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CONTINUED on page 14



I enjoy studying U.S. presidential and ancient Roman history, particularly through biographies of those who have helped shape their times. Though these impactful people vary greatly from one another, common themes, nonetheless, unite them. Most were bright and/or talented. Most worked exceedingly hard to excel in their work. However, nearly all, not just most, are persons of historic interest because unique cir-

CONTINUED on page 18

PAGE 12

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ACEP *Now* The Official Voice of Emergency Medicine

PERIODICAL

Are you aware of the variety of support resources available for ELIQUIS patients?

Think ELIQUIS for the treatment of DVT/PE.

DVT: deep vein thrombosis; PE: pulmonary embolism.

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.

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events after Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including ELIQUIS, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in atrial fibrillation patients. If ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Bleeding Risk:** ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding.
 - Concomitant use of drugs affecting hemostasis increases the risk of bleeding, including aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs.
 - Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.
 - The anticoagulant effect of apixaban can be expected to persist for at least 24 hours after the last dose (i.e., about two half-lives). An agent to reverse the anti-factor Xa activity of apixaban is available. Please visit www.andexxa.com for more information on availability of a reversal agent.
- **Spinal/Epidural Anesthesia or Puncture:** Patients treated with ELIQUIS undergoing spinal/epidural anesthesia or puncture may develop an epidural or spinal hematoma which can result in long-term or permanent paralysis.

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





Eliquis[®]

(apixaban) tablets 5mg
2.5mg

In the hospital. At discharge. At home.
Consider ELIQUIS.



To learn more about transition of care
resources, contact your ELIQUIS representative or call

1-855-ELIQUIS

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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

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

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

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.

IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS

- **Combined P-gp and Strong CYP3A4 Inhibitors:** Inhibitors of P-glycoprotein (P-gp) and cytochrome P450 3A4 (CYP3A4) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, or ritonavir). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with combined P-gp and strong CYP3A4 inhibitors.

Clarithromycin

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

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

PREGNANCY CATEGORY B

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

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

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Bristol-Myers Squibb



ELIQUIS® (apixaban) tablets, for oral use

Rx ONLY

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

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

(B) SPINAL/EPIDURAL HEMATOMA

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

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

(B) SPINAL/EPIDURAL HEMATOMA

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

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

[see Warnings and Precautions]

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

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

INDICATIONS AND USAGE

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

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

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

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

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

DOSAGE AND ADMINISTRATION (Selected information)

Temporary Interruption for Surgery and Other Interventions

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

CONTRAINDICATIONS

ELIQUIS is contraindicated in patients with the following conditions:

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

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation

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

Bleeding

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

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

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

Reversal of Anticoagulant Effect

An agent to reverse the anti-factor Xa activity of apixaban is available. The pharmacodynamic effect of ELIQUIS can be expected to persist for at least 24 hours after the last dose, i.e., for about two drug half-lives. Prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa may be considered, but have not been evaluated in clinical studies [see Clinical Pharmacology (12.2) in full Prescribing Information]. When PCCs are used, monitoring for the anticoagulation effect of apixaban using a clotting test (PT, INR, or aPTT) or anti-factor Xa (FXa) activity is not useful and is not recommended. Activated oral charcoal reduces absorption of apixaban, thereby lowering apixaban plasma concentration [see Overdosage].

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

Spinal/Epidural Anesthesia or Puncture

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

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

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

Patients with Prosthetic Heart Valves

The safety and efficacy of ELIQUIS (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 ^a				
	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)	-

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

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

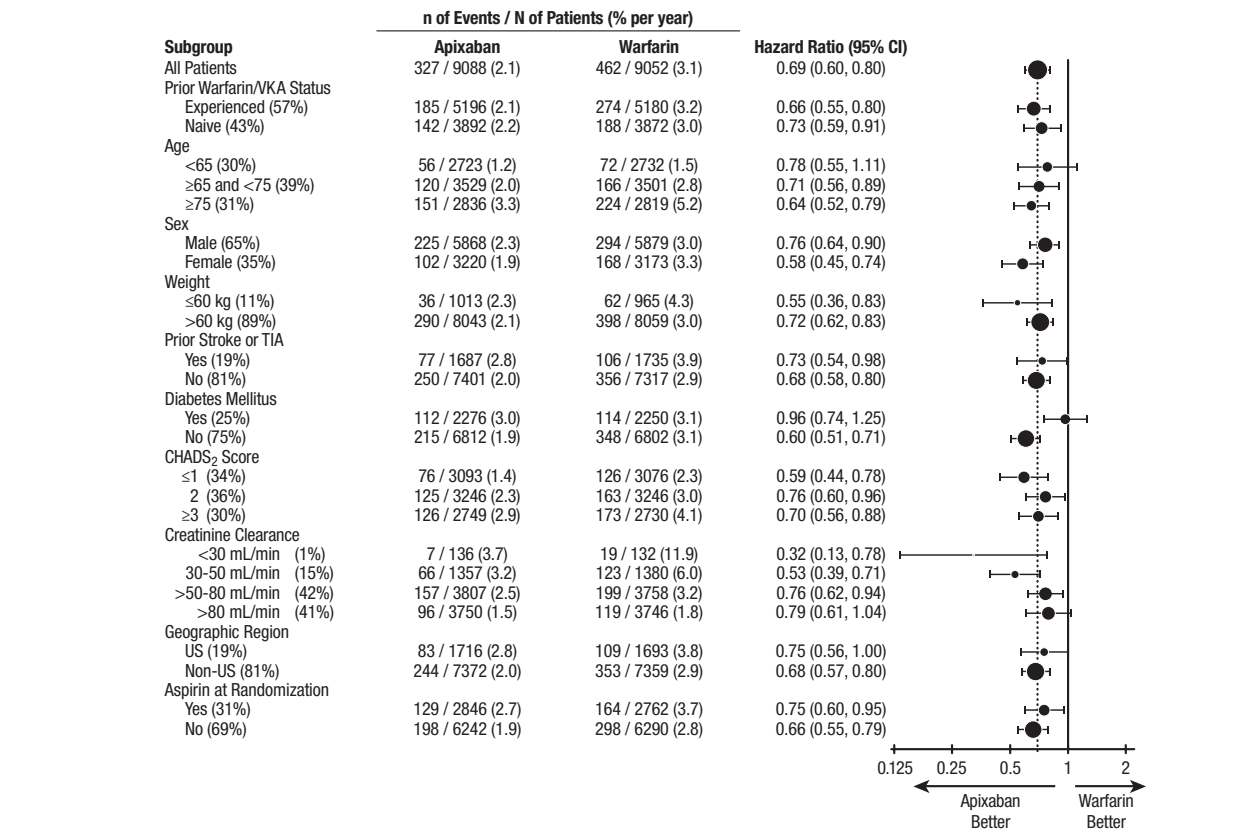
[‡] Intracranial bleed includes intracerebral, intraventricular, subdural, and subarachnoid bleeding. Any type of hemorrhagic stroke was adjudicated and counted as an intracranial major bleed.

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

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

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

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



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

In ARISTOTLE, the results for major bleeding were generally consistent across most major subgroups including age, weight, CHADS₂ 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 12±2 days	ELIQUIS 2.5 mg po bid 12±2 days
	First dose 12 to 24 hours post surgery	First dose 9 to 15 hours prior to surgery	First dose 9 to 15 hours prior to surgery
All treated	N=2673	N=2659	N=1501
Major (including surgical site)	22 (0.82%) [†]	18 (0.68%)	9 (0.60%) [‡]
Fatal	0	0	0
Hgb decrease ≥2 g/dL	13 (0.49%)	10 (0.38%)	8 (0.53%)
Transfusion of ≥2 units RBC	16 (0.60%)	14 (0.53%)	9 (0.60%)
Bleed at critical site [§]	1 (0.04%)	1 (0.04%)	2 (0.13%)
Major + CRNM [¶]	129 (4.83%)	134 (5.04%)	53 (3.53%)
All	313 (11.71%)	334 (12.56%)	104 (6.93%)

* All bleeding criteria included surgical site bleeding.

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

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

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

[¶] CRNM = clinically relevant nonmajor.

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

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

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

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

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

Vascular disorders: hypotension (including procedural hypotension)

Respiratory, thoracic, and mediastinal disorders: epistaxis

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

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

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

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

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

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

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

The safety of ELIQUIS has been evaluated in the AMPLIFY and AMPLIFY-EXT studies, including 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.

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

AMPLIFY Study

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

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

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

Table 5: Bleeding Results in the AMPLIFY Study

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

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

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

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

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

AMPLIFY-EXT Study

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

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

Table 7: Bleeding Results in the AMPLIFY-EXT Study

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

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

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

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

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

Other Adverse Reactions

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

Blood and lymphatic system disorders: hemorrhagic anemia

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

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

Musculoskeletal and connective tissue disorders: muscle hemorrhage

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

Vascular disorders: hemorrhage

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

Eye disorders: conjunctival hemorrhage, retinal hemorrhage, eye hemorrhage

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

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

DRUG INTERACTIONS

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

Combined P-gp and Strong CYP3A4 Inhibitors

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

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

Clarithromycin

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

Combined P-gp and Strong CYP3A4 Inducers

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

Anticoagulants and Antiplatelet Agents

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

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

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

Labor and Delivery

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

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

Nursing Mothers

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

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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

Renal Impairment

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

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

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

Patients with End-Stage Renal Disease on Dialysis

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

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

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

Hepatic Impairment

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

OVERDOSAGE

Overdose of ELIQUIS increases the risk of bleeding *[see Warnings and Precautions]*.

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

In healthy subjects, administration of activated charcoal 2 and 6 hours after ingestion of a 20-mg dose of apixaban reduced mean apixaban AUC by 50% and 27%, respectively. Thus, administration of activated charcoal may be useful in the management of apixaban overdose or accidental ingestion. An agent to reverse the anti-factor Xa activity of apixaban is available.

PATIENT COUNSELING INFORMATION

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

Advise patients of the following:

- Not to discontinue ELIQUIS without talking to their physician first.
- That it might take longer than usual for bleeding to stop, and they may bruise or bleed more easily when treated with ELIQUIS. Advise patients about how to recognize bleeding or symptoms of hypovolemia and of the urgent need to report any unusual bleeding to their physician.
- To tell their physicians and dentists they are taking ELIQUIS, and/or any other product known to affect bleeding (including nonprescription products, such as aspirin or NSAIDs), before any surgery or medical or dental procedure is scheduled and before any new drug is taken.
- If the patient is having neuraxial anesthesia or spinal puncture, inform the patient to watch for signs and symptoms of spinal or epidural hematomas *[see Warnings and Precautions]*. If any of these symptoms occur, advise the patient to seek emergent medical attention.
- 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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EDITORIAL STAFF

MEDICAL EDITOR-IN-CHIEF
Kevin Klauer, DO, EJD, FACEP
kklauer@acep.org

EDITOR
Dawn Antoline-Wang
dantolin@wiley.com

ART DIRECTOR
Chris Whissen
chris@quillandcode.com

ACEP STAFF

EXECUTIVE DIRECTOR
Dean Wilkerson, JD, MBA, CAE
dwilkerson@acep.org

DIRECTOR, MEMBER COMMUNICATIONS
AND
MARKETING
Nancy Calaway, CAE
ncalaway@acep.org

CHIEF OPERATING OFFICER
Robert Heard, MBA, CAE
rheard@acep.org

COMMUNICATIONS MANAGER
Jordan Grantham
jgrantham@acep.org

PUBLISHING STAFF

EXECUTIVE EDITOR/
PUBLISHER
Lisa Dionne Lento
ldionne@wiley.com

ASSOCIATE DIRECTOR,
ADVERTISING SALES
Steve Jezzard
sjezzard@wiley.com

ADVERTISING STAFF

DISPLAY ADVERTISING
Dean Mather or Kelly Miller
mjmrvcia@mrvcia.com
(856) 768-9360

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Kevin Dunn
kdunn@cunnasso.com
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NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP

Congratulations to the 2019 ACEP Award Winners

The Board approved the following award winners during its April meeting and congratulates the recipients. The winners will be honored at ACEP19 in Denver.

- **John G. Wiegstein Leadership Award:** Sandra M. Schneider, MD, FACEP
- **James D. Mills Outstanding Contribution to Emergency Medicine Award:** Ramon W. Johnson, MD, FACEP
- **Judith E. Tintinalli Award for Outstanding Contribution in Education:** William “Ken” Milne, MD, FACEP
- **Outstanding Contribution in Research Award:** Rebecca M. Cunningham, MD, FACEP; and Gail D’Onofrio, MD, FACEP
- **Outstanding Contribution in EMS Award:** Robert E. O’Connor, MD, FACEP
- **Colin C. Rorrie, Jr. Award for Excellence in Health Policy:** Peter J. Jacoby, MD, FACEP
- **Policy Pioneer Award:** Megan L. Ranney, MD, FACEP
- **John A. Rupke Legacy Award:** Juan A. Gonzalez-Sanchez, MD, FACEP
- **Honorary Membership Award:** Lowell Gerson, PhD, and Laura Gore
- **Pamela P. Bensen Trailblazer Award:** Andrew I. Bern, MD, FACEP
- **Diane K. Bollman Chapter Advocate Award:** Elena Lopez-Gusman
- **Spokesperson of the Year (2018):** Benjamin A. Savitch, MD, FACEP
- **Council Meritorious Service Award:** John H. Proctor, MD, FACEP
- **Teamwork Award:** Anne Zink, MD, FACEP; Laura Tilly, MD, FACEP; Brad Gruehn; and the SHIELDS Act Team
- **Horizon Award:** Zachary Jarou, MD
- **Champion of Diversity & Inclusion:** Bruce Lo, MD, FACEP
- **Curmudgeon Award:** Bradford L. Walters, MD, FACEP

- Government Services)
- Ryan Stanton, MD, FACEP (KY)
- Thomas Sugarman, MD, FACEP (CA)

Board of Directors Considers Influenza, Firearm Safety Research, Academic Protected Time, and More During April Meeting

The ACEP’s Board of Directors convened April 10–11, 2019, and discussed several issues impacting the specialty of emergency medicine. Among their decisions, they voted in favor of:

- Surveying the Council for a representative viewpoint on firearm safety, firearm injury-related research, and College policy
- A policy statement from the EMS Committee about salary and benefits considerations for EMS professionals
- A policy statement about violence prevention and intervention in EMS systems
- Hosting ACEP24 in Las Vegas
- Creating a national wellness award to celebrate institutions or organizations that demonstrate best practices when it comes to physician wellness, with the inaugural award presented during ACEP20
- Partnering with the Center for Improvement in Healthcare Quality to develop an accreditation process for freestanding emergency centers
- Approving an influenza ED best practices information paper
- Submitting a white paper to *Annals of Emergency Medicine* about the potential impact of the Accreditation Council for Graduate Medical Education’s proposed policy that would lessen the requirement for protected time for core faculty

Emergency Physician Named Chief Executive Officer of AOA

ACEP Board member Kevin Klauer, DO, EJD, FACEP, has been appointed chief executive officer of the American Osteopathic Association (AOA), the professional membership organization for more than 145,000 osteopathic physicians and medical students. As CEO, he will be responsible for strategy, operating results, organizational growth, and advocacy.

“We are thrilled for Dr. Klauer to join the AOA as our next CEO,” said AOA President William S. Mayo, DO. “The DO profession is undergoing significant growth, with approximately one in four medical students attending a college of osteopathic medicine. This is a pivotal moment for the osteopathic profession and health care overall, and we are confident in Dr. Klauer’s experience to lead us through a dynamic and evolving landscape.”

Dr. Klauer, an ACEP member since 1992 and current Medical Editor in Chief of *ACEP Now*, will finish his current term on the ACEP Board in October and will help transition a new emergency physician into the role of *ACEP Now* Medical Editor in Chief. See page 10 for a letter from Dr. Klauer about the transition and his new role.

Candidates Announced for Board, Council

The following candidates are running for ACEP leadership positions in 2019. Elections will take place at the Council meeting in Denver preceding ACEP19. More information on the candidates will be forthcoming.

President-Elect

- Jon Mark Hirshon, MD, FACEP (MD)
- Mark Rosenberg, DO, FACEP (NJ)

Council Speaker

- Gary Katz, MD, FACEP (OH)

Council Vice Speaker

- Kelly Gray-Eurom, MD, FACEP (FL)
- Andrea Green, MD, FACEP (TX)
- Howard Mell, MD, FACEP (IL)

Board of Directors (four open positions)

- Michael Baker, MD, FACEP (MI)
- Jeffrey Goodloe, MD, FACEP (OK)
- Rachele (Shelley) Greenman, MD, FACEP (NJ)
- Gabor Kellen, MD, FACEP (AACEM)
- Pamela Ross, MD, FACEP (VA)
- Gillian Schmitz, MD, FACEP (incumbent,

CONTINUED on page 8



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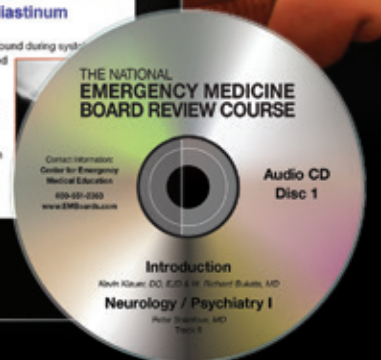
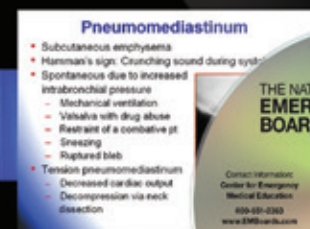
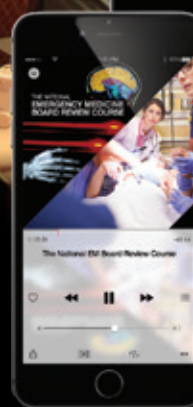
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THE BREAK ROOM



Vax-Debate

David,

With all due respect to you as a physician, I would like to share an alternative perspective on the vaccine safety conundrum [in response to "Advocating for Vaccination," February 2019].

