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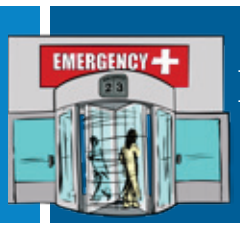

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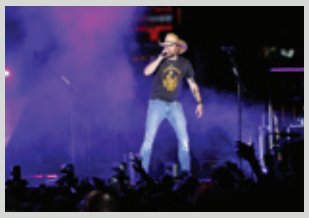

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ANTHEM

ACEP STANDS UP FOR PRUDENT LAYPERSON

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For more clinical stories and practice trends, plus commentary and opinion pieces, go to:
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ACEP'S FIRST GENTLEMAN

EP PILLARS OF SUPPORT
Honoring the people who support us

Matty Parker, husband of ACEP Past President Dr. Rebecca Parker, on standing beside an ACEP leader

The specialty of emergency medicine is the safety net for our nation's health care system. What—or more important, who—fortifies that safety net? Emergency medicine is filled with gratification but includes just as many challenges. Those in our lives serve as the pillars of support for us as emergency physicians, the unseen foundation that allows for our return to the trenches day in and day out. This column will highlight the pillars of support in many emergency physicians' lives. Thank you to those who support us.

To start the series, *ACEP Now* Medical Editor in Chief Kevin Klauer,

CONTINUED *on page 14*

SHINING A LIGHT ON HUMAN TRAFFICKING

FBI expert outlines the challenges of helping trafficking victims

Human trafficking is an incredibly challenging problem to try to solve because it hides in the shadows. Not only are traffickers motivated to keep their activities under the radar of law enforcement, often victims are, too. Is that young woman with the broken arm who was brought to your emergency department by a male "friend" a victim of trafficking? What about the shy young man with the black eye and sexually transmitted infection? And if they are, what can you do about it?

Cynthia M. Deitle, JD, spent two decades with the FBI's Civil Rights program, which includes a program to combat human trafficking. Her experience ranged from working on individual trafficking cases to being chief of the Civil Rights unit, giving her a broad understanding of the trafficking problem in the United States and the bureau's efforts to combat it. She recently sat down with *ACEP Now* Medical Editor-in-Chief Kevin Klauer, DO, EJD, FACEP, to talk about some of the challenges she faced while try-

CONTINUED *on page 12*

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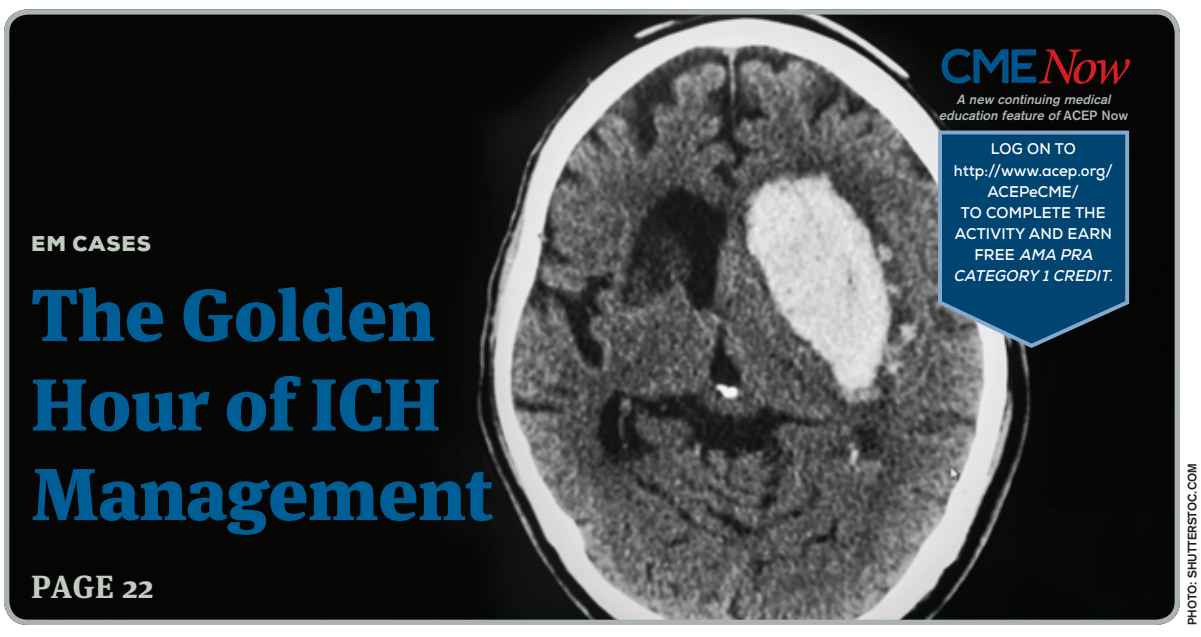

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NOW AVAILABLE

THE ELIQUIS STARTER PACK
Designed to support DVT/PE treatment initiation

Not actual size.

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

Eliquis®
(apixaban) tablets

THE ELIQUIS STARTER PACK OFFERS YOUR PATIENTS:

- Their first **30-day supply** of ELIQUIS treatment complete with daily dosing instructions
- **2 separate wallets** per box
  - **Wallet 1** contains ELIQUIS treatment for days 1-14 along with directions on how to step down dosing after week 1
  - **Wallet 2** contains ELIQUIS treatment for days 15-30
- **Refill reminder:** prompts DVT/PE patients to refill their ELIQUIS prescription

No cost to eligible patients when using the ELIQUIS **Free Trial Offer***

For more information, speak to your ELIQUIS Sales Representative or visit hcp.eliquis.com

DVT=deep vein thrombosis; PE=pulmonary embolism.

*Eligibility Requirements and Terms of Use apply.

WARNINGS AND PRECAUTIONS (cont'd)

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

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

ADVERSE REACTIONS

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

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

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

DRUG INTERACTIONS

- **Strong Dual Inhibitors of CYP3A4 and P-gp:** Inhibitors of cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or

DRUG INTERACTIONS (cont'd)

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

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

PREGNANCY CATEGORY B

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

INDICATIONS

ELIQUIS is indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE following initial therapy.

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

432US1703762-02-01 12/17

Bristol-Myers Squibb Pfizer

ELIQUIS® (apixaban) tablets, for oral use

℞ ONLY

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

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

(B) SPINAL/EPIDURAL HEMATOMA

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

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

(B) SPINAL/EPIDURAL HEMATOMA

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

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

[see Warnings and Precautions]

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

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

INDICATIONS AND USAGE

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

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

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

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

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

DOSAGE AND ADMINISTRATION (Selected information)

Temporary Interruption for Surgery and Other Interventions

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

CONTRAINDICATIONS

ELIQUIS is contraindicated in patients with the following conditions:

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

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation

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

Bleeding

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

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

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

Reversal of Anticoagulant Effect

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

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

Spinal/Epidural Anesthesia or Puncture

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

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

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

Patients with Prosthetic Heart Valves

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

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

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

ADVERSE REACTIONS

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

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

Clinical Trials Experience

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

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

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

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

Bleeding in Patients with Nonvalvular Atrial Fibrillation in ARISTOTLE and AVERROES

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

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

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

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

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

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

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

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

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

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

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

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

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

Other Adverse Reactions

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

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

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

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

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

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

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

* All bleeding criteria included surgical site bleeding.

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

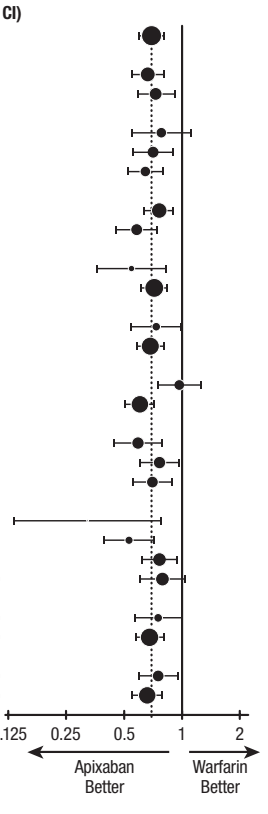
‡ Includes 5 subjects with major bleeding events that occurred before the first dose of apixaban (administered 12 to 24 hours post surgery).

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

¶ CRNM = clinically relevant nonmajor.

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

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



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

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

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

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

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

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

Vascular disorders: hypotension (including procedural hypotension)

Respiratory, thoracic, and mediastinal disorders: epistaxis

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

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

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

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

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

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

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

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

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

AMPLIFY Study

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

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

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

Table 5: Bleeding Results in the AMPLIFY Study

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

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

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

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

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

AMPLIFY-EXT Study

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

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

Table 7: Bleeding Results in the AMPLIFY-EXT Study

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

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

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

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

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

Other Adverse Reactions

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

Blood and lymphatic system disorders: hemorrhagic anemia

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

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

Musculoskeletal and connective tissue disorders: muscle hemorrhage

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

Vascular disorders: hemorrhage

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

Eye disorders: conjunctival hemorrhage, retinal hemorrhage, eye hemorrhage

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

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

DRUG INTERACTIONS

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

Strong Dual Inhibitors of CYP3A4 and P-gp

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

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

Strong Dual Inducers of CYP3A4 and P-gp

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

Anticoagulants and Antiplatelet Agents

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

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

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

Labor and Delivery

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

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

Nursing Mothers

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

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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

Renal Impairment

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

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

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

Patients with End-Stage Renal Disease on Dialysis

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

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

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

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

Hepatic Impairment

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

OVERDOSAGE

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

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

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

PATIENT COUNSELING INFORMATION

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

Advise patients of the following:

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

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NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP


ACEP

David McKenzie (left) with Kenneth Brin, MD, PhD, chair of the CPT Editorial Panel

ACEP Staff Takes Home Award

During the recent American Medical (AMA)Association CPT Advisors meeting awards presentation, ACEP Reimbursement Director David McKenzie was honored with the Specialty Society Staff Excellence Award. This is the highest award available for specialty society staff serving the CPT process and the nomination comes from AMA CPT staff. Mr. McKenzie was recognized for his excellent assistance in developing code change applications, education on CPT codes, and support of members and staff. Mr. McKenzie won the award previously in 1998, and in 2015, he won the Excellence in Education Award.


ACEP

ACEP President Dr. Paul Kivela (left) with Sen. Bill Cassidy.

ACEP on the Hill

ACEP President Paul Kivela, MD, MBA, FACEP, recently met with Sen. Bill Cassidy, MD (R-LA), to discuss S. 1530, the Medicare Choices Empowerment and Protection Act, regarding psychiatric boarding in the emergency department, on which Sen. Cassidy is the lead Republican. Also discussed was ACEP's interest in the Senate's reauthorization of the Pandemic and All Hazards Preparedness Act and out-of-network billing for emergency services.

During the meeting, Sen. Cassidy agreed to address ACEP members during the 2018 Leadership and Advocacy Conference to provide an update on the latest health care initiatives being considered by Congress. He will be speaking at 8:45 a.m. on Tuesday, May 22.

