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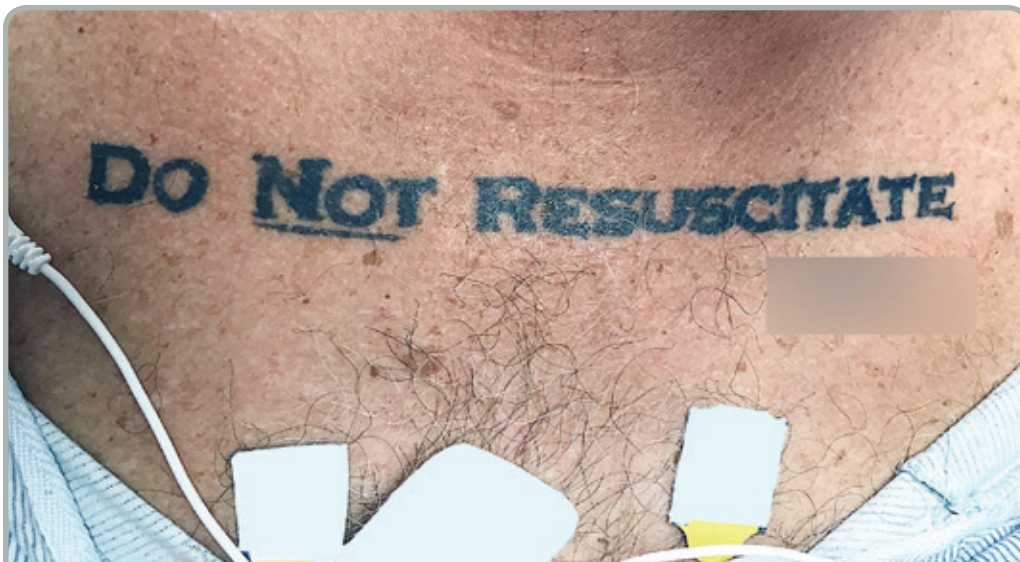


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WHAT TO DO WITH DNR TATTOOS?

DNR TATTOOS
MAY NOT
BE VALID

by LAURA VEARRIER, MD, MA

A recent *New England Journal of Medicine* article presented a case in which a “Do Not Resuscitate” (DNR) tattoo (see Figure 1) created an ethical dilemma for the emergency and critical care physicians caring for the patient, who were guided by a questionable recommendation from their ethics consultants.¹ The unknown patient presented to the emergency department unconscious and in critical condition. “Do Not

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TIME TO EXPAND STROKE TREATMENT WINDOW?

Pushing the envelope
for mechanical
thrombectomy

by ALEXEI WAGNER, MD, MBA; AND
SAM SHEN, MD, MBA



A NEW
SPIN

Until now, the window to treat acute stroke with tissue plasminogen activator (tPA) or endovascular thrombectomy was six hours, maximum. Many centers wouldn't administer tPA after four hours.

Although many emergency physicians can attest to the professional satisfaction of successfully administering treatment to a patient who otherwise would have had a lifelong, debilitating neurologic deficit, most can also point to the intense frustration felt when a patient presented with a stroke that fell outside the treatment window. The treatment time limit cruelly limited the number of patients who could regain the ability to move or speak.

Progress has been made in the implementation of operational efficiencies to facilitate the early, prehospital identification of stroke symptoms; rapid EMS stroke diagnosis; rapid CT imaging; and, if appropriate, the timely administration of tPA and thrombectomy. However, the six hour problem remained—endovascular thrombectomy was previously recommended only if performed within six hours of symptom onset.

But we have good news: With the recent publications of the DAWN and DEFUSE3 trials, there's new hope.

The DAWN trial demonstrated that select patients with acute ischemic stroke

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ACEP AT 50 YEARS

SMASHING THE EM GLASS CEILING

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**DARE TO BE
DIFFERENT**

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...with purpose
...for patients

**Choose the
only NOAC
with...**

**Extensive safety and efficacy data in the most patients
studied with NVAF at a higher risk* of stroke¹⁻⁵**

AND

**A major bleeding rate as low as aspirin with superior
efficacy in recurrent DVT/PE risk reduction^{†6}**

[†]After 6 months initial treatment.

*CHADS₂ scores 3 to 6 in pivotal NOAC phase 3 trials: ROCKET AF (N=12,402), ARISTOTLE (N=5502), ENGAGE-AF (N=11,200), and RE-LY (N=5882).

INDICATIONS

XARELTO® is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF). There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled.

XARELTO® is indicated for the treatment of deep vein thrombosis (DVT). XARELTO® is indicated for the treatment of pulmonary embolism (PE). XARELTO® is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

IMPORTANT SAFETY INFORMATION

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

A. Premature discontinuation of XARELTO® increases the risk of thrombotic events

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

B. Spinal/epidural hematoma

Epidural or spinal hematomas have occurred in patients treated with XARELTO® 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 non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, see Drug Interactions
 - ♦ A history of traumatic or repeated epidural or spinal punctures
 - ♦ A history of spinal deformity or spinal surgery
 - ♦ Optimal timing between the administration of XARELTO® 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 for thromboprophylaxis.

DVT = deep vein thrombosis; NOAC = non-vitamin K antagonist oral anticoagulant; NVAF = nonvalvular atrial fibrillation; PE = pulmonary embolism.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- ♦ Active pathological bleeding
- ♦ Severe hypersensitivity reaction to XARELTO® (eg, anaphylactic reactions)

WARNINGS AND PRECAUTIONS

- ♦ **Increased Risk of Thrombotic Events After Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- ♦ **Risk of Bleeding:** XARELTO® increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO® in patients with active pathological hemorrhage.
 - A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable.
 - Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. These include aspirin, P2Y₁₂ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, NSAIDs, selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs).
- ♦ **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis. To reduce the potential risk of bleeding associated with the concurrent use of XARELTO® and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO®. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO® is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (ie, 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO®. The next XARELTO® dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO® for 24 hours. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.
- ♦ **Use in Patients With Renal Impairment:**
 - **Nonvalvular Atrial Fibrillation:** Periodically assess renal function as clinically indicated (ie, more frequently in situations in which renal function may decline) and adjust therapy accordingly. Consider dose adjustment or discontinuation of XARELTO® in patients who develop acute renal failure while on XARELTO®.
 - **Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population.
 - **Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue the treatment.
- ♦ **Use in Patients With Hepatic Impairment:** No clinical data are available for patients with severe hepatic impairment. Avoid use of XARELTO® in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.
- ♦ **Use With P-gp and Strong CYP3A4 Inhibitors or Inducers:** Avoid concomitant use of XARELTO® with known combined P-gp and strong CYP3A4 inhibitors. Avoid concomitant use of XARELTO® with drugs that are known combined P-gp and strong CYP3A4 inducers.
- ♦ **Risk of Pregnancy-Related Hemorrhage:** In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant

effect of XARELTO® cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

- ♦ **Patients With Prosthetic Heart Valves:** The safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO® is not recommended in these patients.
- ♦ **Acute PE in Hemodynamically Unstable Patients/Patients Who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

DRUG INTERACTIONS

- ♦ Combined P-gp and strong CYP3A4 inhibitors increase exposure to rivaroxaban and may increase the risk of bleeding.
- ♦ Combined P-gp and strong CYP3A4 inducers decrease exposure to rivaroxaban and may increase the risk of thromboembolic events.
- ♦ XARELTO® should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (eg, erythromycin) unless the potential benefit justifies the potential risk.
- ♦ Coadministration of enoxaparin, warfarin, aspirin, clopidogrel, and chronic NSAID use may increase the risk of bleeding.
- ♦ Avoid concurrent use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.

USE IN SPECIFIC POPULATIONS

- ♦ **Pregnancy:** The limited available data on XARELTO® in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO® for the mother and possible risks to the fetus when prescribing XARELTO® to a pregnant woman.
 - **Fetal/Neonatal adverse reactions:** Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.
 - **Labor or delivery:** The risk of bleeding should be balanced with the risk of thrombotic events when considering the use of XARELTO® in this setting.
 - There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage.
- ♦ **Lactation:** Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XARELTO® and any potential adverse effects on the breastfed infant from XARELTO® or from the underlying maternal condition.
- ♦ **Females and Males of Reproductive Potential:** Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.
- ♦ **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

OVERDOSAGE

- ♦ Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. The use of activated charcoal to reduce absorption in case of XARELTO® overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable.

ADVERSE REACTIONS IN CLINICAL STUDIES

- ♦ The most common adverse reactions with XARELTO® were bleeding complications.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.

References: 1. Patel MR, Mahaffey KW, Garg J, et al; and the ROCKET AF Steering Committee, for the ROCKET AF Investigators. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med*. 2011;365(10):883-891. 2. Granger CB, Alexander JH, McMurray JJV, et al; for the ARISTOTLE Committees and Investigators. Apixaban versus warfarin in patients with atrial fibrillation. *N Engl J Med*. 2011;365(11):981-992. 3. Connolly SJ, Ezekowitz MD, Yusuf S, et al; and the RE-LY Steering Committee and Investigators. Dabigatran versus warfarin in patients with atrial fibrillation. *N Engl J Med*. 2009;361(12):1139-1151. 4. Giugliano RP, Ruff CT, Braunwald E, et al; for the ENGAGE AF-TIMI 48 Investigators. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med*. 2013;369(22):2093-2104. 5. Savaysa® [prescribing information]. Parsippany, NJ: Daiichi Sankyo, Inc. 2015. 6. Weitz JJ, Lensing AWA, Prins MH, et al; for the EINSTEIN CHOICE Investigators. Rivaroxaban or aspirin for extended treatment of venous thromboembolism. *N Engl J Med*. 2017;376(13):1211-1222.

Brief Summary of Prescribing Information for XARELTO® (rivaroxaban)

XARELTO® (rivaroxaban) tablets, for oral use
See package insert for full Prescribing Information

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

A. Premature discontinuation of XARELTO increases the risk of thrombotic events
Premature discontinuation of any oral anticoagulant, including XARELTO, increases the risk of thrombotic events. If anticoagulation with XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see Dosage and Administration (2.3, 2.8), in full Prescribing Information, Warnings and Precautions, and Clinical Studies (14.1) in full Prescribing Information].