Without acknowledging our Vaccine Injury Compensation Program has paid out more than \$4 billion to vaccine victims over the last 34 years, you have concluded all vaccines are safe for all.

Without mentioning our National Childhood Vaccine Injury Act (NCVIA) or the reasons it was created by Congress, you go on to encourage emergency physicians to become vaccine advocates.

Without mentioning the Vaccine Adverse Event Reporting System (VAERS) or the role emergency physicians should be playing in this passive vaccine safety net, you ignore the fact that 99 percent of possible vaccine-related events are not being considered by the same physicians you suggest become vaccine advocates instead of doing what is more ethical and moral for injured children and their parents.

Without any mention of a \$101 million dollar settlement awarded a Florida MMR injured child or the daughter of a Johns Hopkins pediatric neurologist, you ask EM doctors to ignore both NCVIA and VAERS.

Without mentioning a Centers for Disease Control and Prevention-funded Harvard study using an enhanced VAERS showed the actual incidence of illness and injury following vaccines given to Pilgrim Health subscribers was 2.4 percent, you suggest the real incidence is one in a million.

Without further comment on the code of Hippocrates, I urge anyone to find a study on the safety of injected aluminum on the day of

birth and each well baby visit during the first year or injections of mercury and aluminum into a pregnant woman.

David Denton Davis, MD
La Jolla, California

Dr. Talan Responds

Thank you for your comments illustrating some concerns about vaccinations. As you have concerns as a physician, just imagine those of our patients.

As long as there are medications and attorneys, there will be side effects and lawsuits. I agree that we have a duty to report all serious medication-related adverse events. It's helpful to emergency physicians to know about the Vaccine Adverse Event Reporting System (VAERS) that mandates this monitoring. The reporting and investigation of side effects of the original whole-cell pertussis and initial rotavirus vaccines (RotaShield) led to their recall and development of safer and more effective products. Many would point to this as evidence of the success for our current vaccine monitoring efforts.

The Vaccine Injury Compensation Program

(VICP) was established through the National Childhood Vaccine Injury Act of 1986 (along with VAERS) to indemnify vaccine manufacturers because their fear of jury awards, like the one you mention, could dissuade them from producing vaccines, but not because vaccines were inherently dangerous products. Just like life-saving antibiotics that we routinely prescribe, vaccines rarely cause serious reactions,

such as anaphylaxis that is estimated at one in 1–2 million vaccine doses. However, almost all vaccine side effects (let's accept the "2.4 percent" you mentioned) are mild and transient. The VICP is a no-fault program in which awards are provided if there is any reasonable association of the vaccine and the side effect. Of note, while conditions like shoulder injury related to the injection

and vasovagal syncope are covered, autism, the most prominent current concern, is not a compensated condition.

The bases for my opinions about the safety of vaccines, relative to their great benefits, are scientific investigations in hundreds of thousands of individuals and their associated fol-

lowed millions of person-years, some of which I referenced, and the conclusions of medical and public health authorities like the Centers for Disease Control and Prevention, the World Health Organization, and the American Academy of Pediatrics. In fact, since my article, another major study was published that found no associated risk of autism among 657,461 Danish children (representing 5,025,754 person-years) who received the MMR vaccine.¹ Adjuvant vaccines, such as Prevnar and Hib, which have virtually eliminated childhood bacterial meningitis, contain aluminum, but in an amount that is minimal relative to normal human exposure, such as through dietary exposure. However, even with enhanced reporting of temporally associated symptoms by emergency providers, it may be difficult to satisfy skeptics who may attribute cause-and-effect relationships with any number of childhood conditions.

So let's be vigilant and informed. The elimination or near elimination of life-threatening diseases due to vaccines is irrefutable, as evidenced by the new outbreaks of measles in the areas of the United States where vaccination rates are low. The readers can weigh the relative merit of our opinions. I am encouraging our emergency medicine colleagues, who are in a unique position as their community's medical safety net, to advocate for vaccination with patients and parents. Below is a reference to actual data that may facilitate such dialogue, like the one we have had here.

David A. Talan, MD, FACEP, FAAEM, FIDSA
Los Angeles, California

Reference

1. Hviid A, Hansen JV, Frisch M, Melbye M. Measles, mumps, and rubella vaccination and autism: a nationwide cohort study. *Ann Intern Med*. 2019 March 5. doi: 10.7326/M18-2101. [Epub ahead of print]



FROM THE COLLEGE | CONTINUED FROM PAGE 6

ACEP Advocates for Workplace Violence Protections for Health Care Workers

Violence in the emergency department is a serious and growing concern. ACEP's 2018 survey reported that nearly half of emergency physicians polled had been physically assaulted, with more than 60 percent of assaults occurring in the past year. ACEP recently worked with Congressional offices to refine for H.R. 1309, The Workplace Violence Prevention for Health Care and Social Service Workers Act, and sent a letter of support asking Congress to consider how emergency departments in particular are staffed to ensure the important provisions of this legislation are implemented appropriately. ACEP's letter requested additional clarity of the legislation's wording to ensure any new federal requirements do not create any unintentional burdens for entities that do not directly control the health care workplace. Read more at www.acep.org/EDsafety.

ACEP Submits Statement on Surprise Billing, Bundled Payments

On April 2, 2019, ACEP submitted a statement for the record to the House Committee on Education and Labor's Subcommittee on Health, Employment, Labor, and Pensions that urged

legislators to take into account the unique nature of emergency medicine, while examining the surprise billing issue. The letter explains how EMTALA has disincentivized health plans from entering into fair and reasonable contracts to provide services at appropriate in-network rates.

This letter also explains ACEP's stance on recent proposals related to bundled payments being discussed as part of negotiations to develop federal balance billing legislation: "We also note our strong concerns with proposals that would either provide a single bundled payment from a hospital for emergency services or would set a benchmark payment at a certain level of Medicare rates. A bundled payment would not actually address the underlying cost issues, but instead merely shift the venue for negotiation under the assumption that hospitals would somehow be able to better negotiate with physicians than insurers."

ACEP, NAEMT Celebrate EMS Week

The 45th National EMS Week is May 19-25, 2019, bringing together local communities and medical personnel to publicize safety and honor the dedication of EMTs. In 1974, President Gerald Ford authorized EMS Week to celebrate EMS practitioners and the important work they do in our nation's communities. Presented by ACEP and the National Association of EMTs



(NAEMT), our EMS Week 2019 theme is "BEYOND the CALL." Each weekday has a different emphasis:

- May 20: Education
- May 21: Safety Tuesday
- May 22: Emergency Medical Services for Children Day
- May 23: Save-A-Life (CPR and Stop the Bleed)
- May 24: EMS Recognition Day

Looking for ways to celebrate EMS practitioners during EMS Week? Visit www.naemt.org/initiatives/ems-week for ideas. ➔

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Farewell, and Thank You

A MESSAGE FROM ACEP NOW'S MEDICAL EDITOR IN CHIEF



ACEP

Dear friends and colleagues,

Opportunity often finds you when you're ready, but not, necessarily, when you're looking for it.

On June 1, 2019, I will begin a new role as the Chief Executive Officer of the American Osteopathic Association (AOA). I cannot begin to express my excitement and enthusiasm to serve in this new role and my gratitude and appreciation to the AOA Board of Trustees for selecting me. I will serve the AOA and the osteopathic profession and community with the same passion, effort, and dedication with which I have so willingly committed to ACEP, our specialty, and our members for so many years. However, this new role will require my full commitment and attention, prompting my decision to step away from my ACEP roles.

The AOA Board of Trustees and my fellow ACEP Board members support me in completing my term on the ACEP Board, which culminates this October. However, I will not be available to serve beyond October and will not run for a second term, which is the usual course for ACEP Board members. Serving you as one of your ACEP Board members has truly been an honor and a distinction, which

I will remain thankful for throughout my life and career.

In addition, I have resigned my position as *ACEP Now's* Medical Editor in Chief. My six years of service to ACEP in this capacity have truly been a labor of love. I have enjoyed and celebrated the success the publication has achieved in winning APEX awards for journalistic excellence every year since our transition from the former name, *ACEP News*, and format, and achieving the highly coveted #1 readership position in our space. Many hands make light work. The outstanding ACEP staff and our publishing partner, John Wiley and Sons, have been instrumental in building this publication and establishing *ACEP Now* as "The Official Voice of Emergency Medicine."

Our recent ACEP membership survey results reflect that ACEP members value this publication, among the top-rated membership resources, and thus, our commitment to the members and our readership must and will continue.

New beginnings should not be overshadowed by the finality of transitions, but reflect the opportunity for new ideas, new leadership and others to contribute and achieve new organizational heights, built on the foundations

created by our predecessors.

To that end, I am committed to working with our staff, membership, and readership to help identify my successor. I am also committed to mentoring and onboarding the new Medical Editor in Chief to ensure their success and an ever-brighter future for *ACEP Now*.


I am in your debt and that of ACEP for the wonderful opportunities afforded me by this incredible organization. You are my friends, my colleagues, and my family. You have done far more for me than I could ever hope to repay.

Please accept my humble thanks and deeply felt gratitude.

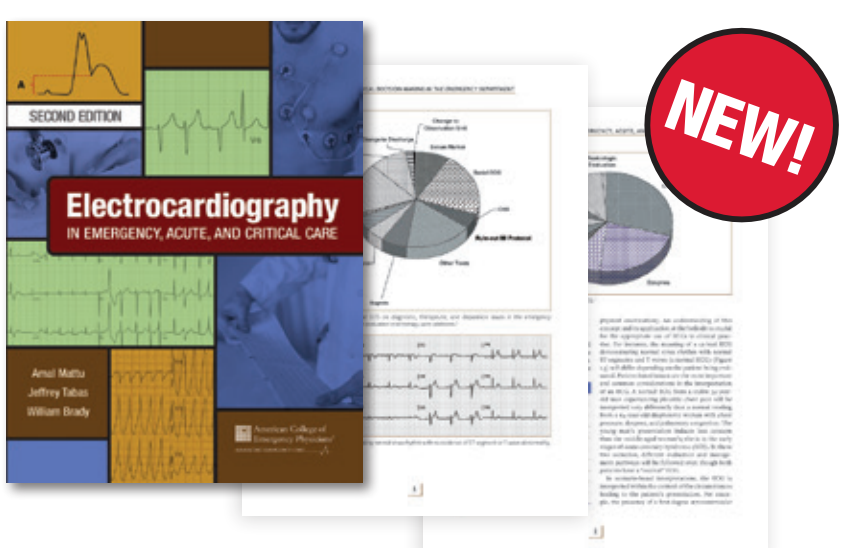
Sincerely,

Kevin

KEVIN M. KLAUSER, DO, EJD, FACEP, is chief medical officer—hospital-based services and chief risk officer for TeamHealth as well as the executive director of the TeamHealth Patient Safety Organization. He is a clinical assistant professor at the University of Tennessee and Michigan State University College of Osteopathic Medicine.



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SUICIDE CONTAGION IN ADOLESCENTS

The role of the emergency department

Suicide is the second-leading cause of death among youth and young adults ages 10 to 24 in the United States.¹ In 2016, the rate of suicide among persons ages 15 to 24 was 13.15 per 100,000 individuals.² According to the 2015 national Youth Risk Behavior Survey, 17.7 percent of youth in grades 9 through 12 reported seriously considering suicide in the previous 12 months, 8.6 percent of youth reported making at least one suicide attempt in the previous 12 months, and 2.8 percent reported a suicide attempt that required medical treatment.³

Suicide contagion is the process by which one suicide facilitates the occurrence of another through direct or indirect awareness of the prior suicide. Two main types of

Indication and Usage

HYPERRAB® (rabies immune globulin [human]) is indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

Limitations of Use

Persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer should receive only vaccine.

For unvaccinated persons, the combination of HYPERRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis.

Beyond 7 days (after the first vaccine dose), HYPERRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

Important Safety Information

For infiltration and intramuscular use only.

Severe hypersensitivity reactions may occur with HYPERRAB. Patients with a history of prior systemic allergic reactions to human immunoglobulin preparations are at a greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available for treatment of acute allergic symptoms, should they occur.

HYPERRAB is made from human blood and may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The most common adverse reactions in >5% of subjects during clinical trials were injection-site pain, headache, injection-site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

Do not administer repeated doses of HYPERRAB once vaccine treatment has been initiated as this could prevent the full expression of active immunity expected from the rabies vaccine.

Other antibodies in the HYPERRAB preparation may interfere with the response to live vaccines such as measles, mumps, polio, or rubella. Defer immunization with live vaccines for 4 months after HYPERRAB administration.

Please see brief summary of Prescribing Information on adjacent page or visit HyperRAB.com for full Prescribing Information.

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suicide clusters have been discussed in the literature: mass clusters, which are media-related (suicides are grouped in time but not space), and point clusters, which are local (suicides are contiguous in time and space).^{4,5} Emergency clinicians are often primary points of contact for persons at elevated risk for suicide, and they have the ability to alter a patient’s clinical course. It is imperative that frontline providers learn to recognize the risk factors, provide proper screening, and refer patients for treatment. There is strong evidence that emergency departments and emergency physicians are critical to such injury prevention and intervention efforts.⁶

TYPES OF CONTAGION

In adolescents, many studies have demonstrated a strong association between major

depression and suicide. In a recent large U.S.-based longitudinal study, the relative risk of exposure to suicide was 2.96 to 7.67 depending on the relationship (friend or family member) to the person who attempted suicide.⁷ Bullying has been identified as increasing the risk of suicidal behaviors, particularly in youth with underlying suicide risk factors (eg, mental health problems, substance use, early childhood adversity such as abuse, and other psychosocial stressors). Bullying can be physical, verbal, or relational (eg, rumors and social exclusion). The Centers for Disease Control and Prevention (CDC) reported that, in 2013, 23.7 percent of boys and 15.6 percent of girls were bullied at school, while cyberbullying was experienced by 21 percent of girls and 8.5 percent of boys.⁸ Increases in suicidal ideation and/or suicide attempts are observed

in both bullies and victims. Media exposure has been investigated as a source of suicide contagion. Traditionally, this has been divided into fictional and non-fictional exposure to suicide, with books, newspapers, television, and radio being the major sources of content. Recently, the internet, with multiple social platforms and news outlets, has greatly increased the opportunity for individuals to be exposed to fictional and nonfictional suicides. The association between nonfiction reporting and suicidal behavior is stronger. This is particularly true of teenage observers, especially when the subject of the report is similar to the observer in terms of age, sex, and nationality. When reporting suicides, the news media often oversimplifies the causes, attributing the act to single factors, such as financial

disasters, broken relationships, or failure in examinations. What is often overlooked is the most common factor leading to suicide: mental illness.⁹ This style of reporting can increase the risk of suicide contagion. It has also been noted that the suicide of a celebrity, along with the amount, duration, and prominence of coverage, proportionally increases the suicide rate.¹⁰ The risk for suicide contagion as a result of media reporting can be minimized by factual and concise media reports of suicide, which is in accordance with CDC recommendations.^{10,11} The internet offers adolescents social contact through websites, social media, forums, video imaging/sharing, and blogs. The internet has the potential to offer support and protect adolescents’ mental health by reducing social isolation, increasing self-esteem, and offering crisis support as well as outreach and access to therapy. Unfortunately, information on the internet may have both positive and negative effects, as there is also a potential for harm with access to pro-suicide sites, communities encouraging suicide, and increased contact with suicidal individuals, which can result in contagion through normalization of suicide, cyber suicide pacts, and descriptions of how to commit suicide.¹² **SCREENING FOR SUICIDE RISK IN EMERGENCY DEPARTMENTS** Starting in 2010, The Joint Commission recommends all medical patients in hospitals be screened for suicide risk. Although “at-risk” patients may be seen in primary care or inpatient settings, for more than 1.5 million youth, the emergency department is their only point of contact with a health care provider. Screening in the emergency department may also be more acceptable to patients and their families and, in many cases, is nondisruptive to workflow. In 2012, three pediatric emergency departments developed a brief instrument for the emergency department. The Ask Suicide-Screening Questions tool recommends asking four less-specific questions before moving to the all-important, “Are you having thoughts of killing yourself right now?” More information about the Ask Suicide-Screening Questions tool may be found on the National Institute of Mental Health website at www.nimh.nih.gov/labs-at-nimh/asq-toolkit-materials. **RISK REDUCTION** The CDC has developed a conceptual framework for the prevention and local containment of suicide clusters.¹³ The recommendations advocate for a coordinated interdisciplinary approach led by a community coordinating committee composed of representatives from the school district, municipal government, mental health services, medical facilities, emergency medical services, academia, clergy, parent organizations, survivor support groups, and the media. Emergency departments should coordinate with the community coordinating committee to ensure timely patient referral for appropriate counseling. When suicide is the cause of death of an emergency department patient, the attending emergency physician may have an opportunity to shape media coverage. Whenever possible, emergency physicians communicating with reporters should sensitize them to the problem of suicide contagion and remind or familiarize them with the CDC’s recommended

CONTINUED on page 27

HyperRAB[®]
Rabies Immune Globulin (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HYPERRAB[®] safely and effectively. See full prescribing information for HYPERRAB. HYPERRAB [rabies immune globulin (human)] solution for infiltration and intramuscular injection Initial U.S. Approval: 1974

INDICATIONS AND USAGE

HYPERRAB is a human rabies immune globulin indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies. Limitations of Use: Persons previously immunized with rabies vaccine that have a confirmed adequate rabies antibody titer should receive only vaccine. For unvaccinated persons, the combination of HYPERRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis. Beyond 7 days (after the first vaccine dose), HYPERRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

DOSAGE AND ADMINISTRATION

For infiltration and intramuscular use only. Administer HYPERRAB within 7 days after the first dose of rabies vaccine.

