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NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP

COVID-19 Resources and Help

At time of publication, the COVID-19 pandemic is front and center. The situation continues to change rapidly, but here is a rundown of ACEP's COVID-19 resources and news as of early April:

CLINICAL

Our **COVID-19 Clinical Alert** page (acep.org/covid-19) is updated daily with the newest resources. More than 200 resources are organized into the following categories:

- Member Updates
- Breaking News
- Clinical Assessment and Management
- Testing
- Personnel
- ED/Hospital
- Federal Updates
- System/Community
- EMS/Disaster
- Literature
- Patient/Diagnosis-Specific Resources

COMMUNITY

Peer to Peer: Nearly 4,000 emergency physicians from across the world are sharing lessons learned, ED strategies, and personal experiences on the front lines in the **COVID-19 Forum** at engaged.acep.org.

For Your Families: Invite your family members to join the ACEP Families group on Facebook, a place to connect with others who understand the unique challenges of having a loved one on the front lines of this pandemic.

MIND

It's important to prioritize your mental health right now because serving in the emergency department during this COVID-19 era is traumatic and tiring in so many ways.

- ACEP members receive three free counseling sessions, available 24/7 via text, online chat, or phone call with a National Board of Medical Examiners-certified wellness coach. This program is strictly confidential. Learn more at www.acep.org/support.
- Doxy.me has a free peer support program for physicians at <https://doxy.me/physiciansupportline>.
- Headspace has a free meditation collection at www.headspace.com/covid-19.
- The National Academy of Medicine has curated an extensive list of resources for system-level support at www.nam.edu.

ACEP Fights to Protect EPs During Pandemic

Pushing for PPE: ACEP is pursuing solutions to the PPE shortage through every channel. View ACEP's Policy Statements on PPE, including your right to wear self-purchased

and donated PPE, at www.acep.org/covid19-physician-protections. We are utilizing social media and grassroots actions to put pressure on legislators to take action. Nearly 35,000 ACEP members have sent more than 100,000 emails to Congress asking for more PPE.

ACEP is partnering with EM physician-led GetUsPPE.org to ensure that PPE needs are met nationwide. Many corporations are reaching out to us to help with the PPE shortage, and we are coordinating those companies with GetUsPPE.org to make sure the corporate donations go to those with the most urgent needs.

ACEP President Bill Jaquis, MD, FACEP, wrote to the President of AAMC asking that medical students be released from participating in patient contact, preserving the scarce PPE you need now. They agreed.

Policy Priorities: We have taken our fight to federal agencies, Capitol Hill, and the White House. We pushed for coverage of evaluation and testing for COVID-19 with no cost-sharing, expanded syndromic surveillance, and temporary increases in states' federal medical assistance percentage (FMAP) for the duration of the emergency.

ACEP worked tirelessly to remove surprise medical billing from COVID legislation—facing down the insurance industry on your behalf. Dr. Jaquis was the only person representing EM in a high-level medical briefing at the White House, and he lobbied for PPE, expanded access to testing, and liability protections.

ACEP wrote to Congressional leadership urging that emergency physicians be included in the COVID-19 stimulus package. We convened a virtual briefing with ACEP emergency physicians from Washington State to educate Congressional staff on the COVID-19 fight from the ground and help them prepare for outbreaks in their own districts.

We persisted until CMS made sweeping changes to the benefit of emergency medicine, including new guidance on EMTALA that allows medical screening exams to be delivered via telehealth and the addition of ED E/M codes to the list of approved Medicare telehealth services. We hosted a webinar with CMS so you could ask questions about their changes to EMTALA and telehealth. Read more at www.acep.org/cms-covid19-changes.

ACEP sent a letter to the HHS secretary securing relief in your Merit-based Incentive Payment system reporting and requesting liability protections during this crisis.

Stay updated on all federal and regulatory announcements at www.acep.org/covid19-advocacy. 📢

CALL FOR COVID-19 RESEARCH

The *Annals of Emergency Medicine* and *JACEP Open* welcome late-breaking manuscripts related to the COVID-19 pandemic. Please send pre-submission inquiries to annemergmed@acep.org or jacepopen@acep.org.



Eliquis[®]
(apixaban) tablets 5mg
2.5mg

In the emergency department, both safety and efficacy matter

For appropriate patients with DVT/PE, consider **ELIQUIS** at discharge



DVT=deep vein thrombosis; PE=pulmonary embolism.

INDICATION

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.

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

AMPLIFY^{1,2} Study Design

A randomized, double-blind, phase III trial to determine whether ELIQUIS was noninferior to enoxaparin/warfarin for the incidence of recurrent venous thromboembolism (VTE)* or VTE-related death in 5400 patients with objectively confirmed, symptomatic proximal DVT/PE. 2693 patients were randomized to ELIQUIS 10 mg orally twice daily for 7 days followed by 5 mg orally twice daily for 6 months, and 2707 patients were randomized to standard of care, which was initial enoxaparin 1 mg/kg twice daily subcutaneously for at least 5 days (until INR ≥ 2), followed by warfarin (target INR range: 2.0-3.0) orally for 6 months. The primary efficacy endpoint was recurrent VTE* or VTE-related death, and the primary safety endpoint was major bleeding.

≈90% of patients in the AMPLIFY trial had an unprovoked DVT/PE at baseline.¹

- The 10% of patients with a provoked DVT/PE were required to have an additional ongoing risk factor in order to be randomized†

*Recurrent symptomatic VTE (nonfatal DVT or nonfatal PE).

†Risk factors included previous episode of DVT/PE, immobilization, history of cancer, active cancer, and known prothrombotic genotype.

To learn more about ELIQUIS, visit hcp.eliquis.com

IMPORTANT SAFETY INFORMATION (CONT'D)

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 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.
- **Increased Risk of Thrombosis in Patients with Triple Positive Antiphospholipid Syndrome (APS):** Direct-acting oral anticoagulants (DOACs), including ELIQUIS, are not recommended for use in patients with triple-positive APS. For patients with APS (especially those who are triple positive [positive for lupus anticoagulant, anticardiolipin, and anti-beta 2-glycoprotein I antibodies]), treatment with DOACs has been associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy.

ADVERSE REACTIONS

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

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

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

DRUG INTERACTIONS

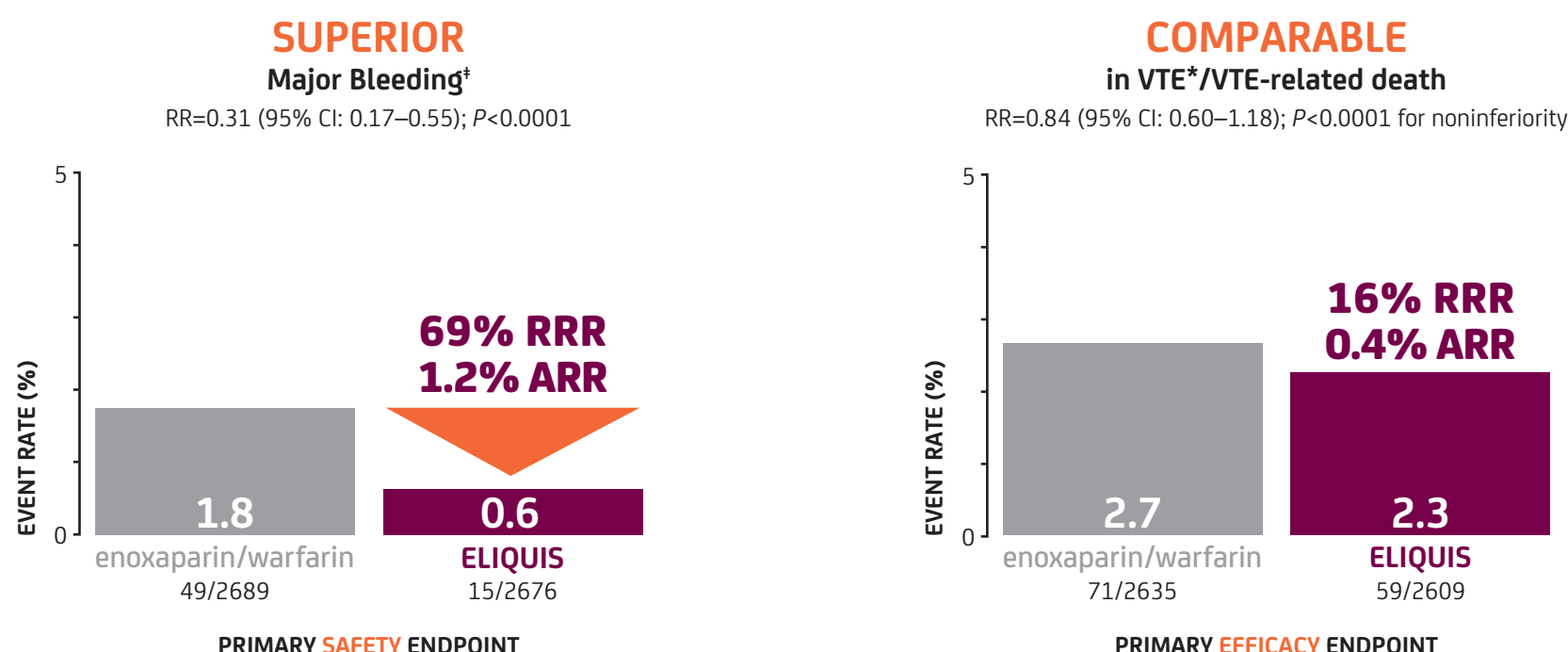
- **Combined P-gp and Strong CYP3A4 Inhibitors:** Inhibitors of P-glycoprotein (P-gp) and cytochrome P450 3A4 (CYP3A4) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is 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.

FOR THE TREATMENT OF DVT/PE

Only ELIQUIS demonstrated BOTH superiority in major bleeding events AND comparable efficacy vs enoxaparin/warfarin¹



ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding¹

- Discontinuation rate due to bleeding events: 0.7% in ELIQUIS-treated patients vs 1.7% with enoxaparin/warfarin¹
- In AMPLIFY, the most commonly observed adverse reactions in ELIQUIS-treated patients (incidence $\geq 1\%$) were epistaxis, contusion, hematuria, menorrhagia, hematoma, hemoptysis, rectal hemorrhage, and gingival bleeding¹

Major bleeding was defined as clinically overt bleeding accompanied by at least one of the following^{2,3}:

- A decrease in hemoglobin of ≥ 2 g/dL; 2) A transfusion of 2 or more units of packed red blood cells; 3) Bleeding that occurred in at least 1 of the following critical sites: intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, or retroperitoneal; 4) Fatal bleeding

ARR=absolute risk reduction; CI=confidence interval; HR=hazard ratio; INR=international normalized ratio; RR=relative risk; RRR=relative risk reduction.

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

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS (cont'd)

- 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

- The limited available data on ELIQUIS use in pregnant women are insufficient to inform drug-associated risks of major birth defects, miscarriage, or adverse developmental outcomes.

Treatment may increase the risk of bleeding during pregnancy and delivery, and in the fetus and neonate.

- Labor or delivery:** ELIQUIS use during labor or delivery in women who are receiving neuraxial anesthesia may result in epidural or spinal hematomas. Consider use of a shorter acting anticoagulant as delivery approaches.

LACTATION

- Breastfeeding is not recommended during treatment with ELIQUIS.

References: 1. Eliquis [package insert]. Bristol-Myers Squibb Company, Princeton, NJ, and Pfizer Inc, New York, NY. 2. Agnelli G, Buller HR, Cohen A, et al; for AMPLIFY Investigators. Oral apixaban for the treatment of acute venous thromboembolism. *N Engl J Med*. 2013;369(9):799-808. Supplement available at http://www.nejm.org/doi/suppl/10.1056/NEJMoa1302507/suppl_file/nejmoa1302507_appendix.pdf. Accessed December 5, 2018. 3. Agnelli G, Buller HR, Cohen A, et al. Apixaban for extended treatment of venous thromboembolism. *N Engl J Med*. 2013;368(8):699-708. Supplement available at http://www.nejm.org/doi/suppl/10.1056/NEJMoa1207541/suppl_file/nejmoa1207541_appendix.pdf. Accessed December 18, 2018.

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



Eliquis
(apixaban) tablets 5mg/2.5mg

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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 ELIQUIS-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 ELIQUIS-treated patients undergoing hip or knee replacement surgery occurring at a frequency of <0.1%:

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

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

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

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

AMPLIFY Study

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

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

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

Table 5: Bleeding Results in the AMPLIFY Study

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

* CRNM = clinically relevant nonmajor bleeding.

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

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

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

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

AMPLIFY-EXT Study

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

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

Table 7: Bleeding Results in the AMPLIFY-EXT Study

	ELIQUIS 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 (apixaban) 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 ELIQUIS 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 ELIQUIS compared to placebo. The rate of ISTH major bleeding was 2.8% per year with ELIQUIS versus 0.6% per year with placebo in patients receiving single antiplatelet therapy and was 5.9% per year with ELIQUIS 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

Risk Summary

The limited available data on ELIQUIS use in pregnant women are insufficient to inform drug-associated risks of major birth defects, miscarriage, or adverse developmental outcomes. Treatment may increase the risk of bleeding during pregnancy and delivery. In animal reproduction studies, no adverse developmental effects were seen when apixaban was administered to rats (orally), rabbits (intravenously) and mice (orally) during organogenesis at unbound apixaban exposure levels up to 4, 1 and 19 times, respectively, the human exposure based on area under plasma-concentration time curve (AUC) at the Maximum Recommended Human Dose (MRHD) of 5 mg twice daily.

The estimated background risk of major birth defects and miscarriage for the indicated populations 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% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

Pregnancy confers an increased risk of thromboembolism that is higher for women with underlying thromboembolic disease and certain high-risk pregnancy conditions. Published data describe that women with a previous history of venous thrombosis are at high risk for recurrence during pregnancy.

Fetal/Neonatal adverse reactions

Use of anticoagulants, including ELIQUIS, may increase the risk of bleeding in the fetus and neonate.

Labor or delivery

All patients receiving anticoagulants, including pregnant women, are at risk for bleeding. ELIQUIS use during labor or delivery in women who are receiving neuraxial anesthesia may result in epidural or spinal hematomas. Consider use of a shorter acting anticoagulant as delivery approaches *[see Warnings and Precautions]*.