And in the Statehouse

In February, the Utah State Senate recognized ACEP's 50th anniversary by honoring members of the Utah ACEP Board.


ACEP

From left: John Dayton, MD, FACEP, Utah ACEP President; Matthew Hollifield, MD, and Kathleen Lawliss, MD, FACEP, Utah ACEP Board members; and James Antinori, MD, FACEP, past Utah ACEP President, on the floor of the Utah State Senate.

Collaboration with ACS

For the first time, emergency physicians have been invited to formally participate as members of the Criteria Revision Team for the American College of Surgeons (ACS). ACEP Board of Directors members Debra Perina, MD, FACEP, and Christopher Kang, MD, FACEP, will represent emergency medicine to review and revise the criteria for a chapter in the "Orange Book," also known as *Resources for Optimal Care of the Injured Patient 2014*.

Making Change Happen for You

ACEP leaders are always working to protect and improve your practice environment. Here's some of what the ACEP leadership has done for you lately:

Members of ACEP and ACEP staff met with the U.S. Department of Veterans Affairs (VA) to discuss care of geriatric patients in VA emergency departments. Among the issues discussed were ways to identify veterans who present to our emergency departments—especially those with mental health issues—and connect them with VA outpatient resources. Also discussed was the potential participation of VA hospitals in the ACEP Geriatric ED Accreditation program.

ACEP Board of Directors member Aisha Liferidge, MD, FACEP, along with senior ACEP staff, attended a two-day conference with the National Institute on Drug Abuse on Jan. 26 and 27, 2018, to discuss potential treatment of patients with opioid addiction. ACEP member Gail D'Onofrio, MD, FACEP, led the meeting. Dr. D'Onofrio is the chair of emergency medicine at Yale School of Medicine in New Haven, Connecticut, and is a well-respected researcher in substance abuse disorders.

On Jan. 24, 2018, ACEP President Paul Kivela, MD, MBA, FACEP, and members of ACEP's senior staff, Loren Rives, Laura Wooster, and Sandra Schneider, MD, FACEP, met with the Centers for Medicare and Medicaid Services (CMS) to discuss mental health and sedation. CMS was very supportive of emergency physicians' ability to screen all patients with emergency conditions, including those with mental health issues. They continue to agree that emergency physicians are "uniquely qualified" to perform sedation. More clarification is to come.

2018 Course Topics

- Which Dizzy Patient Needs an MRI?
- ACS – The First Hours of Care
- Acute Heart Failure: Diagnostic Pearls
- Acute Heart Failure: Therapeutic Pearls
- Role of the ED in Non-Heart-Beating Donors
- Skin and Soft Tissue Infection Pearls
- Unusual But Important Cardiac Syndromes - Part 1
- Unusual But Important Cardiac Syndromes - Part 2
- Pneumonia Care Controversies
- New ED Gizmos and Gadgets
- Low-Risk Chest Pain – Who Goes Home?
- Pearls from *ED Leadership Monthly* - Part 1
- Pearls from *ED Leadership Monthly* - Part 2
- Syncope 2018: Is Anything New?
- Sexual / Racial / Ethnic Disparities in the ED
- Pearls from *Risk Management Monthly* - Part 1
- Pearls from *Risk Management Monthly* - Part 2
- Expanded ED Pain Management Options
- Acute Ischemic Conditioning for MIs and Stroke
- Pediatric Severe Asthma in the ED
- Ear, Nose and Throat Potpourri
- Endovascular Stroke Treatment Issues
- Integration of PAs and NPs into the ED
- Adverse Effects of Biologics Marketed on TV
- Adult Severe Asthma in the ED
- Practice-Changing Urology Pearls
- Visual Diagnosis Challenges - Part 1
- Visual Diagnosis Challenges - Part 2
- Important Recent EM Literature - Part 1*
- Important Recent EM Literature - Part 2*
- Hot Topics in Emergency Operations*
- Diagnostic and Therapeutic Controversies*

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

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THE BREAK ROOM

Alternative Investment Strategies

ACEP Now reader Devin Woelzlein, MD, responded to December's End of the Rainbow column by James M. Dahle, MD, FACEP, "Chasing Markets Can Be a Poor Long-term Investing Strategy," with an alternative set of investment recommendations, including:

- "Investing in only paper assets is also a poor long-term strategy. Most of these portfolio recommendations are coming from financial advisers who are trying to sell you various paper assets or who only know paper assets."
- "If you are just now investing and plan on betting long on the stock market (that prices will continue to rise), you are chasing the market. I recommend paying for a subscription service to help you."
- "The real 'old money' families, those in Europe who survived centuries of war, pillaging, and regime changes, focused on the 'one-third, one-third, one-third' strategy. The thirds are land, gold, and fine art."
- "As for cryptocurrencies, there is money to be made here, but be extremely careful."

Visit **ACEPNow.com/category/breakroom** to read his complete investment strategy recommendations and Dr. Dahle's response.

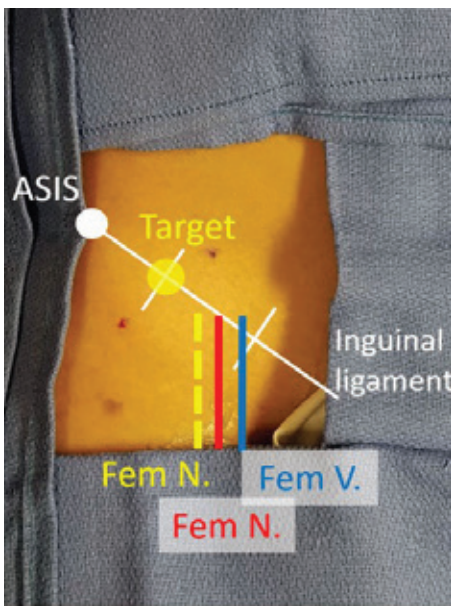

Figure 1: The inguinal ligament may be divided into thirds, with the target site for injection being the lateral one-third mark. This lies lateral to the femoral nerve and vasculature.

Correction

The January Sound Advice column, "Control Hip Fracture Pain Without Opioids" (pp. 20–21) had an error in Figure 1. The femoral artery and vein were mislabeled. The correct figure is above.

TOXICOLOGY Q&A

PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

Famous Flower

This purple bloom has a Hollywood history

by JASON HACK, MD

QUESTION: In what popular book and movie was this flower referenced?

ANSWER *on page 10*

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Toxicology Q&A Answer

QUESTION ON PAGE 8

ANSWER: Harry Potter and the Sorcerer's Stone

"As for monkshood and wolfsbane, they are the same plant, which also goes by the name of aconite. Well? Why aren't you all copying that down?" There was a sudden rummaging for quills and parchment. Over the noise, Snape said, "And a point will be taken from Gryffindor House for your cheek, Potter." - *Harry Potter and the Sorcerer's Stone by J.K. Rowling*

Also, on the TV show Dexter, the character Hannah McKay uses aconite to dispatch victims.

Toxins

Monkshood's toxins are aconitine, mesaconitine, and hypaconitine. Aconitine and mesaconitine bind to the open state of the voltage-sensitive sodium channels, blocking their inactivation.

The roots and root tubers are more toxic than the flowers, which are more toxic than the leaves and stems.

Symptoms

General symptoms include nausea, vomiting, abdominal pain, diarrhea, sweating, dizziness, hyperventilation, difficulty breathing, confusion, and headache. Neurological symptoms include paresthesias, numbness of face and mouth, and limb weakness. Cardiac symptoms include hypotension, palpitations, chest pain, bradycardia, ventricular dysrhythmias (tachycardia, torsade de pointes, and/or fibrillation), junctional rhythms, cardiac arrest, and death.

MONKSHOOD

Aconitum carmichaelii

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

PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

OPINIONS FROM EMERGENCY MEDICINE

A NEW SPIN

CORRELATION DOES NOT EQUAL CAUSATION

How the Surviving Sepsis Campaign got almost everything wrong

by DAVID A. TALAN, MD, FACEP

What could be wrong about a campaign to promote sepsis survival? Looking back on the history of the Surviving Sepsis Campaign (SSC), just about everything. Understand, though, this knowledge is borne with the benefit of hindsight; there are lessons to be learned for all of us.

The initial SSC recommendations in 2004 were an attempt by many individuals in critical care and other professional societies (including ACEP) to improve sepsis care on the heels of what finally appeared to be new life-saving interventions.[1]

Although introduced and received with much enthusiasm, the SSC recommendations were soon called into question in a *New England Journal of Medicine* article critical of pharma sponsors that made products associated with these recommendations, particularly Eli Lilly who made Xigris.[2] Looking back, even the least cynical would acknowledge that many of the strongly recommended approaches from the initial 2004 and 2008 guidelines were later shown to be not only ineffective or unnecessary but also dangerous.[1,3] Specifically, the following were recommended in 2004 and then later removed:

- **Activated protein C (Xigris):** Demonstrated ineffective, associated with an increased risk of bleeding, and withdrawn from the market (Xigris recommended against in 2012).
- **Dopamine among first choices for fluid-unresponsive septic shock:** Associated with more arrhythmias and a higher mortality rate than norepinephrine (norepinephrine recommended in 2012).
- **Tight glucose control (<150 mg/dL):** Associated with severe hypoglycemia and increased mortality compared with target glucose levels up to 180 mg/dL (goal changed to ≤180 mg/dL in 2012).
- **Red blood cell transfusion to maintain hemoglobin ≥10 g/dL:** Not found to be associated with improved outcomes compared with ≥7 g/dL (goal changed to 7–9 g/dL in 2008).
- **Early goal-directed therapy (EGDT) resuscitation based on serial central venous O2 saturation assessments:** Found to have no survival benefit compared with usual care (EGDT parameters not mentioned in 2016).

In retrospect, a clear theme of the original recommendations was that many were based on early, positive, but not well-validated results. For example, the EGDT recommendation was based on a single-center trial that involved 263 participants.[4] While the Xigris trial was multicenter and involved 1,690 participants, the results had not been validated in another investigation at the time the SSC recommended it.[5]

In response to the remarkably rigorous multisite, multinational debunking of EGDT—first by the ProCESS trial and later by the ARISE and ProMISe trials, with almost 5,000 total participants—the SSC responded by pointing out the 18 percent mortality in the usual care arm "illustrates a dramatic change in the management and outcomes of patients with septic shock" compared with the higher mortality rate in the original EGDT trial.[4] Temporal associations of SSC bundle compliance and lower mortality rates were also offered as support of SSC efforts.

Just as we should not get too far out in front with recommendations based on exciting but insufficient evidence, we should also be cautious about overstating cause and effect from temporal associations. In other words, just because it rained the night before and you woke up with frogs on your lawn, doesn't mean it rained frogs.