Postexposure prophylaxis, along with rabies vaccine, after suspected exposure to rabies	HYPERRAB 20 IU/kg body weight OR 0.0665 mL/kg body weight Single dose	<ul style="list-style-type: none">Administer as soon as possible after exposure, preferably at the time of the first rabies vaccine dose.Infiltrate the full dose of HYPERRAB thoroughly in the area around and into the wound(s), if anatomically feasible.Inject the remainder, if any, intramuscularly.
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DOSAGE FORMS AND STRENGTHS

300 IU/mL solution for injection supplied in 1 mL and 5 mL single-dose vials.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

- Severe hypersensitivity reactions, including anaphylaxis, may occur with HYPERRAB. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions.
- HYPERRAB is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

The most common adverse reactions in >5% of subjects in clinical trials were injection site pain, headache, injection site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Repeated dosing after administration of rabies vaccine may suppress the immune response to the vaccine.
- Defer live vaccine (measles, mumps, rubella) administration for 4 months.

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of us came to emergency medicine from pre-hospital or military backgrounds, where we had more immediate firsthand experience. Firearm injury is an issue that impacts all of us.

We see how it's getting worse. More and more of us are joining the awful club of having had to treat a mass shooting. More and more of us have had family members or friends who have been injured. More and more emergency physicians are being hurt or killed, most tragically and notably with the shooting death of Tamara O'Neal, MD, outside her emergency department at Mercy Hospital in Chicago.

However, we also know that we don't have to accept injury or disease outbreaks as a *fait accompli*. We have a long history of mobilizing, as emergency physicians, to identify and then reduce patterns of injury. Doing this work is nonpartisan; it's based on science and great research. Through this public health approach, emergency medicine has been a critical leader in national and local efforts to reduce car crash deaths and child abuse, plus is leading the charge against opioid overdose deaths, human trafficking, and more.

Emergency medicine is also a leader in developing a public health approach to reduce firearm injuries. Through this approach, we can make a difference in the prevalence, severity, and long-term consequences of gunshot wounds across the country.

A short list of actions by ACEP includes:

- Six years of work by the ACEP Trauma & Injury Prevention Section to highlight the importance of addressing firearm injury as a public health problem
- Lectures on firearm injury prevention at ACEP17 and ACEP18
- A firearm injury prevention policy that was rewritten in 2013 and is currently being reevaluated by the Public Health & Injury Prevention Committee in addition to the original task force
- Completion of a Technical Advisory Group on emergency medicine–relevant firearm injury research, culminating in a publication in *Annals of Emergency Medicine* in 2016¹
- Active advocacy for federal funding and universal background checks, in accordance with ACEP's firearm injury prevention policy
- Completion of two surveys of emergency

physicians' firearm injury prevention practices and beliefs through the EM-PRN network

- Donating \$20,000 to the American Foundation for Firearm Injury Reduction in Medicine (AFFIRM), a not-for-profit organization founded and led by emergency physicians

Additionally, emergency physicians have led national non-ACEP-affiliated efforts to change the trajectory of this epidemic. A short and incomplete list includes:

- Development of the "What You Can Do" video series on screening and counseling by Garen J. Wintemute, MD, MPH, at UC-Davis Health in Sacramento, California
- Development of the National Institutes of Health–funded Firearm Safety Among Children and Teens consortium, led by Rebecca Cunningham, MD, FACEP, and Patrick Carter, MD, at the University of Michigan in Ann Arbor, with the collaboration of numerous emergency physicians across the country
- Leadership of the National Network of Hospital-Based Violence Intervention Programs by Kyle Fischer, MD, MPH, of the University of Maryland in College Park; Robert Gore, MD, of Kings County Hospital in Brooklyn, New York; and many more
- Development of novel coalitions between gun shop owners and firearm injury prevention researchers led by Marian (Emmy) Betz, MD, MPH, at the University of Colorado-Denver
- Promotion of the #StopTheBleed training by Eric Goralnick, MD, FACEP, at Brigham and Women's Hospital in Boston
- Development of a scholarship fund in honor of Dr. O'Neal by the University of Illinois-Chicago residency and a memorial research fund in her name by the AFFIRM and FemInEM
- The #ThisIsOurLane movement, covered in *The New England Journal of Medicine* with a piece by myself, Dr. Betz, and Cedric Dark, MD, MPH, of Baylor College of Medicine in Houston²

Individual emergency physicians have written numerous publications and led local movements as well. There simply isn't space to list them all.

Lastly, emergency physicians have led the

charge to develop new sources of research funding. Firearm injury prevention research is currently funded at about 2 percent of what would be predicted, and the Centers for Disease Control and Prevention still has \$0 for this public health issue.

In 2017, AFFIRM was founded under the leadership of Christopher Barsotti, MD, FACEP, FAAEM, in response to this continued lack of substantive federal funding for firearm injury prevention research. Its underlying concept is that the public's health is our job and that we cannot solve the firearm injury epidemic by treating patients who have already been shot. Instead, we need a full-scale collaborative effort, the collective will of medicine, to bend the curve on firearm injuries and deaths.

The mission of AFFIRM is to reduce firearm injury deaths through research, innovation, and evidence-based practice. AFFIRM knows that through clinically relevant research and dissemination of best practices, we can stop many shooters before they shoot. AFFIRM has the partnership of almost 20 medical societies, including ACEP, the Emergency Medicine Residents' Association (EMRA), and the Emergency Nurses Association. It represents physicians and health care professionals along the political spectrum who are united in the belief that we need to find a new way forward; the old ways of fighting this epidemic aren't working. Examples of AFFIRM's work include:

- Under the leadership of Dr. Betz, the chair of the Research Council, AFFIRM is co-funding research grants with the Emergency Medicine Foundation and EMRA, as well as with the Firearm Safety Among Children and Teens consortium, based off of ACEP's published research agenda, to spur innovative, clinically relevant approaches to reducing the firearm injury epidemic.
- AFFIRM developed the Dr. Tamara O'Neal Memorial Research Fund last November, in collaboration with Dr. O'Neal's friends, co-residents, and family. This fund honors Dr. O'Neal's memory. Its goal is to create meaningful change in her name by funding research that addresses the issues she most cared about, including sponsorship of people of

color and development of youth mentorship programs.

- AFFIRM is developing infographics, blog posts, podcasts, and educational slide decks under the leadership of Nikita Joshi, MD, AFFIRM's director of education and outreach, along with numerous other members of AFFIRM's advisory board and research council, to help disseminate all of this awesome work.
- Finally, AFFIRM is organizing a series of events across the country this fall, "AFFIRM Across America," to highlight the personal stories of all of us who have treated or been personally affected by gun violence—and to create hope. Emergency physician Charlotte Lawson, MD, is leading this initiative.

Emergency medicine is once again at the forefront of change. We are creating a path forward that isn't "us versus them." It's all of us together, speaking out on behalf of our patients and communities, to tackle firearm injury the same way we've addressed every public health epidemic in history, through nonpartisan research, evidence-based practice, and community-oriented solutions.

To learn more about AFFIRM, please visit www.affirmresearch.org. ➔

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1. Ranney ML, Fletcher J, Alter H, et al. A consensus-driven agenda for emergency medicine firearm injury prevention research. *Ann Emerg Med*. 2017;69(2):227-240.
2. Ranney ML, Betz ME, Dark C. #ThisIsOurLane - firearm safety as health care's highway. *N Engl J Med*. 2019;380(5):405-407.



DR. RANNEY is director of emergency digital health innovation and special projects and associate professor in the department of emergency medicine and department of health services, policy and practice at Brown University and the Injury Prevention Center of Rhode Island Hospital in Providence. **Disclosure:** She serves as AFFIRM's chief research officer, a volunteer position.

GLOBE TROTTER

High-yield ocular ultrasound applications in the emergency department

by KATRINA D'AMORE, DO, MPH; SARAH BOLAN, MD; AND NICOLE YUZUK, DO

Part 3 of a 3-part series. Visit ACEPNow.com to read parts 1 and 2.

Common Emergency Department Application

Structure: Vitreous Humor/Body

Evaluate for: Vitreous hemorrhage, vitreous detachment

The vitreous humor, which goes by several names, is a transparent gelatinous mass that occupies 80 percent of the volume of the eye, filling the space between the lens and the retina. The vitreous is more fluid-like centrally and more gelatinous on its peripheral edges. This vitreous body is surrounded by a collagenous membrane that is in contact with the retina. Because its composition is 99 percent water, a normal vitreous will appear anechoic on ultrasound, giving the posterior chamber a completely black appearance. In the case of vitreous hemorrhage, one will note echogenic material in the posterior chamber (see Figure 1). This increased echogenicity may be obvious or subtle. Woo et al found that the sensitivity of ED physicians utilizing POCUS for vitreous hemorrhage was only 43 percent, but the specificity was 94 percent.¹

Vitreous detachment is another pathological condition encountered in the emergency department. It occurs when the vitreous membrane separates from the retina and is most often atraumatic. On ultrasound, this may

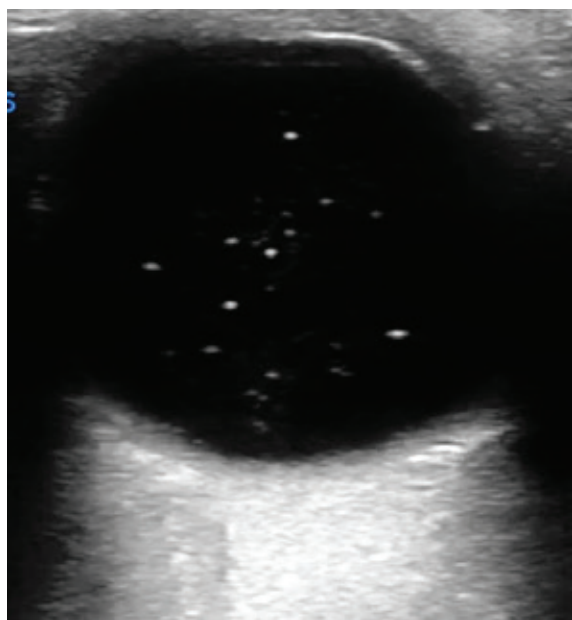


Figure 1: In vitreous hemorrhage, echogenic material is visible in the posterior chamber.

appear similar to a retinal detachment, but a vitreous detachment is more globular and not likely to appear undulating or move along with patient eye movements (see Figure 2). In contrast to the retina, a detached vitreous will not be tethered by any specific structural attachments.

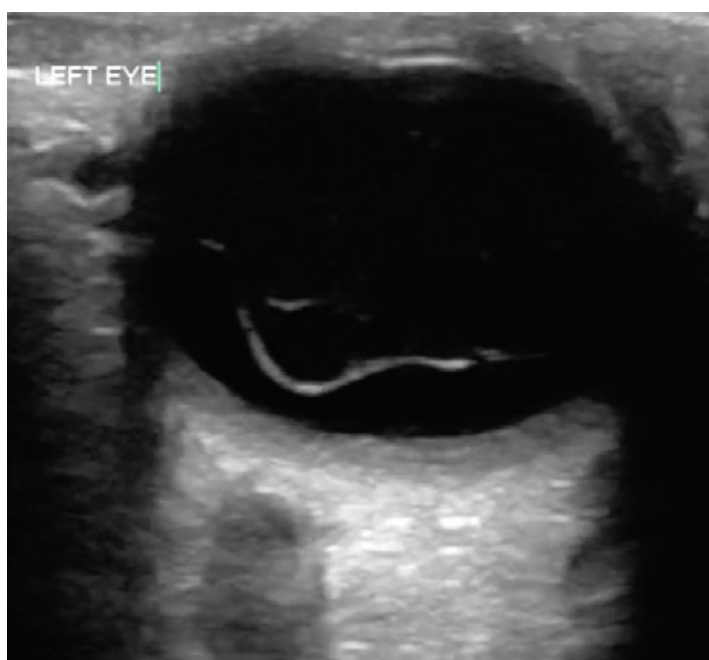
Tips & Tricks: When suspicion is high, increase the ultrasound gain to pick up subtler vitreous hemorrhages.

Ocular ultrasound is easy to learn and can rapidly assess ocular emergencies. With practice, you can easily incorporate POCUS into your diagnostic algorithm and rule in or out important ocular pathology. +

References

1. Woo MY, Hecht N, Hurley B, et al. Test characteristics of point-of-care ultrasonography for the diagnosis of acute posterior ocular pathology. *Can J Ophthalmol*. 2016;51(5):336-341.

Figure 2: Vitreous detachment may appear similar to a retinal detachment but is more globular and not tethered by any specific structural attachments.



Ultrasound Technique

- 1 Explain this bedside procedure to your patient prior to starting. As this is a dynamic scan, the patient will have to move his or her eyes side to side and up and down to allow complete visualization of the posterior segment.
- 2 The orbit is a superficial structure. Therefore, a high-frequency linear transducer should be used.
- 3 For comfort and to prevent a mess, place a Tegaderm film dressing over the patient's closed eye and gently press out any pockets of air. Remember, air is the enemy of ultrasound.
- 4 When performing ocular ultrasound, a copious amount of gel should be used, which will prevent contact of the transducer with the eyelid and minimize direct pressure. The gel can be applied directly over the Tegaderm (see Figure 2).



FIGURE 3: Place a Tegaderm film dressing over the patient's closed eye, gently press out any pockets of air, and apply a copious amount of gel directly over the Tegaderm.

- 5 Visualize the orbit in both transverse (see Figure 3) and longitudinal planes. After scanning through, the patient should be asked to move his or her eye right to left and up and down. A combination of still images and dynamic scanning clips will best document your exam.



FIGURE 4: Transverse visualization of the orbit.

- 6 Repeat these steps on the unaffected eye.
- 7 Contraindications to the exam include high suspicion of globe rupture.
- 8 Always supplement your ocular POCUS exam with a visual acuity and intraocular pressure measurement for a well-rounded emergency eye exam.

TIPS & TRICKS

Stabilize your scanning hand by placing your thumb or pinky finger (whichever is medial) on the bridge of the patient's nose (see Figure 5). This will also prevent you from applying too much pressure.



FIGURE 5: Stabilize your scanning hand by placing your pinky finger on the bridge of the patient's nose.

ACEP4U: Drug Shortages

HOW ARE WE ADVOCATING FOR YOU?

by JORDAN GRANTHAM

We know the ongoing shortage of lifesaving medicines is one of the biggest problems emergency physicians deal with on a daily basis. You shouldn't have to wonder what medicines might be available on any given day. You shouldn't have to constantly find alternatives for drugs that aren't available, and your time shouldn't be spent being trained and retrained about what drugs to use and what new protocols are in place every time a new drug shortage is announced. Not only do drug shortages make it harder for emergency physicians to practice, but this problem jeopardizes the health of ED patients. The medication substitutes are often less effective or come with different side effect profiles.

ACEP has been a leading voice on this issue, bringing it to public attention and pushing for progress at the federal level. Below is a timeline of our federal advocacy activities related to drug shortages:

May 2018

- ACEP conducted a survey of members and found that nine out of 10 emergency physicians had experienced a drug shortage in the last month.
- We drafted a congressional sign-on letter urging US Food and Drug Administration (FDA) Commissioner Scott Gottlieb to establish a task force to identify the root causes of drug shortages and develop recommendations to address them. We then secured bipartisan, bicameral sponsors for the House and Senate letters from Rep. Brett Guthrie (R-KY), Rep. Mike Doyle (D-PA), Sen. Bill Cassidy, MD (R-LA), and Sen. Chris Murphy (D-CT), respectively.
- ACEP's public relations team distributed a press release of drug shortage survey results in the lead up to the 2018 Leadership & Advocacy Conference (LAC).
- At LAC on May 22, 2018, the drug shortage problem was one of two topics we raised on the Hill (the other being our opioid bills). LAC participants urged members of Congress to sign the letter asking the FDA to establish the task force. Ultimately, the House letter closed with 107 representative signatures, and the Senate letter was signed by 31 senators.

June 2018

- *The New York Times* reached out to ACEP after seeing our press release on the drug shortage survey results, and we worked with them to develop an article that brought more national attention to the issue.¹

“So many substances are short, and we're dancing every shift,” said Dr. James Augustine, an [emergency physician] in Cincinnati.

— *The New York Times*, July 1, 2018

July 2018

- In direct response to the congressional letters authored by ACEP, FDA Commissioner Gottlieb announced the creation of a new Drug Shortage Task Force charged with identifying and addressing the root causes of drug shortages affecting the health care system. This was an important step forward for ACEP's drug shortage advocacy efforts; it was exactly what our congressional letter had requested.

