACA, and Beyond

Congress inserted the Emergency Medical Treatment and Active Labor Act (EMTALA) into a budget bill in 1986 in response to national media focus on stories of unstabilized insured patients, including inpatients, being sent from private hospitals to public hospitals after a "billfold" biopsy. It was signed into law by President Ronald Reagan in 1987

and placed obligations on all hospitals to medically screen patients to determine if an emergency medical condition exists prior to inquiring about payment or insurance, provide care until stabilized for those with an emergency medical condition, and, if a transfer is required, to make it within the provisions of EMTALA. EMTALA has had many changes over the years, and its effects, both good and bad, are significant. It continues to be a major force in the provision of emergency care and establishing emergency departments and emergency physicians as the safety net for the United States.

The Patient Protection and Affordable Care Act (ACA), in response to a growing number of Americans who were uninsured because of low income or rising costs of insurance, passed in 2010 and was signed by President Barack Obama. It reinforced emergency care as an essential health benefit and expanded health insurance coverage for millions of Americans, either through private insurance or Medicaid expansion by states that chose to do so. Mired in politics and the challenges of change, its lasting effects will continue to play out. Increased coverage has not translated to increased access to care and already stressed emergency departments have seen volumes rise.

Three interconnected trends are reshaping both the emergency department and emergency medicine: the aging of the population, growth of chronic disease, and the move from inpatient to outpatient care. These older patients are more complicated and require complex evaluation and treatment. The disposition mindset has reversed. In the past, we admitted patients to have them worked up. Now, these patients are worked up to determine if they need to be admitted. As a result, emergency physicians are increasingly the decision makers for hospital admissions and have expanded their scope to manage observation units. These trends will likely continue and grow to include more telehealth, telemedicine, admissions to "hospital at home," and placing satellite emergency departments placed in the communities closer to the patients.

Emergency medicine can look back at 50 years of change and recognize that our growth and advancement are underscored by the profession's commitment to the needs of patients and communities. It has always been this way and always will be. +

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ACEP members on one of their Congressional visits during the day on the Hill.



PHOTOS: ACEP

**ABOVE:** U.S. Surgeon General Jerome Adams, MD, MPH, address the audience at LAC.

**RIGHT:** Emergency physician U.S. Rep Raul Ruiz, MD (D-CA), speaks to LAC attendees.



# ACEP on the Hill

## Report from the 2018 Leadership & Advocacy Conference

by L. ANTHONY CIRILLO, MD, FACEP

This year's ACEP Leadership & Advocacy Conference (LAC) held May 20–23 in Washington, D.C., provided ACEP members a wonderful opportunity to get updated on the key national and state issues affecting the practice of emergency medicine and have their voices heard on the crucial issue of health care reform in Washington, D.C.

LAC is really four amazing meetings in one. Although the conference didn't officially start until Monday, the pre-meetings on Sunday focused on giving attendees a jumpstart on the basics of health care advocacy. The first official day of LAC was Monday's Leadership Summit focusing on issues that enable all of us to be more mindful and effective leaders. Tuesday was the day when attendees became advocates, culminating with official visits to members of Congress on Capitol Hill. The last day of the conference was the Solutions Forum focusing on two key topics: opioids and end-of-life care.

This year's meeting was packed with both great ACEP speakers and invited guests from Congress and the federal government. Given the upcoming elections in November, together with current debates and votes on key issues, the conference and our advocacy on the Hill were a great success.

### The "Pre-Game" Meetings

With nearly 150 EM residents and medical student included in the more than 700 attendees at the conference, Emergency Medicine

Residents' Association (EMRA) and the ACEP Young Physicians Section (YPS) once again started the action on Sunday with their Health Policy Primer program. This half-day session included great presentations beginning with the "Intro to Health Policy" talk by Rachel Solnick, MD who serves as EMRA's legislative advisor, followed by "How is the Government Running Healthcare" by Jeet Guram, MD, senior advisor to CMS Administrator Seema Verma. Vidor Friedman MD, FACEP, from the ACEP Board of Directors closed the conference with "A Roadmap to Getting Involved," encouraging the attendees to be persistent in their advocacy efforts and to work within ACEP's many opportunities to be contributors in the health policy arena. This year a new half-day Chapter Leadership Session was added to the conference's Sunday schedule. This session provided nuts-and-bolts solutions for current and future chapter leaders. Topics in the program included leading an effective state advocacy program, financial leadership at a chapter level, building an effective board, and a review of the resources available to state chapters from national ACEP.

### The Kickoff

The Leadership Summit portion of the conference on Monday began with presentations challenging attendees to focus on how we each can personally develop a better toolkit as leaders to foster both personal wellness and the wellness of those we lead and mentor.

## LAC 2018: A First-Timer's Perspective

by TOMMY EALES, DO

Despite growing up and attending college in the Washington, D.C., metro area, I somehow managed to avoid spending any significant amount of time on Capitol Hill. In the past, the flight home from Indianapolis was characterized by the excitement of reuniting with friends and family for a short, often chaotic visit. This time, I experienced a healthy mixture of excitement and anxiety for finally experiencing what it was like to meet with legislators and advocate for the critical issues facing emergency medicine today.

While the first days of the conference were jam-packed with energizing speakers, the most inspiring session to me was part of the Health Policy Primer presented by EMRA and the ACEP YPS. The session featured an open forum, panel-style discussion with several top health policy journalists: Sarah Kliff of Vox, Dan Diamond of Politico, and Julie Rovner of Kaiser Health News.

It was intriguing to learn how health policy journalism is created and consumed in the rapidly changing world of media. As an open forum, there were many tough questions from the audience that inspired heartfelt and difficult responses from the panel. Several questions spurred a thought-provoking discussion regarding the disconnect that is often present between reality and public perception of key health care issues, such as billing in the emergency department. The panelists concluded by encouraging physicians to become involved in journalism to help bridge the gap on key issues.