B. Spinal/epidural hematoma
Epidural or spinal hematomas have occurred in patients treated with XARELTO 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 non-steroidal 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 XARELTO and neuraxial procedures is not known

[see Warnings and Precautions and Adverse Reactions].

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

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

INDICATIONS AND USAGE

Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation: XARELTO is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. There are limited data on the relative effectiveness of XARELTO and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled [see Clinical Studies (14.1) in full Prescribing Information].

Treatment of Deep Vein Thrombosis: XARELTO is indicated for the treatment of deep vein thrombosis (DVT).

Treatment of Pulmonary Embolism: XARELTO is indicated for the treatment of pulmonary embolism (PE).

Reduction in the Risk of Recurrence of Deep Vein Thrombosis and/or Pulmonary Embolism: XARELTO is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: XARELTO is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

CONTRAINDICATIONS

XARELTO is contraindicated in patients with:

- active pathological bleeding [see Warnings and Precautions]
- severe hypersensitivity reaction to XARELTO (e.g., anaphylactic reactions) [see Adverse Reactions]

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including XARELTO, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO to warfarin in clinical trials in atrial fibrillation patients. If XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see Dosage and Administration (2.3, 2.8) and Clinical Studies (14.1) in full Prescribing Information].

Risk of Bleeding: XARELTO increases the risk of bleeding and can cause serious or fatal bleeding. In deciding whether to prescribe XARELTO to patients at increased risk of bleeding, the risk of thrombotic events should be weighed against the risk of bleeding.

Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO in patients with active pathological hemorrhage. The terminal elimination half-life of rivaroxaban is 5 to 9 hours in healthy subjects aged 20 to 45 years.

Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. These include aspirin, P2Y₁₂ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) [see Drug Interactions], selective serotonin reuptake inhibitors, and serotonin norepinephrine reuptake inhibitors.

Concomitant use of drugs that are known combined P-gp and strong CYP3A4 inhibitors increases rivaroxaban exposure and may increase bleeding risk [see Drug Interactions].

Reversal of Anticoagulant Effect: A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable [see Clinical Pharmacology (12.3) in full Prescribing Information]. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of rivaroxaban. Partial reversal of prothrombin time prolongation has been seen after administration of prothrombin complex concentrates (PCCs) in healthy volunteers. The use of other procoagulant reversal agents like activated prothrombin complex concentrate (APCC) or recombinant factor VIIa (rFVIIa) has not been evaluated.

Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis [see Boxed Warning].

To reduce the potential risk of bleeding associated with the concurrent use of XARELTO and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO [see Clinical Pharmacology (12.3) in full Prescribing Information]. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known.

An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (i.e., 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO [see Clinical Pharmacology (12.3) in full Prescribing Information]. The next XARELTO dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO for 24 hours.

XARELTO® (rivaroxaban) tablets

Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.

Use in Patients with Renal Impairment: Nonvalvular Atrial Fibrillation: Periodically assess renal function as clinically indicated (i.e., more frequently in situations in which renal function may decline) and adjust therapy accordingly [see Dosage and Administration (2.4) in full Prescribing Information]. Consider dose adjustment or discontinuation of XARELTO in patients who develop acute renal failure while on XARELTO [see Use in Specific Populations].

Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population [see Use in Specific Populations].

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO should discontinue the treatment [see Use in Specific Populations].

Use in Patients with Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment.

Avoid use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy since drug exposure and bleeding risk may be increased [see Use in Specific Populations].

Use with P-gp and Strong CYP3A4 Inhibitors or Inducers: Avoid concomitant use of XARELTO with known combined P-gp and strong CYP3A4 inhibitors [see Drug Interactions].

Avoid concomitant use of XARELTO with drugs that are known combined P-gp and strong CYP3A4 inducers [see Drug Interactions].

Risk of Pregnancy-Related Hemorrhage: In pregnant women, XARELTO should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (e.g., a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

Patients with Prosthetic Heart Valves: The safety and efficacy of XARELTO have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients or Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of XARELTO is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the labeling:

- Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation [see Boxed Warning and Warnings and Precautions]
- Bleeding risk [see Warnings and Precautions]
- Spinal/epidural hematoma [see Boxed Warning and Warnings and Precautions]

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

During clinical development for the approved indications, 18560 patients were exposed to XARELTO. These included 7111 patients who received XARELTO 15 mg or 20 mg orally once daily for a mean of 19 months (5558 for 12 months and 2512 for 24 months) to reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (ROCKET AF); 6962 patients who received XARELTO 15 mg orally twice daily for three weeks followed by 20 mg orally once daily to treat DVT or PE (EINSTEIN DVT, EINSTEIN PE), 10 mg or 20 mg orally once daily (EINSTEIN Extension, EINSTEIN CHOICE) to reduce the risk of recurrence of DVT and/or PE; and 4487 patients who received XARELTO 10 mg orally once daily for prophylaxis of DVT following hip or knee replacement surgery (RECORD 1-3).

Hemorrhage: The most common adverse reactions with XARELTO were bleeding complications [see Warnings and Precautions].

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 4.3% for XARELTO vs. 3.1% for warfarin. The incidence of discontinuations for non-bleeding adverse events was similar in both treatment groups.

Table 1 shows the number of patients experiencing various types of bleeding events in the ROCKET AF trial.

Table 1: Bleeding Events in ROCKET AF*- On Treatment Plus 2 Days

Parameter	XARELTO N=7111 n (%/year)	Warfarin N=7125 n (%/year)	XARELTO vs. Warfarin HR (95% CI)
Major Bleeding†	395 (3.6)	386 (3.5)	1.04 (0.90, 1.20)
Intracranial Hemorrhage (ICH)‡	55 (0.5)	84 (0.7)	0.67 (0.47, 0.93)
Hemorrhagic Stroke§	36 (0.3)	58 (0.5)	0.63 (0.42, 0.96)
Other ICH	19 (0.2)	26 (0.2)	0.74 (0.41, 1.34)
Gastrointestinal (GI)¶	221 (2.0)	140 (1.2)	1.61 (1.30, 1.99)
Fatal Bleeding#	27 (0.2)	55 (0.5)	0.50 (0.31, 0.79)
ICH	24 (0.2)	42 (0.4)	0.58 (0.35, 0.96)
Non-intracranial	3 (0.0)	13 (0.1)	0.23 (0.07, 0.82)

Abbreviations: HR = Hazard Ratio, CI = Confidence interval, CRNM = Clinically Relevant Non-Major.

* Major bleeding events within each subcategory were counted once per patient, but patients may have contributed events to multiple subcategories. These events occurred during treatment or within 2 days of stopping treatment.

† Defined as clinically overt bleeding associated with a decrease in hemoglobin of ≥2 g/dL, a transfusion of ≥2 units of packed red blood cells or whole blood, bleeding at a critical site, or with a fatal outcome.

‡ Intracranial bleeding events included intraparenchymal, intraventricular, subdural, subarachnoid and/or epidural hematoma.

XARELTO® (rivaroxaban) tablets

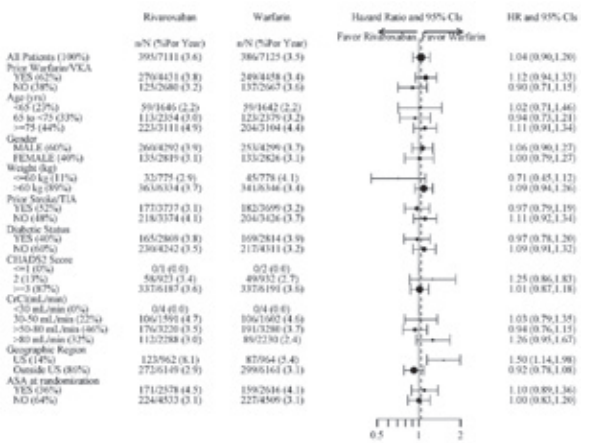
§ Hemorrhagic stroke in this table specifically refers to non-traumatic intraparenchymal and/or intraventricular hematoma in patients on treatment plus 2 days.

¶ Gastrointestinal bleeding events included upper GI, lower GI, and rectal bleeding.

Fatal bleeding is adjudicated death with the primary cause of death from bleeding.

Figure 1 shows the risk of major bleeding events across major subgroups.

Figure 1: Risk of Major Bleeding Events by Baseline Characteristics in ROCKET AF – On Treatment Plus 2 Days



Note: The figure above presents effects in various subgroups all of which are baseline characteristics and all of which were pre-specified (diabetic status was not pre-specified in the subgroup, but was a criterion for the CHADS2 score). The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be over-interpreted.

Treatment of Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE): EINSTEIN DVT and EINSTEIN PE Studies: In the pooled analysis of the EINSTEIN DVT and EINSTEIN PE clinical studies, the most frequent adverse reactions leading to permanent drug discontinuation were bleeding events, with XARELTO vs. enoxaparin/Vitamin K antagonist (VKA) incidence rates of 1.7% vs. 1.5%, respectively. The mean duration of treatment was 208 days for XARELTO-treated patients and 204 days for enoxaparin/VKA-treated patients.

Table 2 shows the number of patients experiencing major bleeding events in the pooled analysis of the EINSTEIN DVT and EINSTEIN PE studies.

Table 2: Bleeding Events* in the Pooled Analysis of EINSTEIN DVT and EINSTEIN PE Studies

Parameter	XARELTO† N=4130 n (%)	Enoxaparin/ VKA† N=4116 n (%)
Major bleeding event	40 (1.0)	72 (1.7)
Fatal bleeding	3 (<0.1)	8 (0.2)
Intracranial	2 (<0.1)	4 (<0.1)
Non-fatal critical organ bleeding	10 (0.2)	29 (0.7)
Intracranial‡	3 (<0.1)	10 (0.2)
Retroperitoneal‡	1 (<0.1)	8 (0.2)
Intraocular‡	3 (<0.1)	2 (<0.1)
Intra-articular‡	0	4 (<0.1)
Non-fatal non-critical organ bleeding§	27 (0.7)	37 (0.9)
Decrease in Hb ≥ 2 g/dL	28 (0.7)	42 (1.0)
Transfusion of ≥2 units of whole blood or packed red blood cells	18 (0.4)	25 (0.6)
Clinically relevant non-major bleeding	357 (8.6)	357 (8.7)
Any bleeding	1169 (28.3)	1153 (28.0)

* Bleeding event occurred after randomization and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule in EINSTEIN DVT and EINSTEIN PE studies: XARELTO 15 mg twice daily for 3 weeks followed by 20 mg once daily; enoxaparin/VKA [enoxaparin: 1 mg/kg twice daily, VKA: individually titrated doses to achieve a target INR of 2.5 (range: 2.0-3.0)]

‡ Treatment-emergent major bleeding events with at least >2 subjects in any pooled treatment group

§ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥2 units of whole blood or packed red blood cells

Reduction in the Risk of Recurrence of DVT and/or PE: EINSTEIN CHOICE Study: In the EINSTEIN CHOICE clinical study, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 1% for XARELTO 10 mg, 2% for XARELTO 20 mg, and 1% for acetylsalicylic acid (aspirin) 100 mg. The mean duration of treatment was 293 days for XARELTO 10 mg-treated patients and 286 days for aspirin 100 mg-treated patients.