Data

Animal Data

No developmental toxicities were observed when apixaban was administered during organogenesis to rats (orally), rabbits (intravenously) and mice (orally) at unbound apixaban exposure levels 4, 1, and 19 times, respectively, the human exposures at the MRHD. There was no evidence of fetal bleeding, although conceptus exposure was confirmed in rats and rabbits. Oral administration of apixaban to rat dams from gestation day 6 through lactation day 21 at maternal unbound apixaban exposures ranging from 1.4 to 5 times the human exposures at

the MRHD was not associated with reduced maternal mortality or reduced conceptus/neonatal viability, although increased incidences of peri-vaginal bleeding were observed in dams at all doses. There was no evidence of neonatal bleeding.

Lactation

Risk Summary

There are no data on the presence of apixaban or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Apixaban and/or its metabolites were present in the milk of rats (see Data). Because human exposure through milk is unknown, breastfeeding is not recommended during treatment with ELIQUIS (apixaban).

Data

Animal Data

Maximal plasma concentrations were observed after 30 minutes following a single oral administration of a 5 mg dose to lactating rats. Maximal milk concentrations were observed 6 hours after dosing. The milk to plasma AUC (0-24) ratio is 30:1 indicating that apixaban can accumulate in milk. The concentrations of apixaban in animal milk does not necessarily predict the concentration of drug in human milk.

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 ELIQUIS 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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FACEPs IN THE CROWD

More than 12,000 ACEP members have achieved Fellow status with the College and use the FACEP designation with pride! This month, we're spotlighting some ACEP Fellows whose pets are truly the pick of the litter.

KORY KAYE, MD, FACEP

After retiring in January after 33 years in emergency medicine, Kory Kaye, MD, FACEP, has more time to devote to her hobby of the last 25 years: dog agility competitions. Dr. Kaye and Kaemon, her Shetland sheepdog, have earned many trophies over the years, including winning the American Kennel Club's national agility competition in 2016. Dog sports have grown in popularity since she got her start, and now she gets to compete twice per month. "Dog agility is the most amazing blend of right-brain and left-brain activity I have ever experienced," Dr. Kaye said. She said training dogs requires patience and empathy, while the agility courses, held secret until the competition day, require quick, analytical thinking. She said the sport has a lot of the elements that drew her to emergency medicine: "All the highs and



lows, quick thinking, rapid decision making, and adjusting when things are not going the way you expected."

KERRY YANCY, MD, FACEP

Kerry Yancy, MD, FACEP, an assistant professor of pediatric emergency medicine at the University of Mississippi Medical Center in Jackson, has always been a "cat person," but she took it to the next level when she started exhibiting her cats during medical school. She's competed in 27 states and three countries with her award-winning Somalis, Turkish Vans, and household pets, including a Somali that was named one of the best in the world by The International Cat Association (TICA). Dr. Yancy describes it as "a way to just be a cat person and not a doctor to an entire small section of the world, almost like I have a second identity." She and her kids compete together, and she's made some of her best friends through TICA shows. "I tell my residents that to survive in EM emotionally, we all *must* have a nonmedical



hobby," she said. "It's a great way to connect with the world and to nurture one's own mind and spirit."

KNOW AN EMERGENCY PHYSICIAN WITH AN INTERESTING HOBBY WHO SHOULD BE FEATURED IN "FACEPS IN THE CROWD"? SEND YOUR SUGGESTIONS TO ACEPNOW@ACEP.ORG.

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THE BREAK ROOM

A Note to Emergency Physicians in Training: Is COVID-19 the Ultimate Learning Opportunity?

What a wild time to be an EM physician, let alone an EM physician in training. I'm sure that all program directors are getting questions that are difficult to answer since there isn't necessarily an answer or there are only two bad answers to the question. Likewise, medical schools or training institutions may remove some elements of choice that should be available to you.

Here's the old fart's perspective on what's happening, directed toward learners.

This is really, really going to suck, and it's not going away in two to three weeks. This is a long-haul situation. Having noted that basic truth, this is also a learning opportunity for health care workers that has been unparalleled for more than a century. It is rich in experiences, no matter what choice an individual makes, in disaster care, infectious disease/epidemiology, clinical and public health, the psychology of infectious disease disaster on society, your institutions, your clinical workplace (all the component people), your supervisors and leaders, and your peers. It will provide a test and an introspection (hopefully) of your individual and collective professionalism. What drives your decision making when your obligations as an EM doc conflict head on with your personal mission-directed values? Which trumps which? Are the tenants and tendrils of professionalism weakened or dead?

I am happy that EM physicians are on the front line in the weeks/months to come. EM docs are flexible, think fast on their feet, know how to stretch resources and improvise, are

dedicated to serving patients first, and can provide important leadership at the ground level. What better group to learn as they are doing (we don't even get the advantage of the first in the triad of "see one, do one, teach one")? I know we have fantastic leaders who will lead from the front and will be role models for finding our way through uncharted territory. Watch them. Learn from them. I hope that other institutions are able to share such a gift with their learners.

The majority of U.S. Army soldiers and Marines in World War II noted that they did what they did for their comrades, not for the lofty ideals that drove them to volunteer to serve. When push comes to shove during the upcoming months, this may become the determining factor for each of you. And if so, how rich will that experience be?

This will likely be the event that will define your future professional identity.

Even if you end up working excessive hours, or conversely are "locked out" of the emergency department, keep a diary during this—even if it's dictating a few impressions periodically into an app on your phone. This may provide important learning points for the future or a place of introspection. Some of you will question your decision to serve as an EM physician. What better test of that decision?

And importantly, the more you learn through this experience, the better positioned you will be when the next one, perhaps even more deadly, encircles the globe once again. It will happen again during your career.

Carey Chisholm, MD
Professor Emeritus, Department of
Emergency Medicine
Indiana University School of Medicine

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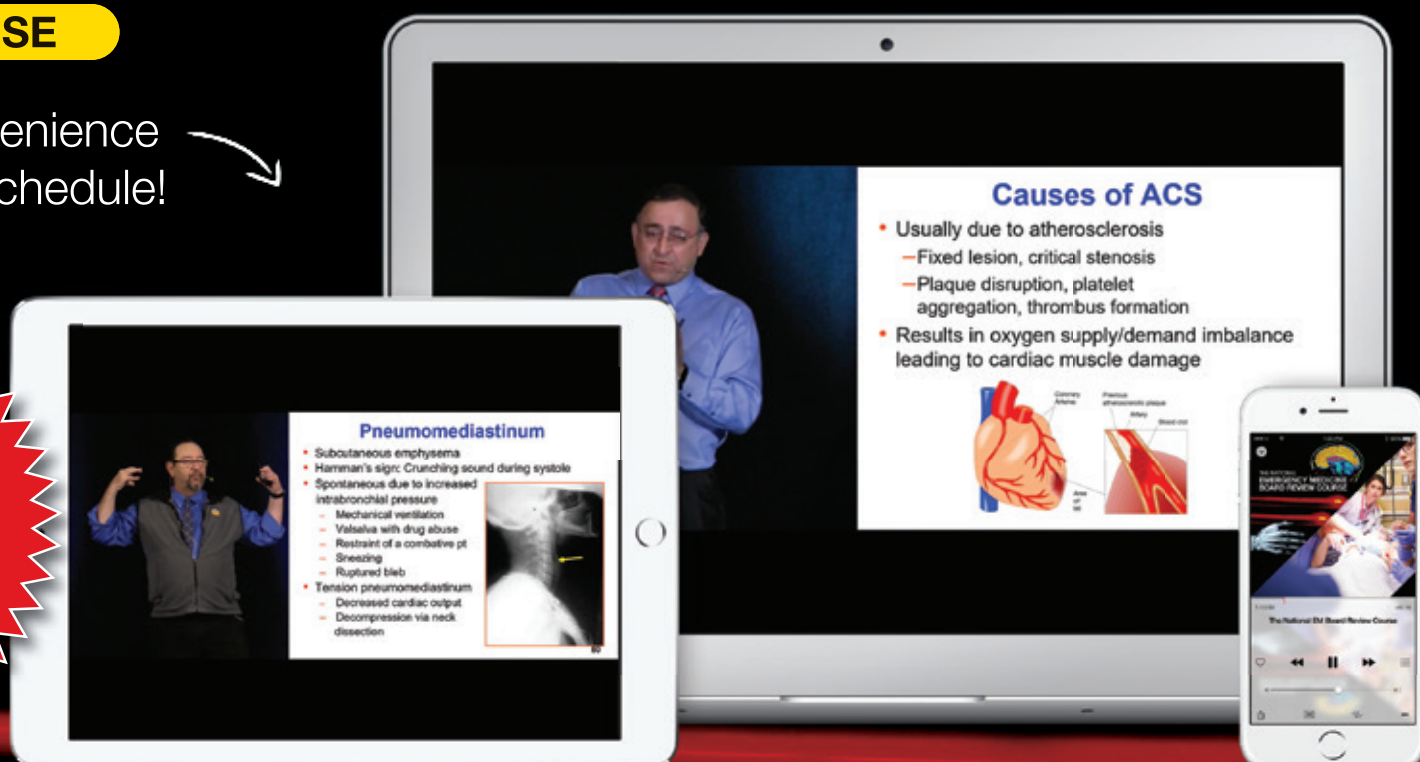
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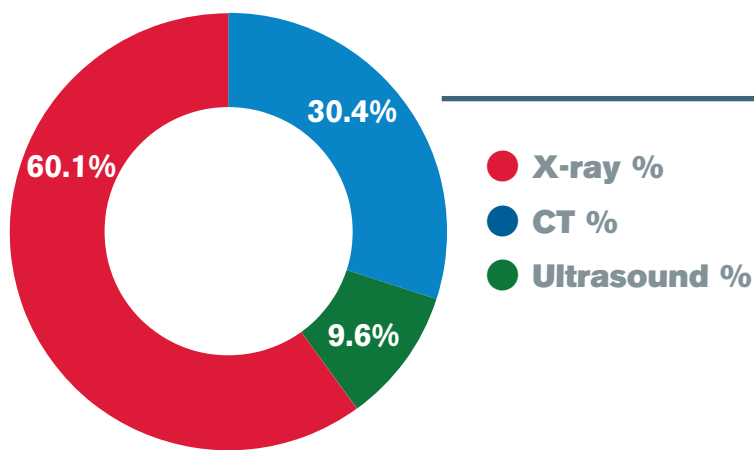
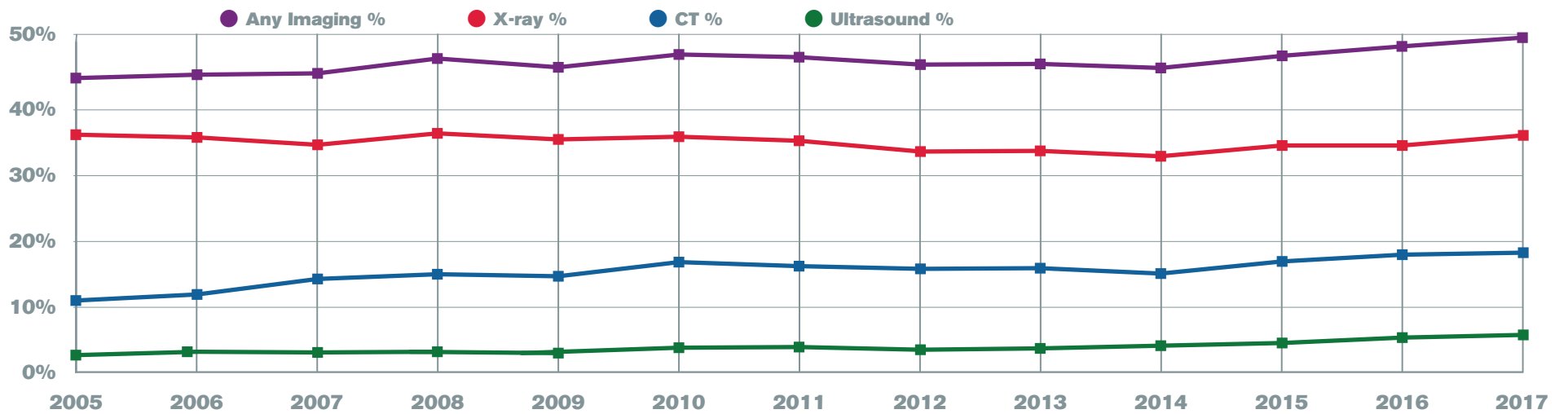
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Trends in U.S. Emergency Department Imaging



The percentage of patients receiving diagnostic imaging in the ED continues to increase. Although CT and ultrasound utilization has increased, plain film radiography has remained relatively stable.

SOURCE: CDC NHAMCS



by **SAM ASHOO, MD, FACEP**, founder and CEO of Admin EM. More at admin-em.com.



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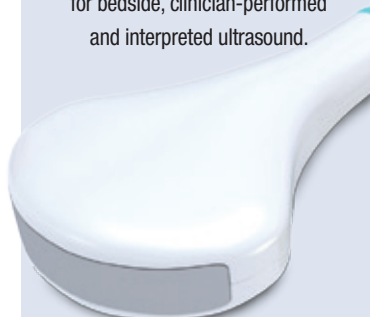
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TOXICOLOGY Q&A

Ancient Chemical Weapon



by **JASON HACK, MD, FACEP, FACMT**

QUESTION

What beautiful bloom was used by the Greek army against the city of Kirrha?

ANSWER on page 12

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Operation Needed—or Not?

ED MANAGEMENT OF WEBER B ANKLE FRACTURES

by JOSEPH NOACK, MD; AND
SPENCER TOMBERG, MD

In the emergency department, isolated fibular ankle fractures are frequently characterized using the Danis-Weber classification system. This fracture classification system, based on the level of the fibular fracture in relation to the ankle joint, can help determine which injuries are likely to require surgical intervention. The Weber classification is simple, reliable, and reproducible, and thus it has been utilized routinely by emergency physicians.^{1,2}

Injuries to the distal fibula, below the talar dome, are classified as type A and are stable fractures. Weber C fractures are above the ankle joint and are associated with a syndesmotic injury. Weber C fractures are almost always unstable and require surgical intervention. Weber B fractures occur at the level of the tibiofibular ligaments, just above the talar dome, and happen primarily through a mechanism of ankle supination and external rotation (SER).³ These type B fractures are sometimes stable, and patients can ambulate on them as tolerated; in other cases, they are unstable and require open reduction and internal fixation (ORIF). The focus of this article is to help emergency physicians choose the proper method for determining that stability.

Do They Need an Operation?