To wit, Lindenauer et al demonstrated that coincident with the SSC, more patients, including low-risk ones, were being given a sepsis diagnostic code.[6] For example, patients with pneumonia who were at an intermediate risk of death had been shifted from the "pneumonia bucket" to the "sepsis bucket," lowering the mortality rates of both. In reality, though, sepsis survival rates had not changed.

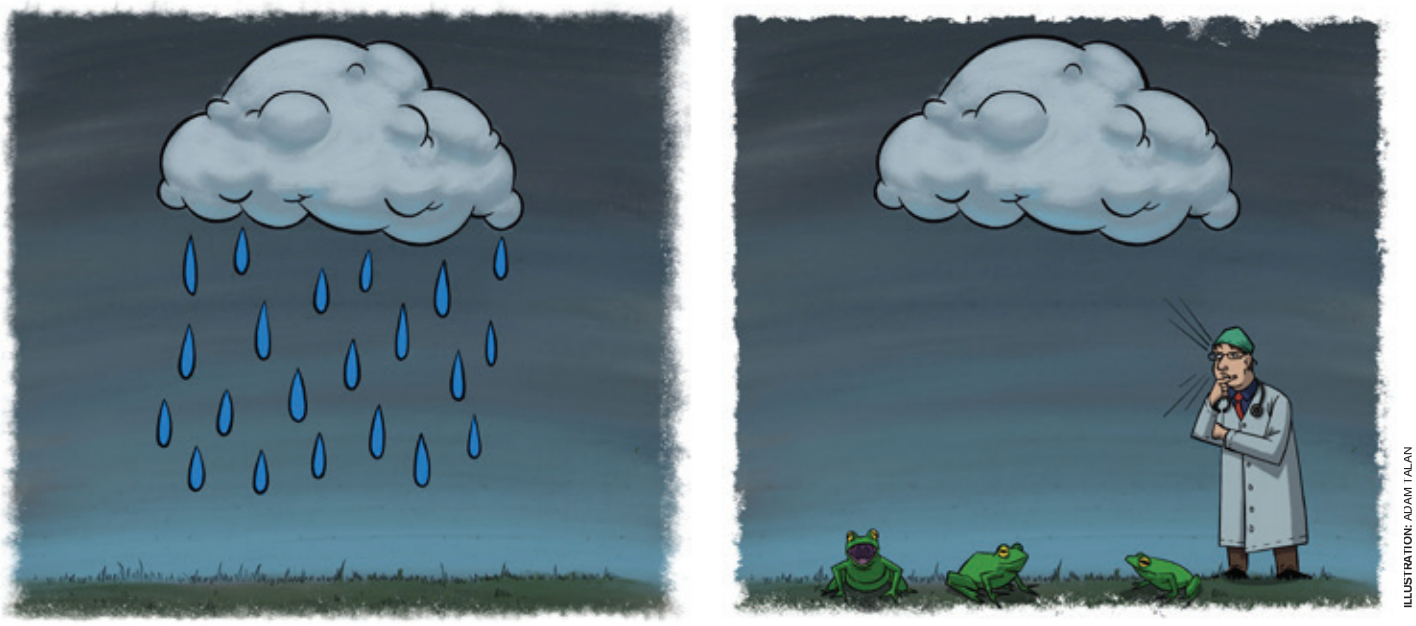

ILLUSTRATION: ADAM TALAN

Just because it rained the night before and you woke up with frogs on your lawn, doesn't mean it rained frogs.

Sepsis and severe sepsis diagnosis–related group codes are also associated with significantly higher payment than pneumonia codes alone. In addition, it's up to the physician's judgment whether the patient has sepsis or just systemic inflammatory response syndrome (SIRS), and all that's required is documenting "sepsis" in the notes. Severe sepsis requires organ dysfunction, including an elevated lactate alone. The attention brought to sepsis by the SSC likely promoted earlier recognition, although we do not know the extent to which SIRS and then lactate screening led to unnecessary care and costs. And Centers for Medicare and Medicaid Services, thank you for the new sepsis core measure requirements in time for this year's flu season, especially the lower lactate threshold of 2 mmol/L. This new directive illustrates the trade-off of enhanced screening to catch a few cases of bacterial sepsis earlier and the unintended consequence of excessive care for many stable but dehydrated patients with a benign viral illness.

What remains of SSC recommendations? Primarily fluid resuscitation, now at 30 cc/kg initially and then additional fluid based on further assessments of perfusion, and timely antibiotics. However, even fluid resuscitation is now under debate and study.

The current fluid strategy promoted by the SSC, based largely on the EGDT bundle, is typically with total amounts of 50–70 cc/kg (eg, 5 L) in the first six hours of care.[7] This liberal fluid approach may be pressor-sparing and limit complications from hypoperfusion. Alternatively, a restrictive fluid approach of <30 cc/kg (eg, ≤2 L) in the first six hours, which relies on earlier use of vasopressors, may prevent complications from tissue edema that interfere with oxygen delivery and organ function. However, such a change will need to consider any increased risk of digital or limb amputations, which may be associated with expanded use of vasopressors.

This may sound crazy, but there are several lines of evidence that support a restrictive fluid approach, including a randomized controlled trial of children with severe malaria, a severity-adjusted analysis of 23,513 septic adults that found each liter beyond five associated with a mortality increase, and a recent randomized controlled trial of adults with septic shock showing significantly improved survival among those getting 2 versus 3.5 L in the first six hours.[8-10] A randomized trial of a liberal versus restrictive fluid approach for septic ED patients is currently being planned by the Prevention and Early Treatment of Acute Lung Injury network.

I asked Peter DeBlieux, MD, an emergency medicine and critical care specialist at Louisiana State University in New Orleans, for his perspective. He said, "Despite some missteps, the best aspect of SSC is promoting recognition; early recognition of sepsis means sooner antibiotics, source control, and care coordination with consultants. Continued recognition of the need for research to improve outcomes for this major killer is critically important."

One of my mentors once told me it's best to be neither the first nor the last to embrace an innovation. Unfortunately, in many ways, we're back to where we started with sepsis.

Editor's Note: *Visit ACEPNow.com to view the references for this article.*

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

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ILLUSTRATION: CHRIS WHISSEN PHOTOS: SHUTTERSTOCK.COM

It can be challenging to identify and help victims of trafficking.

HUMAN TRAFFICKING | CONTINUED FROM PAGE 1

ing to help trafficking victims and what emergency department staff can do to try to help suspected victims. Here is Part 1 of that conversation; Part 2 will appear in the April issue.

KK: What's your educational background?

CD: I went to The Ohio State University and received a Bachelor of Arts degree in political science. I then went on to earn my Juris Doctor degree from the New England School of Law in Boston, and I also earned a Master of Law degree at the George Washington University National Law Center in Washington, D.C., and also from New York University School of Law in New York City. The first master's degree had a concentration in constitutional law, and the second had a concentration in criminal law.

KK: Tell us about your career working on behalf of trafficking victims.

CD: I joined the FBI in 1995. I specialized for 20 out of 22 years working within our Civil Rights program. Our Civil Rights program has four sub-programs underneath it. The first one is hate crimes, the second one is what we call color of law or police brutality, the third is human trafficking, and the fourth is what we call FACE [Freedom of Access to Clinic Entrances], fighting abortion extremism. First, I was a street agent in a New York City office for 12 years. I was promoted and worked in Washington, D.C., from 2007 to 2011, and I was promoted to chief of the Civil Rights unit and then transferred to the Boston FBI office, where I worked on civil rights and public corruption. I finished my FBI career in the Knoxville FBI office, specializing in intelligence and, more specifically, human trafficking. I've seen human trafficking in New York, Boston, Washington, D.C., and Knoxville, Tennessee. I've worked those cases as an agent, supervised investigations, and seen it from a 30,000-foot level as the chief of the Civil Rights unit. I have a good idea of what the country looks like in terms of where we had the most human trafficking cases and what those cases looked like.

Unless you have attention focused on it, a lot gets overlooked. It will get overlooked all too often as a crime problem [ie, prostitution]. You may see it in other facets, where a gang investigation, for example, has a human trafficking element. Gang members can make a

Cynthia M. Deitle, JD

lot of money engaging in trafficking. They can prostitute women against their will and earn a lot of very quick money. They need money, and they need people. One way to get money very quickly is to traffic young girls in the commercial sex trade and earn a lot of money really fast.

Human trafficking can cross over into immigration issues if we see victims coming in from outside the United States and they are held in some type of labor situation [ie, agriculture, landscaping, hair or nail salons, massage parlors, or working as a domestic servant for a family]. We see them all over our communities, but if we don't know the size of trafficking we're not going to know what we're looking at. Another thing that law enforcement and the FBI try to do is bring attention to the problem. We want to bring attention to the issue so people know what they're looking at and then know what to do about it so that victim can be recovered and rescued and hopefully can be put back on a path to survival.

Although the exact numbers are hard to track, with underreporting by some and overreporting by others, any student of history in the United States or anyone with a social justice conscience would say it's one victim too many. How dare the United States outlaw slavery and still be perpetuating the slave industry, which is what we're doing. If you have employers, whether it's a pimp or a landscaping company who are forcing an individual to work, that's slavery.

KK: How challenging can it be to identify and help a trafficking victim?

CD: There have been dozens trafficking victims that I would be the first one to say, "The situation in which I have found you, I swear you are a victim of trafficking." Even though I say that and write that down in a report somewhere, that victim might tell me to go pound sand. She might tell me to go away. She's going to tell me she doesn't want to talk to me and she's going to leave. I have no legal authority to hold her or to force her to self-identify. If she's done nothing wrong, and I can't hold her as a perpetrator of a crime or because she has an outstanding warrant, there's no legal way to hold her.

There's one girl I encountered three times. On the third try, she wanted to cooperate. She wanted to talk to me, and the only reason was that she had been told by the county, the sheriff's department, that if she was arrested one more time for prostitution that she would be registered as a sex offender in the state. That was something that would hang over her like a scarlet letter for the rest of her life, and she was not going to have that. She said, "I can't get arrested again, so what do you want to know?" It wasn't about, "I need services, I need health care, I'm afraid of my pimp, come rescue me." I've had many other situations in which I encountered a girl, a victim of trafficking, and she told me to go pound sand and I never saw her again. Some of those women popped up in another jurisdiction. Including the concern about possible trafficking in a database has been very helpful.

KK: What I'm hearing from you is a lot of these cases weren't reported as human trafficking, so you're overturning stones and finding these victims. It's not a deliberate process to, let's say, investigate four claims of human trafficking that were reported by the sheriff's department.

CD: You're exactly right. We had a case in east Tennessee where a girl was discovered by Knox County on the side of the road. She was in a physical altercation with her pimp and she was getting the better of him, and he called 911. The sheriff's department shows up on the side of the road. She's hitting him, and she says, "I did, I hit him with a tire iron." She knew full well she would go jail, and she told her public defender, "Yes, I hit him because he had been keeping me in a state of involuntary servitude, in a state of slavery, in a state of trafficking, for about a week or 10 days." She was completely done, and she thought the one way to get away from him was to get arrested. Kevin, I would love to know the answer to why some victims are able to escape and others are in a trafficking situation for years. Why was she one of the few that said, "I am not doing this?"