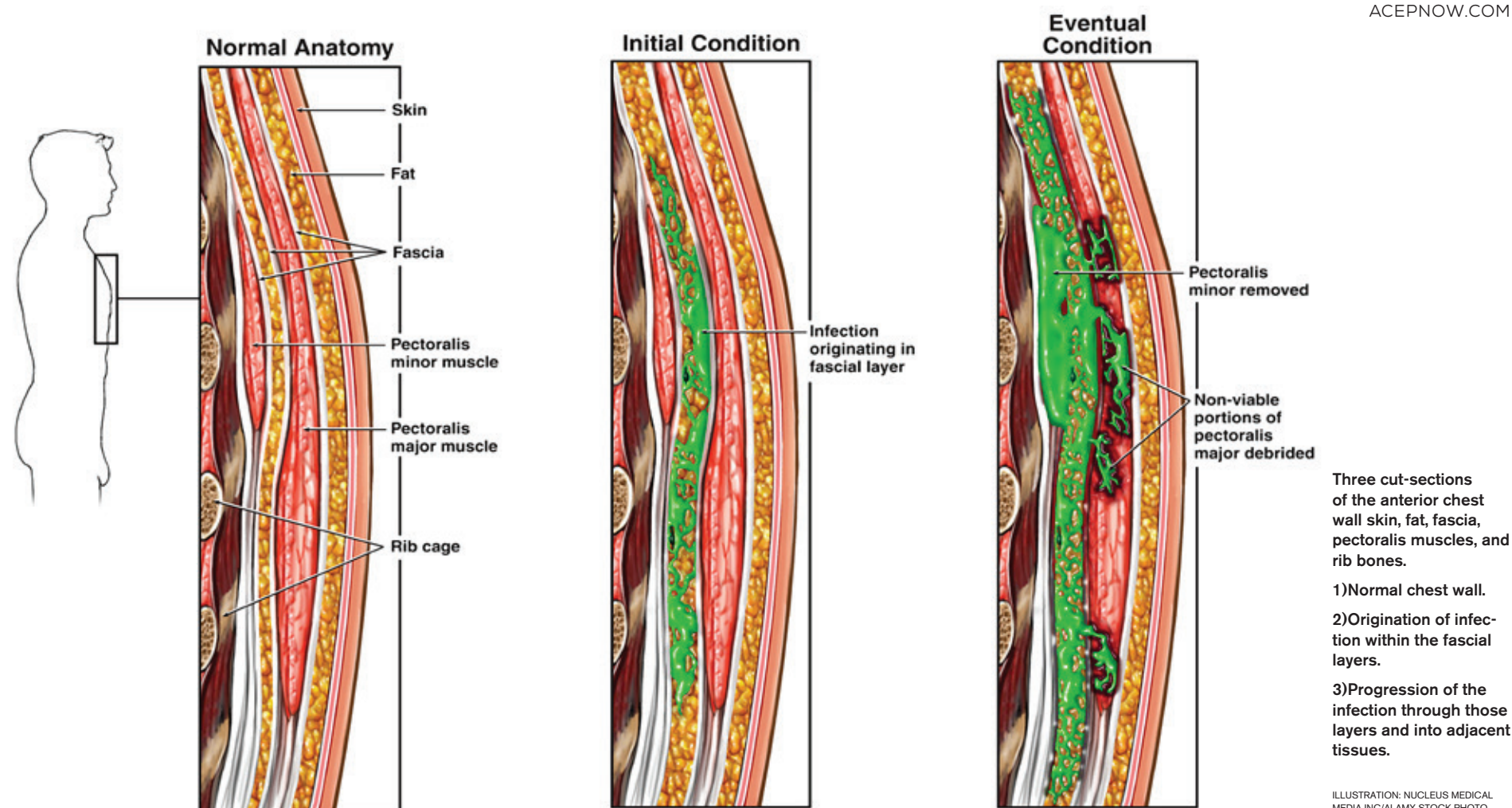
Finally, the day on the Hill arrived. As I prepared to walk into the first of many meetings, I was nervous to meet with my legislators. After all, who would listen to a junior resident discussing advocacy initiatives? While my information packet provided me with all of the details I could ever need, it was nerve-wracking to think that my limited experiences would collectively represent my colleagues and patients. But after a few minutes of speaking with the legislator and her assistant, all apprehension had dissipated. For physicians, advocacy is instinctive. After all, the majority of our clinical work revolves around advocating for our patients. Whether in the resus bay or on the Hill, the principle is the same—do the right thing for the patient. It's difficult to know whether my individual efforts influenced any policy decisions, but I certainly felt proud to advocate for my patients at this level.

Although this was my first time participating in LAC, it will certainly not be my last. If there's one thing that I learned from the experience, it's that the conference instills pride in the work that we do every day. Since returning to Indianapolis, I find myself energized and inspired to continue advocacy efforts in my community. As emergency physicians, we operate on the front lines of the health care system—our unique perspective has the potential to inform critical issues that make a real difference for our patients. If we do not continue to advocate for them, no one else will. +

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CONTINUED on page 27





## EM CASES | CONTINUED FROM PAGE 1

berg to what lies beneath.

The diagnostic difficulty also lies in the fact that there are no lab test results or even imaging that can definitively rule out necrotizing fasciitis. In fact, the diagnosis is a clinical one that can only be confirmed with surgical exploration. Therefore, it is imperative that if you have anything more than the slightest suspicion based on your clinical exam, you consider early consultation with a surgeon for definitive diagnosis and surgical debridement as well as start empiric antibiotics. Lab findings that are suggestive but not diagnostic of necrotizing fasciitis include coagulopathy, hypoalbuminemia, thrombocytopenia, lactic acidosis, creatine phosphokinase elevation, and C-reactive protein (CRP) elevation, which all tend to occur in later stages of disease.<sup>1</sup>

While clinical decision tools, such as the Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score that includes CRP, white blood cell count, hemoglobin, sodium, creatinine, and glucose, might help raise your suspicion for necrotizing fasciitis, validation studies showed that a LRINEC cutoff of six points only had a negative predictive value of 92.5 percent.<sup>2,3</sup> While these lab findings and imaging findings of subcutaneous air and fascial thickening on X-ray, CT, and MRI can help support the diagnosis, they should not delay definitive treatment in the operating room in clinically obvious cases and should never override clinical judgment.

Findings on point-of-care ultrasound, which has the advantage of speed over other imaging modalities, may help support the diagnosis but again cannot rule it out.<sup>4</sup> The reason that the absence of subcutaneous air on imaging cannot rule out the diagnosis is that one of the two types of necrotizing fasciitis is caused by non-gas-producing bacteria. In fact, imaging findings are often similar to those of cellulitis, with increased soft-tissue thickness and opacity.<sup>5</sup> Gas in the soft tissues is seen in only a minority of cases, but if you do see it, your suspicion for necrotizing fasciitis should be significantly raised.

### Clues to Early Detection of Necrotizing Fasciitis

Even though a history of diabetes, immunocompromised state, and recent surgery are often cited as risk factors, necrotizing fasciitis can occur in otherwise healthy patients after a minor traumatic injury.<sup>1,6,7</sup>

The Infectious Diseases Society of America recommends clinicians look for findings such as persistent severe pain, bullae, skin necrosis or ecchymosis, crepitus from gas in the soft tissues, edema that extends beyond the margin of erythema, cu-

taneous anesthesia, signs of systemic toxicity, and rapid spread over hours especially during antibiotic therapy.<sup>8</sup>

Vital signs are vital. Scrutinize them; most patients will have tachycardia and/or tachypnea out of proportion to fever. If you see what appears to be cellulitis on the lower abdomen, examine the perineum for signs of Fournier gangrene.<sup>9</sup>

Note that while severe pain out of proportion to physical exam findings is suggestive of necrotizing fasciitis, a minority of patients will report little pain and may have a laissez-faire attitude toward their illness, likely due to analgesic effects of local nerve destruction. This same mechanism may account for localized skin hypesthesia that some patients with necrotizing fasciitis may have. The edema of necrotizing fasciitis not only tends to spread beyond the margin of erythema but often has a tense quality, making the skin feel hard or “wooden.”