Table 3 shows the number of patients experiencing bleeding events in the EINSTEIN CHOICE study.

Table 3: Bleeding Events* in EINSTEIN CHOICE

Parameter	XARELTO† 10 mg N=1127 n (%)	Acetylsalicylic Acid (aspirin)† 100 mg N=1131 n (%)
Major bleeding event	5 (0.4)	3 (0.3)
Fatal bleeding	0	1 (<0.1)
Non-fatal critical organ bleeding	2 (0.2)	1 (<0.1)
Non-fatal non-critical organ bleeding§	3 (0.3)	1 (<0.1)
Clinically relevant non-major (CRNM) bleeding¶	22 (2.0)	20 (1.8)
Any bleeding	151 (13.4)	138 (12.2)

* Bleeding event occurred after the first dose and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule: XARELTO 10 mg once daily or aspirin 100 mg once daily.

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⁵ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥ 2 units of whole blood or packed red blood cells.

[†] Bleeding which was clinically overt, did not meet the criteria for major bleeding, but was associated with medical intervention, unscheduled contact with a physician, temporary cessation of treatment, discomfort for the patient, or impairment of activities of daily life.

In the EINSTEIN CHOICE study, there was an increased incidence of bleeding, including major and CRNM bleeding in the XARELTO 20 mg group compared to the XARELTO 10 mg or aspirin 100 mg groups.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: In the RECORD clinical trials, the overall incidence rate of adverse reactions leading to permanent treatment discontinuation was 3.7% with XARELTO.

The rates of major bleeding events and any bleeding events observed in patients in the RECORD clinical trials are shown in Table 4.

Table 4: Bleeding Events* in Patients Undergoing Hip or Knee Replacement Surgeries (RECORD 1-3)

	XARELTO 10 mg	Enoxaparin [†]
Total treated patients	N=4487 n (%)	N=4524 n (%)
Major bleeding event	14 (0.3)	9 (0.2)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	2 (<0.1)	3 (0.1)
Bleeding that required re-operation	7 (0.2)	5 (0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	4 (0.1)	1 (<0.1)
Any bleeding event [‡]	261 (5.8)	251 (5.6)
Hip Surgery Studies	N=3281 n (%)	N=3298 n (%)
Major bleeding event	7 (0.2)	3 (0.1)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	1 (<0.1)	1 (<0.1)
Bleeding that required re-operation	2 (0.1)	1 (<0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	3 (0.1)	1 (<0.1)
Any bleeding event [‡]	201 (6.1)	191 (5.8)
Knee Surgery Study	N=1206 n (%)	N=1226 n (%)
Major bleeding event	7 (0.6)	6 (0.5)
Fatal bleeding	0	0
Bleeding into a critical organ	1 (0.1)	2 (0.2)
Bleeding that required re-operation	5 (0.4)	4 (0.3)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	1 (0.1)	0
Any bleeding event [‡]	60 (5.0)	60 (4.9)

* Bleeding events occurring any time following the first dose of double-blind study medication (which may have been prior to administration of active drug) until two days after the last dose of double-blind study medication. Patients may have more than one event.

[†] Includes the placebo-controlled period for RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

[‡] Includes major bleeding events

Following XARELTO treatment, the majority of major bleeding complications (≥60%) occurred during the first week after surgery.

Other Adverse Reactions: Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in the EINSTEIN DVT and EINSTEIN PE studies are shown in Table 5.

Table 5: Other Adverse Reactions* Reported by ≥1% of XARELTO-Treated Patients in EINSTEIN DVT and EINSTEIN PE Studies

Body System Adverse Reaction	XARELTO 20 mg N=1718 n (%)	Enoxaparin/VKA N=1711 n (%)
EINSTEIN DVT Study		
Gastrointestinal disorders		
Abdominal pain	46 (2.7)	25 (1.5)
General disorders and administration site conditions		
Fatigue	24 (1.4)	15 (0.9)
Musculoskeletal and connective tissue disorders		
Back pain	50 (2.9)	31 (1.8)
Muscle spasm	23 (1.3)	13 (0.8)
Nervous system disorders		
Dizziness	38 (2.2)	22 (1.3)
Psychiatric disorders		
Anxiety	24 (1.4)	11 (0.6)
Depression	20 (1.2)	10 (0.6)
Insomnia	28 (1.6)	18 (1.1)
EINSTEIN PE Study	XARELTO 20 mg N=2412 n (%)	Enoxaparin/VKA N=2405 n (%)
Skin and subcutaneous tissue disorders		
Pruritus	53 (2.2)	27 (1.1)

* Adverse reaction with Relative Risk >1.5 for XARELTO versus comparator

Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in RECORD 1-3 studies are shown in Table 6.

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Table 6: Other Adverse Drug Reactions* Reported by ≥1% of XARELTO-Treated Patients in RECORD 1-3 Studies

Body System Adverse Reaction	XARELTO 10 mg N=4487 n (%)	Enoxaparin [†] N=4524 n (%)
Injury, poisoning and procedural complications		
Wound secretion	125 (2.8)	89 (2.0)
Musculoskeletal and connective tissue disorders		
Pain in extremity	74 (1.7)	55 (1.2)
Muscle spasm	52 (1.2)	32 (0.7)
Nervous system disorders		
Syncope	55 (1.2)	32 (0.7)
Skin and subcutaneous tissue disorders		
Pruritus	96 (2.1)	79 (1.8)
Blister	63 (1.4)	40 (0.9)

* Adverse reaction occurring any time following the first dose of double-blind medication, which may have been prior to administration of active drug, until two days after the last dose of double-blind study medication

[†] Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

Other clinical trial experience: In an investigational study of acute medically ill patients being treated with XARELTO 10 mg tablets, cases of pulmonary hemorrhage and pulmonary hemorrhage with bronchiectasis were observed.

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of XARELTO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders: agranulocytosis, thrombocytopenia

Gastrointestinal disorders: retroperitoneal hemorrhage

Hepatobiliary disorders: jaundice, cholestasis, hepatitis (including hepatocellular injury)

Immune system disorders: hypersensitivity, anaphylactic reaction, anaphylactic shock, angioedema

Nervous system disorders: cerebral hemorrhage, subdural hematoma, epidural hematoma, hemiparesis

Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome

DRUG INTERACTIONS

General Inhibition and Induction Properties: Rivaroxaban is a substrate of CYP3A4/5, CYP2J2, and the P-gp and ATP-binding cassette G2 (ABCG2) transporters. Combined P-gp and strong CYP3A4 inhibitors increase exposure to rivaroxaban and may increase the risk of bleeding. Combined P-gp and strong CYP3A4 inducers decrease exposure to rivaroxaban and may increase the risk of thromboembolic events.

Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Interaction with Combined P-gp and Strong CYP3A4 Inhibitors: Avoid concomitant administration of XARELTO with known combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole and ritonavir) [see *Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information*].

Although clarithromycin is a combined P-gp and strong CYP3A4 inhibitor, pharmacokinetic data suggests that no precautions are necessary with concomitant administration with XARELTO as the change in exposure is unlikely to affect the bleeding risk [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

Interaction with Combined P-gp and Moderate CYP3A4 Inhibitors in Patients with Renal Impairment: XARELTO should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (e.g., erythromycin) unless the potential benefit justifies the potential risk [see *Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information*].

Drugs that Induce Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) [see *Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information*].

Anticoagulants and NSAIDs/Aspirin: Coadministration of enoxaparin, warfarin, aspirin, clopidogrel and chronic NSAID use may increase the risk of bleeding [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

Avoid concurrent use of XARELTO with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs [see *Warnings and Precautions*].

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: The limited available data on XARELTO in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO for the mother and possible risks to the fetus when prescribing XARELTO to a pregnant woman [see *Warnings and Precautions*].

Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Clinical Considerations: *Disease-Associated Maternal and/or Embryo/Fetal Risk:* Pregnancy is a risk factor for venous thromboembolism and that risk is increased in women with inherited or acquired thrombophilias. Pregnant women with thromboembolic disease have an increased risk of maternal complications including pre-eclampsia. Maternal thromboembolic disease increases the risk for intrauterine growth restriction, placental abruption and early and late pregnancy loss.

Fetal/Neonatal Adverse Reactions: Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.

Labor or Delivery: All patients receiving anticoagulants, including pregnant women, are at risk for bleeding and this risk may be increased during labor or delivery [see *Warnings and Precautions*]. The risk of bleeding should be balanced with the risk of thrombotic events when considering the use of XARELTO in this setting.

Data: Human Data: There are no adequate or well-controlled studies of XARELTO in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage. In an *in vitro* placenta perfusion model, unbound rivaroxaban was rapidly transferred across the human placenta.

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Animal Data: Rivaroxaban crosses the placenta in animals. Rivaroxaban increased fetal toxicity (increased resorptions, decreased number of live fetuses, and decreased fetal body weight) when pregnant rabbits were given oral doses of ≥10 mg/kg rivaroxaban during the period of organogenesis. This dose corresponds to about 4 times the human exposure of unbound drug, based on AUC comparisons at the highest recommended human dose of 20 mg/day. Fetal body weights decreased when pregnant rats were given oral doses of 120 mg/kg during the period of organogenesis. This dose corresponds to about 14 times the human exposure of unbound drug. In rats, peripartur maternal bleeding and maternal and fetal death occurred at the rivaroxaban dose of 40 mg/kg (about 6 times maximum human exposure of the unbound drug at the human dose of 20 mg/day).