KK: When you are in a position of such oppression, you must have a very strong personality to be able to overcome that and do what she did.

CD: Most of the women in these situations are paralyzed by fear, and they do not want to do anything to bring attention to them or their situation because they're convinced they'll get deported if they are undocumented or convinced that the trafficker is going to tell the victim's parents what she has been doing with these johns in hotel rooms. She's going to be ashamed of videos or pictures taken of what she's been doing. Many are afraid that the pimp will carry out his threat to kill her because he's already beaten her to a pulp on numerous occasions. A lot of times, and this is very sad, her life was pretty crappy before she got involved in this situation. She thinks, "I can have that kind of crappy life, or I can be with this guy and make some money. Well, all right, I'll stay with this guy for a little while."

Some of those women are then convinced by the pimp to recruit other women. That first victim becomes what we term "the bottom." The bottom then will recruit other girls because the bottom knows that if they recruit other girls, they don't have to do it anymore. They can become the one that takes the pictures and puts them online but doesn't have to be the one who is engaging in sex with the john. So you're right. The vast majority of the victims that I've encountered are going to stay for a while. "A while" could be a year or six months, but they are going to stay because it's just too paralyzing to think of how they get out of this.

Next month, in Part 2 of this interview, Ms. Deitle will outline some techniques that emergency department staff can use to help suspected victims of human trafficking.

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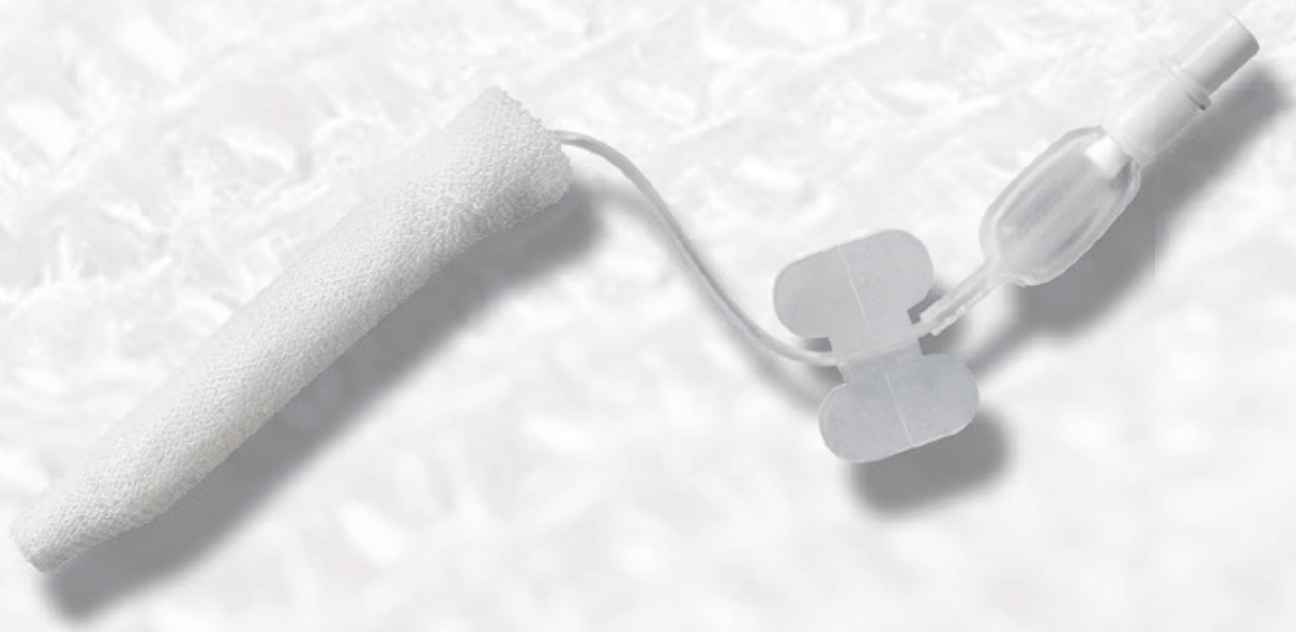

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DO, EJD, FACEP, recently sat down with Matty Parker, husband of immediate ACEP Past President Rebecca Parker, MD, FACEP, to discuss his experience being married to an ACEP president and the challenges and rewards of supporting an emergency physician.

KK: Tell us about you, Matty.

MP: The first job I ever held was as a professional baker. I did that because my father very graciously trained me through his bakery, which he owned for about 40 years. I was a dishwasher, floor washer, and cake decorator. I found the love of music and learned to play trombone along the way. I taught music during the summers, helping to pay for college, and graduated from the University of Texas at El Paso with a degree in English and American literature. I was a middle school teacher. For 20 years, I taught instrumental music during the summers, and that's how I met Becky. She was teaching trumpets, and I was teaching trombones and baritones with a group out of Casper, Wyoming, the Troopers Drum and Bugle Corps.

KK: It has been wonderful to meet you through Becky, and your level of commitment has been pretty substantial. When did all that begin?

MP: I think it began when Becky became a part of her first democratic group in Illinois, and we had to sign to put our house on the line for the group. I thought I better find out what the specialty is and what it does because now I'm on the line for it. It was well worth it. I learned a lot about her business. She showed such a passion for it, just as she helped me with my passions over the years, and I can't thank her enough for that. I went to my first ACEP conference 20 years ago.

KK: Can you speak to your family's time investment in ACEP?

MP: Before Becky ran for an ACEP office, I helped write a speech for an ACEP election. I am a writer—my degree is in English and American literature—and somebody asked Becky to look at their speech. She said, "That's not what I do, but my husband is a writer. Would you like him to look at the speech?" I looked at it—it was for Cherri Hobgood—and she was very gracious. She introduced me as her speech writer. It was very nice of her. I knew that my goals as an English teacher and a writer could complement what Becky was doing. The things I enjoyed doing just found a natural home in the things Becky was so passionate about.

KK: How do you feel this experience enriched or fulfilled you?

MP: When I started working with Becky on her ACEP duties, I met some extraordinary people who were a lot of fun, and I made friends with them over the years. I looked forward to seeing them year after year; I made my own friends. Some were spouses. Some were physicians.

PHOTOS: MATTY PARKER

TOP: The Lincoln Lookout- The Parker family see the sights in Washington, D.C.

ABOVE: Jacob the Baker - The Parkers' son Jacob baking with his dad.

LEFT: Duet Time - Matty Parker and his son Joshua practice the trombone.

But I always had a good time. They gave us great advice about our own children whenever we had questions about what was coming up in our life. It was just an amazing resource of friends and family that supplemented our lives in general.

KK: How do you recommend other spouses, life partners, and significant others not be swallowed up by emergency medicine? How do you recommend maintaining your persona and your life while still supporting your spouse?

MP: I am always willing to tell Becky when it's too much or if something's not worth it. I'll ask her what her goals are, and I'll say, "These are my goals." We've always had an open line of communication so that I have been willing to turn to her and say, "I can't do that now." I think, in the end, open communication is the key. It can be overwhelming. There are so many amazing things going on in the College that it could swallow you up. You just need to be willing to keep your eye on what is important to you, and it all will balance itself out.

KK: Great advice. Has it ever created conflict or controversy in your relationship?

MP: Of course there is conflict, but like I said, in the end, you just need to keep your eye on what you want [as a couple]. What do you want to get out of the experience, and what do you want to give to the experience? If you can keep those things in perspective, which is not as easy as it sounds, then you can fight through it—and yes, sometimes you fight through things. I don't know if you've met my wife, but she's tough. I don't think I'm telling any secrets.

KK: Like others who share a life with a physician, do you ever get the sense that it's hard for Becky to separate her roles? She is clearly in a position of authority within emergency medicine, ACEP, and other professional circles. It's very easy for that to carry over to one's personal life.

MP: Yes. We worked that out a long time ago, but still you're right. Once she gave up all of her practice management duties and could just focus on being a physician and a physician leader, I think that took a lot of the stress off of her. I think her stress levels have been quite manageable, even for a physician, and it's made everything a lot easier from my perspective.

KK: You're a very supportive spouse. What goals have you had that she's been able to support you with?

MP: There are some teaching things that I wanted to do that she helped me with during the summer for most of her ACEP career, which was pretty great. Right now, my goals are to make sure that my children get into middle school. After that, I want to go back to doing some things that I wanted to do, and it's worked out pretty well. I'm thinking about

CONTINUED *on page 16*

CALL FOR IDEAS

Emergency medicine is tough, and it would be ever tougher without the people who provide critical support at home, allowing emergency physicians to provide the best care possible. Do you know of a spouse, significant other, life partner, family member, or other individual we should interview for a future EM Pillars of Support column? We want to hear from you! Send your suggestion and a brief explanation of why they are a critical supporter of the EM community to **dantolin@wiley.com**. We may feature them in a future issue.

ACEP Becomes a National Organization

Founding fathers discuss ACEP's first national gathering

ACEP was founded on Aug. 16, 1968, by John G. Wiegenstein, MD, John A. Rupke, MD, and six other physicians in Lansing, Michigan, who wanted to meet the needs of career emergency physicians.

Around the same time, and with no knowledge of the Michigan activities, Reinald L. Leidelmeyer, MD, of Fairfax, Virginia, led a physician group that practiced emergency medicine full-time, in addition to those in the Alexandria Plan, the original full-time emergency medicine staffing concept led by James D. Mills Jr., MD.

Looking to form a national organization, these founders gathered together in November 1968 at the Marriott Twin Bridges Motel in Arlington, Virginia. In all, 32 physicians from 18 states attended this meeting.

Dr. Wiegenstein and Dr. Rupke recounted some details from that first meeting and many other of ACEP's origin stories in a session titled "Stories from the Past" at the 2003 Michigan College of Emergency Physicians meeting.

You can view the full session online at www.acepnow.com/article/founding-fathers-discuss-acep-gathering.

Here is an excerpt.

JW: At that meeting, Reinald got up and made a little discussion of ambulances and EMS systems and so forth. Then he said, "There's a guy from Michigan and there's a couple of people from Michigan who have formed a little club in Michigan, and we'd like to hear from him." (Audience laughter)

So I got up and presented all this; the ink was still wet practically ... the application blanks, the membership cards, everything. (Holds up papers)

PHOTO: ACEP

They all looked at each other—*I thought we were coming here to form an organization; it's already formed!*

Hannas [R.R. Hannas Jr., MD] stood up and said, "Why don't we all join this group in Michigan? They've got it all together." (Audience laughter)

Little did they know!

...

We decided we would be more national if we got together with a few of those guys at the meeting.