September 2018

- ACEP Board member Aisha Liferidge, MD, MPH, FACEP, participated in a two-day workshop hosted by the National Academies of Sciences, Engineering, and Medicine (NASEM) on medical product shortages during disasters. Dr. Liferidge discussed the unique challenges emergency physicians and their patients face during natural disasters and disease outbreaks and further discussed opportunities to lessen the effects of medical product shortages through

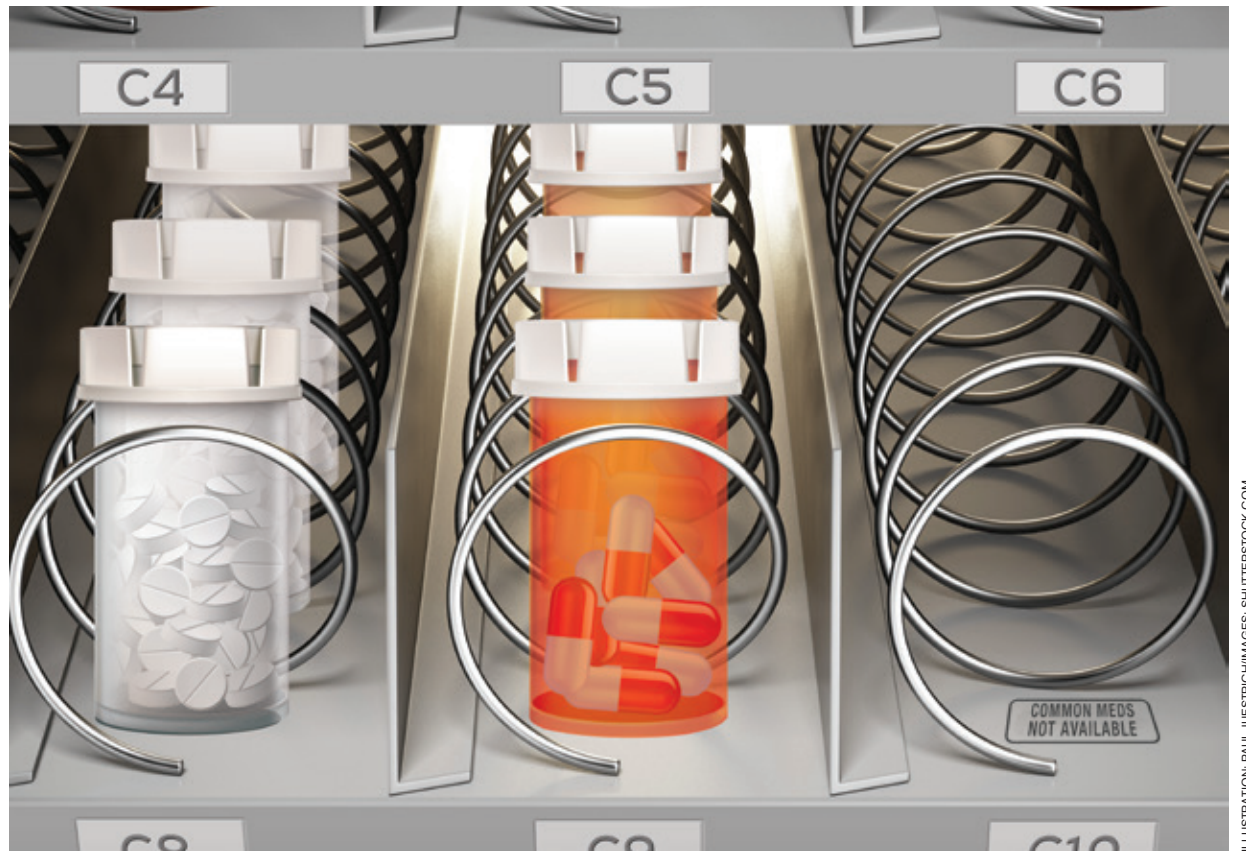


ILLUSTRATION: PAUL JUESTRICH/IMAGES SHUTTERSTOCK.COM

information sharing; improved supply-chain infrastructure; and enhanced collaboration among public, private, and nonprofit stakeholders.

- Then-ACEP President Paul Kivela, MD, MBA, FACEP, attended a drug shortage summit hosted by the American Society of Anesthesiologists, American Hospital Association, and American Society of Health-System Pharmacists. The summit focused on the national security implications of drug shortages and ways to improve the nation's health care infrastructure. Dr. Kivela engaged government speakers about steps that could be taken to lessen shortages for essential medications needed on a daily basis in the emergency department.

October 2018

- ACEP President Vidor Friedman, MD, FACEP, participated in a listening session with the FDA Drug Shortage Task Force. ACEP was one of only 10 groups invited to participate, and Dr. Friedman provided important perspectives on how drug shortages impact care for emergency patients.

November 2018

- ACEP attended an FDA Drug Shortage Task Force public meeting.

January 2019

- ACEP submitted its official response to the FDA Drug Shortage Task Force. We explained how emergency physicians are directly affected by drug shortages each day and how much it negatively affects patient care.

“Shortages of commonly used but essential medications remain an acute problem throughout the health care system, but **these shortages tend to disproportionately affect emergency medicine** (both hospital and pre-hospital) due to its reliance upon generic medications for rapid sequence intubation, seizures, antidotes, resuscitation, as well as analgesics, antiemetics, and anticoagulants.”

— ACEP's letter of response to the FDA Drug Shortage Task Force

May 2019

- ACEP is waiting for the FDA Drug Shortage Task Force to submit its findings and final report to Congress. Based on its recommendations, we expect the House of Representatives and Senate to develop legislation to address the challenges and problems identified in the report. ACEP's Washington, D.C., staff will be actively involved with those discussions and the drafting of potential legislative solutions. Stay tuned. When the time comes, we will be asking for your help to communicate ACEP's recommended solutions to lawmakers.

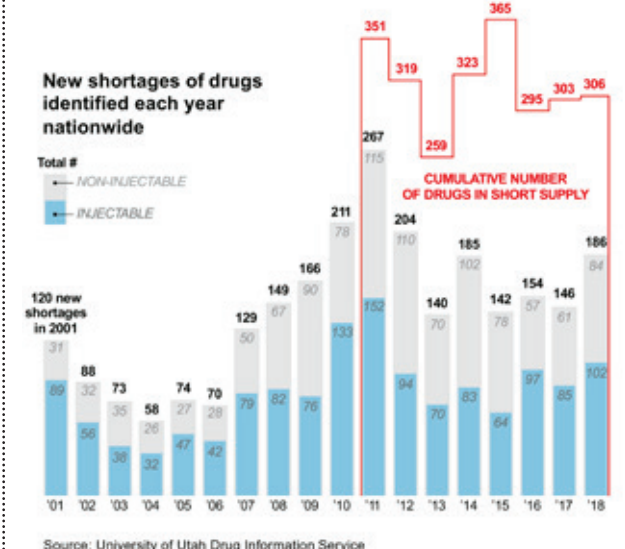
Stay Updated

ACEP is dedicated to providing emergency physicians a strong and unified voice in Washington, D.C., speaking out on the issues that matter most to you and your patients. Want to stay apprised of ACEP's ongoing federal legislative activities? Sign up for the 911 Legislative Network, the premier grassroots network for emergency physicians. Find continual updates about all of ACEP's advocacy work, drug shortages and beyond, on the Federal Advocacy page at ACEP.org. +

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MS. GRANTHAM is a communications manager at ACEP.





ACEP Should Avoid the Firearms Debate

Our professional society should focus on emergency medicine and stay out of divisive political issues

by MARCO COPPOLA, DO, FACEP

As an ACEP member, I share what many other members desire from membership: ACEP should make my life easier by seeking legislation and policies that make me work less hard, preserve our practice environment, and enhance our ability to care for our patients. That's what people want. We did not join ACEP for broad-based, political advocacy. Thus, when ACEP gets involved in issues not specific to the practice of emergency medicine, such as the separating of families at the border, climate change, or the firearms issue, ACEP runs the risk of alienating a good number of members. In other words, emotionally charged issues, which are polarizing, can and often do become divisive, creating a "no win" situation for ACEP.

The firearms issue may, in some cases, be less about patient safety than about furthering a political agenda. If it were solely about patient safety, then we would look to the multitude of peer-reviewed articles and data analyses outside the medical literature that prove that gun control efforts are not effective in reducing crime and injury.

If we examine the issue of research, testimony by John R. Lott, Jr., president of the Crime Prevention Research Center, before the House Committee on Appropriations on March 7, 2019, clarified several important issues:

- The Dickey Amendment has been misinterpreted. It does not prevent (and has not prevented) firearm research. It merely states that the Centers for Disease Control and Prevention cannot advocate for gun control.
- After 1996, firearms research fell as a percentage of all research. However, this is artificial because there was an increase in new journals and published articles, creating a larger denominator. Accounting for this, firearm research remained relatively constant from previous years.
- This has not been widely publicized, but there were three federal funding amendments for firearms research in 1996, 2003, and 2012.
- By 2013, the number of firearms articles rose to 121, to 196 in 2014, and to 344 in 2015.
- The share of federally funded research before 2000 was 2.9 percent, but after 2000 it was 3.3 percent. The share of research that mentioned any funding source before 2000 was 8.5 percent and 18.2 percent after 2000.
- In 2015–2018, the total federal funds

for firearms research was \$43.2 million, a 465 percent increase from 2011–2014, which resulted in 83 projects.

- One cannot apply the "medical method" of studying disease to studying firearm-related issues. (Incidentally, referring to firearm violence as an "epidemic" is erroneous and misleading because "epidemic" refers to a widespread occurrence of an infectious disease, not an action.)
- There is an abundance of firearm literature outside medicine in the economics and criminal justice literature that is peer-reviewed and scientifically sound, but is often ignored by those in medicine. These links direct to the Crime Prevention Research Center (<https://crimeresearch.org/cprc-research/> and <https://crimeresearch.org/data/>) and a policy analysis from the Cato Institute (www.cato.org/publications/policy-analysis/costs-consequences-gun-control). They are a good starting point for a review from "the other side."

The directive followed by the ACEP task force when creating the existing firearms policy in 2013 was not to "legislate" or contradict existing laws. Thus, if we examine legislative issues, ACEP recently advocated for H.R. 8 (requiring a background check for every firearms sale). Unfortunately, the support for that bill may not effect the desired change, because it still does not prevent criminals from obtaining firearms.

Interestingly, California recently decided that a ban on high capacity magazines (more than 10 rounds) is unconstitutional. Should ACEP's current firearms policy be updated to delete the referral to "high capacity magazines" in the last bullet?

I would prefer ACEP concentrate its efforts on the many challenges before us to make our lives easier, such as protecting patient's rights, advocating for access to emergency care, preserving the interests of emergency physicians, ensuring fair reimbursement, etc. We need to stay out of divisive politics and issues.



DR. COPPOLA is chair of the ACEP Leadership Development Advisory Committee and Compensation Committee; past ACEP Council Speaker; brigadier general, commanding, Texas Medical Brigade/Medical Component Command of the Texas State Guard, Texas Military Department.

Disclosure: He chaired the task force that created ACEP's current firearms policy in 2013.

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cumstances afforded them unique opportunities. Stated as a formula: historic achievement = ability + effort + opportunity.

These three elements are neither universally possessed nor reliably attainable. Ability is most common, intense personal effort less so, and special opportunity is notably scarce in comparison to the others (see Figure 1). To reach historic levels of individual achievement in leadership or any endeavor, all three are required.

Three Essential Elements

First, some measure of innate ability is the necessary raw material of any exceptional leader. This being said, many people possess sufficient ability to excel in one or more areas of human endeavor. However, while most incapable people may never become transformational leaders, it is also true that many highly capable people never become exceptional leaders. In a relative sense, ability is essential, abundant, and insufficient. Ability requires two additional elements, each progressively less common, to produce exceptional performance.

The second essential element is effort. Deluded leaders believe their own awesome genius is the key to their success. Grounded leaders understand that the difference between very good and great is usually not intrinsic ability but effort. Hard, focused, sustained effort is essential to shape and polish innate ability to diamond-like brilliance. While there are exceptions, individuals whose performance is truly exceptional still must make an extraordinary effort. Olympic athletes, world-class musicians, high-achieving leaders, etc. frequently started their journeys young, pursued a singular activity with uncommonly intense focus, and sustained this concentrated effort over an unusually long period of time. Thomas Edison's well-known remark memorably captures this sentiment: "Genius is 1 percent inspiration, 99 percent perspiration."

There remains a third essential element, both rare and subject at best to influence but seldom under our control. This third element is opportunity. Some might refer to this as fate, luck, or chance. Countless highly able and hard-working persons live out very productive, high-performing lives without reaching the pinnacle of achievement and prominence in their fields because they lacked opportunity. On this point, egotistic leaders go astray, whereas self-aware and grounded leaders recognize they have benefitted from uncommon opportunity(ies) and, at times, exhibit inspiring humility arising from sincere gratitude for their good fortune.

The Elements in Action

As an example, President Dwight Eisenhower was a young army officer during World War I, after which the U.S. military shrank dramatically in size, promotions were scarce, and careers stagnant. He served in the U.S. Army with distinction for decades, earning accolades from his superior officers but languishing at lower ranks for extended periods with little hope of promotion. Then, World War II changed everything, as the U.S. Army experienced its largest-ever expansion from fewer than 200,000 soldiers in 1939 to more than 8 million soldiers in 1945. This 40-fold growth exponentially increased the need for senior officers and provided previously stagnant but able and hard-working officers the opportunities they needed to achieve prominence on the global stage. Eisenhower, one of these men, served as Supreme Allied Commander in Europe, where he worked closely with the leading men of his age and was ultimately hailed as the man who defeated Hitler. He returned home such a widely acclaimed national hero and with such a rich network of affluent connections that it seemed to many a foregone conclusion he would become president. He is a prime example whose legacy as a person of history rather than a capable but forgotten soldier was made possible by unique opportunity.

How Does This Apply to Us?

As emergency physicians, our academic and professional achievements are evidence of our ability. In large measure, we are intelligent, innovative, and emotionally intelligent. We should take satisfaction in the gifts of ability we have been given. If we seek rarified heights of professional accomplishment, we need to focus further to identify our unique personal abilities toward which to deploy still more effort to enhance our chances of exceptional achievement.

Emergency physicians are also no strangers to focused and sustained effort. Logging 11 years or more of post-high school education and enduring workweeks so intense that they are capped at 80 hours, we epitomize outsized effort applied to maximizing our inherent abilities. Emergency medicine is still a large field, so historic achievement requires further focus. Ultrasound, toxicology, cardiovascular disease, etc. offer paths to focused clinical excellence. Many of

us possess talents in education, health policy, politics, executive management, etc. If we seek to truly excel, we must focus further, identify our differentiating abilities, and refine them through hard and sustained effort.

Even in possession of the above, we still require that essential third element: opportunity.

Opportunity and Choices

For those of you who believe you can change the world and think you are of historic potential, may the wind be at your back! Just remember, armed with all your genius, talent, beauty, and brawn, you will only get so far without the secret sauce of opportunity. Rarest of the three elements, the probability for opportunity can be optimized. It should also motivate us to reflect upon the values we hold, the examples we set, and how we choose to live our lives.

First, figure out in your own life where your unique talents overlap your passions and then commit to long, hard work to be the very best in this sliver of the universe. Beware: This will require forgoing other important parts of your life so that you can devote innumerable hours to the pursuit of excellence. Historic people often sacrifice a lot to be historic. They have been imprisoned, tortured, assassinated, impoverished, and mentally and physically unwell, among other challenges. However, great accomplishment often requires great sacrifice. If you desire graphic illustration of this, spend a weekend watching *Harry Potter*, *The Lord of the Rings*, *The Hunger Games*, etc. The glory of heroism frequently extracts a high cost. It's costly, tedious, and uncertain, but if you want to reach the pinnacle, this intensity is generally required.

Second, grow your network of people both within your area of expertise and in areas directly adjacent to it. In doing this, be sincere, not a suck-up. Genuinely appreciate the company of these others and enjoy your shared interests on their own merits. At the end of the day, being a good person still matters, and over the long haul, it is a substantial asset to you and those with whom you associate. Uncommon opportunities frequently present themselves through these personal relationships. Since you will seldom accurately predict which single relationship will result in your special opportunity, nurturing a wide array of connections increases your odds.

Last but not most important, if your opportunity to make history fails to materialize, remember that misery loves company and that you are in the company of 99.9 percent of all people! However, if you correctly identified an area in which you excel, worked diligently to be your best at it, and forged friendships with others who share your passion, you will have done well. If you step back from your ambitions to reflect on your journey, you may just find that, while books may not be written about you, you have nonetheless enjoyed a life worth living and positively impacted the lives of many others along the way. +



DR. STACK is an adjunct professor at the University of Tennessee Haslam College of Business in Knoxville; an emergency physician at CHI St. Joseph East in Lexington, Kentucky; and past president of the American Medical Association.



FROM TOP: Dwight Eisenhower, Jackie Joyner-Kersey, Jesse Owens, and Marie Curie.



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**as of April 2019*

TREATING HIGH-ALTITUDE ILLNESS

Spot and treat the symptoms of three common syndromes

by ASHLEY A. JACOBSON, MD, AND NEHA P. RAUKAR, MD, MS

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KEY POINTS

1. Do not ignore the signs and symptoms of high-altitude illness.
 - A. **HAPE:** Dry to productive cough with dyspnea within four to six days of arrival
 - B. **AMS and HACE:** Headache, nausea, vomiting, fatigue that progresses to ataxic gait, and encephalopathy within six hours to three days
2. Definitive treatment is descent. Can temporize with:
 - A. **HAPE:** high-flow nasal cannula, rest
 - B. **AMS and HACE:** NSAIDs, antiemetics progressing to dexamethasone, acetazolamide, hyperbaric therapy
3. Prevention: gradual ascent
 - A. **HAPE:** nifedipine, phosphodiesterase 5 inhibitors
 - B. **AMS and HACE:** acetazolamide, dexamethasone

The diagnosis and treatment of high-altitude illness (HAI) require an understanding of the interplay between physics and physiology. As altitude increases, pressure decreases, affecting the partial pressure of oxygen and thus decreasing the amount of oxygen diffusing into the tissues. This hypobaric hypoxia results in a cascade of events known as HAI. In an effort to acclimate, the respiratory rate increases, leading to respiratory alkalosis with metabolic compensation. This also causes an overall left shift of the oxygen-hemoglobin dissociation curve, increasing oxygen uptake in the lungs. Hypoxemia causes increased release of erythropoietin, leading to an increase in red blood cell production and overall better oxygen-carrying capacity to the tissues.