Palpable crepitance is only present in the gas-producing type of necrotizing fasciitis, and its absence does not rule out the disease for the same reason that imaging cannot rule it out. While rapid progression has been considered a hallmark of this disease, necessitating careful patient monitoring for the development of skin changes and systemic inflammatory response syndrome, subacute necrotizing fasciitis has been described.<sup>10</sup>

### Necrotizing Fasciitis Pitfalls in Diagnosis

Because of the wide spectrum of disease, one of the most common pitfalls is assuming the absence of necrotizing fasciitis in the patient who looks well, rates their pain as mild or absent, is afebrile, or has no palpable crepitus. The other major pitfall in the management of necrotizing fasciitis is doing an extensive workup leading to a delay in surgical debridement in cases where clinical suspicion is high.

### The Finger Test for Diagnosis of Necrotizing Fasciitis

In the event that you cannot make a slam-dunk diagnosis of necrotizing fasciitis after a careful clinical assessment and you can't get rapid access to surgical exploration in the operating room or confirmatory imaging, or that the imaging is negative but you still have suspicion for the diagnosis, consider diagnostic confirmation with the finger test.<sup>11</sup> After local anesthesia, make a 2- to 3-cm incision in the skin large enough to insert your index finger down to the deep fascia. Lack of bleeding and/or “dishwater pus” (gray-colored fluid) in the wound are very suggestive of necrotizing fasciitis. Gently probe the tissues

with your finger down to the deep fascia. If the deep tissues dissect easily with minimal resistance, the finger test is positive for necrotizing fasciitis.

### Time-Sensitive Therapy for Suspected Necrotizing Fasciitis

Initial treatment should involve aggressive resuscitation for any signs of hemodynamic instability and early administration of broad-spectrum empiric antibiotics (eg, piperacillin-tazobactam or carbapenem plus vancomycin or linezolid for methicillin-resistant *Staphylococcus aureus* coverage).<sup>12</sup> The sooner the necrotic tissue is debrided in the operating room, the better. Time is tissue. ➕

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# The Block Bag

ED innovation facilitates the implementation of ultrasound-guided nerve blocks

by ARUN NAGDEV, MD; GRAHAM BRANT-ZAWADZKI, MD; AND ANDREW HERRING, MD

**U**ltrasound-guided nerve block (UGNB) is an extremely useful technique for emergency physicians as a multimodal approach to the acutely injured patient. In the emergency department, UGNBs are an adjunct for pain management and can be an ideal way for clinicians to reduce the overreliance on systemic opioids.<sup>1-3</sup> In patients with contraindications to procedural sedation, UGNBs may also be the only suitable method for targeted analgesia. Recent end-point data indicate early ultrasound-guided femoral nerve blocks improve functional outcomes in patients with hip fractures, making the integration into emergency medicine practice imperative.<sup>4</sup> Unfortunately, despite evidence indicating both the feasibility and utility of UGNBs in the ED management of the acutely injured patient, reports indicate poor penetration in emergency medicine clinical practice.<sup>5</sup>

In our 10-year experience with UGNBs, we believe that one of the major limitations for physicians is the lack of a simple location for all supplies needed to perform a UGNB. Using basic design thinking methodology to streamline the process for the clinician, we developed prearranged block bags that contain the basic supplies needed to perform a UGNB.

Our block bags contain the minimum supplies necessary for a basic ED-based UGNB. All anesthetics remain in our ED automated medication dispensing system until ordered by the clinician. Weight-based dosing parameters and a preprocedural timeout checklist are not placed in the block bag but are easily located online to simplify the process (<http://highlandultrasound.com/med-guide>). Lipid emulsion (20%) is kept with our anesthetics, and all providers who are performing UGNBs are familiar with dosing if there is concern for local anesthetic systemic toxicity (see [www.lipidrescue.org](http://www.lipidrescue.org) for details). A standard ED policy should be in place with dosing guidelines and references whenever anesthetics are used (ultrasound-guided or landmark-based).

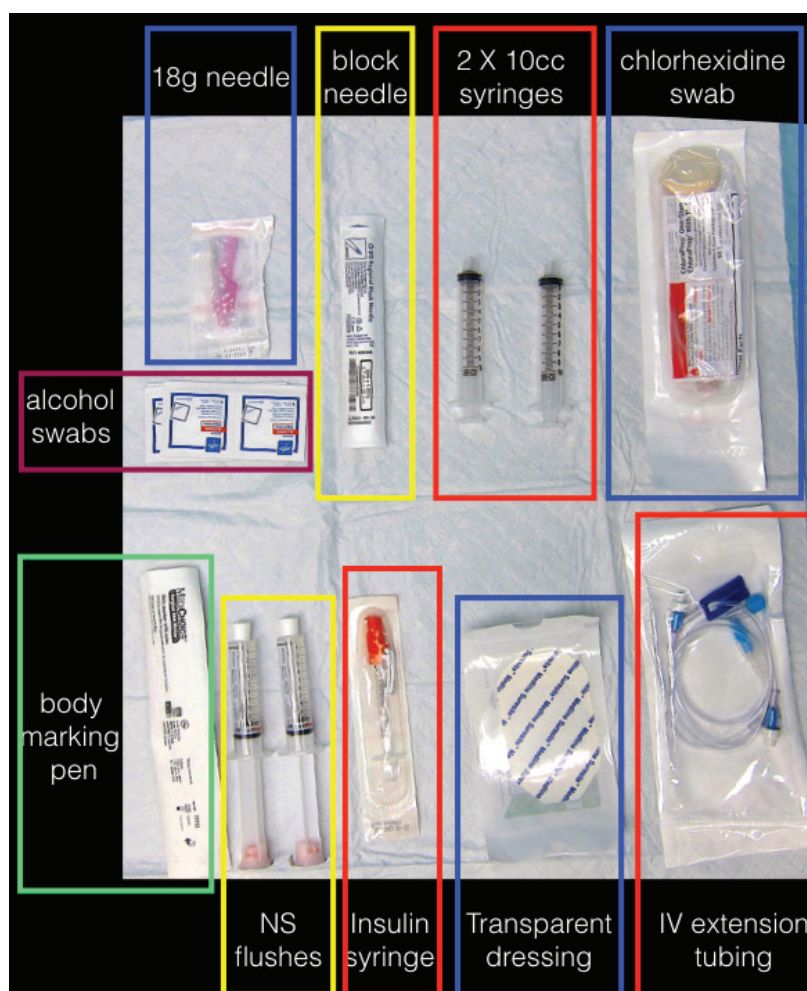
## Assembling the Bag

Each block bag contains (see Figure 1):