The primary consideration regarding need



FIGURE 1: Optimal ankle positioning with gravity stress testing.

JOSEPH NOACK & SPENCER TOMBERG

for operative management of a closed ankle fracture is stability. In general, most stable ankle fractures can undergo nonoperative management by a primary care physician. Unstable ankle fractures are one of the primary indications for orthopedic referral. Any bi- or trimalleolar fracture should be considered unstable because of the disruption of the bony architecture on both the medial and lateral

side of the joint.

With Weber B fractures, the stability of the ankle joint depends on injury to the tibiofibular ligaments and the deltoid ligament. The deltoid ligament, which runs from the medial malleolus to the calcaneus, talus, and navicular bones, plays a vital role in maintaining correct talus positioning. A talar shift of 1 mm results in a 42 percent decrease in tibiotalar

contact area, which can lead to significant increases in contact stress.⁴ In what appears as an otherwise isolated Weber B fibular injury, a tear of the deltoid ligament can be considered “equivalent to a medial malleolar fracture,” qualifying the fracture mechanically as unstable, thus requiring operative management.⁵

CONTINUED on page 18

Toxicology Q&A Answer

QUESTION ON PAGE 10

Answer: Hellebore

Helleborus is derived from two Greek words: *bora*, meaning food, and *helein*, meaning injures/destroys.

Toxins

Hellebore contains glycosides variously named helleborin, hellebrin, and helleborigenin, which are bufadienolides (similar to toad toxin). It also contains other compounds including protoanemonin, flavonoids, phenolic acids, saponins, and ecdysteroids in varying amounts depending on the species.

Toxic Effects

Cardiac glycoside effects predominate, with severe nausea, vomiting, diarrhea, very slow heart rates, arrhythmias, and potentially death. The sap also is a skin irritant, and prolonged skin contact may cause burning. Phytoecdysteroids can mimic the activity of molting hormones in insects, disrupting molting and stopping normal insect development.

Properties of the Plant

These beautiful examples of hellebore flowers show the variety of colors in the bloom. The colored parts of the flower are “septals,” which are modified leaves—not petals—so they remain on the plant for weeks to months. It is an evergreen rhizomatous perennial that

flowers in the colder seasons. It grows in clumps that produce two or three large nodding flowers.

Historical Notes

In the days of Hippocrates, hellebore was used to treat gout, paralysis, insanity, and other diseases. Some historians believe a lethal overdose of hellebore had a role in ending the life of Alexander the Great.

In 585 BC, the Greek army poisoned the water supply to the city of Kirrha by adding massive amounts of crushed hellebore leaves. The citizens were overcome by illness—chemical warfare was alive and well in the ancient world.

Some varieties of hellebore were used to treat worms in children, the idea being to expel the worms by vomiting. +



DR. HACK (OLEANDER PHOTOGRAPHY) is professor of emergency medicine and director of the division of medical toxicology at Brown University in Providence, Rhode Island.

He enjoys taking photographs of beautiful toxic, medicinal, and benign flowers that he stumbles upon or grows in his garden. Contact him at ToxinRI@gmail.com, www.toxinRI.com, or on Instagram at [oleanderphotography](https://www.instagram.com/oleanderphotography).



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HELLEBORE

Helleborus orientalis

COMMON NAMES: **Christmas rose, Lenten rose**

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SALINE LOAD OR CT

WHAT'S THE BEST TEST FOR TRAUMATIC ARTHROTOMY?

by JONATHAN MICHAEL
STRONG, MD, MPH

The Case

An 81-year-old female presents to the emergency department with a right knee injury after slipping on uneven pavement. She has a large 10-cm laceration that extends across the anterior surface of the knee (see Figure 1). Her patella is exposed; however, there is no clearly visible intra-articular surface to indicate violation of the joint capsule. Radiographs of the knee show no fractures or foreign bodies. How will you determine whether the laceration extends into the joint capsule? Does she need to go to the operating room (OR) for irrigation and debridement (I&D) to prevent septic arthritis?

Looking for Leaks: The Saline Load Test

First described in 1975, the saline load test (SLT) is the traditional test utilized to assess for traumatic arthrotomy associated with periarticular wounds.¹ Using sterile technique, an 18-gauge needle, and syringe, the joint capsule is accessed at an area away from the wound using the same approach for performing arthrocentesis. Intra-articular needle placement is confirmed by aspirating a small amount of synovial fluid. Next, sterile saline is slowly injected until the joint capsule becomes distended. The saline should meet little resistance when injected into the joint capsule, as significant resistance suggests extra-articular infiltration. Extravasation of saline from the periarticular wound indicates the joint capsule has been violated, whereas failure of extravasation indicates an intact joint capsule. After injecting the saline, it is important to wait a few minutes and gently move the joint through its range of motion, as this may make slowly leaking saline more apparent. Finally, aspirate the saline from the joint capsule and withdraw the needle from the patient's knee.

Adding methylene blue to the sterile saline previously was thought to improve visualization of leakage; however, this practice is not necessary or currently recommended. Further, the methylene blue may cause a local inflammatory reaction and interfere with knee arthroscopy should the patient need to go to the OR for I&D.

How much saline should you inject? Enough to visibly distend the joint capsule or until you meet resistance, indicating the capsule is nearly full. The amount of saline will vary by the size of the joint and the size of the patient, but *Roberts and Hedges' Clinical Procedures in Emergency Medicine and Acute Care* generally recommends 100–200 mL for the knee, 40–60 mL for the shoulder, 20–30 mL for the ankle and elbow, and 5 mL for the wrist.² Fully loading the joint is very important, as an insufficient amount of saline may lead to false-negative test results.

How Well Does SLT Perform?

How well does this test perform in diagnosing traumatic knee arthrotomy? In 1996, Voit et al compared SLT to clinical judgment alone in 50 patients with periarticular traumatic wounds of the knee. The study found clinical judgment alone had a sensitivity of 57 percent and a specificity of 61 percent when using SLT



FIGURE 1: An 81-year-old female with a 10-cm laceration that extends across the anterior surface of the knee. Her patella is exposed but there is no clearly visible intra-articular surface to indicate violation of the joint capsule.



FIGURE 2: The patient's knee following wound irrigation and repair.

PHOTOS: JONATHAN STRONG

as the gold-standard test. SLT changed management in 40 percent of patients, and the authors concluded that SLT is superior to clinical judgment alone. However, the authors did not consider the possibility of false-positive and false-negative SLT results.

Several subsequent studies evaluated the sensitivity of SLT in patients undergoing elective knee arthroscopy. The sensitivity of SLT in these studies varied considerably, ranging from 36 to 99 percent, owing to differences in SLT technique such as the amount of saline injected, the size of the surgical incision, the position of the knee, and whether the knee was moved through its range of motion. Other patient-specific factors, such as age, sex, and body mass index, also may have played a role. Regardless, it is difficult to apply the results of these studies of elective arthroscopic knee surgery patients to patients presenting to the emergency department with traumatic knee injuries.

In 2013, Konda et al used a novel approach to study SLT in 50 patients presenting to the emergency department with periarticular knee wounds.⁴ In this study, all patients underwent SLT, and those with positive results went to the OR for arthroscopy to confirm the presence or absence of a traumatic knee arthrotomy. Patients with a negative SLT and no other indications for operative management were discharged and monitored for septic arthritis at follow-up. Those who subsequently

developed septic arthritis were considered to have a missed traumatic knee arthrotomy. How well did SLT perform in this study? The authors found a sensitivity of 94 percent and a specificity of 91 percent using this approach. Given the prevalence of traumatic knee arthrotomy in this study, the false-positive rate was 16 percent and the false-negative rate was 3 percent. This false-negative rate was attributed to a single patient who had a negative SLT but went to the OR for a grossly contaminated wound and was found to have a traumatic knee arthrotomy. The authors note that none of the patients discharged after a negative SLT went on to develop septic arthritis; however, the study was underpowered to adequately detect infection in this population.

A Loaded Question: Is SLT Obsolete?

In 2013, Konda et al also published a study investigating CT scan as an alternative to SLT.⁵ In this study of 62 patients presenting to the emergency department with periarticular knee wounds, the presence of intra-articular air on CT scan had 100 percent sensitivity and 100 percent specificity for diagnosing traumatic knee arthrotomy when direct arthroscopic visualization or septic arthritis at follow-up were used as the gold standard for diagnosis. In this same study, the sensitivity of SLT was measured to be 92 percent. The authors con-

clude that “CT scan performs better than the conventional SLT to identify traumatic knee arthrotomies.” An important caveat is that the study was underpowered to detect patients who go on to develop septic arthritis after a negative CT scan.

This leaves emergency physicians in a difficult spot. Currently, SLT is the generally accepted practice when evaluating a patient for a traumatic knee arthrotomy; however, the evidence behind SLT is weak at best. Should we retire SLT in favor of CT scan? How much evidence is needed to change our practice when the current “standard” practice also has only weak evidence behind it?

This is a difficult philosophical question without a clear answer. However, I can offer some advice for the emergency physician facing such a scenario.

First, discuss the scenario with your fellow emergency physicians and subspecialty colleagues. See if there is a generally accepted practice, policy, or protocol at your institution. It is best not to deviate from the generally accepted practices at your institution unless you have a good reason for doing so. Consider crafting a policy or protocol with your colleagues if your institution does not have one.

Second, discuss the scenario with your patient. They may not understand the nuances of evidence-based medicine, but most will understand uncertainty. Explain your thought process, present the patient with options if you feel it is appropriate, reach a decision together, and document as such.

Finally, consider your own philosophy and values. How much evidence do you need to change your practice? What is your risk tolerance? Are you a traditionalist or an early adopter? Do you place more value in the wisdom of collective past experience or the progress that may come with new innovation? This is for you to decide.

Case Resolution

The case is discussed with the on-call orthopedic surgeon, the patient, and her family. Together, it is decided to proceed with CT scan, which shows no intra-articular air. The patient's wound is irrigated and repaired, and she is discharged from the emergency department. Follow-up several weeks later reveals she has suffered no infection complications. ➕

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Figure 1



Radiology teams from our institution have minimized staff and equipment exposure by performing single-view portable radiographs through the windows on doors to isolation rooms. **(LEFT)** The patient is positioned standing or sitting in front of the door inside the isolation room with a nurse/staff wearing a lead shield, holding the plate to the patient's chest. **(CENTER)** The portable machine camera is brought close to the glass, and adjustments are made to the machine to optimize the film. The film is passed by the gowned nurse outside the room with removal of the plastic sheet while passing to the X-ray staff outside the room, keeping the plate clean. **(RIGHT)** While an artifact from the window is sometimes present on the film, our radiologists have been able to read from these for multifocal pneumonia and tube placement.

PREP YOUR ED FOR COVID-19 | CONTINUED FROM PAGE 1

move more quickly.

Though protocols are frequently being revised as we learn more, there are several ways to ready your emergency departments for these patients. These include creative approaches to staff training, improvements in the physical space for isolation capacity, equipment to procure/inventory, and systems for providing patient care to minimize staff exposure.

We hope you can benefit from these recommendations while you have the time to prepare yourselves and your departments. The most important and time-critical component of COVID-19 response protocol is communication.

Consider Activating Your Incident Command System

Your incident command system should include communication early and often between emergency departments, hospitalist services, ICUs, local and state departments of health (DOHs), emergency medicine services (EMS), leads, and outreach leads to vulnerable populations (eg, local skilled nursing facilities [SNFs], jails, homeless shelters). In our experience, SNFs have been particularly vulnerable and have been the source of most patients and fatalities.

Developing communication links with local SNFs for the purpose of creating a transportation and hospital disposition plan prevents proximately located hospitals from being overwhelmed by a single SNF experiencing an outbreak.

The following cheat sheet is in the staff/stuff/space/systems format of simple ideas to consider for preparing.

STAFF

Initiation of Staff Preparations

Fit testing for airborne precautions should be up-to-date within the last month for all staff, including radiology, maintenance, housekeeping, and other ancillary staff. Every physician and nurse should attest to watching the proper donning/doffing technique recommended by the Centers for Disease Control and Prevention (CDC) in the links in the “Resources” sidebar, and in-person training should be considered.

Staff should update their own home personal safety plans, including creating backup

child care plans and stocking household supplies so that when work gets busy, their home plans and supplies are ready and they can concentrate on work.

Communication

Incident command structure should be followed, with centralized communication, messaging, and task delegation, including:

- Identify a liaison to communicate regularly with the local DOH.
- Identify a liaison for communications with the media.
- Identify a COVID-19 hospitalist lead for admissions that are not to the ICU and an intensivist lead for those to the ICU.
- Identify outreach leads for EMS, the homeless and shelter community, SNFs, and jails if your hospital receives these patients.

STUFF

Inventory current amounts of sanitation supplies (especially alcohol-based hand gel and bleach wipes); pulse oximeters; masks, powered air-purifying respirators (PAPRs), and shrouds for PAPR; mirrors for doffing stations; and disposable stethoscopes to anticipate increased needs. We have run short of flu swabs and personal protective equipment (PPE). Consider storing these supplies in ways that prevent hospital personnel and guests from removing them for personal use.

Assess supplies of key medications including antibiotics, sedation, analgesia, neuromuscular blockade, and crystalloid. Plan for use of metered dose inhalers with spacers instead of nebulizers to reduce infectivity.

Establish protocols for handling patient specimens (blood, urine, respiratory viral testing, etc.).

Hospitals should determine how many ventilators are available, including noninvasive positive pressure devices and anesthesia machines; reach out to ambulatory surgery centers for the possibility of using anesthesia machines; and assess the number of extracorporeal life support pumps and circuits available.

SPACE

Develop a department plan designating which

areas of the emergency department will be dedicated to droplet precautions and which areas are negative pressure rooms appropriate to airborne precautions. For areas without an antechamber, consider creating a taped “warm zone” outside of the room for proper doffing. Ensure donning/doffing stations are set up with all needed supplies. Consider taking a photo of the station to post to ensure proper setup. How will you secure these supplies (especially the hand gel and wipes)?

Consider cohorting patients with mild illness who are “patients under investigation” in internal waiting rooms away from well patients or those who could be immunocompromised.

Use phones in the patient rooms to interview noncritically ill patients to reduce trips in and out of the room and to coordinate with nursing or respiratory therapy when they are at the bedside.

Movements

Consider how patients will be transported from the waiting room through the emergency department to the isolation or precautions room. What route will they take to minimize exposure from the emergency department to the floor or unit dedicated within your hospital?