Who was there? Jim Mills. We had all heard about him because he was the Alexandria Plan master. So we said, "By all means, Jim, would you please be on our Board?"

Gave Reinald a seat on the Board. We gave Hannas and Graves [Harris B. Graves, MD], who were there from Nebraska and Missouri.

So we expanded our board by four people and made it, quote, "more national."

...

Another thing that happened at this meeting that is of interest: A fellow came up to me and said, "I want to join right now. I want to fill out the application, and I want you to give me one of those cards."

Now, I hadn't had a card yet, and John hadn't had a card yet. (Audience laughter)

Nobody was really a card-carrying member yet, and this guy insisted.

He gave me $50, gave me the application blank all filled out. And I said, "Well, I'll have to take it back to the office to get it printed."

And he said, "No, just write on it. It's OK."

So I wrote "Robert Ersek, MD." Gave him one of these punch-out cards.

JR: And he gave John $50.

JW: The first $50 that really came from membership. Do you know what he was? He was a neurosurgical moonlighting resident of all people. (Audience laughter)

JR: He never showed up again!

JW: No, we never saw him again. (Audience laughter)

ACEP Stands Up for Prudent Layperson

National and state chapters battle Anthem policy that jeopardizes emergency care

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

by LAURA WOOSTER, MPH

Since early summer, ACEP has been working hard on behalf of its members to protect the prudent layperson standard by advocating for the reversal of a dangerous new policy being enforced by the insurer Anthem BlueCross BlueShield in six states.

First implemented in July in Georgia, Kentucky, and Missouri, and most recently expanded at the start of this year to Indiana, New Hampshire, and Ohio, the policy allows Anthem to retroactively deny coverage of emergency department visits that the insurer deems as "nonemergent." Anthem uses a list of so-called nonemergent ICD-10 codes to flag emergency department claims for medical review, which is then performed by an Anthem-employed physician medical director. However, unlike the more customary review process, no patient chart is requested; the medical director simply reviews the claims form and the limited information it contains on the encounter to make a determination on whether to deny.

As a result, there have been denials that include a pedestrian struck by a vehicle who was taken to the emergency department by EMS (final diagnosis after CT scan and X-rays: contusions and abrasions) and an emergency department patient presenting with severe abdominal pain with fever (final diagnosis: ruptured ovarian cyst). Following a denial, patients are left holding a bill for the entirety of their emergency department visit, which they are now responsible for paying on their own.

In response, ACEP has engaged in a multipronged advocacy strategy, employing a range of tactics and building partnerships with key allies along the way. ACEP has worked closely with chapters in the affected states that have been able to very effectively leverage their local ties with policymakers, coalition partners, and the media. State legislation that includes provisions to counter Anthem's strategy has been introduced in Georgia, Missouri, and Ohio.

In Washington, D.C., ACEP has repeatedly met with key congressional offices for each of the six states to inform them of the policy and provide educational materials to counter Anthem's claims; chapters are working similarly in the district offices for these members of Congress. As a result, in late December, Sen. Claire McCaskill (D-MO) sent Anthem a letter requesting the insurer provide her office with all internal documents and emails leading to the policy's implementation. Noting that "patients are not physicians," the letter reiterated the prudent layperson standard and requested that Anthem explain how the emergency denials policy is not in violation of it. In addition, the senator has asked for communications including discussions about the potential cost savings related to this policy and any associated complaints it may have received.

ACEP also has engaged in substantial public relations efforts along with its chapters, and the resulting media coverage has been very effective in amplifying its advocacy messages and continuing to increase pressure on the insurer. Several stories have received national attention, such as a piece by the Associated Press that was syndicated and carried by more than 100 major outlets across the country, two articles in *Modern Healthcare*, and most recently a feature on Vox.com that brought even more attention to the issue and offers of help from additional congressional offices. ACEP's parody video on the issue also provided an additional opportunity to raise national awareness.

Throughout these efforts, ACEP staff and leadership have met with key Anthem representatives on five separate occasions to voice their concerns and offer constructive alternatives to the policy. Chapters in affected states have met with the insurer, but there has been little headway.

Most recently, ACEP President Paul Kivela, MD, MBA, FACEP, sent an email to contacts at more than 100 emergency department groups asking them to review any Anthem denials they might have in the six affected states and, where possible, provide ACEP with aggregated statistics illustrating them. Having data to cite on the impact and breadth of the Anthem policy is critical to supporting continued advocacy on the issue with state and federal policymakers and making a case for them to take enforcement action. ACEP is also engaged in coalition-building activities with other specialties (eg, the American College of Radiology, the American Academy of Dermatology, and the American College of Surgeons) affected by the damaging Anthem policies in order to maximize resources and bring additional attention to the issue. In addition, ACEP is engaged with consumer groups to ensure the patient voice is heard.

Shortly before press time, Anthem announced it was changing the policy to add additional "always pay" exceptions, including when the emergency department visit was associated with an outpatient or inpatient admission, or when the patient received any kind of surgery, IV medication, or an MRI or CT scan. Anthem also said it will now also request and review medical records before denying claims. While these changes signal the insurer is feeling significant public pressure as a result of a coordinated advocacy effort, ACEP put out a statement noting these changes aren't nearly enough, and that Anthem must withdraw the policy altogether. Sen. McCaskill put out a similar statement and once again called on the insurer to provide the documents she had previously requested.

Stopping Anthem's emergency department retroactive denials policy is critical to ensuring it isn't expanded to the additional eight states in which Anthem has market share and that other payers do not follow with their own dangerous policies.

MS. WOOSTER is ACEP's associate executive director of public affairs.

EM PILLARS OF SUPPORT

CONTINUED FROM PAGE 14

some baking opportunities and also some teaching opportunities. There were some compromises that I willingly made for her to do her presidency, knowing that when she was done, I would get to do some of the things I wanted to do. Those are some of the bargains you have to make going into a relationship.

KK: That's great, and as you said before, communication is important. I've seen it in practice. You two have a great relationship. How has ACEP affected your two boys?

MP: I think they believe that every time we go to a hotel they're going to get the presidential suite, unfortunately. When that's over, they're going to be stunned. It's been great. They did not participate a lot when Becky was on the ACEP Board. When Becky became President, we included them in everything. They got to meet a lot of children from around the country, which was a great experience for them, learning about things that they would never learn about otherwise if it wasn't for ACEP.

KK: We must make certain we maintain a healthy work-life balance. What advice would you give to others who share a life with an emergency physician on maintaining that balance?

MP: Know your goals and stick to them. Know that you're going to have to make some compromises if you're married to a physician who's going to serve the College and recognize as an absolute fact that the person serving is going to lose some perspective on the time drain. You're going to have to remind them. The day Becky was done being President, I could see she started to relax a little bit. She came home and said to me, "I feel like I've been gone," and I said, "You have been." Now we are reintegrating into our nuclear family again.

KK: Any other thoughts or advice for people just handling the daily stresses of an emergency physician?

MP: Sometimes the physician just needs somebody to talk to without any advice or answers. I get that.

I think the stress isn't any different than any other high-profile job. It's going to test your mettle as a spouse. You should know what's important to you and keep that in perspective. Sitting down with your spouse and saying, "These are the things I expect and need to do while you are doing what you do," is very important. Becky always heard me or eventually heard me. It always worked out. That's how we did it.

PHOTO: JA/EVERETT COLLECTION/ALAMY LIVE NEWS

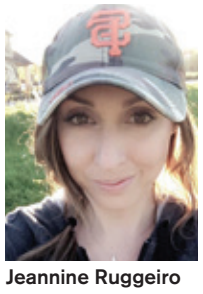
Jason Aldean on stage for Route 91 Harvest country music festival in Las Vegas on Oct. 1, 2017.

PATIENT'S PERSPECTIVES OF VEGAS MASS SHOOTING

Emergency department experiences of a gunshot victim

On Oct. 1, 2017, attendees of the Route 91 Harvest country music festival in Las Vegas were enjoying the event's closing performance by Jason Aldean when tragedy struck. A single gunman opened fire on the crowd from a room in the nearby Mandalay Bay Resort and Casino, injuring 851 people and killing 58. The victims were transported by private vehicle, taxi, and ambulance to nearby hospitals, including Sunrise Hospital & Medical Center, where Scott Scherr, MD, medical director of the emergency department, and his colleagues prepared to treat the injured.

Dr. Scherr



Jeannine Ruggeiro

ACEP Now Medical Editor in Chief Kevin Klauer, DO, EJD, FACEP, recently sat down with Dr. Scherr and Jeannine Ruggeiro, a 28-year-old social work graduate student from Sonoma County, California, who was one of the shooting victims that night, to discuss their experiences in the aftermath of the mass shooting. Here is Part 2 of their conversation. Part 1 appeared in the February issue.

KK: Jeannine, can you share with us your feeling as a person and a patient at that time when you thought you were safe, you were going to run to safety, but you weren't safe anymore?

JR: It was like an out-of-body experience. I remember being on the ground. I felt my back, and I looked at my hand and there was blood all over it. My two girlfriends were running a little bit ahead of me at that point. They didn't know that I had fallen. I was screaming for help, and they ran back to me. Of course, none of us knew what was going on at that point. There was no shelter. We didn't know if it was a shooter in the field; we had no idea if it was multiple shooters. I felt like I was just watching myself, and at that point, I really thought I was going to die. It was a terrifying experience.

KK: Were you shot just in the back, or did you have other injuries?

JR: I was shot just in the back, and due to that, I had a broken rib and a collapsed lung.

KK: Tell us about your symptoms. Beyond the fear of what happened and facing your own mortality, how did you feel physically?

JR: The gunshot wound itself hurt, but it felt more like somebody had just punched me in the back. What hurt the most was I couldn't breathe. As the moments are going on, I remember just yelling because at this point a man, a random man, had picked me up, and he was running with me. He ran out to the parking lot with me. We were behind a vacant ambulance, and I remember not being able to breathe and just saying that over and over, "I can't breathe, I can't breathe." It was just so painful to breathe. I thought I was just going to die there on the concrete.

KK: I can't imagine how scary that must have been. Did you ever reconnect with the person who carried you out of there?

JR: He was amazing. I actually was able to reconnect with him randomly on Facebook. There's a Facebook page called "Find My LV Hero," and I was scrolling through it about two and a half weeks later. I was home from the hospital, and I didn't know his name, didn't know where he lived, and knew nothing about him. All I remember was, when he got me there, we were in the back of a car—a private vehicle took us—and I just remember his big beard staring down at me. I saw this profile picture on Facebook, and I said, "Oh my God, that looks like him!" I read the story he posted looking for me, and it was the same exact memory I had of that night. I contacted him, and we've been in contact since.

KK: Oh, that's wonderful, and thank goodness for him.