1. Two 20-cc syringes
2. 20-g 3.5-inch blunt-tip block needles
3. IV extension tubing
4. Two 10-cc normal saline (NS) flushes
5. 18-g needle
6. Tuberculin (TB) or insulin needle/syringe (for skin wheal)
7. Transparent dressing for probe
8. Alcohol pads and chlorhexidine swab
9. Body marking pen

## Procedural Tips

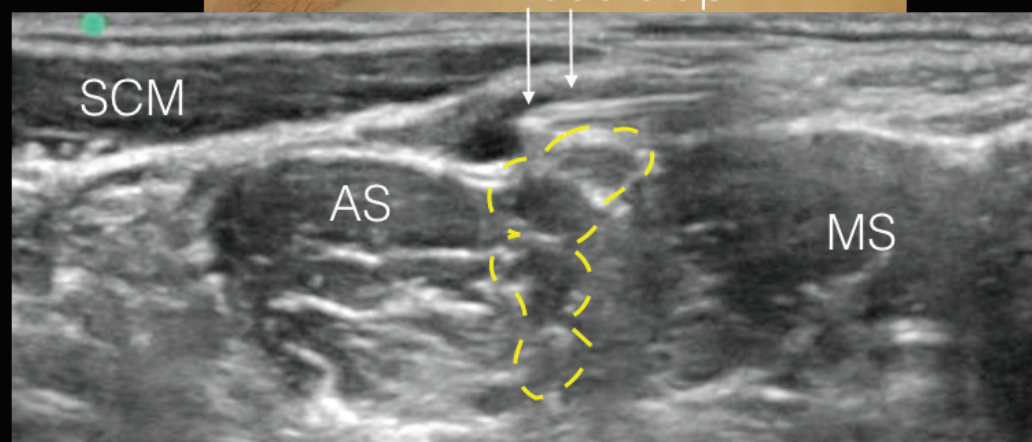
1. Consent should always be obtained before performing a UGNB.



**FIGURE 1 (ABOVE):** The various labeled components are placed in a specimen bag so that clinicians can quickly grab supplies for a UGNB. Anesthetic is ordered by the clinician and brought to the bedside by the nurse.

**FIGURE 2 (LEFT):** For low-volume blocks (less than 10 cc), we recommend a single-operator technique. A two-operator technique (see Figure 3) can be used if the operator is a novice and would benefit from normal saline (NS) hydrodissection to ensure proper needle visualization. The operator is using an in-plane technique to perform an interscalene brachial plexus block. SCM: sternocleidomastoid muscle; AS: anterior scalene muscle; MS: middle scalene muscle; yellow dashed line: brachial plexus at the level of the interscalene muscles.

**FIGURE 3 (OPPOSITE PAGE):** For higher-volume blocks (more than 10 cc), we recommend a two-operator technique. The operator is using an in-plane technique to perform a distal sciatic nerve block in the popliteal fossa. A) NS flush is attached to the IV tubing and block needle. Fluid is flushed to remove air from the circuit. B) After scanning the area and placing a skin wheal (with the insulin or TB syringe), hydrodissect the tissue with NS gently until the needle tip is in the ideal location for anesthetic placement. Remove the NS flush and attach the 10-cc syringe of local anesthetic. Inject slowly (aspirating after every 1-2 cc to ensure lack of vascular puncture) with clear needle tip visualization.





2. A discussion with consulting services (orthopedics, general surgery, etc.) and determination of which injuries are (and are not) ideal for UGNBs should be performed in advance of performing the procedure.
3. Scan the patient to determine the location of the nerve. Position the patient and

ultrasound screen to allow for optimal ergonomics. We recommend that the ultrasound screen and site of injection be in direct view of the clinician so that minimal head movement is needed to perform the block. In most cases, this would mean that the ultrasound system is contralateral to

the site of injury.

4. The patient should be placed on a cardiac monitor for the duration of the block and for about 10 to 15 minutes after completion.
5. Once the ideal location and needle pathway has been determined, a skin wheal should be placed at the expected site of

needle entry.

6. For a low-volume block (10 cc or less), a single operator technique can be used (needle on syringe), as shown in Figure 2.
7. For a higher-volume block (10–20 cc anesthetic), we prefer a two-operator technique (hand on needle), as shown in Figure 3.

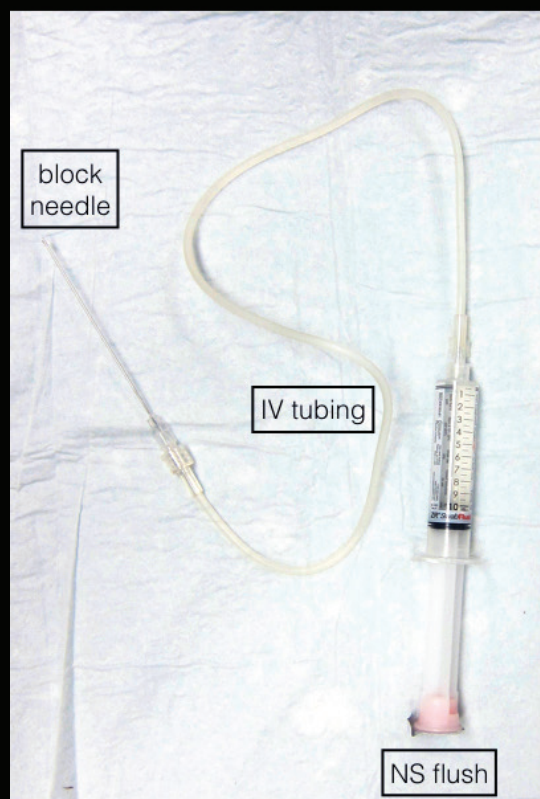
### Conclusion

Putting systems in place that allow clinicians to optimize clinical care is crucial to maintaining best practices and efficient flow in the emergency department. Simple design solutions reduce barriers, increase compliance, and ideally improve patient care. Our simple block bag, which is composed of common items found in most emergency departments, may increase the number of UGNBs performed in your department. With more emergency departments attempting to reduce overreliance on opioids for acute pain management, this design innovation can aid in facilitating the integration of UGNBs into clinical care. ➕

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A



B



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# Think ELIQUIS–

## For your appropriate patients with NVAF or DVT/PE



### 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)

### IMPORTANT SAFETY INFORMATION

#### **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. 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



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DVT: deep vein thrombosis; NVAf: nonvalvular atrial fibrillation; PE: pulmonary embolism.