The most important syndromes that make up the spectrum of HAI are high-altitude pulmonary edema (HAPE) and acute mountain sickness (AMS), which can progress to high-altitude cerebral edema (HACE). Younger athletes and males are at greater risk of HAI since they are more likely to engage in vigorous activity prior to acclimatization or continue ascent despite symptoms. Other risk factors include chronic obstructive pulmonary disease, restrictive lung disease, cystic fibrosis, pulmonary hypertension, congestive heart failure, and sickle cell disease. Contrary to popular belief, neither well-controlled asthma nor pregnancy (up to 3,000 meters) increase the risk of HAI.

High-Altitude Pulmonary Edema

There are two types of HAPE: classic, which occurs in low-altitude residents who rapidly ascend, and reentry, which occurs in high-altitude residents re-ascending after being at low altitudes. The pathophysiology of HAPE consists of breakdown of the pulmonary blood-gas barrier secondary to increased pulmonary artery pressure and uneven pulmonary vasoconstriction resulting in fluid accumulation within the alveoli. This typically occurs around 3,000 meters. Patients present with a dry cough that progresses to a productive cough with frothy pink sputum and increased dyspnea within four to six days of arrival at altitude. Patients demonstrate tachycardia, tachypnea, inspiratory crackles, and low pulse oximetry on physical exam. Chest X-ray reveals patchy infiltrates, but it is not required to make a diagnosis.¹

The treatment of stable patients with HAPE involves simply giving oxygen via high-flow nasal cannula and decreasing cold exposure to resolve the elevation in pulmonary artery pressure. Unstable patients should descend as soon as possible, and if that is not possible, use hyperbaric therapy as indicated.¹ Medications can be used for treatment. However, they are more effective as preventative measures. Nifedipine can reduce pulmonary vascular resistance and decrease pulmonary artery pressure, and phosphodiesterase 5 inhibitors can increase cyclic guanosine 3',5'-monophosphate (cGMP) to augment the pulmonary vasodilatory effects of nitric oxide. Nitric oxide is a potent pulmonary vasodilator, released from endothelial cells, that decreases hypoxic pulmonary vasoconstriction and the pulmonary hypertension associated with HAPE. Inhaled beta-agonists can be used as an adjunct, but they have limited effectiveness as a sole treatment option.²⁻⁴

Acute Mountain Sickness and High-Altitude Cerebral Edema

The pathophysiologies of the neurological forms of HAI—AMS and HACE—are similar in that there is an increase in the permeability of the blood-brain barrier causing reversible vasogenic edema. The mechanism of this increased permeability is unclear. There is a possible increase in cerebral blood flow, loss of intracranial pressure autoregulation, and resultant alterations in endothelial permeability via increased nitric oxide levels and increased vascular endothelial growth factor (VEGF), which promotes angiogenesis. AMS and HACE are along a spectrum of disease, with AMS occurring around 1,500 meters with typical transition to HACE at more than 4,000 meters. The diagnosis for AMS is clinical, with symptoms that resemble a hangover, such as headache, anorexia, nausea, and vomiting.¹ Onset of AMS generally occurs within six to 12 hours of reaching altitude and resolves within one day, but it can recur as ascent continues. The Lake Louise AMS score is the gold standard to self-monitor for AMS during ascent or for a clinician evaluating a patient.^{5,6} HACE is a clinical diagnosis, with onset at 12 hours to three days from ascent. The patient will present with ataxia, encephalopathy, and a progressive decline of mental function and level of consciousness. Pa-

tients may first only appear to be withdrawn; clinical suspicion should be high. Physical examination will reveal a patient with impaired finger-to-nose or heel-to-shin testing. All labs and imaging are fairly nonspecific, but they may show leukocytosis and possibly cerebral edema.^{1,7}

Treatment of AMS consists of symptomatic management with nonsteroidal anti-inflammatory drugs (NSAIDs), antiemetics, and a pause in ascent for 48 hours for acclimatization to occur. Treatment for HACE is immediate descent. If that is not possible, the patient should be treated in a hyperbaric chamber, along with 2–4 L nasal cannula and dexamethasone for alleviation of symptoms related to cerebral edema. In the event the patient becomes unresponsive, consider protecting the airway.^{2,4}

Prescription medications can be used for treatment but are better as preventative measures. Acetazolamide, a carbonic anhydrase inhibitor, initiates metabolic acidosis, theoretically stimulating respiratory drive and hastening acclimatization, but its side effects can be mildly irritating, with peripheral paresthesia, polyuria, and a metallic aftertaste. Dexamethasone can be used to alleviate symptoms, but it does not accelerate acclimatization. The risk with dexamethasone is that it masks symptoms and therefore may increase the risk of AMS progressing to HACE as ascent continues.^{2,4}

For AMS and HACE, the gold standard for prevention is gradual ascent, acetazolamide, and +/- dexamethasone. Dexamethasone is typically used in prevention of AMS/HACE for patients who require rapid ascent but does not hasten acclimatization. There are multiple drugs that, when compared to placebo, do show improvement for prevention, such as acetazolamide and dexamethasone. As a selective 5-hydroxytryptamine receptor agonist and a cerebral vasoconstrictor, sumatriptan shows promising results for AMS prevention; however, only one study has been published, which showed decreased prevalence of AMS in sumatriptan versus placebo when used for prophylaxis.⁸ Further studies would need to be completed prior to utilizing sumatriptan as a preventative medication. Antioxidants, magnesium, ginkgo biloba, and cocoa leave use have very limited data and scattered anecdotal reports, with no significant difference shown when compared to acetazolamide and

dexamethasone.^{2,4,9}

Pediatric Patients

Pediatric patients present a unique cohort in risk factors and presentation for HAI. Risk factors for HAI include congenital cardiopulmonary disease (eg, cardiac shunting, pulmonary hypertension), cystic fibrosis, sickle cell disease, and Down's syndrome. Also at risk are any infants born preterm, those less than six weeks old, and those who required oxygen within their first year of life.

Children typically experience reentry HAPE, the risk of which is increased with any respiratory infection. Kids have increased respiratory distress over one to two days that presents as decreased playfulness, disrupted sleep, and increased fussiness and crying. Treatment and prevention are the same as HAPE in adults.

In AMS and HACE, younger kids present with decreased playfulness, poor sleep, and increased fussiness. Teenagers present sim-

ilar to adults with headache, shortness of breath, nausea, vomiting, and anorexia. The diagnosis is clinical and treatment is the same as for adults. Dexamethasone should not be used for prevention in children as it can lead to adrenocortical suppression.^{1,10} ➔

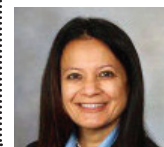
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DR. JACOBSON is an emergency medicine resident physician at Mayo Clinic in Rochester, Minnesota.



DR. RAUKAR is an emergency medicine consultant and associate professor at Mayo Clinic in Rochester, Minnesota.

TYPICAL ELEVATIONS FOR HIGH-ALTITUDE ILLNESS

>4,000 m

SYMPTOMS

AMS/HACE and HAPE

3,000 m

SYMPTOMS

AMS and HAPE

1,500–2,500 m

SYMPTOMS

MILD

<1,500 m

SYMPTOMS

NONE

The Power of EM: A Message from Two Sons

Dr. John Geesbreght has served as a leader and caregiver for his family, community, and emergency medicine

Emergency physicians see people at some of their worst moments—traumatic injury, grave illness, the death of a loved one—and provide compassionate care without expectation of recognition or reward. For emergency physician John Geesbreght, MD, MS, FACEP, these principles have been a driving force in his life, guiding his decisions as a medical director, father, mentor, and member of the Fort Worth, Texas, community.

Dr. Geesbreght was born in south Chicago. The son of immigrant parents, he was inspired to become a physician in elementary school. He went on to practice in the emergency department in Fort Worth, where he served as emergency department medical director of Texas Health Harris Methodist Fort

Worth for more than 40 years, providing care to his family and community. As a leader, Dr. Geesbreght searched for innovative solutions to make sure his emergency department would deliver the best patient care possible.

One of those solutions was founding PhysAssist Scribes, Inc., the first scribe company in the United States, in 1995. Initially, the company recruited pre-med students from Texas Christian University and trained them to work alongside emergency physicians to provide scribe services in the ED to improve communication and documentation, free up physicians' time for patient care, and give students valuable medical experience. Both of Dr. Geesbreght's sons went on to lead the company. Although neither

became a physician, they both were guided by the principles of hard work and compassion they learned from their father and his career.

Dr. Geesbreght's sons, Andrew and Alex, recently sat down with *ACEP Now's* Medical Editor in Chief Kevin Klauer, DO, EJD, FACEP, to discuss their father's career in emergency medicine and the influence he had on their own careers. Alex served as president of PhysAssist prior to its acquisition by TeamHealth in 2014. Andrew served as president of PhysAssist prior to its acquisition by HealthChannels in 2018 and is currently chief leadership officer at HealthChannels.

KK: Alex and Andrew, let's discuss your father's emergency medicine career and how it's influenced your life.

Alex G: The highlight for me was getting to work with my dad for 12 years. I was an attorney for a while and then was general counsel for his emergency medicine group.

When I was 9 years old, I started working, volunteering, with my dad down at the hospital and I thought, "Oh, my dad's a doctor, maybe I'll be a doctor." I was 16, and I used to spend the night. I think I logged in 750 hours of community service through working at the emergency department. I very quickly realized when I got older that I couldn't handle being in that environment, and one of the things that I realized is that my dad never talked about what happened at the [emergency department]. When I started seeing people die, the horrible accidents, heartache, I remember thinking, "How could he not talk about this?"

Although he did shield us from the harm that some of the stories from the ED might do to a little kid, he took those lessons and was able to apply them to our world every day.

He is such a great teacher. He taught us all of these lessons and he had all of this wisdom. He never shared those stories with us, and I don't know why, but I kind of wish he had. This also speaks to his stability and his ability to separate family life from work life.

KK: Andrew? Some thoughts from you?

Andrew G: I learned early on as a child that my dad was doing something very important. I say that because I didn't have to introduce myself. When I said my dad was Dr. Geesbreght, I frankly had intense pride. Any time someone had their worst day, they called my dad and there was a high level of trust in his ability to restore normalcy in families' lives.

In an industry that didn't have generally accepted rules at that time, he

CONTINUED on page 29



Dr. John Geesbreght and his wife, Priscilla.



Dr. Geesbreght (center) is suturing Alex's bicycle injury while his mother, little sister, and brother Andrew watch.

Emergency Physician is First Endowed Chair of TCU and UNTHSC School of Medicine

It turns out Dr. Geesbreght's fatherly influence extends beyond his own children. The Texas Christian University (TCU) School of Medicine recently named its first endowed chair, and the recipient is an emergency physician who describes Dr. Geesbreght as a "father figure" in his medical career.

Terence McCarthy, MD, is the first recipient of the John M. Geesbreght, MD, MS, FACEP, Endowed Chair of Emergency Medicine. Dr. McCarthy is the academic chair for emergency medicine at TCU and a clinical adjunct professor for the physician assistant studies program at the University of North Texas Health Science Center (UNTHSC).

"It's a huge honor to hold a chair that's named after [Dr. Geesbreght]," Dr. McCarthy said via press release. Dr. McCarthy worked with Dr. Geesbreght in the emergency department and described him as a mentor and friend. "In my toughest and most traumatic moments in life, he's been there for me," Dr. McCarthy said via press release.

Stuart D. Flynn, MD, founding dean of the TCU and UNTHSC School of Medicine, described Dr. Geesbreght as a "visionary and gifted operational thinker in emergency medicine." Dr. Flynn said that having him endow the school's first academic chair was "a great honor." +



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.

Winds of EMS Change

New out-of-hospital care models could affect your ED

by JAMES AUGUSTINE, MD, FACEP

“Whoop, whoop, whoop!” The EMS radio alerts the ED staff to an incoming patient. Minutes later arrives a patient who has a 33 percent chance of being moved to an inpatient bed in about five hours, a 5 percent chance of being moved to the ICU in about three hours, and a chance of being moved onto a medical helicopter or onto a medical examiner’s table.

For those emergency physicians working in medical centers that specialize in trauma, burns, acute cardiac intervention, and comprehensive stroke care, those ambulance patients represent the vast majority of patients who pay for such specialty programs and services. For those who don’t like ambulance patients, the future is arriving faster than a medic unit running lights and sirens.

Studying the Emergency Department Benchmarking Alliance (EDBA) data over the last 10 years, we find that EMS arrivals and admission rates are predictable, and ambulance patients continue to represent higher acuity than those arriving in a private automobile or other conveyance. Table 1 demonstrates that about 39 percent of EMS-arriving patients are admitted. Patients arriving by other means have a significantly lower admission rate of about 12.5 percent.

CMS Launches New Payment Model

On Feb. 14, 2019, the Centers for Medicare and Medicaid Services (CMS) announced a new payment model for unscheduled care responders that pays for care that does *not* include transportation to the hospital.¹ The proposed Emergency Triage, Treat, and Transport (ET3) Model will pay for care provided out of hospital, either in person or through telehealth processes. It also pays EMS responders to transport patients by ambulance to alternative out-of-hospital care sites, including urgent care or a primary care provider.

The model’s announced goal is to end the incentives for first responders to transport patients to the emergency department. The program is being introduced by the Center for Medicare and Medicaid Innovation as a method to improve the quality of care for unscheduled health events and is targeted to save the health care system \$1 billion in avoidable ED costs. CMS believes 19 percent of Medicare fee-for-service beneficiaries could be treated at home or in another cheaper facility for their emergency needs. CMS also hopes Medicaid managed care plans and private payers will take an interest in the voluntary model.

Program rules have yet to be written, and it may take six or more months until applicants for the model are recruited. However, EMS providers selected to participate will have options in how they wish to structure the on-site element. Options will include a telehealth-heavy model in which a physician or advanced practice provider provides care on-site or remotely.

TABLE 1: EMS ARRIVAL AND ADMISSION TRENDS

YEAR	% OF ED PATIENTS ARRIVING BY EMS	% OF EMS ARRIVALS ADMITTED	OVERALL ED ADMISSION RATE	% OF WALK-IN PATIENTS ADMITTED
2018	18	39	16.8	13
2017	17	39	17	13
2016	18	39	17	13
2015	17	37	16	12
2014	16	38	16	12
2013	17	39	17	12
2012	16	39	17	12
2011	17	42	18	13
2010	16	43	18	13
2009	16	43	17	12
2008	17	43	17	11

The fact sheet says the demonstration will last five years.

The bottom line? There are evolving models of care that feature alternate providers paid to deliver a variety of services outside of the traditional model of emergency care delivered in the emergency department.

How Will It Affect Your Emergency Department?

The EDBA data over the past 15 years find that EMS arrival and admission rates are very stable and that patients arriving by ambulance continue to represent higher acuity. At the same time, many emergency departments have been unable to open sufficient space to provide care for all arriving patients, and some hospitals have developed processes for diverting ambulances. This issue was recognized by the Centers for Disease Control and Prevention in studies years ago but has not been resolved.² This winter, the media highlighted the ongoing danger of ambulance diversion.^{3,4}

Patients who are high-frequency emergency system users can be identified by case managers, hospitals, emergency departments, or the EMS system. Is the use of out-of-hospital health services a mark of quality for these individuals? There is still a legal issue to address in which a 911 call can be linked to an EMTALA responsibility and the mandate for a medical screening examination before the patient is released.

Will improving field care reduce costs and improve outcomes? Will it decrease less urgent uses of EMS and reduce transports of these lower-acuity patients? If that occurs, will reducing ambulance traffic be good for the emergency department? Might it reduce ED diversion and crowding?

Novel models in an evolving health care delivery platform that utilize mobile resources will be developed. There are already programs

to provide follow-up care for patients released from inpatient status back to their home, patients with recurrent admissions for long-term health problems (eg, congestive heart failure), and patients with a variety of health problems who have demonstrated frequent use of EMS service in the past.⁵

In the current model, hospitals survive on revenue from inpatient service, and patients admitted through the emergency department after EMS transport are major contributors to that revenue stream. The cost of diversion, therefore, is significant. To calculate that cost, let’s count the average number of EMS patients arriving during the busy hours of the day (not including the middle of the night, when diversion is rarely utilized). Assume that arrival rate is a modest two EMS patients per hour. The average hospital revenue for ED services for those two patients is at least \$1,000. If 40 percent of the EMS patients are admitted, and they generate \$6,000 above the direct costs of service per patient, then ambulance diversion for five hours reduces hospital revenue by \$6,000 in direct revenue for the 10 diverted patients plus \$24,000 for the four diverted admissions. That \$30,000 is a direct loss of \$6,000 per hour, plus the loss of the patient for future visits and admissions as well as loss of relationship with EMS.

Today’s Positive EMS Relationship

As demonstrated above, positive cooperative relationships with EMS providers are critical. The ingredients for a positive EMS relationship include:

- Excellent clinical care for the patients brought by EMS
- Courtesy, respect, and professionalism shown to EMS providers
- Open beds for EMS patients to avoid off-loading delays

- Recognition for a job well done
- Respectful and professional communications about opportunities for improvement
- Cleaned and returned EMS supplies
- Replacement of disposable equipment and linens
- A reliable system for submitting EMS reports and including them in each patient’s medical record
- Offering EMS educational programs
- Cooperation with community programs (eg, disaster response)

Effective patient care should be provided at the right place and right time with the right equipment and personnel; it also should be provided at the right price and with the appropriate value. That requires cooperation between emergency physicians and EMS leaders. New systems of unscheduled care will require ED leaders to develop programs with EMS and those who pay for those services, including grant funders for these innovative programs. ➔

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DR. HELMAN is an emergency physician at North York General Hospital in Toronto. He is an assistant professor at the University of Toronto, Division of Emergency Medicine, and the education innovation lead at the Schwartz/Reisman Emergency Medicine Institute. He is the founder and host of Emergency Medicine Cases podcast and website (www.emergencymedicinescases.com).