Lactation: Risk Summary: Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. Rivaroxaban and/or its metabolites were present in the milk of rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XARELTO and any potential adverse effects on the breastfed infant from XARELTO or from the underlying maternal condition [see *Data*].

Data: Animal data: Following a single oral administration of 3 mg/kg of radioactive [¹⁴C]-rivaroxaban to lactating rats between Day 8 to 10 postpartum, the concentration of total radioactivity was determined in milk samples collected up to 32 hours post-dose. The estimated amount of radioactivity excreted with milk within 32 hours after administration was 2.1% of the maternal dose.

Females and Males of Reproductive Potential: Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in the RECORD 1-3 clinical studies evaluating XARELTO, about 54% were 65 years and over, while about 15% were >75 years. In ROCKET AF, approximately 77% were 65 years and over and about 38% were >75 years. In the EINSTEIN DVT, PE and Extension clinical studies approximately 37% were 65 years and over and about 16% were >75 years. In EINSTEIN CHOICE, approximately 39% were 65 years and over and about 12% were >75 years. In clinical trials the efficacy of XARELTO in the elderly (65 years or older) was similar to that seen in patients younger than 65 years. Both thrombotic and bleeding event rates were higher in these older patients, but the risk-benefit profile was favorable in all age groups [see *Clinical Pharmacology (12.3) and Clinical Studies (14) in full Prescribing Information*].

Renal Impairment: In pharmacokinetic studies, compared to healthy subjects with normal creatinine clearance, rivaroxaban exposure increased by approximately 44 to 64% in subjects with renal impairment. Increases in pharmacodynamic effects were also observed [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, patients with CrCl 30 to 50 mL/min were administered XARELTO 15 mg once daily resulting in serum concentrations of rivaroxaban and clinical outcomes similar to those in patients with better renal function administered XARELTO 20 mg once daily. Patients with CrCl 15 to 30 mL/min were not studied, but administration of XARELTO 15 mg once daily is also expected to result in serum concentrations of rivaroxaban similar to those in patients with normal renal function [see *Dosage and Administration (2.4) and Clinical Pharmacology (12.3) in full Prescribing Information*].

Patients with End-Stage Renal Disease on Dialysis: Clinical efficacy and safety studies with XARELTO did not enroll patients with end-stage renal disease (ESRD) on dialysis. In patients with ESRD maintained on intermittent hemodialysis, administration of XARELTO 15 mg once daily will result in concentrations of rivaroxaban and pharmacodynamic activity similar to those observed in the ROCKET AF study [see *Clinical Pharmacology (12.2, 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 ROCKET AF.

Treatment of DVT and/or PE and Reduction in the Risk of Recurrence of DVT and/or PE : In the EINSTEIN trials, patients with CrCl values <30 mL/min at screening were excluded from the studies. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Prophylaxis of DVT Following Hip or Knee Replacement Surgery: The combined analysis of the RECORD 1-3 clinical efficacy studies did not show an increase in bleeding risk for patients with CrCl 30 to 50 mL/min and reported a possible increase in total venous thromboemboli in this population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Hepatic Impairment: In a pharmacokinetic study, compared to healthy subjects with normal liver function, AUC increases of 127% were observed in subjects with moderate hepatic impairment (Child-Pugh B).

The safety or PK of XARELTO in patients with severe hepatic impairment (Child-Pugh C) has not been evaluated [see *Clinical Pharmacology (12.3) in full Prescribing Information*].

Avoid the use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy.

OVERDOSAGE

Overdose of XARELTO may lead to hemorrhage. Discontinue XARELTO and initiate appropriate therapy if bleeding complications associated with overdose occur. A specific antidote for rivaroxaban is not available. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. The use of activated charcoal to reduce absorption in case of XARELTO overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable [see *Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information*]. Partial reversal of laboratory anticoagulation parameters may be achieved with use of plasma products.

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UPDATES AND ALERTS FROM ACEP

How is ACEP Directly Affecting Your Practice?

ACEP leadership and staff works every day to make change at the highest levels that will affect all levels of your practice. Catch up on what leadership has done for you lately in the Leadership Report (acep.org/leadershipreport).



Dr. Mark Rosenberg (left) and Dr. Alexis LaPietra developed the Alternatives to Opioids protocol at St. Joseph's Regional Medical Center.

ACEP Board of Directors member Mark S. Rosenberg, DO, MBA, FACEP, has been appointed to the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force (PTMF). The PTMF was created to determine whether there are gaps or inconsistencies in pain management best practices among federal agencies and propose recommendations for addressing identified gaps and/or inconsistencies.

ACEP and the Centers for Medicare and Medicaid Services (CMS) Center for Clinical Standards and Quality (CCSQ) met on March 1 to discuss quality measures policy, process, and the future vision for CMS' approach to meaningful measures. The meeting was very productive and provided insight to the ACEP team in preparation for developing the next generation of quality measures, validating existing measures, and assessing their applicability to ACEP's Quality Clinical Data Registry, known as Clinical Emergency Data Registry (CEDR).



Laura Wooster, ACEP's associate executive director of public affairs, represented ACEP in a day-long meeting in Washington, D.C., held by HHS' Assistant Secretary for Preparedness and Response, Robert Kadlec, MD, to gain stakeholder input on how to implement his vision for a national medical disaster system. Dr. Kadlec will be sharing more on this vision when he joins ACEP's Public Policy Town Hall during the Leadership and Advocacy Conference on May 21.

ACEP Board member Jon Mark Hirshon MD, PhD, MPH, FACEP, participated in a roundtable held by the House Ways & Means Health Subcommittee on its "Red Tape Initiative" to reduce provider administrative burdens. Dr. Hirshon talked about administrative burdens in the Medicare program that impact emergency physicians and provided recommendations for addressing them.

Last month, ACEP joined with the American Hospital Association and the American



ACEP leaders Alison Haddock, MD, FACEP, and Jay Kaplan, MD, FACEP, in a video ACEP created to bring attention to the Anthem policy that challenges prudent layperson. Watch it at youtube.com/watch?v=ddiQwA4aUi0.

College of Radiology in a joint letter to Anthem Chief Clinical Officer Craig Sammit, MD, to state concerns with the insurer's policy retroactively denying coverage for emergency visits it deems as non-emergent. ACEP also has worked closely on the Anthem issue with Senators Ben Cardin of Maryland and Claire McCaskill of Missouri, who wrote a joint letter to HHS Secretary Alex Azar and Department of Labor Secretary Alexander Acosta expressing concerns about the Anthem policy and seeking information on whether it violates federal laws or regulations.

Last week, two emergency medicine opioid bills that ACEP was heavily involved in developing were introduced in Congress. The "Alternatives to Opioids (ALTO) in the Emergency Department Act" would provide \$30 million (over three years) to establish a demonstration program to nationally test the ALTO protocol developed at St. Joseph's Regional Medical in Paterson, New Jersey, by Dr. Rosenberg and Alexis M. LaPietra, DO, medical director of emergency medicine pain management at St. Joseph's. The program uses alternative pain management protocols to limit the use of opioids in the emergency department. Additionally, the "Preventing Overdoses While in Emergency Rooms (POWER) Act" would provide \$50 million (over five years) in grants to establish policies and procedures for administering medication-assisted treatment (MAT) in the emergency department to opioid overdose patients with subsequent referral to community providers.

ACEP President, Paul Kivela, MD, MBA, FACEP, was formally invited by the National Academy of Sciences (NAS) to participate in a panel to discuss "Leading Changes at the Ground Level" of clinical medicine/healthcare administration at the workshop titled, "Engaging the Private Sector Health Care System in Building Capacity to Respond to Threats to the Public's Health and National Security." Dr. Kivela worked with ACEP's EMS and Disaster Sections for his discussions. ➔



Dr. Jon Mark Hirshon, a member of ACEP's Board of Directors, speaking at the House Ways and Means Health Subcommittee.

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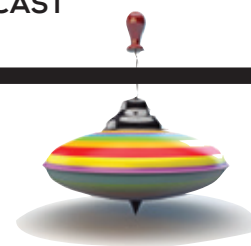
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A NEW SPIN



DID THE ACA REDUCE ED USE?

Increasing access to insurance coverage alone does not lead to a decrease in ED visits

by CEDRIC DARK, MD, MPH; ERIC MAUGHAN, MD;
AND R.J. SONTAG, MD

Will increasing access to health insurance decrease ED utilization by increasing access to primary care providers (PCPs)? On the other hand, does having health insurance make people more likely to visit the emergency department? These questions have important implications for ED capacity, quality of care, and future funding models.

When the Affordable Care Act (ACA) became law, differing opinions emerged about how it might affect ED utilization. Some argued that more insured patients would lead to better access to outpatient care, reducing the need for emergency care, as was seen in Massachusetts following the pre-ACA roll-out of their own state's health insurance expansion (Romney-care).¹ Others contended that more access to care would mean more usage of all types of care, resulting in increased ED visits, as 75 percent of emergency physicians believe.²

ED Usage in Illinois

A recent study, an analysis of ED use before and after Affordable Care Act (ACA) implementation in Illinois, provides evidence against the assumption that ED use would decrease as newly-insured patients received care from PCPs instead of the emergency department, leading to more efficient and less costly health care.³ The authors analyzed ED visits across Illinois from 2011 to 2015, comprising 36 months prior to and 24 months following ACA implementation. Although the number of ED visits by uninsured patients dropped, visits by Medicaid and private insurance patients increased more substantially, leading overall to a 5.7 percent increase in ED usage. Meanwhile, visit acuity appeared to remain constant, as the number of hospitalizations through the emergency department was essentially unchanged throughout the study period.

This study indicates that increasing access to insurance alone does not lead to a decrease in ED visits, and similar results have been found in Massachusetts, Oregon, Kentucky, and Colorado.⁴⁻⁶ A program in Virginia offers an interesting alternative where, in addition to receiving health care, patients were assigned to PCPs.⁷ Although these PCPs were paid at rates higher than those offered by Medicaid, cost per patient had decreased significantly after three years of the program.