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS (cont'd)

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

- **Combined P-gp and Strong CYP3A4 Inhibitors:** Inhibitors of P-glycoprotein (P-gp) and cytochrome P450 3A4 (CYP3A4) increase exposure to apixaban and increase the risk of

### IMPORTANT SAFETY INFORMATION

#### DRUG INTERACTIONS (cont'd)

bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, or ritonavir). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with combined P-gp and strong CYP3A4 inhibitors.

##### *Clarithromycin*

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

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

#### PREGNANCY 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<sup>®</sup> 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.

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Bristol-Myers Squibb





ELIQUIS® (apixaban) tablets, for oral use

Rx 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, or bowel or bladder dysfunction). If neurological compromise is noted, urgent diagnosis and treatment is necessary. Prior to neuraxial intervention the physician should consider the potential benefit versus the risk in anticoagulated patients or in patients to be anticoagulated for thromboprophylaxis.

Patients with Prosthetic Heart Valves

The safety and efficacy of ELIQUIS (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.

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

Subgroup	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)	163 / 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 <sub>2</sub> 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 prespecified, if not the groupings. The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be over-interpreted.

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

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

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

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

Other Adverse Reactions

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

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

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

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

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

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

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

\* All bleeding criteria included surgical site bleeding.

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

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

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

¶ CRNM = clinically relevant nonmajor.



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

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

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

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

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

*Vascular disorders:* hypotension (including procedural hypotension)

*Respiratory, thoracic, and mediastinal disorders:* epistaxis

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

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

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

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

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

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

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

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

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

AMPLIFY Study

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

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

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

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

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

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

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

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

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

AMPLIFY-EXT Study

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

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

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

	ELIQUIS (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.

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

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

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

*Clarithromycin*

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

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

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

#### Anticoagulants and Antiplatelet Agents

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

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

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

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

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

##### Renal Impairment

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

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

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

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

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

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

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

##### Hepatic Impairment

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

#### OVERDOSAGE

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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**DR. DAHLE** is the author of *The White Coat Investor: A Doctor's Guide to Personal Finance and Investing* and blogs at <http://whitecoatinvestor.com>. He is not a licensed financial adviser, accountant, or attorney and recommends you consult with your own advisers prior to acting on any information you read here.

# Retirement Accounts for Independent Contractors

Make the most of your retirement dollars

by JAMES M. DAHLE, MD, FACEP

**Q. I am starting a new position as an independent contractor. My former employer had a 401(k). I want to continue to save for retirement, but I'm not sure how to do it without that 401(k). How can an independent contractor continue to save for retirement?**

**A.** Good news! There are many advantages of being self-employed when it comes to saving for retirement. As an independent contractor (ie, paid on a 1099 instead of a W-2), you are considered to be running your own business. Just like your employer gets to pick the benefits it offers, you now get to choose (and pay for) your own benefits. While you will no longer get a 401(k) match from the employer, you are also no longer limited by the employer's contribution limits, plan fees, or often poor investment options.

The mainstay of retirement saving for an independent contractor should be an individual 401(k), sometimes called a solo 401(k). These plans allow you to make an \$18,500 "employee" contribution (\$24,500 if older than age 50) and then make "employer" contributions of 20 percent of your net income up to the plan contribution limit of \$55,000. While you only get one employee contribution no matter how many jobs or 401(k)s you have, the \$55,000 limit is a per-plan limit. That means if you have an employee job with a 401(k) and do some work as an independent contractor, you can still open an individual 401(k) and just contribute the employer contribution to it.

Solid individual 401(k) plans can be easily opened at any of the large mutual fund or brokerage companies such as Vanguard, Fidelity, Charles Schwab, eTrade, or TD Ameritrade. While all of these plans are good plans with diversified, low-cost investments available, some plans offer features that others do not. For example, Vanguard doesn't allow IRAs to be rolled into their plan. Fidelity and Charles Schwab don't offer a Roth 401(k) option. eTrade and TD Ameritrade charge (admittedly low) commissions to buy and sell many mutual funds and exchange-traded funds.

Be sure the plan you choose has the features you need, such as Roth contributions, IRA rollovers, or 401(k) loans. You will also need to get an Employee Identification Number from the IRS to open an individual 401(k), but this is free and only takes a few minutes online. You do not need to form an LLC or corporation to use an individual 401(k). By virtue of receiving a 1099, you are automatically a sole proprietor, and that is enough to start a plan.

Some doctors, and even their accountants, consider using the slightly simpler SEP-

IRA instead, which has the same \$55,000 total contribution limit. However, thanks to the employee contribution feature of an individual 401(k), you can hit the maximum contribution of \$55,000 with a much lower income. In addition, using the 401(k) instead of a SEP-IRA allows you to do a backdoor Roth IRA since the balance of a SEP-IRA is included in the required pro-rata calculation (explained below) but the balance of a 401(k) is not.

Whether you are employed or self-employed, you can also contribute to a personal backdoor (indirect) Roth IRA and, if married and you have sufficient income, a spousal backdoor Roth IRA. These became permitted in 2010 when Congress began allowing high-earners to do Roth conversions. Instead of a direct Roth IRA contribution, you first contribute to a traditional IRA, which is not deductible due to your high income, and then move that money to a Roth IRA.

Since you never received a deduction, there is no tax cost for the conversion, and the end effect is the same as if you had contributed directly to a Roth IRA. Annual contribution limits are \$5,500 if younger than age

50 and \$6,500 if older than age 50. Be aware that due to the pro-rata rule, the conversion is only tax-free if you have no balance in a SEP-IRA, SIMPLE IRA, or traditional IRA on Dec. 31 of the year of the conversion. If you do have one of those accounts, you may wish to roll it into a 401(k), such as your new individual 401(k), to facilitate future backdoor Roth IRAs.

A health savings account (HSA) can also function as a stealth IRA and is an excellent account to use for retirement savings. Not only does it give you an upfront tax break and tax-protected growth like a 401(k), it also provides for tax-free withdrawals if the money is used for health care. This makes it the most tax-advantaged account available to the investor. These funds can be invested in mutual funds like a typical retirement account. The contribution limit for 2018 is \$3,450 for individuals and \$6,900 for families. If you end up not needing it for health care, you can withdraw the money penalty-free after age 65. However, you would need to pay taxes on that withdrawal, just like a 401(k).