What route will patients take from the emergency department to the inpatient unit?

Use security to facilitate clearing the route, hold the elevator, and ensure that the elevator is cleaned after patient transport.

What route will your used supplies take to be cleaned, and how will your nasal swabs be transported to the lab (eg, we are not using our tube system)?

Diagnostics

Develop plans for terminal cleaning of CT scan rooms and other bedside diagnostic equipment (portable radiology, ultrasound, etc.). For example, will you have a dedicated ultrasound?

We have developed a process to perform portable radiographs through the door window for patients in isolation, reducing risk to staff and the need to clean portable units (see Figure 1). The radiographs have been found to be of acceptable quality for reading using this technique.

SYSTEMS

Staffing

Plan to have a double backup system in place ensuring that if staff members are sick, there is an easy system to call in relief without having to scramble. This system also protects against staff members feeling remorse or hesitation about calling in sick and contributing

PATIENT PRESENTATION
In general, patients have presented with a wide variety of symptoms, including fever, cough, upper respiratory infection symptoms, and hypoxemia. Rapid decompensation was seen in several patients. Generally, those who died were elderly, and some were immunocompromised.
SYNDROME
Some afebrile, some with high fevers lasting more than one week
Shortness of breath, dry cough, some with gastrointestinal symptoms (although uncommon)
Risk factors: older patients, comorbidities
Respiratory failure: acute respiratory distress syndrome (ARDS)/pneumonitis, varying presentations on radiography
Cardiomyopathy, including elevated creatine kinase, has been seen

to dangerous “presenteeism” and coming to work sick.

Consider:

- Canceling communal food in meetings and care areas and moving to tele-education and online meetings.
- Updating staff flu shots.
- Requiring use of scrubs instead of wearing personal clothes to work and encouraging minimization of jewelry and personal items as fomites.
- Using gel-in/gel-out hand hygiene and redoubling efforts to ensure 100 percent compliance for all patients.
- Creating a hospital-wide plan for backup child care so physicians, nurses, and other staff are not staying home to care for their children if schools close.

Training

Arrange in-person donning/doffing training by “supertrainers” for all ED staff. Once an airway plan has been established, use simulation training to get staff comfortable with new procedures and protocols (eg, intubating using the glidescope while in a PAPR with a shroud).

Tracking Systems

Review the current system or create a new one for tracking exposures and symptoms when a COVID-19 exposure happens for staff or when staff members are sick. For example, when will they return to work, and how will they get their test results?

Intubation and Airway Algorithms

Review plans for limiting staff exposure to aerosolization of COVID-19. Consider not using high-flow nasal cannula or noninvasive positive pressure ventilation in the emergency department unless adequate airborne isolation can be guaranteed and limiting use of nebulized medication. Intubation should occur only by those trained in how to intubate while in a PAPR with shroud. Follow a COVID-19-specific protocol for intubation developed by your hospital’s airway leads.

Consider PPE use, use of video laryngoscopy, premade medical airway bags, reentry and intubation checklists, and rapid sequence intubation to decrease aerosolization of particles with bag-valve masks.

Review methods for addressing severe hypoxemia and acute respiratory distress syndrome (ARDS) with ventilation, medication, and other maneuvers with all staff (eg, titration positive end-expiratory pressure, neuromuscular blockade, recruitment maneuvers, and proning).

Bundle Care

Plan ahead for blood draws, ECGs, and medication administration to minimize trips into and out of the patient’s room. Build kits with preassembled supplies to be used in isolation areas. Establish protocols for testing patients in conjunction with your lab’s ability to run these tests.

Create scripts for 911 call centers to ask about COVID-19 risk factors before sending EMS to a scene. Develop scripts for your transfer center to use screening questions regarding symptoms and COVID-19 status with the goal of identifying potential COVID-19 patients prior to ED arrival. Have EMS call ahead to alert emergency department to high-risk COVID-19 patients from the field. Draft outward-facing documents with clear instructions for the community to call their doctor prior to coming to the emergency department to reduce overcrowding.

Interfacility Triage

If your center is a receiving center for stroke or other transfers, ensure that there are COVID-19 screening questions being asked by all accepting physicians and services.

Extracorporeal Membrane Oxygenation (ECMO)

Consider risks and benefits of citywide and regional referral of patients to ECMO centers. Risks of transport may include disease spread, risk to transport personnel, and overwhelming ECMO centers’ general ICU resources. Develop strict criteria for ECMO initiation only to those with the highest chance of survival given the high number of potential ECMO candidates and limited capacity. If patients require transfer from low-resource hospitals, consider triaging potential ECMO candidate patients (young, otherwise healthy, single or

ONLINE RESOURCES

- **ACEP’s COVID-19 Resource Page:** www.acep.org/covid-19
- **PPE Video for Pre-training and “Just in Time” Review:** <https://youtu.be/bG6zISnenPg>
Watching the video does NOT qualify as appropriate refresher training. We recommend that you review the pre-training video before your training session.
- **CDC Website for Current Literature:** www.cdc.gov/coronavirus/2019-ncov/publications.html
- **National Academy of Medicine: Duty to Plan:** Health Care, Crisis Standards of Care, and Novel Coronavirus SARS-CoV-2: <https://doi.org/10.31478/202003b>
- **University of Washington Medicine COVID-19 Resources:** <https://covid-19.uwmedicine.org>

gan failure) to large urban ECMO centers. This may decrease the frequency of patient transports for eventual ECMO referral.

Consider how mobile ECMO retrieval teams may be used to maximize ICU care at referral facilities. Once patients have failed conventional hypoxemia therapies, they will be too

unstable for transport without ECMO. Coordinate with neighboring ECMO centers to exchange experience and knowledge, and potentially develop care guidelines for this patient population.

CONTINUED on page 31

FROM HOSPITAL TO HOME™

FOR YOUR ADULT PATIENTS WITH CABP AND ABSSSI

VISIT NUZYRA.COM/HCP 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 *Chlamydia 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 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.

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 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.

The use of NUZYRA 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 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.

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 (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 NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

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 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 NUZYRA.

Absorption of tetracyclines, including NUZYRA 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 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.

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



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US-NUA-0224 08/19

Clinical signs such as medial ankle pain, swelling, and ecchymosis are not reliable in identifying a deltoid ligament injury.³ For this reason, assessing deltoid ligament integrity is of critical importance in determining the stability of an ankle fracture. To do this, emergency physicians need to employ stress radiographs to assess the stability of the ankle joint.

Evaluation

When evaluating a Weber B fracture, if the initial imaging does not demonstrate obvious evidence of tibiotalar instability, ankle stress testing is indicated. There are three primary methods of performing an ankle stress test.

These include manual, gravity, and weight-bearing techniques.

Manual stress testing has historically been the method utilized to evaluate the stability of the ankle joint. This method involves keeping the ankle at neutral dorsiflexion, rotating the tibia internally at 10°, and applying 8 to 20 pounds of external rotation at the foot.³ This typically requires a physician going to the radiology suite to perform the stress test.

Gravity stress is typically performed with the patient lying in lateral decubitus with the injured side down, allowing the foot and ankle to create a lateral force across the ankle joint, with the foot resting in natural plantar flexion and the leg internally rotated at 10° to 15°

(see Figure 1).⁶ Gravity stress has been shown to be as reliable and less painful than manual stress testing.^{6,7}

Weight-bearing films are a relatively new method of testing for medial stability. Despite initial cadaveric studies demonstrating that weight-bearing films did not accurately provide radiographic evidence of instability, recent clinical studies have shown that weight-bearing radiographs are predictive of stability and that gravity stress radiographs likely overestimate the instability, resulting in up to a tenfold increase in surgeries when a medial clear space (MCS) cutoff of 4 mm is used.^{8–11} One recent study compared patients who had a borderline unstable ankle based on grav-

ity stress imaging (MCS 4–7 mm) but stability on the weight-bearing imaging to patients who had a stable ankle based on gravity and weight-bearing imaging. There was no functional outcome difference between the two cohorts of patients who elected to be managed nonoperatively.¹⁰ The most compelling argument for weight-bearing films is that they stress the ankle joint under physiological conditions that measure stability under realistic and reproducible conditions.

Like gravity stress imaging, weight-bearing films can be performed by a radiology technician without physician assistance. The weight-bearing technique is more reproducible and takes less radiology technician training than

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

either gravity stress or manual stress views.¹⁰ However, from an emergency medicine perspective, one of the most glaring questions is whether patients with an acutely injured ankle can bear enough weight to get adequate radiographs, as the studies comparing stress techniques have been completed in orthopedic clinics three to 10 days after the initial injury. We could not find data pertaining to this particular question.

MRI can be used to evaluate the deltoid ligament, but the degree of the tear does not always equate to instability on stress radiographs.¹²

Specific parameters are evaluated in each stress view of the ankle. For gravity stress views, consensus is leaning to a value for the MCS of <7 mm to define a stable ankle joint. An MCS >4 mm is the historical value used to indicate operative management, but this value has

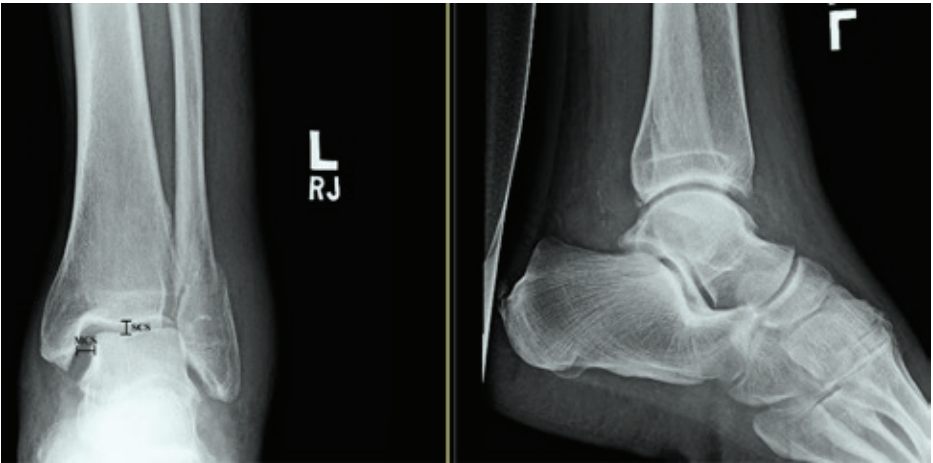


FIGURE 2: Normal ankle mortise view with demonstrated medial clear space (MCS) and superior clear space (SCS).

been shown to lead to a high false-positive rate and unnecessary surgeries, of which 10 percent have surgical complications.^{13,14} An MCS greater than the superior clear space (SCS) of 1 mm or more on mortise view is another sign of ankle instability (see Figure 2). Finally, if the injured side has an MCS that is >2 mm wider than the uninjured side, the ankle can be con-

sidered unstable. Any of these radiographic abnormalities on initial imaging suggest a clinically significant injury to the deltoid ligament and ankle instability.¹³ While the trend is toward adopting the 6 mm threshold for MCS, there is no consensus among orthopedic surgeons and your consultant may use stricter guidelines.^{6,13}

Conclusion

Ankle fractures are a common presentation in emergency departments. While some fractures demonstrate either clear stability or instability based on initial radiographs, Weber B fractures require more diagnostic testing to evaluate the stability of the deltoid and tibi-fibular ligaments. Historically, this has been done with manual stress views. However, the clear trend is that gravity and weight-bearing stress radiographs are able to detect unstable ankles at the same rate, utilize less physician resources, and are less painful for patients. ➕

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NUZYRA® (omadacycline) tablets, for oral use

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 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.

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, urticaria.

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, 8.9% of dose is recovered in the dialysate.

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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SOUND ADVICE

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Ultrasound-Guided Interscalene Nerve Blocks

Tips for success with this pain relief technique

by ARUN NAGDEV, MD; GRAHAM BECHERER-BAILEY, DO; ROB FARROW, DO; AND DANIEL MANTUANI, MD, MPH

Ultrasound-guided single injection nerve blocks have become a valuable tool in the multimodal strategy for pain control in the acutely injured emergency department patient. Specifically, the ultrasound-guided interscalene brachial plexus block (ISNB) has been shown to be ideal in the emergency department for pain control after upper-extremity fractures (distal clavicle and humerus) and as an alternative to procedural sedation for glenohumeral reductions. Other indications include large abscess drainage, burns, deep wound exploration, and complex laceration repair.¹⁻⁴

In more than 10 years of clinical experience performing and teaching this invaluable tool to numerous residents and faculty, we have learned a couple simple tips that can help improve block success. The first deals with a simplified/alternative method to locate the relevant sonoanatomy, and the second defines a fascial landmark that can be targeted for anesthetic deposition. Awareness of common pitfalls may reduce block difficulty and allow the single injection ultrasound-guided interscalene nerve block to become integrated into the multimodal pain management of the acutely injured emergency department patient.

For a more detailed explanation of this procedure that includes safety principles, patient positioning, and block basics, please refer to the previous article on ultrasound-guided femoral nerve blocks published in *ACEP Now* (Dec. 2011, available at www.acepnow.com/article/ultrasound-guided-femoral-nerve-block).

1) Simplify the hunt for the “stoplight” sign: Use the traceback technique.