CONTINUED *on page 18*

> "I felt like I was just watching myself, and at that point, I really thought I was going to die. It was a terrifying experience."
>
> *–Jeannine Ruggeiro*

Tell us about your experience at the hospital. Help us understand what that's like.

JR: There were medical providers waiting outside the door with a gurney, and they helped get me out of the back of the car. I was swept away from my friends, and I was just panicked. I was asking all the providers, "Am I going to die? Am I going to die?" And they all kept saying, "No," but I asked, "Are you just lying to me? Am I going to die?" Seeing all the other patients, it was just scary. I felt happy to be at the hospital, but at that point we still didn't know what was going on, so I was really worried.

KK: I can't imagine what you went through. Can you tell us what they did to care for you?

JR: I was laying there, they started IVs, and they gave me some pain meds. Eventually, they did put a chest tube in. I remember them writing on my bed sheets, I guess my vitals or something, because I remember they threw them out and then they were frantically looking for them. The nurses and the doctors were so great, and there was one nurse in particular that really kept coming back to check on me and would just stand by my bed and talk to me, really putting me at ease throughout the night.

KK: Jeannine, I have to ask you, having put in a bunch of chest tubes, is it as bad as it seems? Emergency physicians like to do procedures, but that has always been something that I've never wanted to go through personally.

JR: It was so painful! It was awful! Even for the first 10 minutes after it went in I was like, "Something's wrong! This isn't right!" But they said, "No, no, it's fine."

KK: What were some of the most comforting things that somebody said or did for you that got you through the night?

JR: This one nurse, [Kathleen Millhiser], who I don't think actually worked at Sunrise, was talking to me about her daughter. She was around my mom's age and was talking about her daughter, who was around my age, and it was just nice to have that comfort with someone that I felt was there for me. Just that moment of peace of talking to her, because it was so frantic, put me a little bit at ease.

KK: Scott, any comments that you have in listening to Jeannine and her experiences?

SS: Pretty emotional, I think. You know, that night a lot of bravery from not only the patients but the doctors and nurses and staff was displayed. For Jeannine to have to wait in order to be cared for and for us to understand how scared these folks were is important. Also, to realize that there were so many times that we were taking care of patients and they would say, "I'm fine, go to somebody sicker," "I'm fine, go to somebody sicker," that allowed us to focus on the most unstable patients. It's just moving to hear somebody from the other side of the stethoscope; it was pretty impactful for me.

KK: Jeannine, I don't know if you'll really sense how valuable your comments will be to other emergency physicians out there.

JR: Thank you.

SS: I think everybody's going to come away with something to learn. I just can't thank Jeannine enough for her time and her willingness to do this.

KK: Jeannine, how has all of this affected you?

JR: I really had a fearless, carefree attitude before, but I do feel more guarded and more aware of my surroundings now when I'm out places. Just thinking about the families that lost somebody that night and the providers that had to go through that as well, it really changed my perspective. I mean, it sounds cliché, what people say a lot of the time, but really appreciate the people that are around you. In a split second, everything changed for me.

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

Worst Headache of Your Life

Can the Ottawa Subarachnoid Hemorrhage Rule help determine which headache patients need additional testing?

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

The Case

A 38-year-old man presents to the emergency department with sudden onset of a severe frontal headache (HA) beginning two hours earlier while at work. He is feeling nauseated but hasn't vomited. There was no loss of consciousness, fever, or neck pain. He reports that it feels like his previous tension HA, but it did not resolve with ibuprofen this time. His physical examination is normal.

Background

Headaches represent around 2 percent of emergency department visits each year. Of these presentations, 1 to 3 percent turn out to be a subarachnoid hemorrhage (SAH).[1–3]

There are other causes of sudden onset of headache besides migraine and SAH. These include cough, exertion, and sexual intercourse (postcoital) as well as potentially life-threatening conditions like sinus thrombosis, vascular dissection, intracerebral hemorrhage, vasospasm, and aneurysmal subarachnoid hemorrhage.[4–7]

Most sudden-onset headache cases are ultimately from benign, non-life-threatening causes like migraine HA. About 5 percent of SAHs are misdiagnosed on the first emergency department visit.[8] Part of the reason is because 50 percent of SAH patients present with no neurologic deficits.[9] Unfortunately, one-quarter of aneurysmal SAH victims die within one day, and 50 percent of SAH survivors never return to work.

Early identification of SAH reduces these adverse outcomes if subsequent neurosurgical interventions (coiling or clipping) occur emergently.[10] Therefore, it is important to consider the possibility of aneurysmal SAH in emergency department patients presenting with severe headache.

The traditional method of working up a SAH has been non-contrast CT followed by a lumbar puncture (LP). A recent systematic review and meta-analysis has quantified the limitations of this approach.[11] A team out of Ottawa has developed a clinical decision instrument to try to limit the number of patients who need to be investigated further while not increasing the number of missed SAH cases.

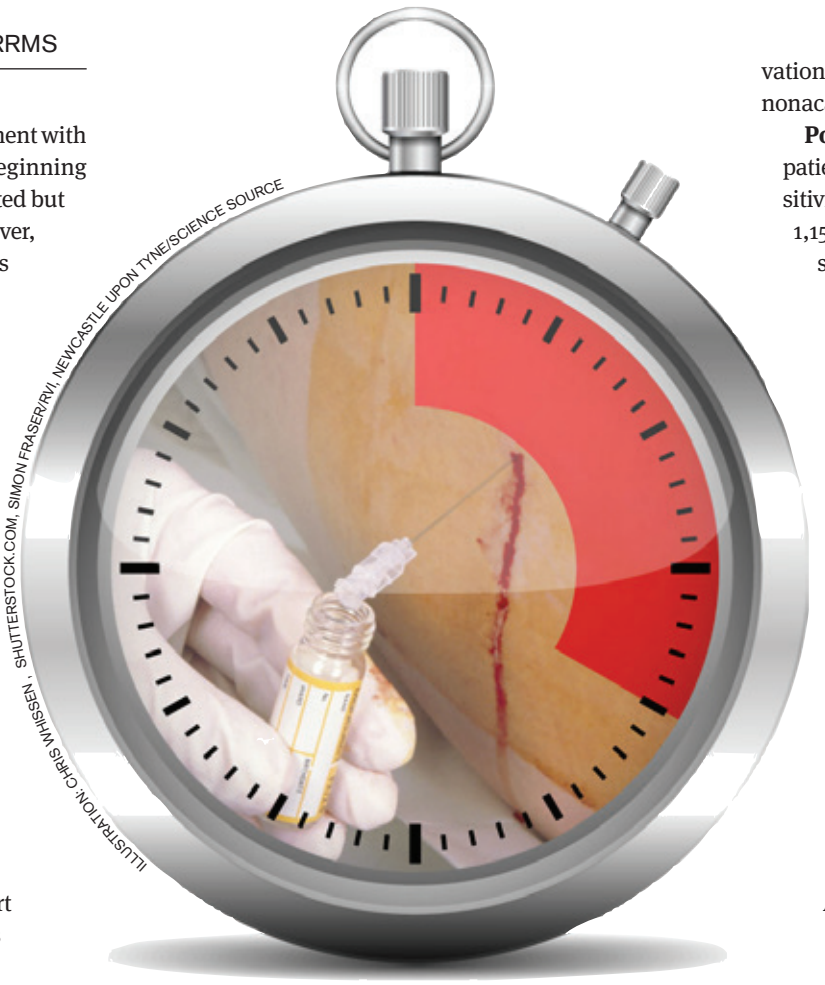
Clinical Question

In patients with acute-onset HA, can the Ottawa SAH Rule decrease the number of patients who need further diagnostic evaluation without increasing missed cases of SAH?

Reference

Perry JJ, Sivilotti MLA, Sutherland J, et al. Validation of the Ottawa Subarachnoid Hemorrhage Rule in patients with acute headache. *CMAJ*. 2017;189(45):E1379-E1385.

- **Population:** Alert patients 16 years and older with new acute severe nontraumatic headache that reaches maximal intensity in less than one hour of onset.
  - » **Exclusions:** Patients with similar HA on three or more occasions over last six months, new neurological deficits, history of trauma or previous aneurysms, SAH, ventricular shunt, hydrocephalus, or brain tumors.
- **Predictors:** Positive Ottawa SAH Rule.
- **Criterion Standard:** CT ± LP.
- **Outcome:** Performance of the Ottawa SAH Rule (sensitivity, specificity, likelihood ratios, and negative predictive value).



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Authors' Conclusions

"We found that the Ottawa SAH Rule was sensitive for identifying subarachnoid hemorrhage in otherwise alert and neurologically intact patients. We believe that the Ottawa SAH Rule can be used to rule out this serious diagnosis, thereby decreasing the number of cases missed while constraining rates of neuroimaging."

Key Results

This prospective study enrolled 1,153 patients, of whom 67 (5.8 percent) had confirmed SAH. Five-hundred ninety potentially eligible patients were not enrolled, of whom 33 (5.6 percent) had confirmed SAH.

- **Performance of the Ottawa SAH Rule:**
  - » 100 percent sensitive (95% CI, 94.6%–100%)
  - » 13.6 percent specific (95% CI, 13.1%–15.8%)
  - » Positive likelihood 1.16 (95% CI, 1.13–1.19)
  - » Negative likelihood ratio 0.0 (95% CI, 0–0.5)
  - » Negative predictive value 100% (95% CI, 96.9%–100%)

The Ottawa SAH Rule did not miss any cases of SAH. If the rule had been applied, 5 percent fewer patients (89 percent down to 84 percent) would have undergone additional testing (CT or LP).

Evidence-Based Medicine Commentary

External Validity: The six enrolling sites were the same hospitals that participated in the original Ottawa SAH Rule derivation studies. This could limit the external validity to other nonacademic or nonurban emergency departments.

Power and Precision: The study planned to enroll 1,200 patients with 75 cases of SAH to achieve near 100 percent sensitivity with tight confidence intervals. The study included 1,153 patients with 67 SAH cases. Therefore, the study was slightly underpowered, and the lower end of the sensitivity was 94.6 percent. This is less precise than they were hoping to achieve.

Shared Decision Making: One unmeasured obstacle to more efficient uptake of decision aids is the engagement of patients and families in the complex discussions around diagnostic evaluations. The science of developing patient decision aids is distinct from that of validating clinical decision rules and requires both a rigorous implementation strategy and sustainable funding environments.

Bottom Line: The Ottawa SAH Rule needs external validation, a meaningful impact analysis performed, and patient acceptability of incorporating this rule into a shared decision-making instrument before being widely adopted.

Case Resolution

The patient is not high risk by the Ottawa SAH Rule. After his HA resolves with IV metoclopramide, you explain the differential diagnosis of HA, including SAH. Your clinical gestalt is that the HA characteristics aren't typical for SAH and more consistent with his previous tension headaches. You discuss the Ottawa SAH Rule and the fact that he has none of the high-risk criteria and his risk of SAH would be less than 1 percent. He is reassured and discharged home with instructions for follow-up.