Another option for independent contrac-

tors, although more rarely used, is a personal defined benefit/cash balance plan. This retirement account is best thought of as an extra IRA masquerading as a pension. It has higher expenses than an individual 401(k) due to a requirement for annual actuarial calculations and typically is not invested as aggressively. However, the contribution limits can be quite high, particularly for physicians in their 50s or 60s. It is an option worth exploring for someone interested in saving large amounts for retirement.

Investing in a nonqualified, taxable brokerage or mutual fund account for retirement is also an option. While the tax and asset protection benefits are much more limited, the additional flexibility can be a useful feature. Alternative investments, such as real estate, are also much easier to invest in outside of retirement accounts.

As you can see, an independent contractor has plenty of excellent options to use for retirement savings. While the main pillar should be an individual 401(k), a Roth IRA, HSA, cash balance plan, and taxable account provide additional options. ☺



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DOGMA FEELS  
RIGHT  
UNTIL YOU STEP  
IN IT

SKEPTICS' GUIDE TO  
EMERGENCY MEDICINE



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Tranexamic Acid for  
Postpartum Hemorrhage

Can TXA decrease maternal mortality?

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

The Case

A 27-year-old primiparous woman arrives at the emergency department after a prolonged labor at home; she is fully dilated and crowning. She has no significant health history and is only taking prenatal vitamins.

Obstetrics and pediatrics are called stat, but the patient rapidly delivers in the emergency department—a healthy 6-pound, 8-ounce girl with only a first-degree laceration. Pediatrics arrives quickly and provides neonatal assessment. Obstetrics, however, is busy doing an emergency cesarean delivery.

Shortly after the delivery of the placenta, the patient has brisk vaginal bleeding. Her vital signs are normal and stable. Lab tests are requested, and the nurse has already given oxytocin 10 mg IM and started an IV. Knowing that uterine atony is the number-one cause of postpartum hemorrhage (PPH), you start performing fundal massage. While waiting for obstetrics to show up, you think about drugs other than oxytocin that could be used for PPH (methylergonovine, misoprostol, and prostaglandins), and you remember reading something about tranexamic acid (TXA).

Background

TXA is a synthetic analog of the amino acid lysine and acts as an antifibrinolytic agent. It binds to lysine receptor sites on plasminogen, blocking its action on fibrin. The ultimate result is that the fibrin matrix structure is maintained and bleeding is reduced.

PPH is defined by the World Health Organization as “a cumulative blood loss of greater than or equal to 1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process.” PPH is one of the leading causes of maternal mortality around the world.<sup>1</sup>

The American College of Obstetricians and Gynecologists published guidelines for the management of PPH, including the use of TXA. It gives TXA a Level B recommendation: “Given the mortality reduction findings, tranexamic acid should be considered in the setting of obstetric hemorrhage when initial medical therapy fails.”<sup>2</sup>

Clinical Question

In women with PPH, does TXA improve survival?

Reference

WOAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised,

Table 1: Key Results from the WOMAN Trial

	TXA	PLACEBO	RELATIVE RISK
All-Cause Mortality or Hysterectomy	5.3%	5.5%	0.97; 95% CI, 0.87–1.09; <i>P</i> = 0.65
All-Cause Mortality	2.3%	2.6%	0.88; 95% CI, 0.74–1.05; <i>P</i> = 0.16
Hysterectomy	3.6%	3.5%	1.02; 95% CI, 0.88–1.07; <i>P</i> = 0.84
Mortality Due to Bleeding	1.5%	1.9%	0.81; 95% CI, 0.65–1.00; <i>P</i> = 0.045
Adjusted Mortality			0.78; 95% CI, 0.62–0.98; <i>P</i> = 0.03
Mortality Due to Bleeding Treated Less Than Three Hours	1.2%	1.7%	0.69; 95% CI, 0.52–0.91; <i>P</i> = 0.008

- double-blind, placebo-controlled trial. *Lancet*. 2017;389(10084):2105-2116.
- **Population:** Women older than 16 years with a diagnosis of PPH after vaginal birth (>500 mL blood loss) or cesarean delivery (>1,000 mL blood loss) or blood loss causing hemodynamic instability and the clinician was uncertain whether to use TXA.
    - » **Exclusions:** If the clinician felt that TXA would clearly be or not be beneficial.
  - **Intervention:** 1 g TXA slowly infused with the optional second 1 g dose if bleeding continued for 30 minutes or more or stopped and restarted within 24 hours.
  - **Comparison:** Placebo.
  - **Outcome:**
    - » **Primary:** All-cause mortality or hysterectomy within 42 days.
    - » **Secondary:** Mortality due to bleeding, thromboembolic events, surgical interventions, other complications, adverse events, quality-of-life measurements, and thromboembolic events in breast-fed babies.

Authors' Conclusions

“Tranexamic acid reduces death due to bleeding in women with post-partum haemorrhage with no adverse effects. When used as a treatment for postpartum haemorrhage, tranexamic acid should be given as soon as possible after bleeding onset.”

Key Results

They enrolled 20,021 women in the trial. Maternal death occurred in 2.4 percent of all women within 24 hours, and 9 percent of the deaths were within one hour after randomization.

For the primary outcome of all-cause mortality or hysterectomy, there was not a statistical difference (see Table 1).

EBM Commentary

**1) Inclusion Criteria:** The inclusion criteria in this study were vague. Clinical diagnosis of

PPH was based on a subjective estimation of blood loss. Hemodynamic instability was not defined, and the clinician had to be unsure whether to use TXA.

**2) Power Calculation:** The trial was originally powered for a 25 percent relative reduction (1 percent absolute) in all-cause mortality or hysterectomy. After the trial started, they figured out the decision to do a hysterectomy usually was made at the same time as randomization. Therefore, they recalculated the sample size for a 25 percent relative reduction (0.75 percent absolute) in all-cause mortality. As a result, the sample size increased from 15,000 to 20,000.

Trials are often criticized for being underpowered but not for being overpowered. Trials are usually designed to find a difference between two things, and if you have a large enough trial, you will find a statistical difference because no two things are identical. Despite having more than 20,000 women, they did not find a difference in all-cause mortality.

**3) Subgroup Analyses:** A number of subgroup analyses for the primary composite outcome were considered a priori. The only statistical difference observed was if TXA was given in less than three hours postpartum. This result should be viewed with skepticism because subgroup analyses are considered hypothesis-generating and should not be over-interpreted.

**4) Fragility of the Study:** The fragility index is a way to measure the robustness of the results obtained.<sup>3</sup> It is calculated by converting one patient (treatment or control) from a “non-event” to an “event.” In this case, how many women would have to have a different outcome for the study not to be statistically significant (*P* ≥ 0.05)?