As the name implies, the interscalene brachial plexus can be found between the anterior and middle scalene muscles in the neck (commonly called the “stoplight” sign because of the vertically oriented anechoic C5-C7 nerve roots). To locate this landmark, the classic teaching has been to initially place a high-frequency linear transducer in a transverse orientation (probe marker facing to the right of the patient) at the level of the larynx, identifying the internal jugular vein (IJV) and carotid artery (CA). Then slowly slide the transducer laterally until the border of the clavicular head of the sternocleidomastoid muscle (SCM) comes into view (at the top of the ultrasound screen). At this level, the anterior and middle scalene muscles lie just below the SCM and act as important sonographic landmarks. Between the muscles lie the anechoic and round C5-C7

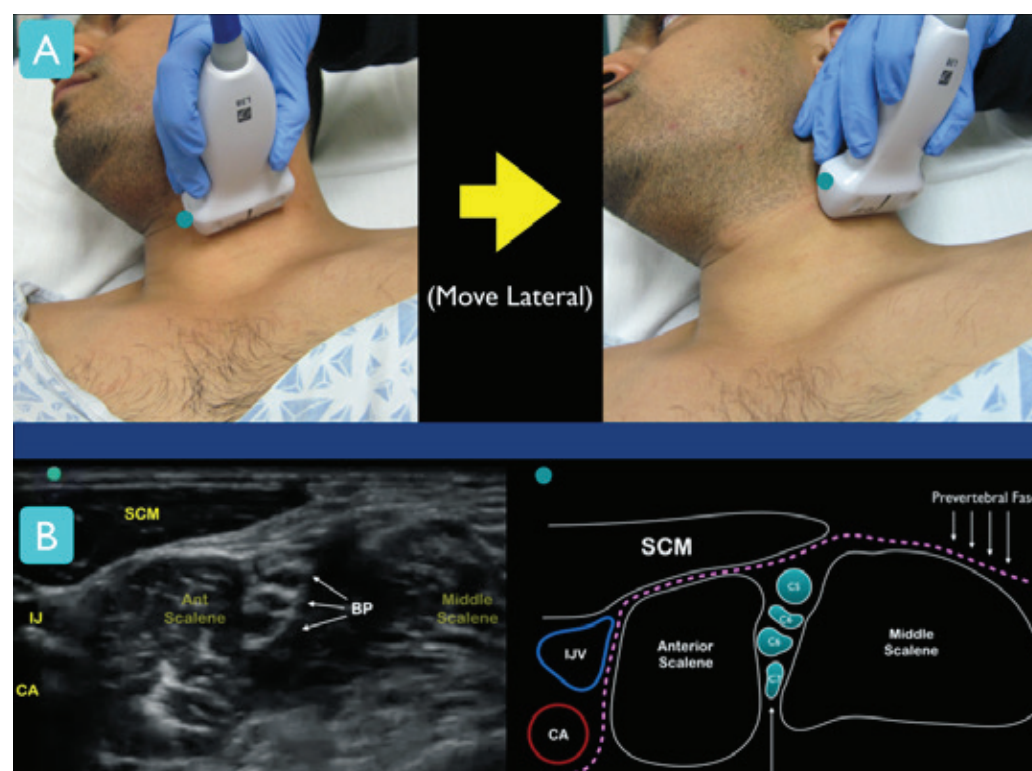


Figure 1

FIGURE 1A: Classic technique for locating the interscalene brachial plexus. At the level of the larynx, slide lateral until the ultrasound landmarks are noted

FIGURE 1B: Just under the sternocleidomastoid muscle (SCM), locate the anterior and middle scalene muscles. The interscalene groove will contain the nerve roots of the brachial plexus. Note the internal jugular vein (IJV) and carotid artery (CA) on the medial aspect of the anterior scalene muscle.

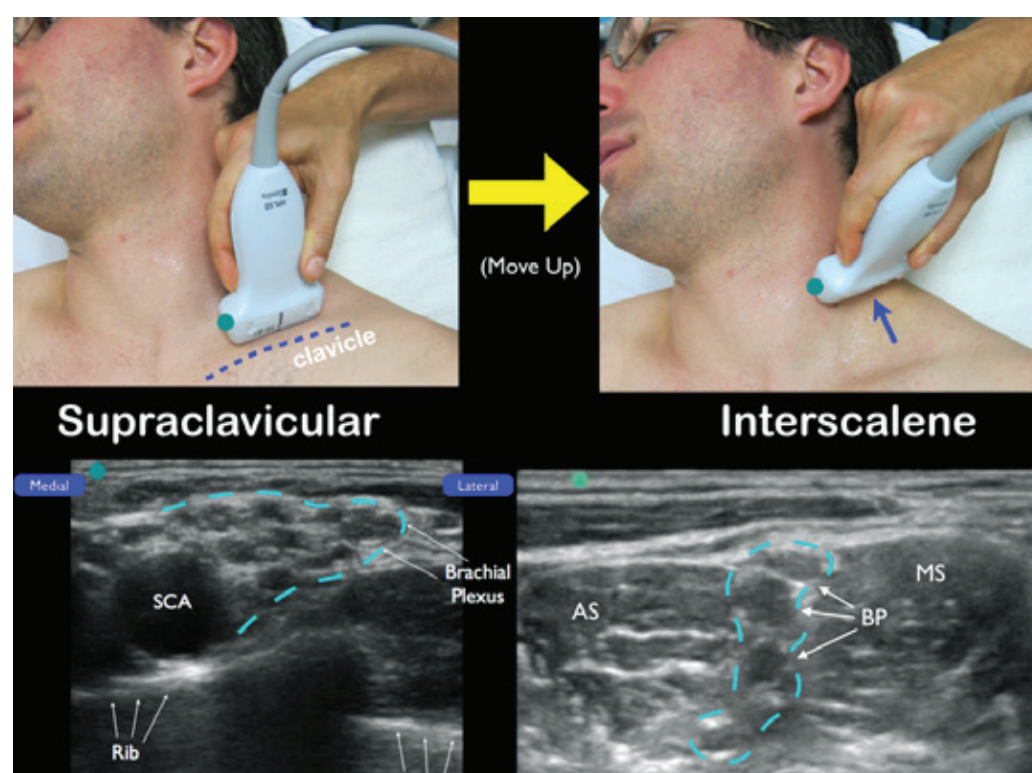


Figure 2

An alternative technique to locate the interscalene brachial plexus. Start with the transducer in the supraclavicular fossa. Locate the subclavian artery (SCA) in cross-section and note the brachial plexus just lateral (dotted blue line). Slide up the neck until the interscalene brachial plexus (BP) is located in between the anterior scalene (AS) and middle scalene (MS) muscles.

roots of the brachial plexus, the stoplight sign (see Figure 1).

Unfortunately, this ultrasound landmark can be difficult to locate for the less-experienced sonographer. Variation of individual neck anatomy and lack of clear sonographic landmarks make locating the stoplight sign in the interscalene groove frustrating for many of our learners. For this reason, we commonly teach an alternative technique that relies on visualizing the subclavian artery in cross-section in the supraclavicular fossa. The traceback technique (as it has been called) starts by

placing the transducer transversely in the supraclavicular fossa and aiming caudally until the subclavian artery is visualized. The brachial plexus lies just posterolateral to the artery at this level and will appear as a tight group, a hypoechoic “cluster of grapes.” Follow these hypoechoic structures cephalad until they form the stoplight sign within the interscalene groove at the level of the larynx (see Figure 2). We have found this alternative technique to be invaluable for our learners (and even experienced clinicians).^{5,6}

2) A fascial landmark to improve safety: Get anesthetic under the prevertebral fascia.

When performing ultrasound-guided femoral nerve blocks, we recommend depositing anesthetic under the fascia iliaca (lateral to the femoral nerve) to improve success. This target allows the clinician to enter far away from the nerve bundle, inject normal saline for hydrodissection, and then gently deposit anesthetic. This “stay away” approach has been our

CONTINUED on page 22

standard teaching technique (if possible) for all ultrasound-guided nerve blocks. Similarly, when performing the ultrasound-guided ISNB, the prevertebral fascia can act as an ideal sonographic landmark. This fascial plane lies on top of both the middle and anterior scalene muscles and allows the clinician a target that is far from the brachial plexus nerve roots (see Figures 3 and 4). With this ultrasound landmark in view, the clinician can come from a lateral to medial in-plane approach, then deposit anechoic normal saline (for hydrodissection) under the prevertebral fascia (far away from the interscalene brachial plexus). After getting under the fascial plane and visualizing fluid track down into the interscalene groove, anesthetic can safely be placed in the fluid-filled potential space (see Figures 5 and 6). In our opinion, placing the needle tip directly into the interscalene groove and between the nerve roots is not advisable, and it may lead to unwanted intraneural injections.

Conclusion

The ultrasound-guided ISNB is an ideal tool for emergency providers when treating patients with acute upper-extremity injuries. The two simple tips can help improve block success. Having an alternative technique to locate the interscalene brachial plexus and having a defined safe target (the prevertebral fascia) that is far away from the nerve roots can help circumvent problems that we notice in our learners. We hope that these small adjust-

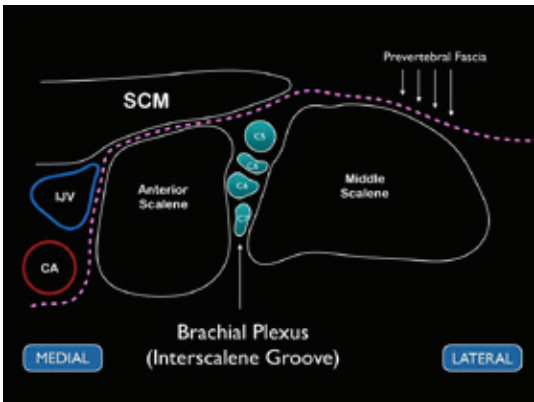


Figure 3

Schematic representation of the interscalene brachial plexus. Note the prevertebral fascia located above the middle and anterior scalene muscles.

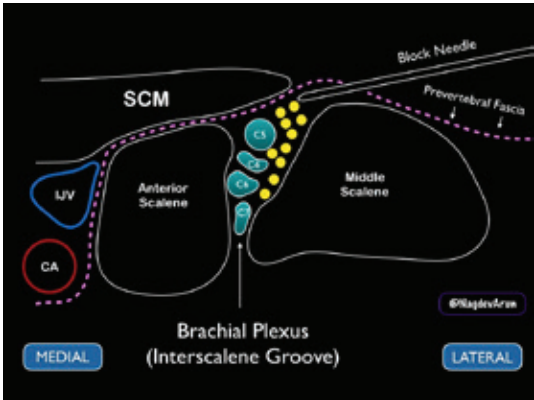


Figure 5

Schematic of how the needle tip should be placed just under the prevertebral fascia (and away from the roots of the brachial plexus).

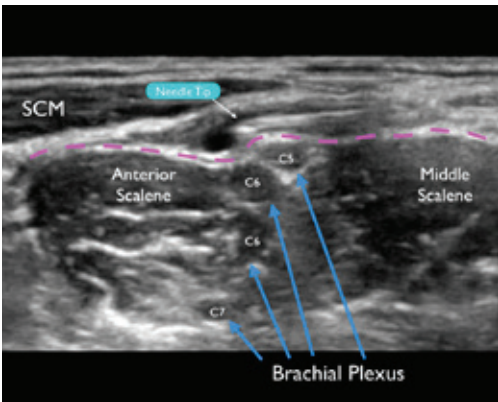


Figure 4

Ultrasound image of a failed block. Note that the needle tip is above the prevertebral fascia (pink dotted line). A small amount of anechoic anesthetic can be noted deposited above this important sonographic landmark.

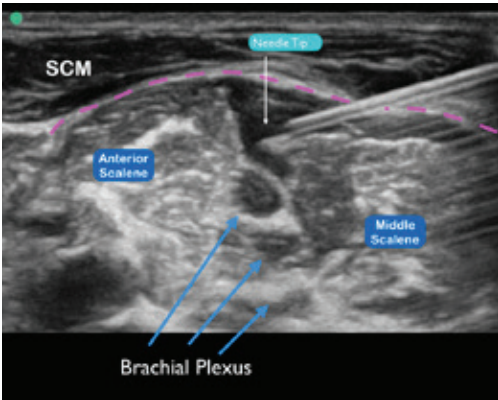


Figure 6

Ultrasound image of the needle tip under the prevertebral fascia (pink dotted line) with anechoic anesthetic deposited near the interscalene brachial plexus.

ments will help make the ultrasound-guided ISNB an important tool in your clinical practice and part of your multimodal strategy for pain management. +

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A Mentee or Protégé: Is There a Question?

Mentorship is valuable, but a sponsor can open doors

by JENICE BAKER, MD, FACEP

I've had a mentor since I was 13 years old. My mentors afforded me experiences as a high school student that many of my peers lacked. I worked at scientific laboratories at Mount Sinai in New York City, interned at executive offices, and traveled to Puerto Rico to study marine biology, all before my junior year



in high school. In college, my biology professor helped me navigate a premed major and wrote a letter of recommendation for medical school.

My emergency medicine residency director mentored me as a medical student and supported me during the match and residency life. As a young attending, I took pride in mentoring medical and high school students along their path.

Then my current medical director, Alfred Sacchetti, MD, FACEP, did something I was not used to—he told me to apply for the board of NJ-ACEP. He didn't just give advice on my career, he used his influence to create opportunities for my career advancement. Now I am the associate director of my department, and I realized that Dr. Sacchetti was more than a mentor. He was and is a sponsor, and there is a huge difference.

Mentor Versus Sponsor

This difference is stated perfectly by *Harvard Business Review*: "While a mentor is someone who has knowledge and will share it with you, a sponsor is a person who has power and will use it for you."¹ This concept is very different from the culture of medicine and residency training where the focus is on the attainment of knowledge. Many residency programs and academic attending positions have mentorship tracks ingrained in curricula and pathways for career advancement. In fact, women overall have more mentors than men. However, despite all that mentoring and the fact that 50 percent of medical students are women, only 18 percent of hospital CEOs and 16 percent of medical school deans are women. Quite frankly, knowledge alone is not enough. Career advancement in general and within the house of medicine is about who you know and their willingness to use their power to sponsor your advancement—and willingness to sponsor is affected by implicit race and gender biases. If a sponsor is unaware of these biases, they may continue to elevate the groups who have traditionally benefited from sponsorship while overlooking underrepresented groups.

The question is, does the house of medi-



cine need more sponsors or does the face of sponsorship need a face-lift? To glean some answers, I decided to ask my very own sponsor, Dr. Sacchetti.

JB: How do you see your role in career advancement for your staff?

AS: Everything I have been able to accomplish in my career can be traced back to opportunities given me by someone else. Whether as a speaker for a conference, an author for a book, or member of a committee, someone had to open that door for me.

I have never forgotten the role these people have played in my own career development and have incorporated that as part of my mission as a leader in emergency medicine. Whenever I encounter a clinician working to advance their career, I feel it is my responsibility to do all I can to help them. If their goal is to be a great emergency physician, then I need to put them into a position to practice great emergency medicine. If they wish to have an administrative career, then I need to provide them entry to any position with related administrative activities. If they wish to become an author or researcher, then I must invite them to join in any projects with which I am involved.

There are very many talented emergency practitioners out there. The only thing stopping them from advancing their careers is the chance to prove what they can do to the right individual. My job is to give them that chance.

JB: Should sponsees seek you out directly?

AS: As a leader, it is my role to be aware of any individual who needs help advancing their career. In that respect, these individuals should not have to seek me out. That said, it is not possible to be aware of everyone who could benefit from my help. To address that issue, I need to make it as clear as possible that I am a resource for career advancement. I need to be visible and approachable for anyone who might need some help with the direction of their career choices.