Thank you to Christopher Carpenter, MD, MSc, of Washington University, who is the deputy editor of Academic Emergency Medicine *and a faculty member of an emergency medicine and critical care course.*

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

References

1. Vermeulen M, van Gijn J. The diagnosis of subarachnoid haemorrhage. *J Neurol Neurosurg Psychiatry.* 1990;53(5):365-372.
2. Perry JJ, Stiell I, Wells G, et al. Diagnostic test utilization in the emergency department for alert headache patients with possible subarachnoid hemorrhage. *CJEM.* 2002;4(5):333-337.
3. Morgenstern LB, Huber JC, Luna-Gonzales H, et al. Headache in the emergency department. *Headache.* 2001;41(6):537-541.
4. Landtblom AM, Fridriksson S, Boivie J, et al. Sudden onset headache: a prospective study of features, incidence and causes. *Cephalalgia.* 2002;22(5):354-360.
5. Delasobera BE, Osborn SR, Davis JE. Thunderclap headache with orgasm: a case of basilar artery dissection associated with sexual intercourse. *J Emerg Med.* 2012;43(1):e43-47.
6. Pascual J, Iglesias F, Oterino A, et al. Cough, exertional, and sexual headaches: an analysis of 72 benign and symptomatic cases. *Neurology.* 1996;46(6):1520-1524.
7. Dodick DW, Brown RD Jr, Britton JW, et al. Nonaneurysmal thunderclap headache with diffuse, multifocal, segmental, and reversible vasospasm. *Cephalalgia.* 1999;19(2):118-123.
8. Vermeulen MJ, Schull MJ. Missed diagnosis of subarachnoid hemorrhage in the emergency department. Stroke. 2007;38(4):1216-1221.
9. Weir B. Headaches from aneurysms. *Cephalalgia.* 1994;14(2):79-87.
10. Schievink WI. Intracranial aneurysms. *N Engl J Med.* 1997;336(1):28-40.
11. Carpenter CR, Hussain AM, Ward MJ, et al. Spontaneous subarachnoid hemorrhage: a systematic review and meta-analysis describing the diagnostic accuracy of history, physical examination, imaging, and lumbar puncture with an exploration of test thresholds. *Acad Emerg Med.* 2016;23(9):963-1003.

BRINGING DATA TO THE BEDSIDE

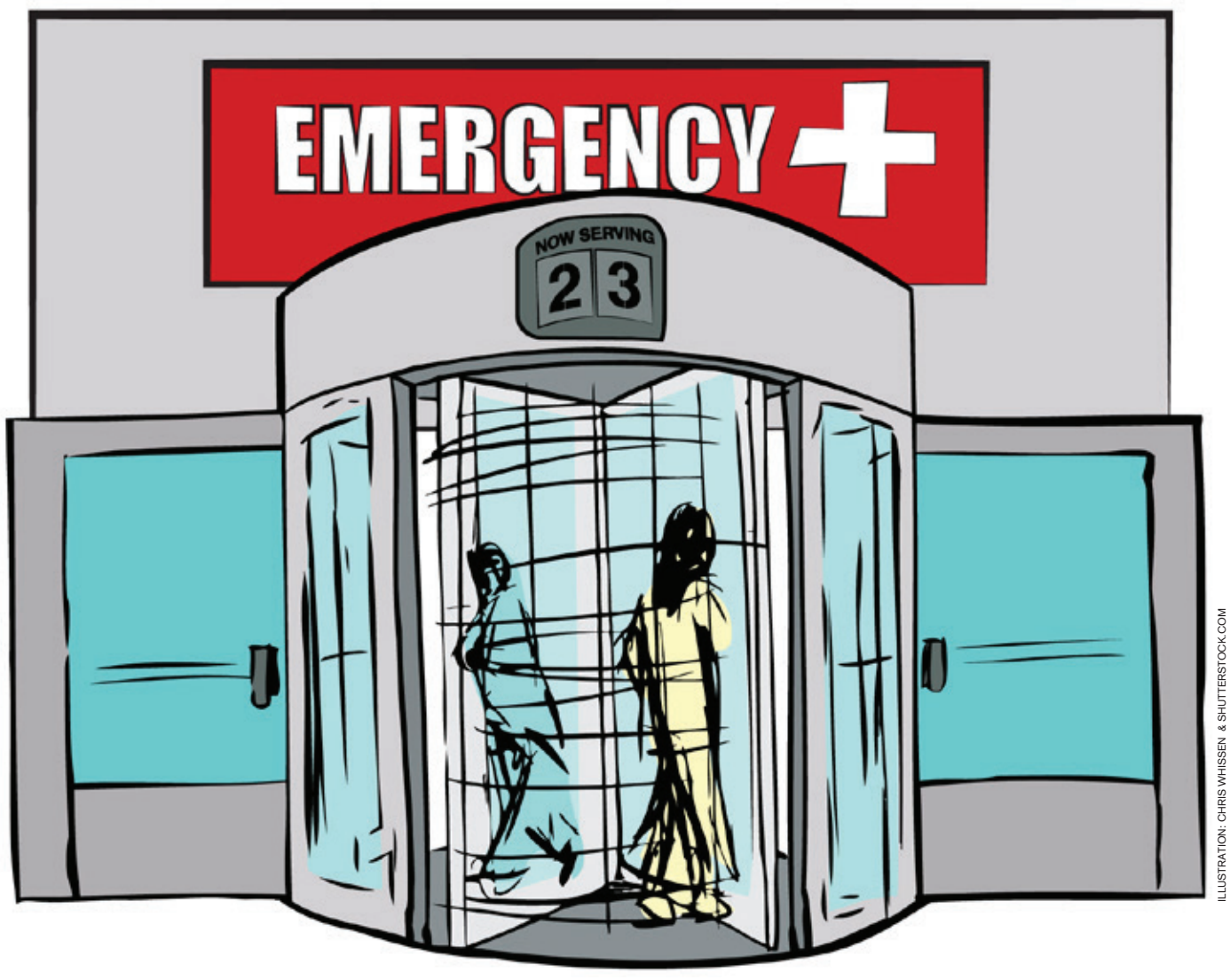
BENCHMARKING ALLIANCE

DR. AUGUSTINE is chair of the National Clinical Governance Board of US Acute Care Solutions in Canton, Ohio; clinical professor of emergency medicine at Wright State University in Dayton, Ohio; vice president of the Emergency Department Benchmarking Alliance; and a member of the ACEP Board of Directors.

Return ED Visits: Poor Performance or Flawed Metric?

Identifying if the return visit issue qualifies as an important quality or performance measure

by JAMES J. AUGUSTINE, MD, FACEP



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As part of the triple aim, there is a very concerted effort to develop markers of high-quality care in all of American health care. The Centers for Medicare and Medicaid Services has developed reporting and payment targets for physicians and for hospitals, and a significant amount of reimbursement will be based on performance measures.

For more than 20 years, emergency physicians have been faced with hospital programs that report ED return visits, usually in a 72-hour window. Multiple studies have characterized the return visit rate as a poor marker of quality. Definitions have been unclear, and strategies to address associated factors have been very nonspecific.

One study of return visits focused on the patient-driven factors.[1] Emergency medicine is a specialty driven by timeliness of care and perceived patient need. Research has found that patients used the emergency department based on their perception of good value. Patients returned due to perceived inability to access timely follow-up care, needed care that was not available, and concern about the progression of the original medical problem. The majority of patients had a primary care physician but felt that resources needed for completion of care would be accessed in a more timely manner by returning to the emergency department.

Patient-driven factors for return visits are highlighted in the book *Quality Matters: Solutions for a Safe and Efficient Emergency Department* by Shari Welch, MD. Her suggestion is that emergency departments should intentionally and systematically return high-risk patients to ensure the best patient outcomes.

From a quantitative basis, the Centers for Disease Control and Prevention National Hospital Ambulatory Medical Care Survey data in this area have always been enlightening. The latest data are from the 2014 reporting year:

- About 5.7 percent of ED visits were made by patients who had been seen in the same emergency department in the preceding 72 hours.
- About 4.8 percent of ED visits were for "follow-up."
- In about 3 percent of ED visits resulting in hospital admission, the patient had been seen in the same emergency department within the prior 72 hours.

This is a very important baseline history. Other studies have found return rates to any emergency department in a particular region average 7.55 percent over a five-year period.[2,3] These authors reflect on the utility of regional health information exchanges to further track and improve the care of patients having return visits and further improve the value of the emergency department in providing care for patients with ongoing medical issues that did not result in inpatient care on the initial visit.

Reasons for return visits to the same emergency department may include a scheduled revisit for wound check, the worsening of an original medical problem, a complication from the treatment, repeat diagnostics or treatment, the desire for reassurance, and many others. When the patient visits another emergency department, some other factors may be causative. It may reflect movement to a higher level of care. It may also reflect an initial patient encounter that was unsatisfactory, ended with a concern that wasn't addressed, or was followed by a complication.

With these many factors in the mix, it is very likely that return frequency does not accurately reflect quality.

There is benefit to timely data collection and sharing among emergency departments. The Emergency Department Benchmarking Alliance is a large group of high-performance American emergency departments that share a commitment to quality and development of performance measures that has served its member hospitals and the industry since 1994. However, the return visit issue is not an area that the alliance has identified as an important quality or performance measure, even with repeated efforts to differentiate "scheduled" and "unscheduled" return visits.

In the development of the Clinical Emergency Data Registry, ACEP evaluated potential quality measures that could be utilized. The return visit issue was discussed and dismissed. ACEP's decision may portend the eventual death of this quality measure for both research and performance comparison.

Some payer-supported work is critical of ED work that results in a bounce back and admission.[4] However, recent systematic studies concluded that return visits resulting in hospital admission are not an indicator of poor care.[5,6] These ED visits may be a fruitful source of cases for quality improvement activities, but they rarely identify deficiencies in initial ED care and are associated with shorter, lower-cost admissions when they do occur. It was suggested that high-quality care occurs when patients are seen in the emergency department, undergo appropriate testing and treatment, and are released because they do not meet admission criteria. The discharge instructions to "return if the condition worsens or if there are complications of treatment" result in less cost and exposure to hospital comorbidities for many persons and, on average, shorter stays for patients who choose to return.

A strategy of encouraging return ED visits may be very prudent. That is likely a satisfier for ED patients and their families, and it accurately reflects the value of having emergency departments available for patients, especially for return visits.