This was a negative trial for the primary outcome of all-cause mortality or hysterectomy. However, there was a statistical difference in death due to bleeding. But the fragility index of this secondary outcome was zero, which emphasizes the lack of robustness of

the WOMAN trial.<sup>4</sup>

The fragility index for the subgroup analysis of the secondary outcome of bleeding mortality treated in less than three hours is nine. This means if nine women switched from an event to a non-event in either group, the results of this hypothesis-generating result would no longer be considered statistically significant.

**5) External Validity:** The vast majority of these patients came from developing countries. It is unclear what resources their health care system had to address PPH compared to the United States and if these results could be applied to our health care system.

Bottom Line

This study does not provide good evidence that TXA improves survival in women with PPH.

Case Resolution

The fundal massage and oxytocin seem to work, and the bleeding slows. The patient is still hemodynamically stable when the obstetrical team arrives. She is transferred to the postpartum unit for further management and does not receive TXA.

*Thank you to Nick Papalia, MD, who is currently completing his third year of obstetrics and gynecology residency at the University of Calgary in Alberta, for his help with this review.*

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

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

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



## Are Pediatric Lungs Just Little Adult Lungs?

### Question 1: For pediatric asthma, does albuterol and ipratropium (combined) show benefit over albuterol alone?

Depending on where you practice, inhaled short-acting beta-agonists (SABAs) such as albuterol/salbutamol combined with an anticholinergic such as ipratropium go by numerous names (Duoneb, Combivent, A&A, Brevia, Duolin, etc).

They come in both nebulized and metered-dosed inhaler (MDI) formulations.

In kids with asthma exacerbations, practitioners may or may not supplement SABAs with anticholinergic medication (eg, ipratropium bromide). Does some-



thing this simple potentially make a difference?

A 2013 Cochrane systematic review and meta-analysis by Griffiths and Ducharme explored, in particular, whether the addition of anticholinergics to SABAs—when compared to SABAs alone—reduced hospital admissions when treating initial asthma exacerbations.<sup>1</sup> This meta-analysis included 19 studies (N = 2,497 total patients), and ipratropium bromide was the anticholinergic of choice in 18 of these 19 randomized studies. Sixteen of the 19 studies involved multiple doses (predominantly two or three doses), and the patients’ ages ranged from 18 months to 18 years. In regard to the primary outcome of hospital admission, the risk ratio of SABA/anticholinergic to SABA alone was 0.73 (95% CI, 0.63–0.85), suggesting that the addition of an anticholinergic (eg, ipratropium) to SABA (eg, albuterol) decreases hospital admissions. The number needed to treat (NNT) for beneficial effect was 16, and most children treated demonstrated moderate to severe asthma exacerbations at presentation. A previous systematic review by Rowe et al had found similar results regarding hospital admissions.<sup>2</sup>

Since that 2013 Cochrane review, a separate randomized controlled trial by Wyatt et al compared a multi-dose regimen of SABA (salbutamol) plus ipratropium bromide to SABA alone.<sup>3</sup> All patients received corticosteroids, and the salbutamol and ipratropium were delivered only via MDI. The study included 347 children with moderate

asthma exacerbations. The admission rates for these asthma exacerbation treatments demonstrated no significant difference and were 70 percent and 64 percent, respectively, suggesting that ipratropium did not decrease admission rates in this population. One major limitation of this study, though, included missed patients, as the authors missed nearly 75 percent of eligible patients during the enrollment period. With this noted bias, it is difficult to determine the significance of their findings in the overall clinical picture.

### Summary

The addition of anticholinergics (eg, ipratropium bromide) to SABAs (eg albuterol) in the treatment of acute asthma exacerbations in children appears to decrease the risk of admission. Most of these studies incorporate multiple doses of anticholinergic medication. ⊕

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## Cute as a Button?

### Question 2: In children with ingested button batteries in the stomach, which patients are at the highest risk for complications?

In September 2016, the National Capital Poison Center revised its treatment guideline and algorithm for button battery ingestion. While in the past it was not uncommon to endoscopically remove button batteries located in the stomach, the National Battery Ingestion Hotline (NBIH) triage and treatment guideline suggests an observation/reevaluation approach for button batteries in the stomach in children who are asymptomatic, particularly if the patient is older than 12 years. While endo-

scopic removal of esophageal button batteries is standard—even in asymptomatic patients—treatment of the asymptomatic button battery in the stomach may be a little more tricky, and the data are rather limited.

A three-year retrospective study by Lee et al described 12 button battery ingestions with one in the esophagus, five in the stomach, and six distal to the duodenum.<sup>1</sup> The authors report that

“none showed any symptoms after the ingestion” and mention that batteries greater than 1.5 cm in diameter or 3V batteries—compared to 1.5V batteries—appear to be a higher risk for moderate to severe complications. While the authors do mention an increase in case studies demonstrating complications in younger children, they state that their study did not find a correlation between age and risk of complications.<sup>2,3</sup>

Another four-year retrospective study by Rios et al described 25 button battery ingestions retrieved from both the esophagus (n = 10) and stomach (n = 12).<sup>4</sup> Three endoscopic retrievals were unsuccessful secondary to migration of the battery distal to

the duodenum. Eight out of 10 (80 percent) of the esophageal-lodged batteries had symptoms, while 11 out of 15 (73 percent) of the stomach or distal battery locations were asymptomatic. While there were 12 gastric-located button batteries—which were predominantly asymptomatic—six out of 12 (50 percent) had mucosal damage, with a trend of younger age (median 1 year, 10 months) when compared to those children without mucosal lesions (median 3 years, 1 month;  $P = 0.23$ ). There was no significance in time of ingestion ( $P = 0.75$ ) in cases of gastric button batteries with and without mucosal injury. This may suggest that practitioners have a higher level of concern for asymptomatic younger children even when the battery is localized to the stomach.

### Summary

The National Capital Poison Center has an algorithm to help guide treatment of button battery ingestions. While asymptomatic ingestions may be observed and reevaluated, younger

patients, higher voltage (ie, 3V), and diameters greater than 1.5 cm appear to contribute to an increased risk of complication, even when localized to the stomach. ⊕

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# CODING WIZARD



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

## WHAT YOU NEED TO KNOW WHEN WORKING WITH ADVANCED PRACTICE PROVIDERS

by MICHAEL LEMANSKI, MD, FACEP, FAAFP

**Question:** How should examinations performed by advanced practice providers (APPs) be documented?

**Answer:** Physician assistants (PAs) and advanced practice registered nurses (APRNs) are commonly referred to as APPs. PAs must always work in collaboration with a supervising/participating physician. In contrast, many states allow APRNs to practice independently, while others impose limited restrictions. That being said, when working in an emergency

department, they are generally incorporated into the workforce in the same way. Three levels of oversight can occur. First, depending on state licensing, patients may be seen by an APP, and this may or may not require review or co-signature by the physician. Second, patient care or tests results may be reviewed and discussed with the physician. In both of these cases, the visit would generally be billed under the APP's provider number and paid at varying percentages of the physician fee schedule based on the payer. If the physician documents they personally participated in the evaluation of the patient (face-to-face time required), then the visit may be attributed to the physician by some payers using the Centers for Medicare and Medicaid Services shared services rule. It is important to note that payer approaches to reimbursement of claims submitted for services rendered by APPs are variable.