JB: Is there a formalized sponsorship program?

AS: I imagine there are some formalized sponsorship programs, but I am not aware of any. For me, sponsorship is a personal activity when one individual gets advice or help from another rather than a formal activity.

JB: Do you actively give opportunities to diverse physicians?

AS: Diversity clearly contributes to the success of any organization, particularly when the different characteristics of diverse individuals are essential to the accomplishment of an organization's goals. However, embracing diversity simply for the sake of diversity itself is not beneficial and, in fact, can be counterproductive.

If I am to be honest to the patients who seek care at my institution, then it is my responsibility to place the most qualified individuals in

the role of clinician there, regardless of their gender, ethnicity, religion, or any other non-performance-related descriptor. Our mission statement is patient care, and patient care depends on the medical skills of the personnel in our department. In adding any new member to our medical staff, my primary focus has to be on identifying the best individual for the role.

What may go unrecognized in such a statement is that a person's background, culture, and other earmarks of diversity contribute to their qualifications. For example, a clinician who speaks both English and Spanish would be better able to elicit a history in a predominantly Spanish-speaking patient population, greatly enhancing their ability to deliver care. Such an individual may be selected not because of their diversity but because their diversity makes them a better clinician and a better member of the department. However, if that same individual was unable to perform key resuscitation procedures, then their language skills would have no beneficial impact on patient outcomes. The advantage of their diversity to the department would be nullified by their lack of clinical performance.

In direct answer to your question, absolutely I look to encourage diversity in our department but never at the expense of medical quality.

The relationship of sponsor to protégé is not top-down. The protégé needs to own this process. First, you must excel in your field—we are all doctors with type A personalities, so I know we all can excel. Your performance is critical because the sponsor will use their "status chips" on your behalf. Second, within your organization, identify the key players and influential decision-makers. These individuals may not only be your boss but likely someone more senior than your boss. This person may be in your field but at a different company or organization. Your mentor may even introduce you to a great potential sponsor. Use these networking opportunities to actively seek out a sponsor. Third, be clear and state the goals you would like to achieve with their sponsorship. And you don't just need one sponsor. Stretching your network with mentors to grow internally and sponsors to expand externally is crucial to everyone's career development. If we in medicine want to be more diverse, we need to rethink our traditional mentorship tracks, create sponsorships, and educate sponsors about implicit biases and advantages of diverse teams that will ultimately benefit the sponsor and protégés alike. 🙌

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DR. DAHLE blogs at www.whitecoatinvestor.com and is a best-selling author and podcaster. He is not a licensed financial adviser, accountant, or attorney and recommends you consult with your own advisers prior to acting on any information you read here.

Fund Your 401(k)

It's an easy way to get started investing

by JAMES M. DAHLE, MD, FACEP

Q. I know I should get started investing, but I just haven't gotten around to it. What is the easiest way for me to get started?

A. You might think that every emergency physician in the land is attuned to the importance of proper financial management in reducing burnout, facilitating career options, and providing for a dignified retirement. Unfortunately, you would be wrong. I recently had the opportunity to speak to a large group of physician leaders of a well-known national contract management group. In preparation for the talk, data from the company revealed that one-third of the physician employees had never contributed a dime to the company 401(k), despite the company offering a generous match for doing so. The average balance in the 401(k) was a very low six-figure amount, enough to provide a monthly income of just over \$500. To describe these savings habits as “inadequate” would be a gross understatement.

Surveys of physicians in their sixties show that 25 percent have a net worth of less than \$1 million and 12 percent have a net worth of less than \$500,000. Net worth, the most important number to track in personal finance, includes all of their assets (checking and savings accounts, home equity, investments, retirement accounts, and “stuff”). Presumably, most of these doctors enjoyed 20 to 30 years of physician-level paychecks, but they have little left to show for it. While divorces, illnesses, and disabilities affected some, the vast majority of these doctors simply made poor choices—they spent too much, saved too little, invested in an unreasonable way, refused to learn basic financial principles, and did not insure against financial catastrophes.

The most important aspect of achieving a dignified retirement is to save some money—and more than you might think. A good rule of thumb is to save 20 percent of your gross income for retirement. I often tell medical students, “If you cannot live, and live well, on 80 percent of a physician income, you have a spending problem, not an earning problem.” They all laugh because it is so obviously true. When I use that line with mid-career doctors, they don't think it is funny at all. It is amazing how good we are at growing into our income, no matter what our income may be.

Get Started with a 401(k)

The easiest way to get started saving for retirement is to use the 401(k) or simi-

lar retirement plan provided by your employer. In our “401(k) world,” you have a second job as your own pension fund manager, whether you are prepared to do so or not. Ask your employer for the “summary plan description”—they are required by law to provide it if you ask for it. Read it and then figure out how to log in to your online account. Learn what your money is invested in (or what it can be invested in) and how to change your contribution rate and investments.

Many employers provide a “match” to plan participants. That is, if you put in some of your money, the employer will put in some money, too. If you do not contribute enough to get the full match, you are essentially leaving part of your salary on the table. Don't be satisfied with merely obtaining the entire match amount. Figure out a way to contribute the maximum amount possible to the 401(k). In 2020, an employee can contribute up to \$19,500 (\$26,000 if you're older than 50) to a 401(k), and when combined with the employer match, the total annual contribution can be as high as \$57,000 (\$63,500 if older than 50). Since the average emergency physician income these days is in the upper \$300,000 range, and 20 percent of that is about \$75,000 per year, maxing out your 401(k) should represent the bare minimum in retirement saving. Yet a third of doctors are not contributing at all.

Inside the 401(k), you can invest your money in a variety of mutual funds, where your money is pooled with that of other investors and managed by a professional. As employers have realized they have a fiduciary duty to their employees, they are generally providing at least a few of the low-cost, broadly diversified index funds you should be using for the bulk of your investments. In some 401(k)s, you will be able to use a simple “life cycle” or “target retirement” fund, where all you have to do is pick the fund with the date closest to when you think you will retire. It may be called “Target Retirement 2035 Fund” or similar. These “fund of funds” are the one-stop shop of investments and will provide you a diversified mix of investments that rebalances automatically and gradually becomes less aggressive as you approach retirement.

Financial Benefits of Maximizing Savings

Aside from providing a place for you to invest for retirement, 401(k) plans, like their cousin the 403(b), provide significant tax, estate planning, and asset protection benefits. Money you contribute to a 401(k) is not taxed in that year. If your marginal tax rate (the rate at which the next dollar you earn is taxed) is 35 percent, contributing \$10,000 to the 401(k) will reduce your tax bill by \$3,500. The money inside that account will then grow in a tax-protected way, without the growth-retarding “tax drag” normally applied to investments as they distribute dividends and capital gains each year. While you will have to pay taxes on the money when you distribute it from the account in a few decades, most physicians will be able to pull out the money at a far lower tax rate than they saved when they put it in. Without much other taxable income in retirement, many doctors end up paying rates of 0 to 12 percent on a large percentage of their withdrawals. Saving at 35 percent and paying at 12 percent is a winning strategy.

Your 401(k) will also allow you to designate beneficiaries, so that money will pass directly and rapidly to your heirs without going through the expensive and public process of probate. 401(k)s and similar retirement plans also receive exceptional asset protection in every state. In the unlikely event of an above-policy-limits judgment forcing you to declare bankruptcy, you would be able to keep everything in your 401(k).

Your 401(k) is one of your most important benefits of employment and is a great place to start investing for retirement. Take advantage and get started today. If you are already using your 401(k), discover what you are invested in and make plans to maximize this benefit. ➔



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DR. PENZA is clinical associate professor of emergency medicine at the Warren Alpert School of Medicine of Brown University in Providence, Rhode Island; associate director (education) of the Emergency Digital Health Innovation program at Brown; and creator and host of the podcast “Doctors and Litigation: The L Word.”

Experts and Testifiers, Part 1

Who's to blame for unfair litigation?



by GITA PENSA, MD

Note: Part 1 of this two-part column discusses the ethics of expert testimony and standard of care. In Part 2, we will discuss options open to physicians who feel they have been the victims of unethical testimony.

As much as physicians complain about plaintiff's attorneys, consider this: No malpractice case can go forward without a physician expert who is willing to testify that the case has merit. So who *actually* is to blame for unfair litigation?

Neither judges nor juries have in-depth medical knowledge; medical experts are required on each side to help explain the facts understandable to laypeople. To testify as to the standard of the plaintiff's damages, the expert's damages are indeed the plaintiff's negligence. They are part of the judicial process; ethical, knowledgeable experts are needed, both to defend physicians who are unfairly blamed and to support plaintiffs who have truly been harmed by malpractice.

However, unethical or exaggerated medical testimony is a common source of distress among physicians undergoing litigation. Although many experts are ethical in their practice, there are also “hired guns” who earn millions of dollars over time for their questionable opinions. In a 2010 survey of ACEP members on medical-legal issues, the most common free-form responses were “regarding expert witness testimony and a general sense of dismay and betrayal regarding malpractice litigation.” In addition, 87 percent of respondents felt ACEP should give members more guidance on the provision of expert testimony.¹

Challenge of Being an Ethical Witness

Most physicians who become medical expert witnesses have no extra training or certification to fill that role. The training they do receive often comes from attorneys who instruct them how to persuade juries to their side's advantage, not how to deliver unbiased factual testimony and interpret standard of care. That

same ACEP survey revealed fewer than half of emergency physicians who serve as experts keep any records of their testimony, and even if they did, there is no regular oversight of expert witnesses or their testimony, although ACEP members may submit testimony for review after their case is completely closed.

The survey also revealed that the majority of respondents were unaware that ACEP has published ethical guidelines for emergency medicine expert witnesses.² In my first trial, the emergency medicine expert was an academic from Canada who had never practiced in the United States and was paid highly to opine on care provided in a community emergency department in the United States. On the stand, he reported he was simply unaware of ACEP's first ethical guideline: to qualify as an expert in emergency medicine in the United States, the physician “shall be currently licensed in a state, territory, or area constituting legal jurisdiction of the United States as a doctor of medicine or osteopathic medicine.”

The appeal of expert witness work is undeniable. Experts often earn hundreds of dollars more per hour than physicians are paid to work clinically. Expert work can be done at any hour from the comfort of home. But as physicians comment in my *Doctors and Litigation* podcast, there is a tremendous financial incentive to provide attorneys with the skewed testimony they desire; if a physician delivers supportive (preferably strongly worded) opinions, that expert will likely have additional lucrative cases referred to them and may have the opportunity to testify at trial, which can pay many thousands of dollars for a single day.

One interviewee noted that when he returned opinions that did not support an attorney's assertions, they simply failed to engage him thereafter, finding instead a more compliant expert. Another physician described an instance where a plaintiff's attorney did not accept his original opinion stating no malpractice had occurred and instead sent him a rewritten version with a different conclusion, asking him to simply sign it (with the promise of additional revenue).

Consequences of Unfair Testimony

Physicians who knowingly provide exaggerated or unfair testimony may think of this as a “victimless crime,” but this severely underestimates the impact on physician defendants' stress, which has directly led to suicide in some known cases.³ More often, as indicated in the ACEP survey, it adds to litigation stress in its entirety, which can have severe repercussions on the defendant. It also fuels unwarranted litigation and increases insurance and litigation costs.

Even well-meaning physicians can unknowingly do damage as experts by not understanding the concept of “standard of care.” We are inclined to judge one another's work harshly when it falls short of perfection, and we all strive for perfection ourselves, but “standard of care” is not perfect care. Standard of care is “minimally competent care”—what a minimally competent physician might do in a similar environment, with similar resources, faced with a similar case.⁴

Another concern that remains unaddressed is that there is no requirement for academic physicians to declare conflicts of interest when they have earned income as experts on a given topic. This is disconcerting, as highly paid experts who regularly testify on one side of a given topic have a very strong incentive to give presentations and continue publishing articles that support that opinion. When they speak at conferences or take to social media espousing these views, it advertises to attorneys searching for experts on that topic. In turn, attorneys point to those appearances and publications to bolster the expert's perceived credibility and “unbiased opinion” as an expert in court.

How to Be a Good Expert Witness

Experts should familiarize themselves with and staunchly adhere to ACEP's expert witness guidelines.² However, I have my own common-sense suggestions for your consideration.

- Don't do expert work at all if you have to overstate or misrepresent your credentials or expertise.
- Don't do expert work if you have stopped working clinically or if you are in training

or only a few years into practice.

- Don't testify about matters you don't have extensive personal experience with or if you have never regularly practiced in a similar setting.
- Don't testify in cases regarding specialties in which you are not board-certified.
- Don't let attorneys choose your words or skew your language to benefit one side. Do not overstate your opinion. Do not deliberately omit information.
- Your income from expert work should not exceed 30 percent of your clinical income in any given year.
- Don't equate a bad outcome with malpractice.
- Be mindful of hindsight bias. If you think you likely would have done the same things as that defendant, say so.
- Your role is not to persuade anyone; it is to interpret the facts and state whether the standard of minimum competence was met.
- Take the time required to fully understand the case. Do not equate bad charting with malpractice, even if it means digging for information. If you subsequently learn additional information, reserve the right to change your opinion.
- Finally, testify unto others as you would have them testify unto you—honestly, objectively, dispassionately, and with a clear understanding of the medical facts, as well as the defendant's practice environment and the legal definition of standard of care. ➕

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Pandemic Preparedness for Residencies

by KIMBERLY CHERNOBY, MD, JD;
DEVIN DOOS, MD; ANDREA PURPURA, MD; AND EMILY WAGNER, MD

Editors' Note: This article was accepted on March 11, 2020, and was accurate at that time. Because information about SARS-CoV-2 and COVID-19 is evolving rapidly, please verify these recommendations and information.

As chief residents, we are proud to lead a group of residents who provide around-the-clock staffing for three busy hospitals. Additionally, our residents travel internationally to provide medical care, travel to conferences to disseminate their scholarly work, and raise families. The recent spread of SARS-CoV-2, the novel coronavirus that causes COVID-19, has raised a series of challenges over the last few days and weeks that have caused us to consider how we might prepare as a residency for this and other pandemics.