These potentially counterintuitive results highlight the complexity of health care reform. While providing health insurance may lead to fewer ED visits for some patients (ie, young adults), that effect does not hold universally. Of course, this immediate increase in ED use may be an anomaly in a long-term trend toward less ED use, though studies from Oregon have shown this effect to be long lasting.⁸ Additionally, there may be benefits to health insurance (ie, financial security, increased PCP visits, or potentially improved overall health) that are not captured in this study. However, while removing financial barriers to receiving care is likely an important part of reforming our health care system, this study indicates that health insurance expansion alone is unlikely to lead to more efficient health care delivery through reduced ED usage.

ED Utilization Trends

Another study investigated changes in ED utilization rates at a national level based on the hypothesis that increases in



Medicaid-covered populations would result in proportional increases in ED visits.⁹ They also predicted a change in the payer mix that would result in fewer uninsured visits and more Medicaid-covered visits. States that opted not to expand Medicare coverage under the ACA served as the control group.

Overall, the authors estimated 10 additional ED visits per 1,000 people. As predicted, Medicaid expansion resulted in more visits by patients with Medicaid. The proportion of visits covered by Medicaid increased from 35 percent pre-ACA to 48 percent during the study. The authors argue that some of this increase may be temporarily caused by pent-up demand from patients who needed health care but could not afford it prior to the ACA. A reciprocal decrease in the proportion of uninsured visits was noted (from 23 percent down to 11 percent).

Further analyzing the data provides interesting insights into the chief complaints that became more common for patients with Medicaid. The largest increases were for dental and mental health visits, which aligns with the disproportionate number of Medicaid-eligible patients who report less than excellent mental health.¹⁰

Naturally, increased visits raise questions about the effects on emergency departments. Without an increase in capacity, more visits may mean overcrowding, decreased quality of care, and worse patient outcomes. Changes in payer mix affect the hospital's bottom line, since Medicaid generally reimburses less than private insurance. However, Medicaid reimbursement is higher than that from self-pay patients. Furthermore, recognizing that there are fewer uninsured patients, the ACA reduces payments for hospitals serving a disproportionately high level of uninsured patients.¹¹ The balance of these clinical and financial forces should continue to be explored. ➕

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presenting from 6–24 hours of symptom onset have improved 90-day outcomes after mechanical thrombectomy compared to medical therapy alone.¹

The DEFUSE3 trial showed similar results of improved outcomes with endovascular thrombectomy for ischemic stroke patients 6–16 hours after they were last known to be well.² The patients best served featured proximal middle-cerebral-artery or internal-carotid-artery occlusion, and a region of tissue that was ischemic but not yet infarcted.

This evolving treatment paradigm, while groundbreaking, requires new emergency department and collaborative workflows to identify appropriate stroke patients and activate the correct treatment pathway.

A New Stroke Protocol

Stanford University's department of emergency medicine collaborated closely with other departments to develop a novel Stroke Code Extended protocol that expedites evaluation and treatment of patients with large-vessel debilitating strokes that, prior to the protocol, would have limited treatment options. The protocol was crafted by a multidisciplinary team of stakeholders from the departments of neurology, emergency medicine, nursing, radiology, and hospital staff. We designed and

implemented the new stroke code process using quality improvement principles, such as adherence to standard work, pre-existing protocol preservation, planned outcome measures, and widespread education. Mock code simulations provided iterative feedback before we launched the process.

The team created the protocol for patients presenting with stroke symptoms at 8–24 hours *without* changing the pre-existing code process for patients presenting before 8 hours. Emergency physicians rapidly triage and activate all stroke codes if the patient presents as greater than or equal to 6 on the National Institutes of Health Stroke Scale (NIHSS). However, the new protocol excludes a bedside pharmacy evaluation and moves directly to alerting the stroke team to come to the patient's bedside in the emergency department. **[Editor's Note: Visit ACEPNow.com to see a flowchart of Stanford's new stroke protocol.]**

Other unique protocol elements include expedited CT angiogram and perfusion imaging, and mobilization of the interventional neuro-radiology team for thrombectomy. The CT angiogram and perfusion imaging is critical in determining the amount of brain tissue at risk of infarct, and therefore whether thrombectomy would be indicated. To determine patients appropriate for thrombectomy with adequate

salvageable tissue, the team looks at the ratio of ischemic tissue to the initial infarct volume (ischemic core), and an absolute volume of potentially reversible ischemia (penumbra).

The Stroke Code Extended also requires the emergency department attending to perform and document a NIHSS score on all suspected stroke patients. Although this is a core emergency medicine skill, Stanford instituted an educational initiative to certify our entire faculty and residency in performing the assessment. This was accomplished through online training modules and traditional lecture-style didactics.

In addition, immediately upon arrival at the bedside, the neurology resident now performs an NIHSS stroke scale assessment. Our goal is to study the inter-rater reliability between neurology- and emergency medicine-completed NIHSS stroke scales.

Beyond the New Protocol

Parallel to our initiative to identify and treat extended strokes, Stanford's neurology department has performed significant educational outreach to referral hospitals to facilitate the rapid transport of stroke patients to Stanford Hospital even if they're outside the tPA window but still likely to benefit from thrombectomy. In addition, the Stanford School of Medicine has found that collaboration between the emergency medicine and neurology departments is instrumental in improving the treatment of acute stroke.

Looking ahead, we will evaluate the implementation of this protocol by collecting stroke quality metrics, measuring NIHSS inter-rater reliability, and monitoring the stroke mimic rate. We look forward to sharing further insights about our protocol and results. ➔

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Smashing the EM Glass Ceiling

The path to leadership in the 70s

by PAMELA P. BENSEN, MD, MS, FACEP

I started attending ACEP Board of Directors (BOD) meetings in 1971 when Ron Krome, MD, invited me to the BOD meeting in Miami. He introduced me as the first intern in emergency medicine and got the board to add me to the Undergraduate Education Committee as their first resident representative, a commitment to residents that continues today. ACEP was small then, about 300 members, and I met all the leaders and staff attending that third Scientific Assembly. I was hooked on ACEP.

I met new members as the college grew and was appointed to at least one ACEP committee every year. When the Council was created, I became the Maine Councillor, joining four other women on the Council floor. Seldom one to keep my opinions

to myself, I spoke up at meetings and stayed in touch with the staff, board, and committee members.

So, imagine the thrill of answering the phone and hearing an ACEP Past President ask you to run for the ACEP BOD. Funny thing was, I never planned to run for the board until Karl Mangold, MD, called to ask me if the nominating committee could put my name on the ballot. I was overwhelmed and honored; my head grew three sizes that day.

Without another thought, I told him, "Of course, I would be delighted to run."

Later, I explained to my husband, Kork, that no one got elected to the board on the first try, so we didn't need to worry about the impact my rash answer would have on our young family or my job. We had two kids under seven and a house with a 100-percent mortgage. I had a 24-hours-on-3-days-off clinical job, a 30 hours a week unpaid ED directorship, a volunteer EMS teacher-director position, ACEP committee assignments, and I was co-chairing the community 911 committee. Kork had just returned to work on tug boats after a two-year bout with Epstein-Barr virus-induced kidney and liver failure, a Guillain-Barre-like peripheral neuropathy, and was battling an addiction to corticosteroids.

Running for the Board Back Then

Being a board candidate was very different in the 70s. Campaigns were inexpensive and laid back. I did not have to travel to state chapter meetings—many states didn't even have meetings. I only had to answer written questions and attend by-invitation-only big-state-chapter cocktail parties, which were held at the Scientific Assembly, to meet Councillors who didn't know me.

In 1973, the board had appointed Ellen Taliaferro, MD, FACEP, to serve out the board term of Stanley Gold, MD, when he resigned for health reasons. At age five, ACEP had its

first woman board member. We never even thought about a glass ceiling—obviously there was not one.

However, it didn't last. When Ellen ran for the seat she already occupied at the will of the board, the Council did not elect her. The Board had accepted women in leadership, but the Council had not.

As predicted, I lost that first election, the second, and the third. My years as a candidate were separated by years when three other women, Elizabeth Fields, MD, Dr. Taliaferro, and Vera Morkovin, MD, were nominated. They, too, lost their elections.

President after president put me on committees. As my experience increased, I was asked to chair committees. Year after year, I sat on the Council. Every two or three years the nominating committee would ask me to run for the board. Ever the optimist, I kept saying yes, and kept losing.

The year I ran and lost for the fourth time, I was greeted at the post-Council reception by a fellow Councillor. He commiserated that I was the most qualified candidate, "But, you know us southern gentlemen, we jus' couldn't vote for a woman." I was saved from assault and battery charges because my right arm, linked in my husband's, was suddenly immobilized by his.

The nominating committee did not skip a beat. The very next year, they asked me to run again. I was not, as I assured them, a glutton for punishment; I refused. I relented only after three members of the committee called to assure me I was not being asked to be the token female, destined to be led to rejection once again. The committee had discussed the gender situation and my qualifications and was sure I would be elected.

My fifth campaign was different. I decided to confront the gender issue head on. I wanted to make sure the Council saw their glass ceiling. At the meet-the-candidates forum, which had been co-opted from the small chapters event I had started, we were asked what we brought to the board that no one else had. I responded, "I bring a broad perspective," listed my ACEP committee history, detailed the projects I had worked on for the College, and finished my answer with "and I have more estrogen than anyone else running." My serious humor did get a good laugh.

For my closing remarks, at the risk of offending my southern colleague who "jus' couldn't vote for a woman," I repeated that story from my previous loss. I concluded with, "I'm not asking you to vote for me because I am a woman, I am asking you not to vote against me because I am a woman." And this time, I won. In 1982, when ACEP was 14 years old, after five tries, I became the first woman **elected** to the ACEP Board of Directors. Since then, at least one woman has served on the board each year. ☺

DR. BENSEN is president of Medical Education Programs in Buffalo Junction, Virginia.



PHOTOS: ACEP

"I'm not asking you to vote for me because I am a woman, I am asking you not to vote against me because I am a woman."

—Pamela P. Bensen, MD, MS, FACEP



Pamela Bensen, MD, MS, FACEP, the first ever EM Intern in 1971, as seen in the documentary 24/7/365.



Pamela Bensen, MD, MS, FACEP receiving the Council Meritorious Service Award from ACEP cofounder John A. Rupke, MD.

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by PAUL KIVELA, MD, FACEP, ACEP PRESIDENT

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One Board member is under 40, and five are 60 or older. Nearly all geographic areas of the country are represented.

In addition to being attending physicians, there are seven Board members who hold academic physician positions. Some are emergency department directors or EMS directors. Others hold various emergency medicine administration positions in addition to their practice.