See the ACEP FAQ on mid-level providers at [www.acep.org/administration/reimbursement/reimbursement-faqs/medicare-mid-level-provider-faq](http://www.acep.org/administration/reimbursement/reimbursement-faqs/medicare-mid-level-provider-faq) for further details and suggested wording of attestation statements. ➔

Brought to you by the ACEP Coding and Nomenclature Committee.

**DR. LEMANSKI** is associate professor of emergency medicine at the University of Massachusetts School of Medicine–Baystate in Springfield.

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risk for adverse outcomes as determined by Pulmonary Embolism Severity Index (PESI), simplified PESI (sPESI), or the Hestia criteria may be safely discharged from the emergency department on anticoagulation, with close outpatient follow-up.

**QUESTION 4.** In adult patients diagnosed with acute lower-extremity DVT who are discharged from the emergency department, is treatment with a NOAC safe and effective compared with treatment with

**low-molecular-weight heparin (LMWH) and a vitamin K antagonist (VKA)?**

**Patient Management Recommendations**

- **Level A recommendations:** None specified.
- **Level B recommendations:** In selected patients diagnosed with acute DVT, a NOAC may be used as a safe and effective treatment alternative to LMWH/VKA.
- **Level C recommendations:** Selected patients with acute DVT may be safely treated with a NOAC and directly discharged from

the emergency department.

In summary, the evaluation and management of patients with suspected VTE in the emergency department is rapidly evolving and increasingly nuanced. Newer clinical algorithms using PERC and age-adjusted D-dimer may improve the efficiency and effectiveness of evaluations. Similarly, advances in the understanding of whom to treat, in which setting and with what optimal therapy can improve patient-centered outcomes. +

**Reference**

1. Wolf SJ, Hahn SA, Nentwich LM, et al. Clinical policy: critical issues in the evaluation and management of adult patients presenting to the emergency department with suspected acute venous thromboembolic disease. *Ann Emerg Med.* 2018;71(5):e59-e109.

**DR. WOLF** is co-chair of the ACEP Clinical Policies Committee, director of service for emergency medicine at Denver Health Medical Center, and vice chair within the department of emergency medicine at the University of Colorado School of Medicine in Aurora.

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The talk by Thom Mayer, MD, FACEP, FAAP, medical director of the NFL Players Association, on “Rewarding Champions, Corraling Stragglers” took on the tough issue of managing expectations and performance of others—never an easy task. ACEP Board member Aisha Liferidge, MD, MPH, FACEP, led a session on “Glass or Sky: Ensuring Women Lead.” Presentations on developing personal and professional life balance and an update on the changes coming to Maintenance of Certification by ABEM President Terry Kowalenko, MD, FACEP, closed out the

morning program. The afternoon session was kicked off by Amy Walter, national editor of the Cook Political Report, who provided an election 2018 update. The rest of the afternoon was filled with an update by ACEP staff and others on the issues that are shaping how we practice emergency medicine. The afternoon format also allowed participants to attend smaller breakout sessions. Topics and issues covered in the program included:

- “Federal Pay for Performance Programs for EM: MIPS Tips”
- “What’s Ahead for Entitlement Reform”

- “Public Policy Town Hall: Emergency Preparedness,” including special guest speaker Robert Kadlec, MD, assistant secretary for Preparedness and Response for the Department of Health and Human Services
- “How to Change Perceptions of Emergency Care”
- “To the Defense of Our Patients: State Level Responses to Insurer Attacks on the Prudent Layperson”
- “Savvy Social Media and Storytelling for Advocacy”

### Our Day on the Hill

Each year, the highlight of the conference is always our day on the Hill and this year was no exception. Before heading up to Capitol Hill, there were presentations by Sen. Bill Cassidy (R-LA) and Rep. Kyrsten Sinema (D-AZ), who is running for the U.S. Senate. Senator Cassidy is a gastroenterologist who’s understanding of being a physician in a rapidly changing health care system provides him with a perspective that most members

CONTINUED on page 28

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of Congress will never have.

Rep. Sinema shared her very personal story of being homeless as a child and experiencing the frustration of being without health care access after her father was laid off from his job. Despite the disadvantages she faced growing up, Rep. Sinema has demonstrated incredible fortitude and a “never say it can’t be done” attitude throughout her personal and political careers. She is truly a personification of the American dream, showing that with hard work and passion, everyone has the opportunity to be successful in this country, regardless of any challenges you face. In addition to being both a former state representative and now U.S. representative, she has also earned her BA, MSW, PhD, JD, and MBA degrees—a truly inspiring and amazing person!

Our day on the Hill was very successful. Focusing on issues of opioid legislation being considered by Congress, reauthorization of the Pandemic and All-Hazards Preparedness Act, and the ongoing challenge of national drug shortages, ACEP members were able to have positive and productive conversations with members of Congress and key policy staffers, advocating for real-world solutions to health care system issues affecting our patients and their constituents.

#### The Solutions Forum: Real-World Approaches to Real-World Issues

With a new, more focused format developed by ACEP President Paul Kivela, MD, MBA, FACEP, Wednesday’s Solutions Forum gave attendees the opportunity to do a deep dive on the issues of opioids and end-of-life care. The day was kicked off by special guest speaker Vice Admiral Jerome M. Adams, MD, MPH, the U.S. Surgeon General who discussed efforts by the federal government to address the opioid epidemic and emergency medicine’s role in these efforts.

Following presentations on putting prevention and treatment into practice, the session was closed by an update from Debra Houry, MD, MPH, director of the National Center for Injury Prevention and Control, on additional efforts to study the opioid issue and identify best practices for care. The final portion of the conference was a two-part session on end-of-life care and implications for the practice of emergency medicine.

#### Be There Next Year

LAC is a great opportunity for you to become more educated on the political and policy issues that affect how we care for patients at the bedside every day. It is a tremendous opportunity to have your voice heard directly by members of Congress and other federal policymakers so that they can hear directly from those of us who serve as the health care safety net for the nation on a 24-7-365 basis.

Make sure that you come to the next LAC meeting May 5–8, 2019, in Washington, D.C., to be part of the voice of emergency medicine on Capitol Hill! ➔



**DR. CIRILLO** is director of health policy and legislative advocacy for US Acute Care Solutions in Canton, Ohio, and past Chair of the ACEP Federal Government Affairs Committee.

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