Clinical Coverage

Our immediate concern was the possibility of increased need for sick call, particularly in the event of resident quarantine. Routinely, we have daily sick call coverage, and the shift is later repaid by the person activating. If a second absence requires coverage beyond initial sick call activation, the on-call chief solicits same-day availability from the resident pool with chief resident coverage as a backstop. Our solution was to develop a second string of sick call. The upcoming schedule was already published, so we relied on volunteers for this and successfully filled our backup sick call schedule.

The decision to develop a backup sick

call system was not easy. We had concerns about whether this was a resident responsibility. How many layers of coverage are residents responsible for providing? When do we consider mechanisms like altering shift times and duration or having gaps in coverage? When do we pull residents from electives? What happens when we run out of additional sick call volunteers?

Resident Safety, Well-Being, and Health

As emergency medicine residents, we are part of the team on the front line of patient care. This station puts the emergency department team at particularly high risk in an infectious outbreak. Keeping residents safe and healthy is an important goal itself and because they are an integral part of the workforce. We had added concerns about our residents who were pregnant, immunocompromised, or otherwise at increased risk.

Treating affected patients requires safety measures like special triage procedures and use of personal protective equipment (PPE). It is important that programs ensure team members are educated on how to appropriately use PPE and new departmental protocols. Simulation is a powerful training tool when infectious rates are low. We are currently implementing a simulation to model these issues.

We also considered how to involve residents in care of these patients. Residents are not generally excluded from taking care of any patient population, including patients with infectious diseases. However, there are practical issues to consider like the limited

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Coronavirus Impacting Emergency Medicine Residency

by CHRISTA AREFIEVA, MD, MS; AND
DAVID B. HANSEN, DO

Editors' Note: This article was accepted on March 17, 2020, and was accurate at that time. Because information about SARS-CoV-2 and COVID-19 is evolving rapidly, please verify these recommendations and information.

The COVID-19 pandemic has brought fear and panic to our community, but answering the call to action is why we chose to become emergency physicians. We are asking how we can help, not if we can go home. We are proud to serve in our communities, and we are driven to care for any patient with any condition, including one that has brought worldwide fear and drastically altered society. In emergency medicine, we thrive on adapting to our environment and working through the unknown as it unfolds.

However, the pandemic has made a significant impact on our work, our lives, and our training as residents. We are figuring out what to do as the situation evolves. Here at Central Michigan University in Saginaw, we have adjusted in ways that will allow us to excel while serving our patients. There are new precautions to keep residents safe and to safeguard our ability to step up if and when members of our team fall ill. Nonessential duties have been delayed. Many off-service rotations have been canceled. At this time of uncertainty and need, patient care is everything.

While some of us have to stay at home, we are using this time to serve the community. Program leadership has developed ways for those who are self-isolating and social distancing to participate in this rapidly changing environment through the development of

a virtual public health elective. This elective allows us to serve our community as we await our call to duty in this unpredictable environment. The elective involves literature review, demographic analysis, and the dissemination of public education, which could be through social media, lectures, or other means. The residents and our mentors view this public health elective as an opportunity that will benefit residents and, more important, will benefit our patients and our communities.

While some residents continue to work on the front lines, others serve the community in other ways and are prepared to step onto the front line when called upon. We are prepared to pick up shifts if and when emergency department volume increases or to take over shifts for our fellow residents. We are prepared to do what is needed to provide the best care for patients as we navigate through adversity. We support each other, and our resident family has been in virtual contact with each other while social distancing. As residents we are supported by our leadership in caring for ourselves and each other. This allows us to move forward and do what is best for our patients.

Now is a time of fear and uncertainty. We do not know exactly how the coronavirus pandemic will unfold, but we will persevere. This is both a challenging and inspiring time to train in emergency medicine. It is an honor to work alongside our team members as we step up together to serve our patients and our community. +

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Physician Compassion in Emergency Medicine

It's more important than you might think

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

My friend, emergency medicine colleague and educator Barbara Tatham, MD, died of metastatic sarcoma at the age of 32 in October 2019. During her last year of life, in between rounds of chemotherapy and radiation, she gave lectures on compassionate care that were inspired by her journey as a patient. This column is part of my vision to continue her voice as a champion of compassionate care into the future.

Emergency medicine demands we regularly face patients with extreme emotional lability, pain, and suffering. We pride ourselves in adapting to repeated traumatic events, apparently unscathed. We do this to protect ourselves, partly because we all have an innate ability to depersonalize after these repeated traumatic events, as humans do in wars and famines. We also do this so we can expertly execute a pediatric airway or thoracotomy despite the chaos of the emergency department.

This adaptive depersonalization poses a significant problem to quality patient care—and specifically to compassionate care. We have a responsibility to provide compassionate care,



as stated in the American Medical Association Code of Ethics: “A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.”¹ Compassion is an emotional response to another’s pain or suffering that involves

a desire to help. Compassion is not simply “feeling bad” for a patient. It requires a desire to help and act accordingly. Compassion, like any behavior, can be learned—contrary to the popular belief that compassion is an innate quality that one either possesses or does not.

It is no surprise that emergency physicians are not experts in compassionate care because few training programs include it in their curricula. Our ability to provide compassionate care erodes through the course of our training and, as a community, with each passing year.^{2,3} The person (as opposed to the patient) in the stretcher in front of us is more than a particular diagnosis or a disposition dilemma. They are often frightened, anxious, concerned, or emotionally numb. Addressing these emotions is paramount. The good news is that it is easy to provide compassionate care in an efficient manner. There is evidence to suggest that when physicians spend only 40 seconds saying compassionate statements, patient anxiety is significantly reduced.⁴ Although it seems counterintuitive, when you invest time in other people, you feel that you have more time, that you are not in as much of a hurry. Effective communication that incorporates compassionate statements results in shorter, more efficient visits.⁵

Physician Compassion Associated with Improved Patient Outcomes

Patients with life-threatening emergencies benefit from physician compassion, as suggested in one study that showed fewer post-traumatic stress disorder symptoms among patients treated with compassion.⁶ A study of surgical patients demonstrated that compassion delivered by nurses or doctors just prior to surgery resulted in patients anxiety in patients, easier sedation, less need for postoperation opioids, and shorter hospital stays.⁷ A review of physician-patient communication, including compassionate care, and health outcomes in 21 studies demonstrated an association between compassionate care and symptom resolution, function, physiological measures



such as glucose control, pain control, and emotional health.⁸ The more compassionate behavior is used by physicians, the more likely patients are to trust their advice, comply with treatment recommendations, take medications, and follow discharge instructions.⁹

Physician Compassion Associated with Decreased Medical Errors, Physician Burnout, and Litigation

While depersonalization is a coping mechanism for emergency physicians, it is a sign of burnout, along with emotional exhaustion. Physicians who score in the highest tier of depersonalization and emotional exhaustion commit the most medical errors, and those with high empathy scores have more job satisfaction and less burnout.^{10,11} Compassionate care makes us feel good as it gives us a “helper’s high,” the feeling of reward that comes from helping others.¹² Complaints and litigation may be curbed by improved physician compassion.¹³ This is eloquently demonstrated in an ED waiting room study that randomized patients to watch either a simulated physician-patient discharge conversation that included two empathic statements (the physician recognizes that the patient is concerned about their symptoms and that the patient knows their typical state of health better than a physician seeing them for the first time so they did the right thing by seeking evaluation) or one that did not. The group who watched the video that included the empathic statements had significantly fewer thoughts of litigation and complaints about the physician.¹⁴

Physician Compassion Associated with Lower Health Care Costs, Improved Resource Utilization

Patients who receive compassionate care not only tend to re-

cover faster from their illness but are more likely to have fewer visits, tests, and referrals.¹⁵ Furthermore, compassionate care is associated with fewer unnecessary admissions and lower total health care costs.¹⁶ A randomized trial of compassionate care for homeless patients in an urban emergency department found that compassionate care decreased repeat visits to the emergency department.¹⁷

Here are some tips to help improve your compassion:

- Before entering a patient room for a new encounter, leave behind thoughts of your previous patient, regroup, and quiet your mind so you can be present.
- Thank the patient for waiting, make sure they are comfortable, and begin the encounter with an empathetic statement.
- Sit down, lean in, and smile; make the patient feel like you care they are there.
- Let the patient tell their story. Patients only need, on average, 29 seconds to fully describe their main concern yet are typically interrupted after 11 seconds.¹⁸
- Look at the patient and listen to all their concerns.
- Empower them with relevant education and involvement in their treatment plan.
- Set expectations and explain timelines.
- Ask if they have any questions.
- End with a compassionate statement:
 - » “I am here with you.”
 - » “We will get through this together.”

If you asked me if I was compassionate with my patients in the emergency department a year ago, I would have certainly judged myself harshly and said no. After studying compassionate care, compassion is with me almost always. Granted, I still find it hard to incorporate compassionate care when I’m really

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availability of PPE, limiting the number of individuals who come into contact with an identified case, and the fact that all patients are seen by an attending. Currently, we are limiting direct resident involvement in identified ED cases of COVID-19.

Finally, there is the issue of educational activities. Limiting large gatherings can be helpful to prevent transmission of a disease, but certain educational requirements like conference and journal club are organized as large in-person gatherings. We are moving to teleconferencing educational programming where possible.

Prolonged Absence

In the event a resident had to miss a substantial period of work, whether for illness or quarantine, our residents wondered how this time would be compensated and how it would affect their academic progression. Questions of compensation and academic promotion largely fall outside the purview of chief residents; however, we did give consideration to these issues.

Our initial thought was to use leave under the Family and Medical Leave Act (FMLA). Residents at our institution are entitled to additional paid FMLA on top of vacation. With regard to academic progression, there are several factors that affect this, including ensuring the resident has completed required educational rotations. Programs could change a resident's assigned block during leave to electives to avoid delaying graduation. Other options include working from home. For example, we have electives that allow residents to work remotely, permitting them to progress through the academic curriculum without needing to take an absence. An accommodation like this is particularly helpful in the event of quarantine.

Travel

We confronted two issues around work-related travel. The first was the issue of international electives. Several residents were scheduled to leave for global health electives that were canceled under a moratorium on work-related international travel. The second issue was resident travel to national conferences, as there were also restrictions placed on domestic travel. Often these preemptive travel restrictions are in excess of government recommendations, making it difficult for residents to obtain refunds for their travel expenses. Where programs issue travel restrictions in excess of government recommendations, we encourage programs to defray the costs associated with those cancellations.

When residents plan global travel, they could consider obtaining trip insurance, international medical insurance, and medical evacuation insurance—although coverage in settings like pandemics may be limited

Personal

Many of our residents have families that include working spouses and small children. To prepare for possible day care and school closures, an emergency list of temporary, trusted adult babysitters was built to provide our resident parents more childcare options and further protect our sick call.

We also encouraged residents to consider how they might best protect their families should they become ill or require quarantine. Some residents felt their family would be safe to stay in quarantine with them at home, while others considered short-term lodging for their families with relatives or friends.

We have found that we cannot treat a pandemic the same as other disaster preparedness events, such as natural disasters or acts of terrorism. Factors contributing to this include the duration of the event and the infectious nature. Residencies need sustainable solutions that could last for an unforeseeable amount of time without placing an unmanageable burden on residents. The role of residents is a unique one in the health care team. They are both learners and integral members of the patient care team. Our solutions may not be practical for smaller programs, given our size of 73 residents. However, we hope that this article will help prompt further discussion about residency preparedness. 🍌

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ACEP staff is thinking constantly of our members and the health care heroes in emergency departments worldwide. We are so proud of your brave and selfless work to combat this virus. Communications Manager Jordan Grantham captured our sentiment and support with this artwork. Stay safe and know that ACEP is here for you—today and every day.

EM CASES | CONTINUED FROM PAGE 27

stressed and exhausted, and there are certainly ED patients who make it hard to be compassionate. But in those moments when I'm stripped of my compassion, I can feel it. I feel that something huge is missing. What do I do? I pause, I breathe, I pivot, and I pull out a couple of those easy-to-remember compassionate statements and just say them. Suddenly, I feel better; I'm quite sure my patient does, too.

Compassionate care is a skill that can be cultivated and grown by each of us. I contend that compassion needs to be integrated into our training and CME. Learning compassionate care allows us to develop our own resilience as emergency physicians in our demanding environment. Compassion is not simply part of our nature, and we shouldn't take it for granted. When we act out of compassion for a fellow human being, it has profound meaning. It is a real privilege that we all have—to take care of patients in the emergency department and use our knowledge and skills not just to fix their immediate problem but to heal them. You can always find compassion in the chaos of the emergency department. Find your compassion. Cultivate it. Use it.

Try compassionate care for yourselves, your patients, and your colleagues, and keep in mind some of the overall benefits outlined in this article. As you feel more comfortable, model it for others and help change the culture. If you can, start a discussion, make compassionate care known, and allow it to grow. You and your patients will benefit immeasurably. 🍌

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PEARLS FROM THE
MEDICAL LITERATURE

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Breaking Updates in Critical Care and Stroke

Data on VITAMINS, tenecteplase, and mobile stroke units among key research

by RYAN PATRICK RADECKI, MD, MS

Early this year, two important conferences outside our specialty unveiled a spate of new findings whose impact will be felt in our practice. Here's a quick rundown of the most interesting trials presented.

Critical Care Reviews 2020

Held this year in Belfast, Northern Ireland, Critical Care Reviews (CCR) brought to first light several important trials relevant to emergency medicine and critical care. One of the most important, the Vitamin C, Hydrocortisone and Thiamine in Patients With Septic Shock (VITAMINS) trial, was covered in these pages by Jeremy Samuel Faust, MD, MS, MA, FACEP, in February.¹ This trial, one of the first to actually rigorously evaluate a treatment protocol for sepsis featuring thiamine, vitamin C, and corticosteroids, was not able to confirm the hoped-for survival advantage.

A second important trial also has implications for emergency care, the concisely and informatively named "65 trial."² This trial looks primarily at the enshrined target mean arterial pressure (MAP) of 65 mmHg in patients whose physiology is being supported by vasopressors. Like many things in medicine, this target is based on a combination of observational evidence and opinion, and despite this, it remains a "strong" recommendation in the Surviving Sepsis Campaign (SSC) guidelines.³

The 65 trial was a massive undertaking, with 2,463 patients ultimately included in the primary analysis. In this trial, elderly patients with vasodilatory shock and receiving vasopressors were randomized to either "permissive hypotension" or usual care in line with the SSC guidelines. Permissive hypotension meant patients were targeted to a range between 60 and 65 mmHg rather than titrating care to maintain MAP greater than 65 mmHg.