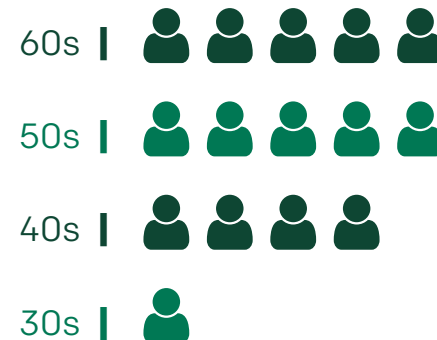
They come from a variety of practice settings, including small independent groups, large emergency physician groups, community hospitals, urban trauma centers, university academic institutions, military hospitals, freestanding emergency departments, and even one rural setting. Members of our Board understand the practice environments of our members.

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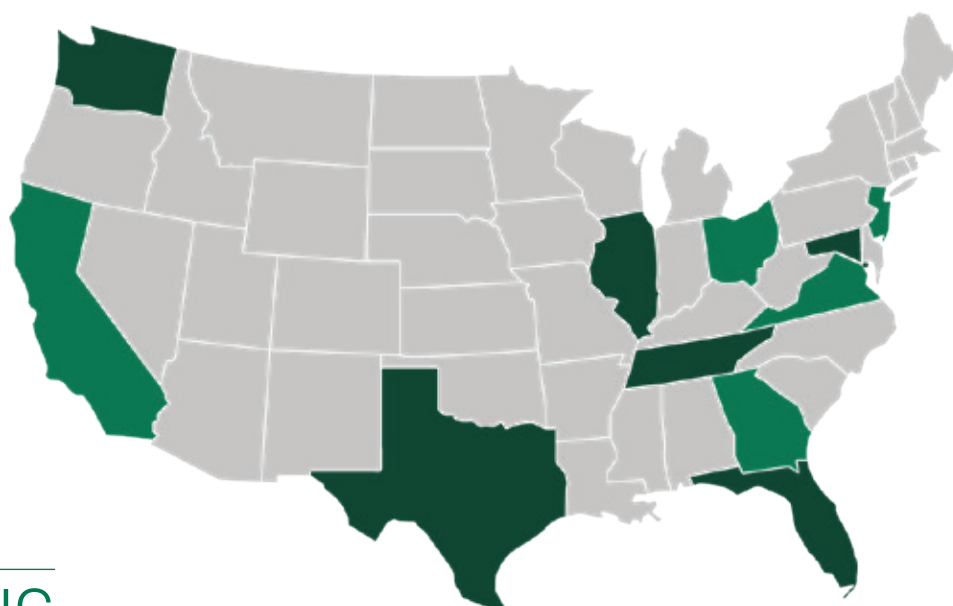
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FBI Expert Discusses How ED Staff Can Spot and Help Human Trafficking Victims

Human trafficking is an incredibly challenging problem to solve because it hides in the shadows. Not only are traffickers motivated to keep their activities under the radar of law enforcement, but often victims are, too. Cynthia M. Deitle, JD, spent two decades with the FBI's civil rights program, which includes a program to combat human trafficking. Her experience ranged from working on individual trafficking cases to being chief of the civil rights unit, giving her a broad understanding of the trafficking problem in the United States and the bureau's efforts to combat it. She recently sat down with *ACEP Now* Medical Editor-in-Chief Kevin Klauer, DO, EJD, FACEP, to talk about some of the challenges she faced while trying to help trafficking victims, and what emergency department staff can use to try to help suspected victims. Here's an excerpt from that conversation. Visit ACEPNow.com to read Parts 1 and 2 of the interview.

KK: Once we have the possible victim alone, should we be very direct or a bit more tangential with our questions?

CD: This will be one of those answers every lawyer and doctor hates: It depends. It depends on the person asking the questions. If

you have one of your nurses in the ER who has been there for 20 years, and she is phenomenal at getting victims of domestic violence and human trafficking to talk to her due to a slow, methodical and caring approach, then you let her do it her way. Or you may have other people just come right out and say, "Honey, who is that guy in the waiting room, he's not your husband. What is going on?" And that might work. It's very personally driven, and it's very situation specific. Go with your strength.

As an FBI agent, I've been in ERs and I know that intake questioning list can be fine-tuned to get at the trafficking situation. "So, are you safe in your home?" She will lie to you and say, "Yes." If you just keep drilling into her domestic situation, you might be able to get at it. "So who lives in your home with you?" Well, right away, Kevin, that presumes she has a home. These domestic trafficking victims don't have a home. They go from hotel to hotel to hotel. "Are you safe in your home? Where do you live? How long have you lived there? Do you rent?" Really try to delve into tripping her up in the answers and getting her to admit what's going on. That's really the key, along with asking her who else you should call. "Is there a grandmother, an aunt, a teacher? Is there somebody else I can call who can come down and be with you? You don't have to stay with him." +

Communication Tips for Reaching Your Opioid-Addicted Patients



by R. COREY WALLER MD, MS, FACEP, DFASAM; AND EVAN SCHWARZ, MD, FACEP, FACMT

Editor's Note: This is the second part of an ongoing series on what emergency physicians can do to combat the opioid epidemic. The series will continue in the June issue.

You're in the midst of a busy shift trying to balance multiple patients when a nurse suddenly grabs you for an unconscious 30-year-old male pulled from a car with agonal respirations. You begin to bag him while ordering a dose of intramuscular naloxone. Within minutes, the patient starts to breathe, sits up confused, and tries to get off the gurney. Before you can blink, someone tells him, "Lay back down, and by the way, you're welcome for saving your life." The situation deteriorates, and both you and the patient leave the encounter dissatisfied, to put it mildly. Later you wonder if things could have played out differently.

It's probably fair to say we've all experienced a similar encounter. Instead of receiving an appreciative "thank you" and

plugging the patient into treatment, it ends with yelling and the patient suddenly walking out while you wonder if it's safe for them to do so. It's easy to assume a near-death encounter would motivate patients to change. But if overcoming addiction were this "easy," no one would ever need a second dose of naloxone. Unfortunately, nearly dying does not always move someone with an opioid-use disorder to the action phase no matter how much we'd like it to.

As such, we must meet the person where they are. If they are ready to change, great! But if they aren't, us pushing remains unlikely to move them, and a change of approach may prove necessary.

Visit ACEPNow.com to learn about adding motivational interviewing techniques to your toolbox for dealing with patients struggling with addiction. +

SEND US YOUR QUESTIONS!

In future articles in this series, we will delineate the best practices for treatment and approach in the emergency department. If you have questions or ideas, feel free to send them our way at schwarze@wustl.edu.

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DNR TATTOO | CONTINUED FROM PAGE 1

Resuscitate” was tattooed across his anterior chest wall, accompanied by his presumed signature.

Without the guidance of next of kin or advanced directive paperwork, the health care team initially decided not to honor the DNR tattoo. However, they later reversed their decision and honored the tattoo after an ethics consultation. The ethics consultants concluded that the tattoo could be presumed to represent the patient’s authentic preferences and that the “law is sometimes not nimble enough to support patient-centered care and respect for patients’ best interest.” The conclusion of the ethics consultants should not set a precedent for future similar cases, as the DNR tattoo was neither legally nor ethically sufficient to guide medical care.

Before delving into the specific insufficiencies of the tattoo, it is useful to review advance care planning (ACP). There are two main forms of ACP documents: advance directives (AD) and physician orders for life sustaining treatment (POLST). ADs are legal documents that can be completed at any time in life to guide future care and/or appoint a surrogate decision maker. ADs must be completed by the person (him/herself) and require either a witness or notary, depending on the state. POLST forms are physician orders for end-of-life (EOL) care designed to be transferred among health care institutions. They are for patients who are seriously ill or frail who are near the EOL and can be completed with the assistance of a surrogate. Table 1 summarizes the differences between ADs and POLST.

The “Do Not Resuscitate” tattoo in the article is neither legally nor ethically sufficient to guide medical care for the following reasons:

1. Tattoos are not legal ADs nor POLST, which are the two ACP documents transferrable among institutions in the United

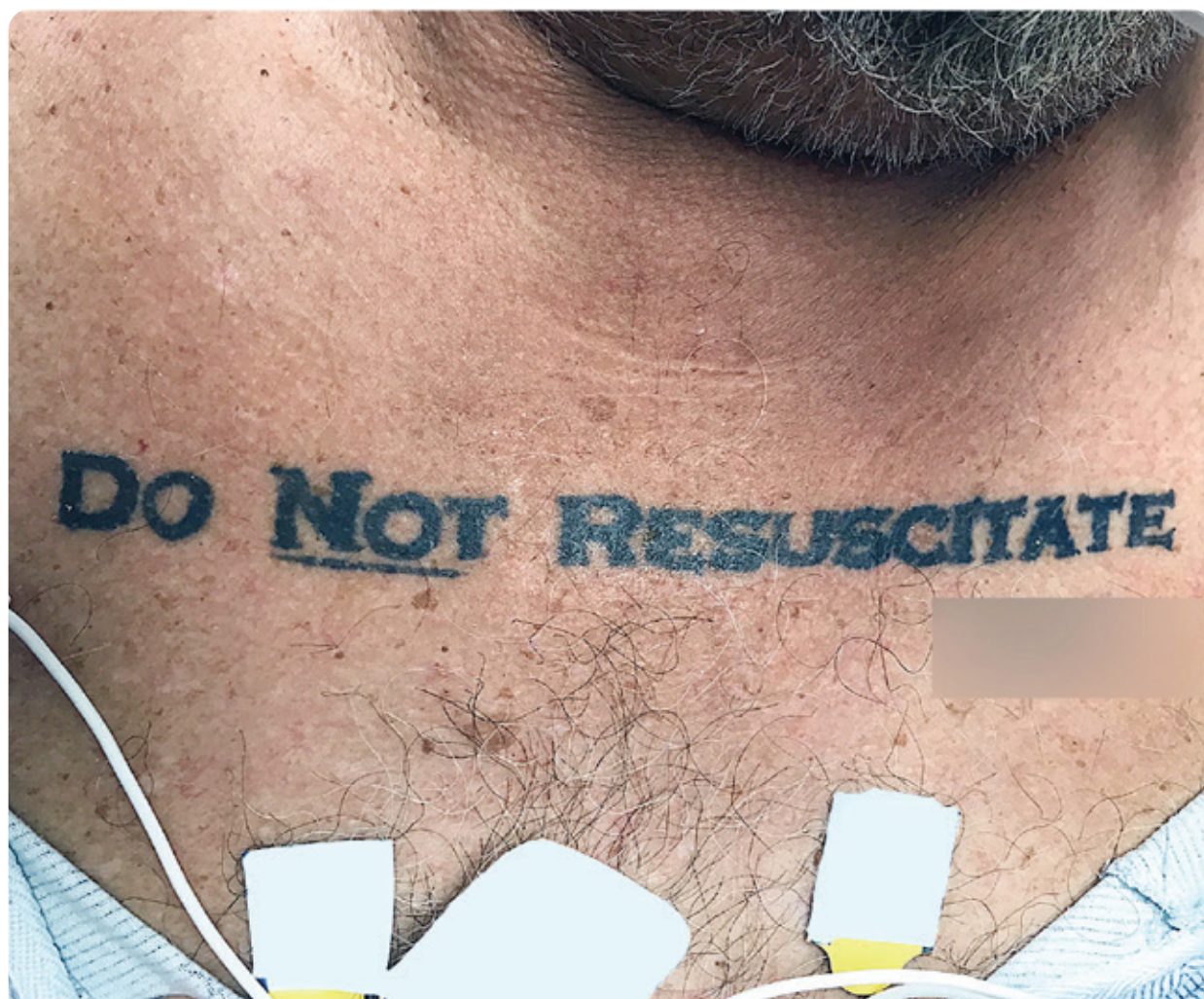
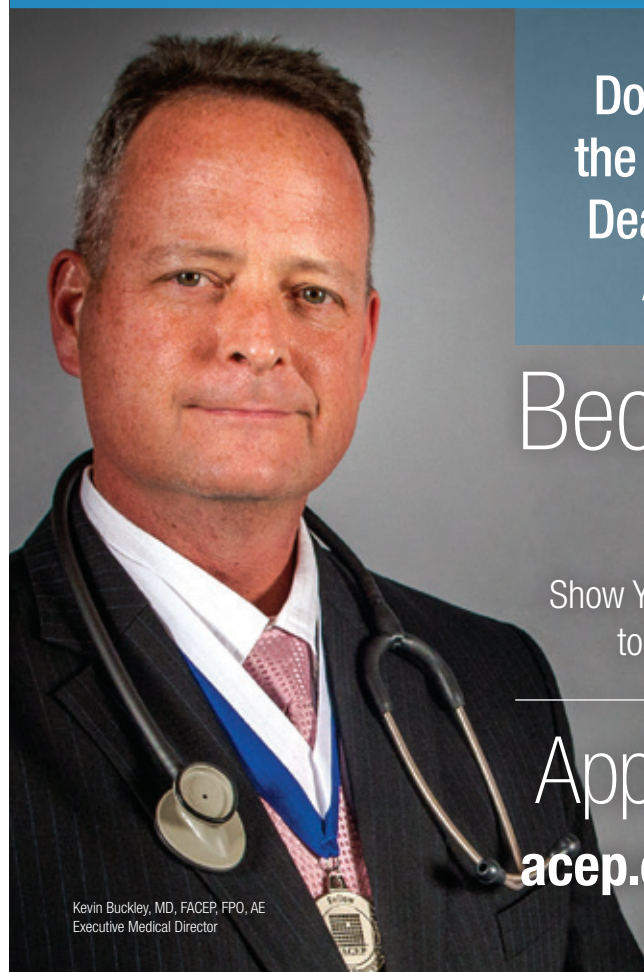


Figure 1: Photograph of the patient's tattoo.

CONTINUED on page 16

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States. The tattoo cannot be considered a wearable AD, as it does not include a witness or notary to complete the legal documentation.

2. Informed decision-making cannot be presumed. Studies have reported that patients have a poor understanding of EOL care terminology, and only about half of emergency department patients surveyed had a correct understanding of the term “Do Not Resuscitate.”² There is no evidence that the tattoo indicates a clear understanding of a DNR status.

3. The tattoo contains insufficient information to guide medical treatment. Does the patient mean no chest compressions, no intubation, no vasopressors? ADs and POLSTs clarify preferences so that providers can better interpret patient wishes, although confusion may still arise as to whether specific interventions are desired.

4. EOL care preferences are dynamic. Depending on factors such as age, health status, prognosis, and advancement of medical technology, a person’s EOL preferences may change.³ In contrast to a tattoo, ADs and POLST forms may be easily amended to reflect a patient’s current wishes.

5. Tattoo regret is common. More than 50 percent of individuals later regret their tattoos.⁴ The most frequent motivation for tattoo removal is poor decision making, often the result of intoxication, leading to subsequent regret. A case report of a DNR tattoo that did not represent a patient’s current wishes has previously been reported.⁵

An important ethical principle for emergency physicians to consider is that withholding and withdrawing life-sustaining treatment are considered ethically equivalent. Therefore, when faced with ambiguity regarding a patient’s wishes, emergency physicians should proceed with life-saving interventions. When further information is obtained, the patient’s care can be appropriately de-escalated in accordance with their preferences.

Table 1: Comparison of ADs and POLST

	AD	POLST
Document type	Legal document	Physician orders
Purpose	Guide EOL care and/or appoint a surrogate	Give medical orders for EOL care
For whom	All adults	Patients near the EOL
Time of completion	Any time	Near the EOL
Decision-maker	The person him/herself	Patient or surrogate
Additional requirements	Witness(es) or notary (state dependent)	Physician signature

A default to proceeding with life-sustaining measures does not mean that tattoos or other non-standard means of communicating preferences should be ignored. The tattoo, an alternative form of communication, should be used as piece of information in the decision-making process. A major limitation of AD and POLST documents is that in most states they must physically accompany the patient and are often not available when providers are making key decisions.

Some states, such as Oregon and California, have electronic databases that providers can access, but the lack of this type of accessible database may cause patients to be concerned that their wishes may not be known. In our era of smartphones, patients should be encouraged to enter “ICE” (In Case of Emergency) data into their phones, which can include medical information and emergency contacts. Emergency providers should

also be encouraged to routinely search for available ICE data on the phones of incapacitated patients. +

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ACEP17 Research Forum in Review

GAME CHANGERS AND OTHER KEY STUDIES

by ALEXANDER T. LIMKAKENG, JR., MD, MHSC, FACEP; AND JOSEPH S. PIKTEL, MD, FACEP

The ACEP Research Forum, held at our annual scientific meeting, focuses on cutting edge research. In 2017, the forum included outstanding expert state-of-the-art talks on how research is incorporated into clinical practice guidelines and how landmark articles come into being. There was also a session including legislators and researchers discussing the opioid crisis. This article highlights just a few of the research abstracts that may help your practice.

You can find all the abstracts presented at the ACEP17 Research Forum in *Annals of Emergency Medicine's* October 2017 supplement.

Multicenter Trial of Rivaroxaban for Early Discharge of Pulmonary Embolism From the Emergency Department (MERCURY-PE)

Peacock W, Diercks D, Francis S, et al

This multicenter, prospective, open label, randomized clinical trial sought to determine what happens to low risk pulmonary embolism (PE) patients who are discharged home straight from the emergency department with rivaroxaban compared to standard care (SC; observation unit stay or inpatient admission). Not surprisingly, mean total hospital days (for any reason) at 90 days after randomization were significantly less for rivaroxaban than SC; 0.8 versus 1.8 days. The composite safety endpoint was similar in both groups. This industry-funded study suggests that carefully selected patients with PE can be managed as outpatients from the emergency department.

Trends in Site of Care for Low-Acuity Conditions Among Those with Commercial Insurance, 2008–2015

Poon SJ, Schuur JD, Mehrotra A

This study examined an insurance database for visits related to three low-acuity complaints. They found not only that emergency departments were seeing a decreasing proportion of these types of visits, but also that this decrease was due to an increase in “new” visits to urgent care and retail clinics (additive visits, not substitution). Thus, these clinics

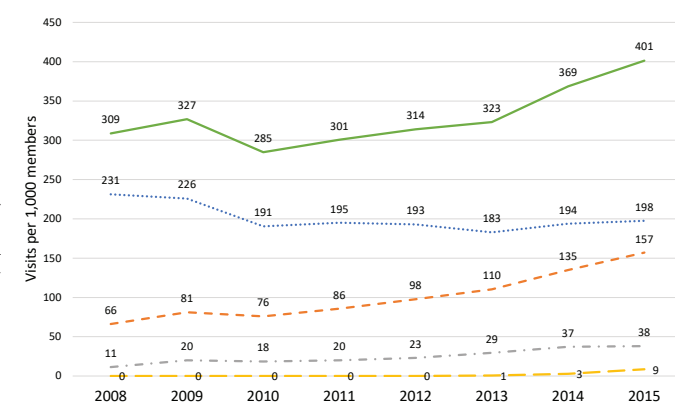


FIGURE 1: Visit rates to acute care venues for all conditions, 2008–2015. ED=emergency department; UC=urgent care; RC=retail clinics; Tele=telehealth.

did not “steal” visits from the emergency department, but “created” visits through supply-induced demand.

Association of State Gun Laws with Pediatric Mortality from Firearms

Patel SJ, Badolato G, Parikh K, et al

In this politically timely abstract, the authors analyzed Centers for Disease Control and Prevention (CDC) data for firearm-related mortality in children 0–21 years of age and measured whether there was a relationship to state-specific Brady Campaign Gun Law Scores for 2015. The CDC noted that 4,528 children died from firearm-related injuries in 2015. Higher pediatric mortality rates were associated with lower (less strict) state-specific gun law scores. More specifically, median mortality rates were lower among the 12 states requiring universal background checks for firearm purchase (3.8 versus 5.7 per 100,000 children) and ammunition (2.3 versus 5.6 per 100,000 children). Although observational, these data provide the best available evidence to guide policy development.