Polytrauma Resuscitation



Reprioritizing the "ABCs" of trauma care

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

While advanced trauma life support has traditionally emphasized the "ABC" (airway, breathing, and circulation) approach for all trauma patients, a more nuanced approach is required in order to avoid catastrophic outcomes in the early resuscitation of the polytrauma patient.

First Priorities in Trauma Resuscitation

Focus should be on physiologic priorities.¹ The most severe, life-threatening injuries should be temporized first. The two

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categories of immediate life threats in trauma include massive external hemorrhage, temporized by local pressure and/or tourniquet, and critical airway compromise. Critical airway compromise can be further divided into critical/refractory hypoxia, which is less than 90 percent oxygen saturation despite optimized noninvasive ventilation; and dynamic airway, which is evolving

disruption of the airway anatomy and/or head and neck injuries that are expected to worsen over the next few minutes.

Second Priorities: "C" Before "A"

After the immediate life threats of massive external hemorrhage and critical airway compromise have been addressed, resuscitation should then focus on hemodynamic optimization before definitive airway management. Endotracheal intubation causes an increase in intrathoracic pressure, resulting

in a decrease in right atrial pressure, which negatively impacts both hemorrhagic and obstructive shock. Pre-intubation hypotension is a significant risk factor for post-intubation cardiac arrest.² Hence, the adage, "Resuscitate before you intubate" in volume-depleted patients. Procedures to relieve obstructive shock, such as bilateral finger thoracostomies and thoracotomy, should be considered prior to endotracheal intubation. A similar "CABC" (circulation, airway, breathing, and circulation) approach has been adapted in the cardiac arrest literature.

Step-wise Approach to Identify Occult Shock

The patient who rolls into your resuscitation room after a worrisome mechanism and with a mean arterial pressure of 30 is in an obvious shock state. However, many trauma patients present in occult shock. Under-recognition of occult shock in trauma is associated with poor patient outcomes.³ The following step-wise approach will minimize your chances of missing occult shock.

1. Calculate the shock index (heart rate divided by systolic blood pressure [SBP]) and/or delta shock index.^{4,5} If the shock index is >1 or the delta shock index ≥ 0.1 , assume occult shock is present.
2. Assess the lowest blood pressure (BP) measured and trend the BP over time; if isolated or persistent SBP <110 , assume occult shock.⁶ A single low BP either in the field or in the emergency department has been shown to predict poor outcomes in trauma patients.
3. Positive focused assessment with sonography in trauma (FAST) with flat inferior vena cava (IVC)? Assume occult shock.
4. Consider a volume challenge to assess for active occult hemorrhage by administering 250 mL of crystalloid under pressure followed by assessment for signs of perfusion. If a patient transiently responds to 250 mL of crystalloid, you may assume active occult hemorrhage.

A shock index of >1 or a delta shock index of ≥ 0.1 is a sign of occult shock and is predictive of post-intubation hypotension, transfusion requirements, injury severity, and mortality.^{4,5} A practical tip to help identify occult shock is to ask

EMS not only what the most recent BP was, but what the lowest BP they recorded was. A single drop in BP in the field or in the emergency department is predictive of the need for surgical intervention and mortality.⁷ One common pitfall in diagnosing shock is ignoring pre-hospital hypotension that normalizes without intervention. An isolated decrease in SBP <105 mmHg is associated with a 12-fold increase in the need for immediate therapeutic intervention.⁸

The shock index is unreliable in patients with altered physiologic compensation such as elderly patients, undertreated hypertension, and patients taking medications that lower the heart rate, such as beta-blockers.⁹ In these patients, consider the delta shock index, which may be a more reliable indicator of occult shock.⁵

Third Priority: Controlled Resuscitation

Consider the following before initiating volume resuscitation. The patient who is bleeding may not appear to be in shock, and the patient who is in shock may not be actively bleeding. Your goal is to not only to identify shock/occult shock, but also to identify active bleeding and obstructive and neurogenic shock. Again, consider a volume challenge to assess for active occult hemorrhage. If there is no response to 250 mL of crystalloid, consider other causes of shock.

Controlled resuscitation (previously termed "permissive hypotension") represents a paradigm shift in trauma resuscitation.¹⁰ Large volumes of crystalloid may contribute to the trauma "triangle of death" (metabolic acidosis, hypothermia, and coagulation derangements).¹¹ While there are fairly well studied resuscitation targets in the first few hours of trauma resuscitation (eg, urine output, lactate clearance, base deficit), there is little evidence to guide us in the first 15 minutes of trauma resuscitation.¹² If there is a delay in starting blood transfusion in a patient presumed to have hemorrhagic shock, consider only small boluses of crystalloid (ie, 250 mL), just enough to maintain adequate tissue perfusion (peripheral pulses present in blunt trauma or central pulses in penetrating injury) and maintain a SBP ≥ 70 . For most trauma patients, consider targeting this SBP throughout your resuscitation. This controlled resuscitation is a reasonable early resuscitation target. One prospective randomized controlled trial comparing controlled resuscitation with usual care showed a number needed to treat of 11 for in-hospital mortality.¹⁰ Keep in mind that the elderly patient, the patient with uncontrolled hypertension at baseline, the patient with a major head injury, and the patient with neurogenic shock may require adjustments to their SBP target.

Fourth Priority: Consideration for Massive Transfusion

Here is a suggested approach to decision-making around massive transfusion protocol (MTP) activation in trauma patients. It is important to integrate your clinical judgment and mechanism of injury, as well as patient age, presence of anticoagulant medication, and comorbidities into your decision-making.¹³

Step 1: If the patient is in an obvious shock state, has an Assessment of Blood Consumption (ABC) score ≥ 2 , a shock index of >1 , or delta shock index of ≥ 0.1 , activate the MTP.¹⁴⁻¹⁶

Step 2: If none of these are present, consider resuscitation intensity.^{17,18} Patients who require four units of any combination of crystalloids or blood products to maintain adequate perfusion are considered to have high resuscitation intensity, which predicts higher mortality, and should be considered for MTP.

Summary

Next time you're faced with a polytrauma patient, consider resequencing the trauma resuscitation by managing massive external hemorrhage and active/dynamic airway first. Then concentrate on hemodynamic optimization before definitive airway management in those patients without active/dynamic airways. Identify occult shock using a shock index of >1 , a delta shock index of ≥ 0.1 , the lowest BP recorded, FAST/IVC assessment, and/or a fluid challenge with clinical exam. Consider the patient's age, blood pressure medications, and baseline blood pressure in assessing for the presence of occult shock, interpreting the shock index, and in deciding to activate your MTP. Large volumes of crystalloid may lead to the "triangle of death;" your goal should be to minimize crystalloids. Controlled resuscitation to a target SBP of ≥ 70 is reasonable in most young, otherwise healthy trauma patients presumed to be in hemorrhagic

CONTINUED on page 28

DOGMA FEELS
RIGHT
UNTIL YOU STEP
IN IT

SKEPTICS' GUIDE TO EMERGENCY MEDICINE



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

ETT Confirmation

Does POCUS "sound" right?

by KEVIN MILNE, MD

The Case

A 52-year-old patient is in cardiac arrest and needs endotracheal intubation. You've read some studies recently saying point-of-care ultrasound (POCUS) could confirm placement.

Background

There are a number of ways to confirm endotracheal tube (ETT) placement. Quantitative waveform capnography is thought to be one of the best methods. However, in cardiac arrest, some studies suggest it is correct only about two-thirds of the time.¹⁻³

An ACEP policy statement lists various methods to confirm ETT placement, which include:

- A physical exam (ie, auscultation of chest and epigastrium, chest wall movement, and condensation/fogging in the tube)
- Direct visualization or video laryngoscopy of the tube passing through the vocal cords
- Pulse oximetry
- Chest X-ray
- Esophageal detector devices
- End-tidal carbon dioxide (CO₂) detection (ie, continuous waveform capnography, colorimetric capnography, and non-waveform capnography)

Clinical Question

What is the accuracy of POCUS for ETT placement confirmation?

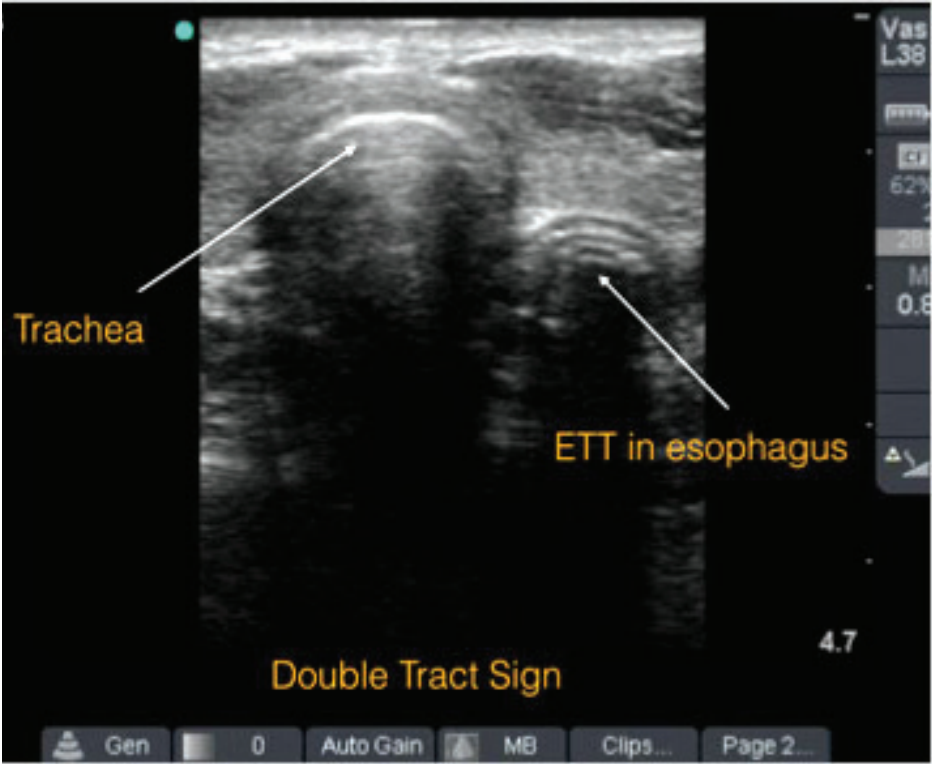
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Gottlieb M, Holladay D, Peksa GD. Ultrasonography for the confirmation of endotracheal tube intubation: a systematic review and meta-analysis. *Ann Emerg Med.* 2018;72(6):627-636.

- **Population:** Prospective or randomized controlled trial (RCT) of adults undergoing assessment of transtracheal POCUS for ETT placement confirmation
 - » **Excluded:** Case reports, case series, retrospective studies, cadaver studies, pediatric studies, and conference abstracts
- **Intervention:** Transtracheal POCUS to confirm ETT placement
- **Comparison:** Confirmatory testing of ETT placement such as end-tidal capnography, colorimetric capnography, or direct visualization
- **Outcome:**
 - » **Primary Outcome:** Accuracy of transtracheal POCUS versus other forms of confirmation
 - » **Secondary Outcome:** Time to confirmation and subgroup analyses

Authors' Conclusions

"Transtracheal sonography is rapid to perform, with an acceptable degree of sensitivity and specificity for the confirmation of endotra-



ACEP EMERGENCY ULTRASOUND SECTION NEWSLETTER, JUNE 2015.

Esophageal intubation will reveal an adjacent hyperechoic curvilinear structure with shadowing and comet-tail artifact posterolateral to the trachea, consistent with the ET tube location within the esophagus. This has been referred to as the "double tract sign."

TABLE 1: DIAGNOSTIC ACCURACY OF TRANSTRACHEAL POCUS FOR ETT PLACEMENT

	POINT ESTIMATE	95% CONFIDENCE INTERVAL
Sensitivity	98.7%	97.8–99.2%
Specificity	97.1%	92.4–99.0%
Likelihood Ratio Positive	34.4	12.7–93.1
Likelihood Ratio Negative	0.01	0.01–0.02
Receiver Operating Characteristic Curve	0.994	0.982–0.998

cheal intubation. Ultrasonography is a valuable adjunct and should be considered when quantitative capnography is unavailable or unreliable."

Key Results

The search identified 15 prospective observational studies and two RCT, including a total of 1,595 patients. A majority of the studies (12 out of 17) were performed in the emergency department. The mean patient age was 55 years, with 57 percent being male. The esophageal intubation rate was 15 percent.

- **Primary Outcome:** Diagnostic accuracy of transtracheal POCUS for ETT placement (see Table 1)
- **Secondary Outcome:** Mean time to confirmation was 13.0 seconds (95% CI, 12.0–14.0).
- **Subgroup Analyses:** These did not

demonstrate a significant difference by location, provider specialty, provider experience, transducer type, or technique.

Evidence-Based Medicine Commentary

1. **Included Studies:** The 17 studies included were relatively small with wide confidence intervals. Fifteen of the 17 were observational studies. Only 216 patients (14 percent) were in RCTs. Thirteen of the 17 studies used convenience sampling instead of consecutive patients, which can introduce bias and thereby limit the strength of the conclusions.
2. **Lack of Gold Standard:** A number of methods are available and often used in combination, but there is no gold standard. Each confirmation method has limitations. Auscultation can prove inac-

curate, especially in loud environments. Chest X-ray takes too long, and as previously mentioned, capnography in cardiac arrest has low sensitivity.

3. **Esophageal Intubation Rate:** This was very high (15 percent) and may be due to studies including medical students and residents in addition to attending physicians. A previous study has shown the rate of esophageal intubation in the emergency department to be only 3 percent.⁴
4. **Fast:** POCUS for ETT placement was not only accurate but also fast, with a mean of 13 seconds. For comparison, it takes 48 seconds for the standard auscultation and capnography combination.⁵ It is not known if this difference in time results in a patient-oriented benefit.
5. **Publication Bias:** The funnel plot analysis demonstrated evidence of publication bias. This is a well-known phenomenon in the medical literature and could have skewed the results to make transtracheal POCUS ETT confirmation look better than it actually is.

Bottom Line

In conjunction with other methods, POCUS represents a potentially fast and accurate method to help confirm ETT placement.

Case Resolution

You directly visualize passage of the ETT through the vocal cords on video laryngoscopy. Waveform capnography confirms an appropriate ETT placement. POCUS is then placed on the neck and also confirms correct tube placement.

Thank you to Chip Lange, an emergency medicine physician assistant and creator of the blog/podcast TOTAL EM and the educational company Practical POCUS.

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

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Appendicitis: Block the Pain

Consider performing an ultrasound-guided TAP block instead of using opioids

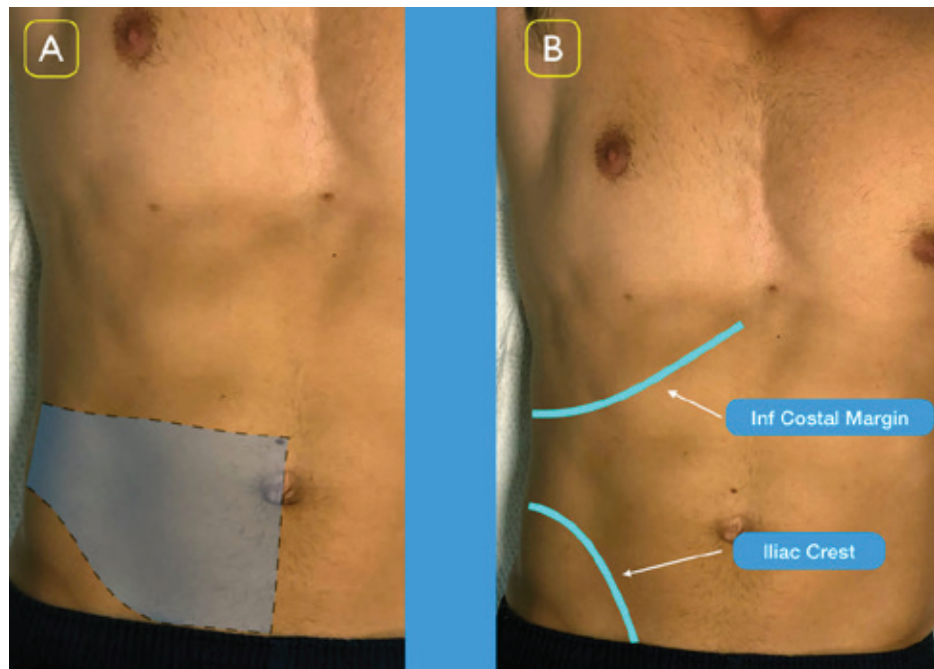


FIGURE 1A: The lateral ultrasound-guided TAP block will provide innervation to the anterior cutaneous branches of T10 to T12 (approximately the space highlighted). **FIGURE 1B:** Surface landmarks that should be palpated (if possible) include the inferior costal margin and the iliac crest. Place the ultrasound transducer between these two landmarks.