The topline, unadjusted results demonstrated no significant difference between treatment strategies.

Overall mortality at 90 days, the primary outcome, was 41.0 percent in the permissive cohort and 43.8 percent with usual care. This small mortality difference favoring permissive hypotension was insufficient to meet statistical significance, although the prespecified adjusted analysis tipped this finding over the line. It would be erroneous to attribute a reliable mortality advantage to treatment with permissive hypotension, but there is no signal of harm.

These results are not surprising if we realize the MAP is not a measure of blood flow through the capillary bed. We are relying on MAP, the pressure of fluid in those larger muscular arteries and arterioles, as a surrogate for end-organ perfusion. This must be balanced against the potential harmful effects of vasopressors.

Interestingly, the actual treatment received by those in the permissive hypotension arm was not terribly hypotensive. The mean MAP while receiving vasopressors in the permissive arm was still 66.7 mmHg compared to 72.6 mmHg in those receiving usual care. A sizable fraction of those in the trial were treated with metaraminol, a vasopressor with primarily alpha-receptor effects, potentially impacting generalizability to settings where norepinephrine is the preferred first-line agent. However, this study neatly shows you need not exercise vigilance in keeping MAP above 65 mmHg at all times.

Other notable work presented at CCR included a 26,000 patient trial comparing proton pump inhibitors to histamine-2 receptor blockers in ICU patients, cardiac catheterization following out-of-hospital cardiac arrest, and global data on the burden of sepsis.

International Stroke Conference 2020

This year's International Stroke Conference (ISC) was not in a charming foreign locale but the less-exotic destination of Los Angeles. As of this writing, many of these breaking presentations are available only as slide decks and abstracts pending peer-reviewed full-text publication in scientific journals. These preliminary data represent windows into their likely downstream effects on stroke care.

One of the most notable emerging themes over the last few years is a movement toward use of tenecteplase rather than alteplase in stroke. Tenecteplase is less expensive and is given as a single bolus dose rather than requiring a

prolonged infusion. The Tenecteplase Versus Alteplase Before Endovascular Therapy for Ischemic Stroke (EXTEND-IA TNK) Part 2 trial looked specifically at dose response to tenecteplase in achieving recanalization in large vessel strokes.⁴ These authors did not observe a difference in outcomes whether 0.4 mg/kg or 0.25 mg/kg was used, but bleeding was marginally increased by the higher dose. A group from the University of Texas at Austin also presented their initial experience incorporating tenecteplase into practice as their primary thrombolytic. In their limited case series, outcomes and safety appeared consistent with their prior experience with alteplase.

Two studies also looked at outcomes associated with mobile stroke units (MSUs), ambulances equipped with non-contrast CT and the capability of administering thrombolytics and anticoagulant reversal agents in the field. An observational study from Melbourne, Australia, sought to quantify the effect of MSU dispatch on subsequent endovascular intervention.⁵ As with thrombolytic therapy, stroke unit dispatch expedited downstream stroke care. However, MSU dispatch to 2,348 cases in their first year yielded only 100 cases of prehospital thrombolysis. A similar observational study in Berlin documented increased thrombolysis and improved three-month outcomes associated with MSU care. Similar to the low yield in the Melbourne study, there were more than 14,500 dispatches to yield only 450 cases of thrombolytic administration.

Last, and most interesting, are the first data regarding whether thrombolytics are necessary prior to endovascular therapy in eligible patients. The entire existence of the endovascular industry stems from the utter lack of efficacy for thrombolytics in large vessel occlusion. The Randomized Study of Endovascular Therapy with Versus Without Intravenous Tissue Plasminogen Activator in Acute Stroke with ICA and M1 Occlusion (SKIP) tested the necessity of alteplase administration as a bridge to endovascular therapy and observed neither an advantage nor reliable disadvantage to its use. Intracranial hemorrhage, however, was increased in those who received alteplase prior to endovascular therapy. These data are just the first of multiple trials looking at this question and will add another layer of decision making to the triage of stroke patients in the emergency department.

The opinions expressed herein are solely those of Dr. Radecki and do not necessarily reflect those of his employer or academic affiliates. +

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CODING WIZARD

NAVIGATE THE
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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.

CODING FOR BEHAVIORAL HEALTH PATIENTS WITH EXTENDED STAYS

by MICHAEL LEMANSKI, MD, FACEP

Question: My emergency department frequently cares for patients while they wait for a bed in a psychiatric facility to become available. How do we code for these extended stays?

Answer: ACEP has long advocated for improved mental health care for behavioral health patients. To that end, the College has been working with the American Medical Association (AMA) to help clarify how to report the services provided by emergency physi-

cians after the patient has been evaluated, treated, and medically cleared for psychiatric evaluation. Optimally, mental health patients requiring an inpatient level of care would be promptly admitted to a psychiatric facility or admitted to a medical unit pending transfer to a psychiatric facility.

Realistically, many patients end up being cared for in the emergency department until an appropriate inpatient psychiatric bed can be located and the patient transferred to another facility. ACEP asked the AMA CPT Editorial Panel how to report Days 2 and 3 of such a stay. In the July 2019 issue of *CPT Assistant*, the AMA instructs us to use subsequent observation codes to report these services. Please see the new ACEP Reimbursement FAQ on Mental Health at www.acep.org/administration/reimbursement/reimbursement-faqs/faqs for detailed information on how to properly code and get paid for providing ongoing care to mental health patients. +

DR. LEMANSKI is associate professor of emergency medicine at UMass Medical School—Baystate Campus, ACEP's alternate advisor to the CPT Editorial Panel, and chair of the ACEP Reimbursement Committee Workgroup 4.



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PREP YOUR ED FOR COVID-19 | CONTINUED FROM PAGE 17

Intubation and Respiratory Support

Personnel from critical care, respiratory therapy, and anesthesiology should convene to develop approaches to support for suspected or confirmed COVID-19 patients with respiratory failure.

Controversy exists about the use of non-invasive positive pressure ventilation and high-flow nasal cannula, which may disperse secretions and therefore virus.

We have opted to perform early tracheal intubation for these patients with placement on mechanical ventilation with a viral filter. Intubation should occur ideally in negative pressure rooms using airborne precautions.

- The intubating clinician should use a PAPR with shroud and follow donning/doffing procedures.
- Minimize additional staff (ideally, one nurse and one respiratory therapist).
- We favor the use of video laryngoscopy to increase the distance between the intubating clinician and patient's aerodigestive tract along with the rapid sequence intubation technique to minimize coughing or dispersion of secretions during bag-mask ventilation.
- Viral filters can be placed in-line with bag-valve masks.
- If sidestream waveform capnography

devices are used, make sure a viral filter is placed in-line proximal to the end-tidal CO₂ adapter (ie, directly on the end of the endotracheal tube, mask, or laryngeal mask airway). Otherwise, contaminated secretions may theoretically leak into the end-tidal CO₂ tubing and perhaps back to the monitoring module.

Code Blue/Clinical Emergency Response

A dedicated plan for response to clinical emergencies should be created for patients with suspected or confirmed COVID-19. The plan should include limiting responding person-

nel, ensuring isolation precautions are maintained, and limiting aerosolizing procedure.

Consider appointing a dedicated isolation "captain" to ensure only essential staff enter the room, appropriate PPE are used, and equipment is decontaminated appropriately. The plan should include early discussions about "do not resuscitate" status with next of kin for critically ill infected patients. ⊕

DR. SHAH, DR. JOHNSON, DR. MITCHELL, DR. STERN, AND DR. BADULAK are in the department of emergency medicine at the University of Washington, Harborview Medical Center in Seattle.

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a week into the epidemic, when we started seeing patients with features of COVID-19 at various facilities across Puget Sound. We had large numbers of patients who had possibly been exposed, many of whom were showing symptoms that could be compatible with the disease.

Since that first case, we've seen a lot of patients with clinical features consistent with other descriptions that have been given—patients with cough, sore throat, and fever. Most patients had typical presentations, though some older adults did not mount a fever response. Many patients have had leukopenia, and some have had high transaminases. Some people had only mild symptoms, but we couldn't definitively diagnose because no testing was available at that time. We had to assume that such patients might have COVID-19, so we sent them home for self-quarantine.

Triage and Treatment

We quickly learned to focus on the patients who appeared very ill. We've found that the clinical presentation was quite different from typical cold symptoms or common flu. Patients might present with a little labored breathing and mild hypoxia. However, the chest X-ray often looked substantially worse than the patient appeared. One could see a classic viral pattern of bilateral patchy ground-glass infiltrates.

We learned to recognize that as a highly alarming sign. In our experience, once patients develop that, the progression to severe respiratory complications is likely. For sick patients coming into the emergency department, this can often happen quickly, within hours. We've seen some patients who went from slight hypoxia on arrival to needing intubation eight hours later, displaying a severe viral pneumonia or even an acute respiratory distress syndrome pattern. We've been surprised by how dangerous this virus is, how it can make certain people very ill very quickly. That is in line with the Chinese experience, but it has still been disconcerting to see up close.

We found that common temporizing measures used for patients with respiratory distress such as bilevel positive airway pressure (BiPAP) and high-flow nasal cannula oxygen don't seem to avert this progression. One might be able to buy a little time this way, but even with these measures, these sick patients have eventually needed intubation. This contrasts with other medical conditions, such as congestive heart failure, where such interventions might be all that are needed. More recent experience suggests that ventilator-sparing strategies may have merit; this is very much a learning process. We've tended to avoid both BiPAP and high-flow nasal cannula because of concerns that they might increase aerosol particle formation and thus make the virus more transmissible to health care workers.

Computed tomography scan seems to be quite sensitive to coronavirus, at least in patients having moderate or severe symptoms, probably even more sensitive than the polymerase chain reaction tests that we have. However, pragmatically, it is not very useful as a screening tool for large numbers of patients due to the time needed to perform the procedure and decontaminate the scanner between uses. It may be useful in some situations when the diagnosis of coronavirus is unclear, but we've mostly been treating presumptively

until test results come back.

Hospital Ops Tips

Our hospitals had learned some lessons from the SARS epidemic in 2003, the H1N1 epidemic in 2009, and the Ebola crisis in 2014, lessons that had been written into their disaster plans. As the scale of the crisis became apparent, the hospitals quickly implemented these plans, which greatly helped with mitigation. Because of inability to test early on, we were unable to contain the crisis in the Puget Sound region, but we did go directly into mitigation to help flatten the disease curve.

The most-effective hospitals that have re-

sponded to this have had an internal command center staffed 24 hours a day. These staffers are knowledgeable about the plan and can coordinate different service lines, ensuring that resources are being allocated where they are needed most. That's been a critical element.

Triaging potential coronavirus patients from other visitors to the emergency department is also essential. In one hospital, we gathered all the patients with respiratory complaints in a single area of the emergency department. Because of the high level of contagiousness of coronavirus, each emergency department in our regional hospitals has had to develop its own way to implement appro-

priate isolation criteria. When private rooms have not been available, some hospitals have performed triage in the waiting room and had patients wait in their cars to be notified via cellphone when a room is available. Some places have also used pop-up tents outside the department to do some prescreening.

Now that we've seen more community transition of the virus, some places have developed drive-through station testing, like the ones used extensively in South Korea. People can drive up, get their temperature and oxygen level tested, and get swabbed to receive the results by phone at home. I think we will see more of those as the epidemic continues.

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.

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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.

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Stellar Staff Response

As the crisis has developed, the staffing needs have changed. Fortunately, the public has received the message to stay away from the emergency department unless they are seriously ill. Recently, patient volumes in the emergency departments have been down in some cases. Because of this, we've been able to shift some workers from a fast-track shift to the respiratory unit so we can have extra focus on the really sick people. We've been very flexible in changing staffing based on the needs of the moment.

We all got fitted for N95 masks for seeing high-risk patients or doing high-risk procedures using full airborne precautions. Our health care workers quickly got in the habit of being very diligent with their personal protective equipment. As has been covered in the

media, some clinicians have been anxious about potential shortages in personal protective equipment. At centers in our region, I don't feel that such worries have impacted care yet. However, we all share concerns about whether the supply chain will hold up on a long-term basis.

Situations like this bring out many fears for health care workers, just like they do in the rest of the population. However, we've seen that events like this also tend to bring out the best in people. People approach it as a war zone; they buckle up and get the work done. If a worker gets sick or has to self-quarantine, someone else steps up to fill the shifts.

What Comes Next

We need guidance from the federal government about how the regulatory framework of

medicine is going to adapt to this widespread epidemic. According to EMTALA, any patient who comes to the emergency room must receive a screening exam and stabilizing treatment. We embrace EMTALA as emergency physicians, but it's not clear exactly how it should be implemented in these innovative modalities of emergency screening and health care delivery. We are pleased to guidance from the Centers for Medicare & Medicaid Services about how EMTALA shall be applied in these settings so that we are confident what we are doing is compliant. Some clinicians also worry about the potential for malpractice suits when delivering medical care under these difficult circumstances. Congressional action could put such concerns to rest.

In my opinion, the hospitals around the

region have displayed an outstanding response to the crisis. However, we already have days in which every intensive care unit bed in the region is full, days in which a specific hospital might have used up all their ventilators. Our hospitals have been very agile in creating more capacity, canceling elective surgeries, and opening new intensive care unit wings. However, we are all very concerned about how the health care system will hold up if we see an exponential growth in transmission. ➕



DR. YORE is Past President of the Washington chapter of ACEP and a practicing emergency physician at North Sound Emergency Medicine in Everett, Washington.

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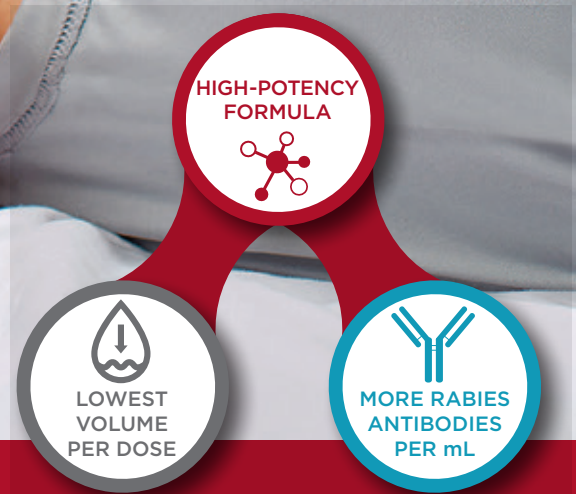
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