References

1. Rising KL, Padrez KA, O'Brien M, et al. Return visits to the emergency department: the patient perspective. *Ann Emerg Med.* 2015;65(4):377-386.e3
2. Shy BD, Kim EY, Genes NG, et al. Increased identification of emergency department 72-hour returns using multihospital health information exchange. *Acad Emerg Med.* 2016;23(5):645-649.
3. Shy BD, Loo GT, Lowry T, et al. Bouncing back elsewhere: multilevel analysis of return visits to the same or a different hospital after initial emergency department presentation [published online ahead of print Sept. 27, 2017]. *Annals Emerg Med.*
4. Duseja R, Bardach NS, Lin GA, et al. Revisit rates and associated costs after an emergency department encounter: a multistate analysis. *Ann Intern Med.* 2015;162(11):750-756.
5. Sabbatini AK, Kocher KE, Basu A, et al. In-hospital outcomes and costs among patients hospitalized during a return visit to the emergency department. *JAMA.* 2016;315(7):663-671.
6. Cheng J, Shroff A, Khan N, et al. Emergency department return visits resulting in admission: do they reflect quality of care? *Am J Med Qual.* 2016;31(6):541-551.

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The Golden Hour of ICH Management

Avoiding extremes of blood pressure, temperature, and glucose while minimizing spikes in intracranial pressure and reversing anticoagulants

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

It is critical to master the management of the patient with intracerebral hemorrhage (ICH) because hematoma expansion typically occurs in the first few hours after the bleed starts, and hematoma volume is the most important predictor of early deterioration.[1] A self-fulfilling prognostic pessimism exists when it comes to ICH, and this pessimism sometimes leads to less-than-optimal care in patients who otherwise might have had a reasonably good outcome if managed aggressively.

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Despite the poor prognosis of these patients overall, there is some evidence to suggest that early aggressive medical management may improve outcomes.[2] As such, the skill with which you manage your emergency department ICH patients matters. In this golden hour, you have a chance to prevent hematoma expansion, stabilize intracerebral perfusion, and give your patient the best chance of survival with a favorable neurological recovery.

Five major considerations in the medical management of ICH should guide your management: blood pressure (BP), coagulation, glucose, temperature, and intracranial pressure (ICP) control.

Blood Pressure Management

For those ICH patients with Glasgow Coma Scale (GCS) scores >7, the current recommendation to lower BP to 140/80 is unlikely to be harmful but may be minimally beneficial. However, two recent trials have failed to definitively show benefit. The INTERACT2 trial was a randomized, controlled trial (RCT) of 2,839 patients with spontaneous ICH and elevated systolic BP who were randomized to intensive treatment (<140) versus guideline-recommended therapy (<180).

Outcomes were modified Rankin score of 3 to 6 (death and major disability) at 90 days. The researchers found no significant difference in primary outcomes.[3] The ATACH-II RCT compared a lower systolic BP target of 110 to 139 mm Hg with a standard target of 140 to 179 in 1,000 patients using IV labetalol, diltiazem, or urapidil. Patients were eligible if they had at least one episode of systolic BP >180 mmHg between symptom onset and 4.5 hours. The trial was stopped early for futility, with no difference in the primary outcome of death or disability (intensive treatment group 38.7 percent versus control 37.7 percent).[4] While the target BP in ICH requires more study, there is no question that hypotension should be avoided at all costs in patients with ICH.

Platelet Transfusions

All patients with a platelet count <50,000 in the setting of ICH require platelet transfusion. However, most hematologists and neurosurgeons recommend platelet transfusion for ICH with a platelet count <100,000 despite the lack of evidence for improved outcomes, especially when the patient requires emergency surgery.

For patients with ICH taking antiplatelet agents, the PATCH trial, a RCT in the Netherlands, United Kingdom, and France, randomized 190 patients with supratentorial ICH and a GCS >8 who had received antiplatelet therapy (mostly aspirin alone) within seven days to standard care or care with platelet transfusion.

An ordinal analysis looking at modified Rankin score and death showed an odds ratio of death of 2.05 in the treatment group. More serious adverse events were reported in patients who received platelet transfusion (42 percent) compared with patients who received standard care alone (29 percent). The researchers concluded that platelets were associated with poorer clinical outcomes overall.[5] It is important to note that these patients were primarily nonsurgical ICH patients. For patients requiring emergency surgery, most neurosurgeons recommend platelet transfusion for patients taking antiplatelet agents.

Reversal of warfarin: Any patient taking warfarin who presents to the emergency department with ICH should receive IV four-factor prothrombin complex concentrates (PCCs) 1,500 units (Octaplex, Beriplex, or Kcentra) as soon as possible and IV vitamin K 10 mg in 50 mL of normal saline over 10 minutes. Treatment should not be delayed for the international normalized ratio results to come back, as hematoma expansion typically occurs within the first hour in patients taking warfarin.[6]

Reversal of dabigatran: Idarucizumab is the reversal agent of choice for dabigitran despite the lack of evidence for improved patient outcomes.[6] If idarucizumab is not available, consider factor eight inhibitor bypass activity (FEIBA). If FEIBA is not available consider four-factor PCC.

Reversal of Xa inhibitors: For Xa inhibitors (eg, apixaban, rivaroxaban) 4-factor PCC at a dose of 50 IU/kg up to 3,000 units is the reversal agent of choice based on limited evidence. Andexanet alfa is a decoy antigen; it competitively binds rivaroxaban and apixaban and is given as an ongoing infusion. The evidence is not convincing for its effectiveness.[6]

Glucose Control

Hyperglycemia is common in patients presenting with ICH and is associated with poor outcomes.[7] The optimal glucose level and the best hyperglycemia management strategy remain undecided. However, both hypoglycemia (<70 mg/dL) and hyperglycemia (>180 mg/dL) should be avoided. A study suggested improved clinical outcomes with tight control of blood sugar to the range of 80 to 110 mg, but this was found to cause occasional hypoglycemia resulting in increased mortality.[8]

Temperature Control in ICH

So-called "brain blood fever" is common in ICH, with 30 to 50 percent of patients developing fever. The presence of intraventricular hemorrhage is the main risk factor for fever. Fever is independently associated with poor outcomes. While there are no available data from RCTs addressing the role of induced normothermia after ICH, current recommendations are to cool febrile ICH patients to a core temperature below 37.5 to 38 °C.[9]

Management of Elevated ICP

Management of elevated ICP starts with meticulous airway management for those patients whom you deem at risk for aspiration. Keep the head of the bed elevated at least 20 degrees to prevent spikes in ICP. Titrate systolic BP to 140 to 160, preferably with an arterial line in place. Consider fentanyl 3–5 mcg/kg pretreatment three minutes before intubation, but beware of the possibility of apnea and provide appropriate analgesia and sedation postintubation. Avoid hypoxemia and hypotension at all costs in ICH. Hyperventilation to a PCO_2 of 30 to 35 is only recommended as a temporary bridge to definitive surgical management in those patients who are actively coning.

Although not routinely indicated, consider hypertonic saline or mannitol based on ICP monitoring, point-of-care ultrasound optic nerve sheath diameter >6 mm, or clear signs of elevated ICP on brain imaging (not simply for low GCS).[10,11] While there is no RCT evidence that hypertonic saline (3% 250 mL over 10 minutes) is superior to mannitol for

CONTINUED *on page 24*

controlling elevated ICP, it may be preferred because there are fewer concerns with sodium derangement and changes in hemodynamics. If you use mannitol, it is advisable to match urinary losses with normal saline administration to avoid hypotension.

While no single medical treatment has been shown to improve outcomes in ICH, if we avoid extremes of blood pressure, temperature, and glucose while minimizing spikes in ICP and rapidly reversing anticoagulants in the emergency department, we will give our ICH patients the greatest chance of a neurologically intact survival.

Thanks to Walter Himmel and Scott Weingart for their contributions to the EM Cases podcast that inspired this article.

References

1. Specogna AV, Turin TC, Patten SB, et al. Factors associated with early deterioration after spontaneous intracerebral hemorrhage: a systematic review and meta-analysis. *PLoS One.* 2014;9(5):e96743.
2. de Oliveira Manoel AL, Goffi A, Zampieri FG, et al. The critical care management of spontaneous intracranial hemorrhage: a contemporary review. *Crit Care.* 2016;20:272.
3. Anderson CS, Heeley E, Huang Y, et al. Rapid blood-pressure lowering in patients with acute intracerebral hemorrhage. *N Engl J Med.* 2013;368(25):2355-2365.
4. Qureshi AI, Palesch YY, Barsan WG, et al. Intensive blood-pressure lowering in patients with acute cerebral hemorrhage. *N Engl J Med.* 2016;375(11):1033-1043.
5. Baharoglu MI, Cordonnier C, Al-Shahi Salman R, et al. Platelet transfusion versus standard care after acute stroke due to spontaneous cerebral haemorrhage associated with antiplatelt therapy (PATCH): a randomised, open-label, phase 3 trial. *Lancet.* 2016;387(10038):2605-2613.
6. Frontera JA, Lewin JJ 3rd, Rabinstein AA, et al. Guideline for reversal of antithrombotics in intracranial hemorrhage: a statement for healthcare professionals from the Neurocritical Care Society and Society of Critical Care Medicine. *Neurocrit Care.* 2016;24(1):6-46.
7. Passero S, Ciacci G, Ulivelli M. The influence of diabetes and hyperglycemia on clinical course after intracerebral hemorrhage. *Neurology.* 2003;61(10):1351-1356.
8. NICE-SUGAR Study Investigators, Finfer S, Chittock DR, et al. Intensive versus conventional glucose control in critically ill patients. *N Engl J Med.* 2009;360(13):1283-1297.
9. Hemphill JC 3rd, Greenberg SM, Anderson CS, et al. Guidelines for the management of spontaneous intracerebral hemorrhage: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2015;46(7):2032-2060.
10. Stevens RD, Shoykhet M, Cadena R. Emergency neurological life support: intracranial hypertension and herniation. *Neurocrit Care.* 2015;23(Suppl 2):S76-82.
11. Raffiz M, Abdullah JM. Optic nerve sheath diameter measurement: a means of detecting raised ICP in adult traumatic and non-traumatic neurosurgical patients. *Am J Emerg Med.* 2017;35(1):150-153.

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CODING WIZARD

NAVIGATE THE CPT MAZE, OPTIMIZING YOUR REIMBURSEMENT

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

DOCUMENTING MEDICAL NECESSITY

by **HAMILTON LEMPERT, MD, FACEP, CEDC**

Question: How do I document medical necessity?

Answer: Medical necessity is defined by Medicare as "health care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." The American Medical Association has a similar but longer definition. To document medical necessity, the chart must convey the reasons diagnostic and treatment decisions were made. Some situations are very obvious, such as an X-ray on an injured ankle. However, some situations are not, such as the back pain patient requiring an MRI. If the clinician documents that there was a concern for cauda equina syndrome, the medical necessity for the MRI now becomes clear, but without that notation, an auditor might deny payment for a higher-level visit because of the lack of medical necessity for the MRI. All patient encounters must fulfill medical necessity. Make sure your documentation supports the actions you take.

Brought to you by the ACEP Coding and Nomenclature Committee.

DR. LEMPERT is chief medical officer, coding policy, at TeamHealth, based in Knoxville, Tennessee.

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