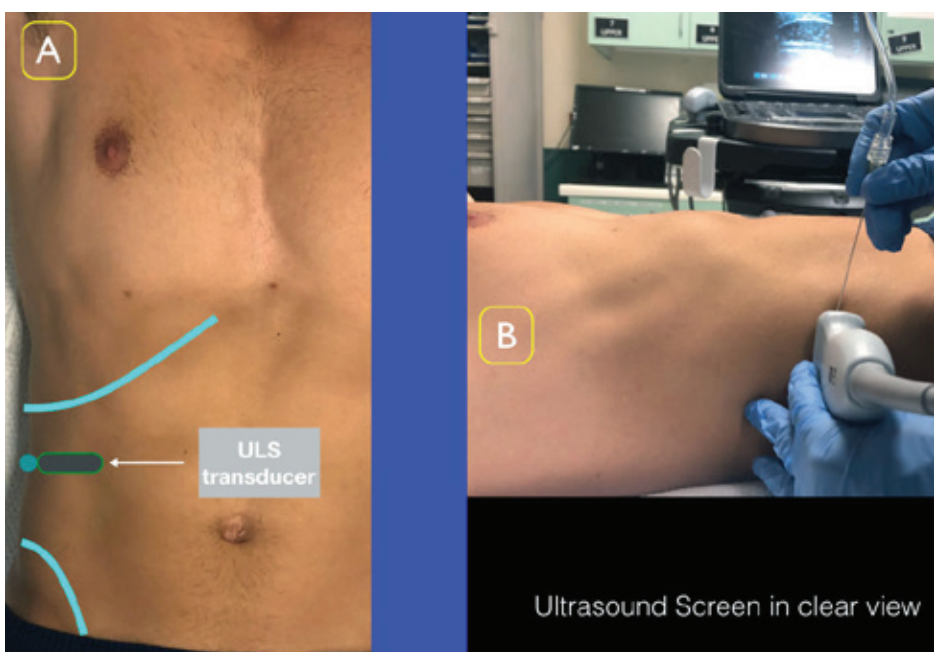
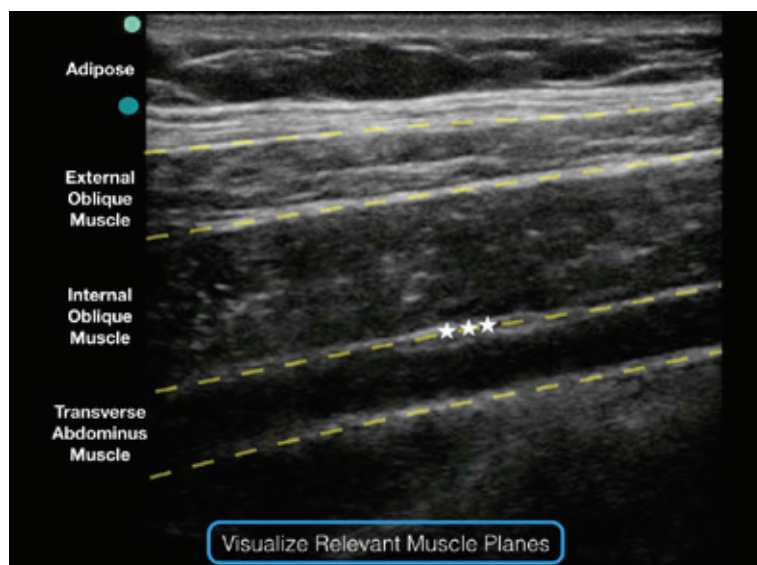


FIGURE 2A: Place the ultrasound transducer between the inferior costal margin and iliac crest. The probe marker should point lateral/posterior. **FIGURE 2B:** Position the ultrasound screen to ensure clear view of the location of injection as well as the ultrasound screen.

FIGURE 3: Note the external oblique, internal oblique, and transverse abdominis muscles on the ultrasound screen. The goal is to deposit anesthetic in the potential space just above the transverse abdominis muscle and just below the internal oblique muscle.



by ARUN NAGDEV, MD, SALLY MAHMOUD, MD, AND DANIEL MANTUANI, MD, MPH

Over the past few years, emergency physicians have begun implementing multimodal strategies for acute pain, reducing the use of opioids. Ultrasound-guided single-injection nerve blocks have slowly become accepted for targeted pain relief over the past decade in the emergency department for hip fractures, rib fractures, deltoid abscess drainage, and other conditions.¹⁻³ Currently, point-of-care ultrasound (POCUS) fellowships require ultrasound-guided nerve blocks as part of the training curriculum to ensure future leaders will provide the next generation of emergency physicians the knowledge to offer optimal pain management.^{4,5}

Over the past decade, our group has been fortunate to work in a hospital that values

interdepartmental collaboration to optimize patient care. More often than not, long delays for patients admitted for surgical pathology (such as acute appendicitis) lead to repeated rounds of intravenous opioid analgesics that ultimately fail to achieve adequate pain control and feature side effects. This led our group to think of alternative methods for pain control in this population rather than standard intravenous opioid regimens.

The ultrasound-guided transversus abdominis plane (TAP) block is a well-established regional anesthetic block used by anesthesiologists for perioperative pain control of the anterior abdominal wall.^{6,7} At our center, after computed tomography (CT) confirmation of appendicitis, ED-performed TAP blocks have been instituted as an alternative analgesic option for alleviating pain from this common diagnosis. This additive analgesic (in addition to other intravenous

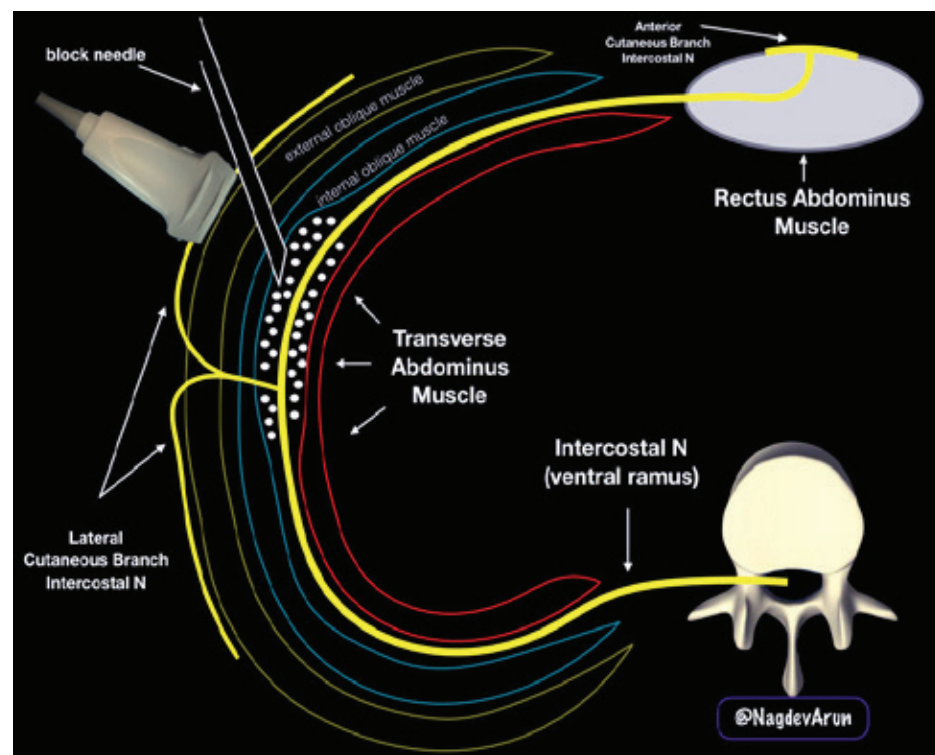


FIGURE 4: A schematic drawing of the ultrasound-guided TAP block. Note that anesthetic fluid should track in the plane between the internal oblique and transverse abdominis muscles.

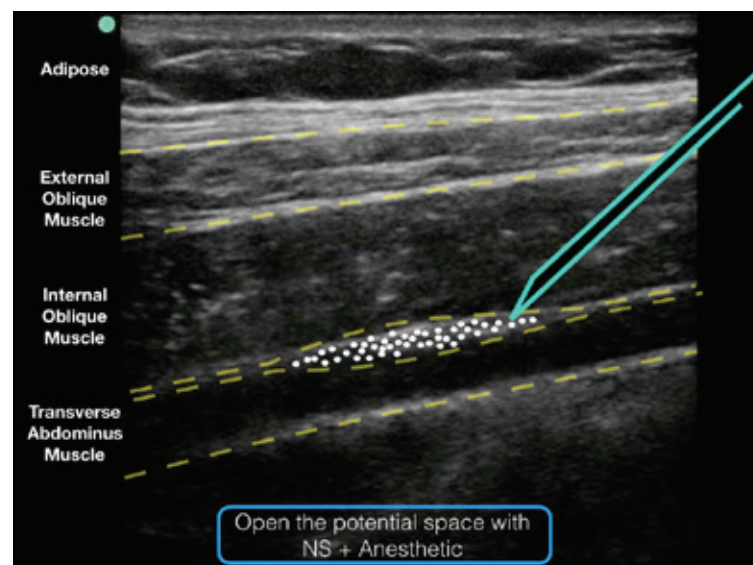


FIGURE 5: An ultrasound representation demonstrating where anesthetic should be placed when performing a TAP block.

agents) has proved effective in our small cohort of patients, who have demonstrated reduced pain scores and need for additional pain medications while awaiting definitive surgical intervention.⁸

The Procedure

After consent, place your patient supine and exposed from the inferior costal margin to the iliac crest, the two surface landmarks for the procedure (see Figures 1A and 1B). Place a high-frequency (13–6 MHz) linear array transducer in transverse orientation above the iliac crest at the mid- to anterior-axillary line (see Figures 2A and 2B) so that the external oblique, internal oblique, and transversus abdominis muscle layers are easily visualized on ultrasound (see Figure 3). This allows for optimal access to your target point: the plane between the internal oblique and transversus abdominis muscles.

Place the ultrasound system in a location contralateral to the patient for a clear view of the block field and the ultrasound screen. For convention, we place the transducer directional marker to the patient's right. Inject a 1–2 mL anesthetic wheal adjacent to the transducer (the needle will enter medially and go lateral/posterior). When optimal visualization is achieved, place a 20- to 22-gauge 90-mm blunt-tipped block needle in-plane (medial to lateral/posterior) and advance it until the needle reaches the interfascial plane between the internal oblique and transversus abdominis muscles. Using a two-person hand-on-needle technique, inject between 20 mL and 30 mL of a long-acting local anesthetic, which are the weight-based dosing limits of bupivacaine and lidocaine with epinephrine (see Figures 4 and 5). Successful deposition can be confirmed on ultrasound by visualization of anechoic fluid tracking in between the internal oblique and transversus abdominis muscles.

Conclusion

Acute pain management is the responsibility of the emergency physician. Multimodal pathways that allow clinicians a method to tailor pain management to the needs of the patient will reduce the reliance on opioid-only algorithms and improve patient care. Our multidisciplinary model for treating pain from acute appendicitis has proved successful due to a non-siloed approach to offering best practices to our patients. ➕

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SUICIDE | CONTINUED FROM PAGE 13

reporting best practices designed to prevent additional deaths.

TEEN SUICIDE RESOURCES

National resources are available to assist communities in providing support to those affected by adolescent suicide. Nonprofit organizations have focused resources on the increasing incidence of cyberbullying and on disadvantaged youth. States also have online resources available that contain a wealth of information. There is a list on resources with links at www.acep.org/SuicideContagionInAdolescents. ➕

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FROM HOSPITAL TO HOME

FOR YOUR ADULT PATIENTS WITH CABP AND ABSSSI



VISIT NUZYRA.COM/AVAILABLE-NOW TO EXPLORE THE CLINICAL DATA AND SIGN UP FOR MORE INFORMATION

INDICATIONS AND USAGE

NUZYRA™ is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

Community-Acquired Bacterial Pneumonia (CABP) caused by the following: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by the following: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.

USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUYZRA and other antibacterial drugs, NUYZRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline class antibacterial drugs, or to any of the excipients.

WARNINGS AND PRECAUTIONS

Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUYZRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients > 65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

The use of NUYZRA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of NUYZRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth.

Hypersensitivity reactions have been reported with NUYZRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUYZRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUYZRA if an allergic reaction occurs.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with NUYZRA. Discontinue NUYZRA if any of these adverse reactions are suspected.

Prescribing NUYZRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

DRUG INTERACTIONS

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUYZRA.

Absorption of tetracyclines, including NUYZRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended during treatment with NUYZRA.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary of Full Prescribing Information on the following pages.



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US-NUA-0056 12/18

shock. Finally, use clinical judgment, mechanism of injury, patient age and comorbidities, shock index, and resuscitation intensity to help you decide when to activate the MTP.

Special thanks to Andrew Petrosoniak, MD, Chris Hicks, MD, and Kylie Bosman, MD, for their expert contributions to the EM Cases podcast that inspired this article. 🎙

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NUZYRA™ (omadacycline) injection for intravenous use

NUZYRA™ (omadacycline) tablets, for oral use

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

For complete details, please see Full Prescribing Information.

INDICATIONS AND USAGE

Community-Acquired Bacterial Pneumonia (CABP)

NUZYRA is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

NUZYRA is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.

USAGE: To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS: NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline-class antibacterial drugs, or to any of the excipients.

WARNINGS AND PRECAUTIONS

Mortality Imbalance in Patients with Community-Acquired Bacterial Pneumonia

-Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established.

All deaths, in both treatment arms, occurred in patients >65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

Tooth Discoloration and Enamel Hypoplasia -The use of NUZYRA during tooth development (last half of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the tetracycline class drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported with tetracycline class drugs. Advise the patient of the potential risk to the fetus if NUZYRA is used during the second or third trimester of pregnancy.

Inhibition of Bone Growth -The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. Advise the patient of the potential risk to the fetus if NUZYRA is used during the second or third trimester of pregnancy.

Hypersensitivity Reactions -Hypersensitivity reactions have been reported with NUZYRA.

Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridium difficile-Associated Diarrhea -*Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration

of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Tetracycline Class Effects -NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests), have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

Development of Drug-Resistant Bacteria: Prescribing NUZYRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS: The following clinically significant adverse reactions are described in greater detail in the Warnings and Precautions section of the labeling:

- Mortality Imbalance in Patients with Community-Acquired Bacterial Pneumonia

• Inhibition of Bone Growth

• Hypersensitivity Reactions

• Tetracycline Class Effects
- Tooth Development and Enamel Hypoplasia

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.

Overview of the Safety Evaluation of NUZYRA: NUZYRA was evaluated in three Phase 3 clinical trials (Trial 1, Trial 2 and Trial 3). These trials included a single Phase 3 trial in CABP patients (Trial 1) and two Phase 3 trials in ABSSSI patients (Trial 2 and Trial 3). Across all Phase 3 trials, a total of 1073 patients were treated with NUZYRA (382 patients in Trial 1 and 691 in Trials 2 and 3) of which 368 patients were treated with only oral NUZYRA.

Imbalance in Mortality: In Trial 1, eight deaths (2%) occurred in 382 patients treated with NUZYRA as compared to four deaths (1%) in 388 patients treated with moxifloxacin. All deaths, in both treatment arms, occurred in patients >65 years of age. The causes of death varied and included worsening and/or complications of infection and underlying conditions. The cause of the mortality imbalance has not been established [see Warnings and Precautions (5.1)].

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In Trial 1, a total of 23/382 (6.0%) patients treated with NUZYRA and 26/388 (6.7%) patients treated with moxifloxacin experienced serious adverse reactions. Discontinuation of treatment due to any adverse reactions occurred in 21/382 (5.5%) patients treated with NUZYRA and 27/388 (7.0%) patients treated with moxifloxacin.

Most Common Adverse Reactions: Table 4 lists the most common adverse reactions occurring in ≥2% of patients receiving NUZYRA in Trial 1.

Table 4: Adverse Reactions Occurring in ≥2% of Patients Receiving NUZYRA in Trial 1

Adverse Reaction	NUZYRA (N = 382)	Moxifloxacin (N = 388)
Alanine aminotransferase increased	3.7	4.6
Hypertension	3.4	2.8
Gamma-glutamyl transferase increased	2.6	2.1
Insomnia	2.6	2.1
Vomiting	2.6	1.5
Constipation	2.4	1.5
Nausea	2.4	5.4
Aspartate aminotransferase increased	2.1	3.6
Headache	2.1	1.3

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In the pooled ABSSSI trials, serious adverse reactions occurred in 16/691 (2.3%) of patients treated with NUZYRA and 13/689 (1.9%) of patients treated with comparator. Discontinuation of treatment

was helping create new standards. He was all the cliché terms: trailblazer, innovator, etc. We watched him do that, and at 75 years old, watching him at his retirement party, with others talking about him, it really crystallized that for me.

We used to talk about him blowing up at the smallest little things, but then when it was a really big deal, when I was at my worst moment, that’s when I could count on a hug and an encouraging word, and the limited amount of time I saw him in the ED, that’s how he was with patients. He was reassuring and calm in their worst moment, and I loved that.

Alex G: One of the things he always said was,

“There are doctors who work in an ER”—now, this is back when they called it an ER—but he said, “There are doctors who work in an ER and then there are ER doctors. I am an ER doctor.”

KK: How do you think his life as an emergency physician helped shape you as young professionals today?

Andrew G: Dad’s ability to handle stress, his restrained empathy, I learned from Dad to optimize my mental hygiene. Alex and I aren’t clinical, but I can say for sure that I’ve learned from him how to manage stress, to appropriately compartmentalize difficult things in our careers.

Alex G: I would say that Andrew got more of the knowing when to be quiet from my dad than I did. I’m far more transparent to a fault, even with employees, but I would say my leadership style is rooted in his; he’s an inspirational leader.

One of his greatest strengths is that he understands almost intuitively what moves the needle. Back when they were doing the ED redesign, how to make people happy in the ED was all the rage. Many of the experts said, “Well, give them coffee,” and “Give them a blanket when they get triaged,” and “Go back,” and my dad said, “They’re not here to get coffee. They can get coffee at home. They

have blankets at home. They’re here to see a doctor.” So, he made certain the very first thing they did was see the doctor. He knew that every moment they waited prior to seeing the doctor was wasted time waiting.

KK: Emergency physicians tend to be selfless and giving. We do not always need recognition for our efforts. Do you have an example of your father’s selflessness?

Andrew G: One thing I learned from my dad that I still carry with me today is all ED doctors have the ability to sort through thousands of different possibilities and deduce a specific solution to whatever the complex problem presents. When Dad used to talk to us about problems, he would look through this complex prism of perspectives and possibilities to help us think through all of those different angles, and that’s something that I know that Alex and I use all the time. I use it daily and I’ve gotten it directly from him. My dad didn’t require public recognition. It was enough for him in almost all cases to just do the right thing.

Recently, I ran into a guy who I played high school soccer with. I hadn’t seen him in probably 25 years. We ran into each other at an over-30 indoor soccer league. He came up to me, put both of his arms on my shoulders, stopped me, looked me right in the eye, and said, “Andrew, it’s Jaime. Do you remember me?” I said, “Of course,” and we hugged, and he launched right into this story. He said, “I just want you to know that your dad changed my life.” So, I sat my bag down and said, “Well, you’ve got my full attention, Jaime. Tell me more.” He said, “You probably don’t know this but in middle school we were at a YMCA tournament and your dad came up to me afterwards and said, ‘Hey, you’re good. Would you like to play on our select team next year?’”

Jaime said he was immediately saddened by this because he knew he couldn’t afford it. His dad wasn’t in his life and his mom worked multiple jobs. He told my dad that he couldn’t afford it, but thank you for the opportunity anyway. So, my dad took his number, and a few days later called him and said, “Jaime, this is Dr. Geesbreght. I don’t know if you remember me, but we talked at the tournament.” Jaime said, “Yes, I remember you.” Dad said, “I just wanted to let you know that we’re going to take care of your league fees so that you can play on our team.” Jaime was saddened even more and said, “I really appreciate it. I can’t pay for travel. I can’t pay for food. I barely have enough for gear.” Dad paused and said, “Well we’re going to take care of all of that for you too.”

What was so astounding is for four years, when he was 14 to 18, my dad unceremoniously took care of every single bill, invoice, fee, lunch, travel, and everything else that would have been a cost to him and his family. My dad took care of this and never told a soul. Jaime said, “He did that because he was so generous. He didn’t need the credit, but he also didn’t want to embarrass me.” So he never mentioned it to anybody. He didn’t tell my mom. He didn’t tell me.

KK: Very touching story that really exemplifies his selfless service. Thank you both for your time and sharing your thoughts with us. Emergency physicians truly have an impact beyond the care they deliver. ☺

NUZYRA™ (omadacycline) injection for intravenous use
NUZYRA™ (omadacycline) tablets, for oral use

due to adverse events occurred in 12 (1.7%) NUZYRA treated patients, and 10 (1.5%) comparator treated patients. There was 1 death (0.1%) reported in NUZYRA treated patients and 3 deaths (0.4%) reported in linezolid patients in ABSSSI trials.

Most Common Adverse Reactions: Table 5 includes the most common adverse reactions occurring in ≥2% of patients receiving NUZYRA in Trials 2 and 3.

Table 5: Adverse Reactions Occurring in ≥2% of Patients Receiving NUZYRA in Pooled Trials 2 and 3

Adverse Reaction	NUZYRA (N = 691)	Linezolid (N = 689)
Nausea*	21.9	8.7
Vomiting	11.4	3.9
Infusion site reactions**	5.2	3.6
Alanine aminotransferase increased	4.1	3.6
Aspartate aminotransferase increased	3.6	3.5
Headache	3.3	3.0
Diarrhea	3.2	2.9

*In Trial 2, which included IV to oral dosing of NUZYRA, 40 (12%) patients experienced nausea and 17 (5%) patients experienced vomiting in NUZYRA treatment group as compared to 32 (10%) patients experienced nausea and 16 (5%) patients experienced vomiting in the comparator group. One patient (0.3%) in the NUZYRA group discontinued treatment due to nausea and vomiting.

*In Trial 3, which included the oral loading dose of NUZYRA, 111 (30%) patients experienced nausea and 62 (17%) patients experienced vomiting in NUZYRA treatment group as compared to 28 (8%) patients experienced nausea and 11 (3%) patients experienced vomiting in the linezolid group. One patient (0.3%) in the NUZYRA group discontinued treatment due to nausea and vomiting.

**Infusion site extravasation, pain, erythema, swelling, inflammation, irritation, peripheral swelling and skin induration.

Selected Adverse Reactions Occurring in Less Than 2% of Patients Receiving NUZYRA in Trials 1, 2 and 3: The following selected adverse reactions were reported in NUZYRA-treated patients at a rate of less than 2% in Trials 1, 2 and 3. **Cardiovascular System Disorders:** tachycardia, atrial fibrillation; **Blood and Lymphatic System Disorders:** anemia, thrombocytosis; **Ear and Labyrinth Disorders:** vertigo; **Gastrointestinal Disorders:** abdominal pain, dyspepsia; **General Disorders and Administration Site Conditions:** fatigue; **Immune System Disorders:** hypersensitivity, **Infections and Infestations:** oral candidiasis, vulvovaginal mycotic infection; **Investigations:** creatinine phosphokinase increased, bilirubin increased, lipase increased, alkaline phosphatase increased; **Nervous System Disorders:** dysgeusia, lethargy; **Respiratory, Thoracic, and Mediastinal disorders:** oropharyngeal pain; **Skin and Subcutaneous Tissue Disorders:** pruritus, erythema, hyperhidrosis, urticarial.

DRUG INTERACTIONS

Anticoagulant Drugs—Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while also taking NUZYRA.

Antacids and Iron Preparations—Absorption of oral tetracyclines, including NUZYRA, is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate, and iron containing preparations.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary—NUZYRA, like other tetracycline-class antibacterial drugs, may cause discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the second and third trimester of pregnancy.

The limited available data of NUZYRA use in pregnant women is insufficient to inform drug associated risk of major birth defects and miscarriages. Animal studies indicate that administration of omadacycline during the period of organogenesis resulted in fetal loss and/or congenital malformations in pregnant rats and rabbits at 7 times and 3 times the mean AUC exposure, respectively, of the clinical intravenous dose of 100 mg and the oral dose of 300 mg. Reductions in fetal weight occurred in rats at all administered doses (see Data). In a fertility study, administration to rats during mating and early pregnancy resulted in embryo loss at 20 mg/kg/day; systemic exposure based on AUC was approximately equal to the clinical exposure level. Results of studies in rats with omadacycline have shown tooth discoloration.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15-20%.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity also has been noted in animals treated early in pregnancy.

Lactation: Risk Summary—There is no information on the presence of omadacycline in human milk, the effects on the breastfed infant or the effects on milk production. Tetracyclines are excreted in human milk; however, the extent of absorption of tetracyclines, including omadacycline, by the breastfed infant is not known.

Because there are other antibacterial drug options available to treat CABP and ABSSSI in lactating women and because of the potential for serious adverse reactions, including tooth discoloration and inhibition of bone growth, advise patients that breastfeeding is not recommended during treatment with NUZYRA and for 4 days (based on half-life) after the last dose.

Females and Males of Reproductive Potential

Contraception Females: NUZYRA may produce embryonic or fetal harm. Advise patients to use an acceptable form of contraception while taking NUZYRA.

Infertility Males: In rat studies, injury to the testis and reduced sperm counts and motility occurred in male rats after treatment with omadacycline.

Females: In rat studies, omadacycline affected fertility parameters in female rats, resulting in reduced ovulation and increased embryonic loss at intended human exposures.

Pediatric Use—Safety and effectiveness of NUZYRA in pediatric patients below the age of 18 years have not been established. Due to the adverse effects of the tetracycline-class of drugs, including NUZYRA on tooth development and bone growth, use of NUZYRA in pediatric patients less than 8 years of age is not recommended.

Geriatric Use—Of the total number of patients who received NUZYRA in the Phase 3 clinical trials (n=1073), 200 patients were ≥65 years of age, including 92 patients who were ≥75 years of age. In Trial 1, numerically lower clinical success rates at early clinical response (ECR) timepoint for NUZYRA-treated and moxifloxacin-treated patients (75.5% and 78.7%, respectively) were observed in CABP patients ≥65 years of age as compared to patients <65 years of age (85.2% and 86.3%, respectively). Additionally, all deaths in the CABP trial occurred in patients >65 years of age. No significant difference in NUZYRA exposure was observed between healthy elderly subjects and younger subjects following a single 100 mg IV dose of NUZYRA.

Hepatic Impairment—No dose adjustment of NUZYRA is warranted in patients with mild, moderate, or severe hepatic insufficiency (Child-Pugh classes A, B, or C).

Renal Impairment—No dose adjustment of NUZYRA is warranted in patients with mild, moderate, or severe renal impairment, including patients with end stage renal disease who are receiving hemodialysis.

OVERDOSAGE No specific information is available on the treatment of overdosage with NUZYRA. Following a 100 mg single dose intravenous administration of omadacycline, 89% of dose is recovered in the dialysate. Visit NUZYRA.com to learn more about NUZYRA

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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DR. FAUST is an instructor at Harvard Medical School and an attending physician in the department of emergency medicine at Brigham & Women's Hospital, Boston. Follow him on Twitter @jeremyfaust.

SMACC Retires

As the popular global critical care conference ends, a new one is set to replace it

by JEREMY SAMUEL FAUST,
MD, MS, MA

In 2013, Scott Weingart, MD, FACEP (@emcrit), declared SMACC (which stands for Social Media and Critical Care), a largely unknown conference held in Sydney, Australia, to be the “best critical care conference in the world.” At that time, Dr. Weingart was one of the attendings in my residency, but more to the point, he had become a major celebrity in the emergency medicine and critical care worlds through his wildly popular EMCrit podcast. For the first time, an emergency medicine podcast was being downloaded in droves and had tremendous influence. Dr. Weingart’s endorsement instantly put an entire conference on the educational map. The following year, SMACC (@smaccteams) was again hosted in Australia and swelled to more than 700 attendees, including many from the United States and around the world. By the time the conference moved to Chicago in 2015, SMACC had become the unofficial in-person reunion of the free open-access medical education (#FOAMed) community, and due to overwhelming demand, the organizers instituted a policy that specified a maximum of 2,000 attendees. They literally declined additional registrations in an effort to keep the confer-



Two emergency medicine experts engage in a friendly evidence-based medicine debate at SMACC in March 2019. The final SMACC exemplified both cutting-edge critical care and the unique style that made the conference so popular.

ence from becoming too large and impersonal.

To the surprise of many, organizers Roger Harris, MBBS (@RogerRdHarris), and Oliver Flower, MBBS, BMedSci (@OliFlower), two of the Australian critical care physician founders

of SMACC, announced that the sixth conference, again to be hosted in Sydney, would be the final one. Thousands of supporters were disappointed. In just a few short years, a medical conference had become an important part

of many people’s lives. How did they do it? Here are some of the moments that highlight its influence, along with an indication of what may replace it.

In 2013, Dr. Flower opened the first-ever SMACC standing behind a lectern. He immediately started to drone on about data, accompanied by a busy PowerPoint slide. Within seconds, a wrestler appeared and literally knocked over the lectern and carried Dr. Flower off stage. He was obviously in on the joke. The gauntlet had been laid down. This would be no ordinary gathering. Just as important as the content, which promised to be cutting-edge critical care, was the style. SMACC talks would be as engaging as TED talks but with quality content that could rival an ACEP or Society of Critical Care Medicine conference.

At SMACC Gold in 2014, Liz Crowe (@LizCrowe2) delivered a talk titled “Swearing Your Way Out of a Crisis.” As a social worker who worked in intensive care environments, she wanted us to recognize our own humanity and that our desire to be “politically correct” or appear to be calm, level-headed providers was depriving us of permission to emote in ways that could be helpful both for us and our patients. This was a watershed moment; medical audiences were not accustomed to

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Rutgers currently is ranked among the nation's top 20 public universities for research and development expenditures. Rutgers Robert Wood Johnson Medical School is first in the state for research and has steadily attracted increased NIH funding and grants in excess of \$1 million, as well as substantially expanded its clinical trials with the launch of a new, world-class adult clinical research center.

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

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Those interested in a position or further information may contact Dr. Tyson Pillow via email pillow@bcm.edu or by phone at 713-873-7045. Please send a CV and cover letter with your past experience and interests.

hearing such valuable insights from social workers at major conferences. This suddenly turned SMACC into a much larger tent gathering than a typical medical conference. From then on, SMACC was seen as a conference where major addresses were just as likely to be given by social workers, nurses, paramedics, and medical educators as they were by researchers and critical care physicians.

SMACC Chicago in 2015 was the pinnacle of “dogma-lysis,” the takedown of perceived wisdom in medicine and the zeitgeist of the #FOAMed community at that time. Whether it was how to treat pain (often with ketamine) or why many guidelines in sepsis were wrong, this was a conference that seemed to celebrate evidence-based iconoclasm. However, Simon Carley, MBChB, MPhil, MD, PhD (@EMManchester), gave a memorable talk about learning from your mistakes that heralded a new shift in SMACC toward an increased interest in the psychology of performing under pressure, as well as learning to deal with stressful situations clinically and interpersonally. Victoria Brazil, MBBS, MBA (@SocraticEM), sparked interest in this topic at earlier SMACCs, and it was taken to new heights by her and others, including Christopher Hicks, MD (@HumanFactorz).

However, clinical and educational innovation was still at the core of SMACC. Highlights from SMACCDUB, held in Dublin in 2016, included Iain Beardsell, MBChB (@DocIB), giving a unique approach to the medical debate on thrombolysis for submassive pulmonary embolism. Rather than prattle on about the evidence, he performed an evidence-based rap to the music of *Hamilton*: “It must be nice, it must be nice, to have evidence on your side!” It was both entertaining and evidence-based, which was SMACC at its best. SMACCDUB was also remembered for a tragedy that occurred shortly after the conference. An ICU physician from Northern Ireland, John Hinds, MB ChB, BAO, died in a motorcycle accident just days after presenting at SMACC. Dr. Hinds had a talent for combining education and humor, and he had given classic SMACC lectures about the “evils” of cricoid pressure as well as the necessity to act fast and honorably in trauma scenarios. Dr. Hinds’ death was a true shock to what had truly become a community. He had made such a large impact both locally and globally that his death eventually was seen as the impetus for Northern Ireland to finally initiate an air-ambulance program in 2016, something that Dr. Hinds had advocated for vigorously during his all-too-short life.

Das SMACC, held in Berlin in 2017, took the conferences’ previous predilections even further. The opening session was a large-scale simulation of a car accident, imagining the resuscitation of the near-future. A drone delivering O-negative blood to the scene was an amazing touch. Additionally, SMACC had become increasingly interested in provider wellness and inspiration. Annet Alenyo Ngabirano, MD (@AAlenyo), an emergency physician from Cape Town, South Africa, introduced us to the southern African word “ubuntu” to describe why we do what we do, compassion and humanity toward others.

The final SMACC, back in Sydney where it all began, somehow solved a problem that had emerged. A victim of its own success, SMACC attendees from various fields and niches of medicine, from prehospital to emergency medicine to intensive care, comprised an unusually large tent. Somehow, the final conference found the balance between inspi-

ration and education. The opening address, the John Hinds Plenary, was delivered by Gill Hicks, MBE, an amazing woman and gifted speaker who survived the July 7, 2007, London bombings. She reminded us why we do what we do. Later in the morning, clinical talks focused on topics such as managing maternal hemorrhage by Katya Evans, MBChB, MMed

(@kat__evans), the South African emergency physician who founded BADem.co.za (Brave African Discussions in emergency medicine), as well as a reminder to think about zebras in medicine that may actually be more common than we realize, such as anti-NMDA encephalitis. This message was delivered by Canadian emergency physician David Carr, MD

(@DavidCarr333). Finding the balance between cutting-edge clinical medicine, medical education, and the psychology of critical and emergency care was no easy task, but the organizers accomplished it.

As the final SMACC unfolded, news of its replacement surfaced. Starting next year, SMACC will collaborate with *The New England Journal of Medicine* and the George Institute for Global Health to create a new meeting called Coda (@CodaChange). Coda promises to build on what SMACC began in order to “solve urgent health challenges around the world,” according to its Twitter page. How they intend to accomplish this tall order remains to be seen. However, with the strengths of the diverse and global community that SMACC has created already in place, anything seems possible. ☺

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

CRITICAL CARE SERVICES INVOLVING A RESIDENT

by TODD THOMAS, CPC, CCS-P

Question: What information must a teaching physician include when reporting code 99291?

Answer: The Centers for Medicare and Medicaid Services (CMS) Transmittal 1548 significantly changed the teaching physician's documentation requirements for critical care encounters with resident participation. Physician documentation of total critical care time alone is not enough to support reporting Current Procedural Terminology (CPT) code 99291.

The teaching physician may refer to the resident's documentation for specific patient history, physical findings, and medical assessment. However, the teaching physician's documentation must provide substantive information as well, including:

- The total time (in minutes) the teaching physician spent providing critical care
- That the patient was critically ill during the time the teaching physician saw the patient
- What made the patient critically ill
- The nature of the treatment and management provided by the teaching physician

Time spent teaching may not be counted toward critical care time, and Medicare auditors might not accept simply adding critical care time to the normal teaching physician attestation. In a recent audit, the following attestation was not allowed for reporting code 99291: "40 minutes of critical care time provided, exclusive of separately billable procedures. I was present with the resident during the history and exam. I discussed the case with the resident and agree with the findings and plan as documented in the resident's note."

In contrast, the following CMS example includes acceptable teaching physician critical care documentation: "The patient developed hypotension and hypoxia. I spent 45 minutes while the patient was in this condition providing fluids, pressor drugs, and oxygen. I reviewed the resident's note and concur with their findings." +

Brought to you by the ACEP Coding and Nomenclature Committee.

DR. THOMAS is president of ERcoder, Inc.



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Rutgers Robert Wood Johnson Medical School**

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