Effect of SEP-1 Core Measure Compliance on Mortality and Hospital Length of Stay

E.A. Gross, G. McGlynn

Fluid Resuscitation of Septic Patients at Risk for Fluid Overload

M. Akhter, M. Hallare, A. Roontiva, et al

We’ve all seen this patient: past medical history of congestive heart failure (CHF) and creatinine of 5.6 who presents in septic shock. The much-discussed SEP-1 quality metric mandates an intravenous fluid bolus (30 ml/kg), but clinicians fear causing pulmonary edema, leading to a need for intubation. These two abstracts look at institutional databases and found that even in patients with CHF and end-stage renal disease (ESRD), following SEP-1 decreased mortality. Furthermore, there was no increase in intubation in septic patients with CHF and ESRD when clinicians followed SEP-1. While noting, once again, the caveat of observational data and likely inclusion bias, this still provides some reassurance to providers caring for septic patients with CHF or ESRD.

A Randomized Study of Naproxen Plus Placebo, Orphenadrine, or Methocarbamol for Acute Low Back Pain

Friedman BW, Irizarry, E, Solorzano, C, et al

Back pain continues to be a common reason for ED visits, and Dr. Friedman and colleagues continue to search for effective treatments. This double-blind trial randomized patients to receive naproxen plus a one-week supply of either orphenadrine (Norflex) 100mg, methocarbamol (Robax-



in) 750mg, or placebo. Unfortunately, 34 percent of naproxen+placebo patients reported moderate or severe low back pain versus 33 percent of naproxen+orphenadrine and 39 percent of naproxen+ methocarbamol patients. This study reinforces an approach that emphasizes nonsteroidal anti-inflammatory drugs and education for patients with musculoskeletal back pain.

Do Intranasal Vasoconstrictors Increase Blood Pressure?

Bellew SD, Johnson KL, Kummer T

This study calls to mind another common ED scenario: the epistaxis patient with severe hypertension. In this elegant randomized, double-blinded, placebo-controlled trial, a convenience sample of patients was assigned to one of four arms: phenylephrine 0.25%, oxymetazoline 0.05%, lidocaine 1% with epinephrine 1:100,000, or bacteriostatic 0.9% sodium chloride in cotton soaked nasal pledgets. They did not find any changes in blood pressure over the 30 minutes after drug administration between any of the arms. This suggests that vasoconstrictors cause minimal acute blood pressure changes when applied nasally via soaked pledgets.

High Sensitivity Troponin T (hsTnT) Identifies Patients at Very Low Risk of Adverse Events

Peacock WF, Baumann B.M, Bruton D, et al

There has been much literature published on the utility of high-sensitivity troponin assays. This study reports on their use in an American cohort. This Roche-funded study examined a three-hour protocol in 1,264 ED patients suspected of having acute coronary syndrome, finding that in the 974 (77.1 percent) patients with both a zero- and three-hour hsTnT<19 ng/L a 30-day adverse cardiac event occurred in seven patients for a negative predictive value of 99.3 percent (95 percent CI, 99.05–99.55).

Telehealth for Low-acuity EMS: One Fire-based System Experience with 10,000 Patients

Gonzalez MG, Persse DE, Gleisberg GR, et al

Telemedicine in the Emergency Department: A Novel, Academic Approach to Optimizing Operational Metrics and Patient Experience

Sharma R, Clark S, Torres-Lavoro J, et al

Finally, we would be remiss if we did not highlight the latest cutting-edge work from our first ever session of abstracts devoted to telemedicine. Both of these abstracts demonstrated the ability of emergency physicians to care for patients via remote communication, the first in the pre-hospital environment, and the second in a fast track scenario. Both abstracts demonstrated that patients could be cared for efficiently and safely while reducing ED visits or time in the emergency department.

Awards

Congratulations are also in order to award winners Brett Schuchardt and Rebecca Kowalski, who were awarded Best Medical Student abstract for “The Ability of Heparin-Binding Protein to Identify Delayed Shock in Emergency Department Sepsis Patients is Impacted by Age and Source of Infection,” and Sumit Patel, MD, who was awarded Best Resident Abstract for “A Comparison of Three Sobering Center Screens Using a Prospective Cohort of Intoxicated Emergency Department Patients,” at the first-ever live award finalists presentation. Congratulations also to Best Young Investigator Naveen Poonai, MD, for “Intranasal Ketamine for Procedural Sedation in Children: A Randomized Controlled Pilot Study” and to Michael Gonzalez, MD, for Best Overall Abstract on his telehealth EMS abstract above.

Find out what’s next for emergency medicine this October at the ACEP18 Research Forum in San Diego! ➔

DR. LIMKAKENG is director of the ACEP Research Forum and associate professor and director of acute care research in the division of emergency medicine at Duke University School of Medicine in Durham, North Carolina. **DR. PIKTEL** is assistant professor of emergency medicine at Case Western Reserve University School of Medicine in Cleveland, Ohio.



Presenters at the ACEP17 Research Forum.

PHOTOS: PAUL KIM AND ACEP



DR. LEVITAN is an adjunct professor of emergency medicine at Dartmouth College's Geisel School of Medicine in Hanover, New Hampshire.

Airway Sorcery

Tips to avoid bad airway vibes

by RICHARD M. LEVITAN, MD

Procedural sedation and emergency airway management are recognized risks to patient safety. Sedation, induction agents, and muscle relaxants can quickly impact oxygen saturation, and desaturation is often precipitous.

What contributes to the sorcery that seems to surround airway management and procedural sedation, and how can we avoid bad outcomes?

Gas Monitoring

First, recognize that with pulse oximetry, we use an imperfect monitor. It lags what's happening in your patient by 30–90 seconds. Moreover, it does not give you an estimation of safe apnea time, even with high values (ie, 94–100 percent), because the asymptotic shape of the pulse oximeter curve displays saturation, not the amount of oxygen in the blood (ie, the partial pressure of O₂ [PaO₂] in a blood gas). A pulse oximeter reading of 95 percent may represent a PaO₂ of 80, while a pulse oximeter reading of 100 percent can represent a PaO₂ of anywhere from 95–600 (see Figure 1).

The argument for CO₂ monitoring is that it monitors ventilation and therefore is immediate as well as forward looking. *The problem:* Most commonly used end-tidal CO₂ detection methods (ie, small bore nasal cannulas) can't provide higher flows (ie, >6 lpm) without popping off the oxygen source. Even if you rig a cannula or other mechanism to place the CO₂ detector into or under a mask, high-flow oxygen given simultaneously affects CO₂ detection.

Perhaps the easiest way around this is to use two cannulas—that is, start with a low-flow cannula with end-tidal CO₂ detection, and if you need higher flows, run oxygen through a standard nasal cannula previously placed on the patient (see Figure 2). Coming off the wall, a standard nasal cannula can deliver flows well above 50 lpm (even though the manometer only goes to 15 lpm) and as high as 70 lpm. “O’s up the nose” at these high flows can dramatically improve oxygenation, assuming the airway remains patent.

Divide the Airway

After more than twenty years of being airway obsessed, I recently began to gain a different perspective of the anatomy and clinical challenges of airway management. I believe it is useful to divide the airway into three sections to improve our anatomic understanding, and more importantly, to guide therapeutic intervention (see Figure 3):

1. The upper airway includes the nasopharynx, mouth, and the hypopharynx down to the larynx. The upper airway is the most common site of airway obstruction due to the soft tissue structures of the palate, tongue, and epiglottis.
2. The middle airway runs from the laryngeal cartilages (larynx) to the bronchi. It is normally patent, stented open by the rigidity of the thyroid and cricoid cartilage, and the tracheal rings.
3. The lower airway includes the lungs and alveoli, where gas absorption occurs across the alveolar-capillary membrane.

To decipher the sorcery of the airway, we must appreciate how sedation, positioning, and our therapeutic interventions and techniques affect the airway at all three levels. Gravity is the enemy of both upper and lower airway patency when the patient is in a supine position. Supine positioning (coupled with poor muscular tone) causes the tongue to fall backwards against the soft palate and contact the posterior pharynx. Oral airways and/or nasopharyngeal airways are often needed to keep the soft palate and tongue from obstructing the airway. This is problematic because some patients may have

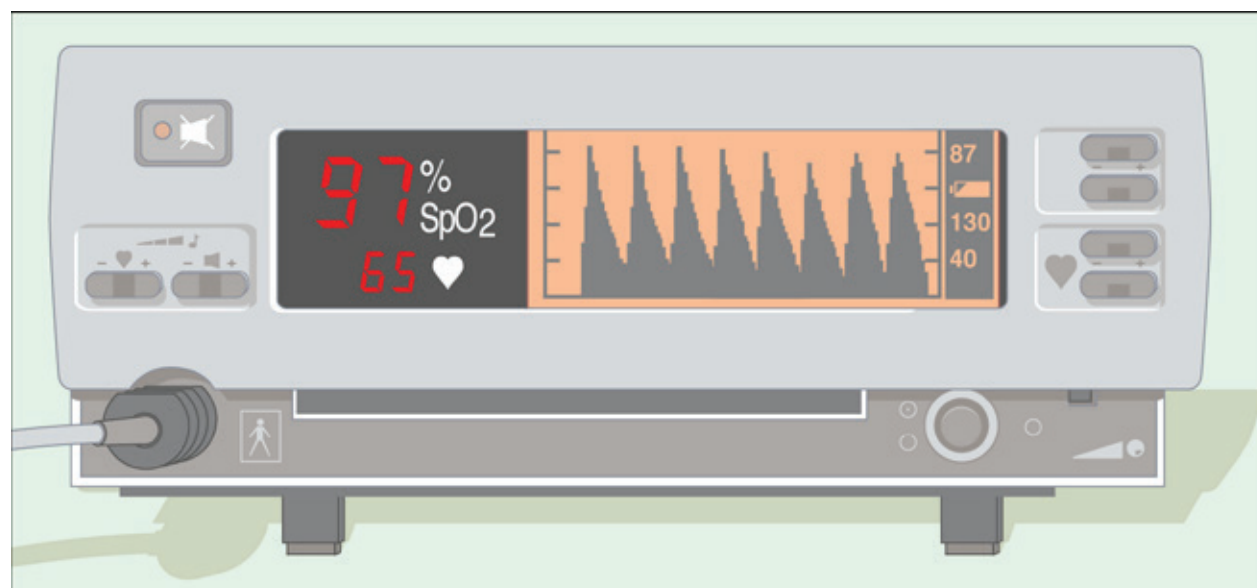


Figure 1 (above): Pulse oximeter reading.

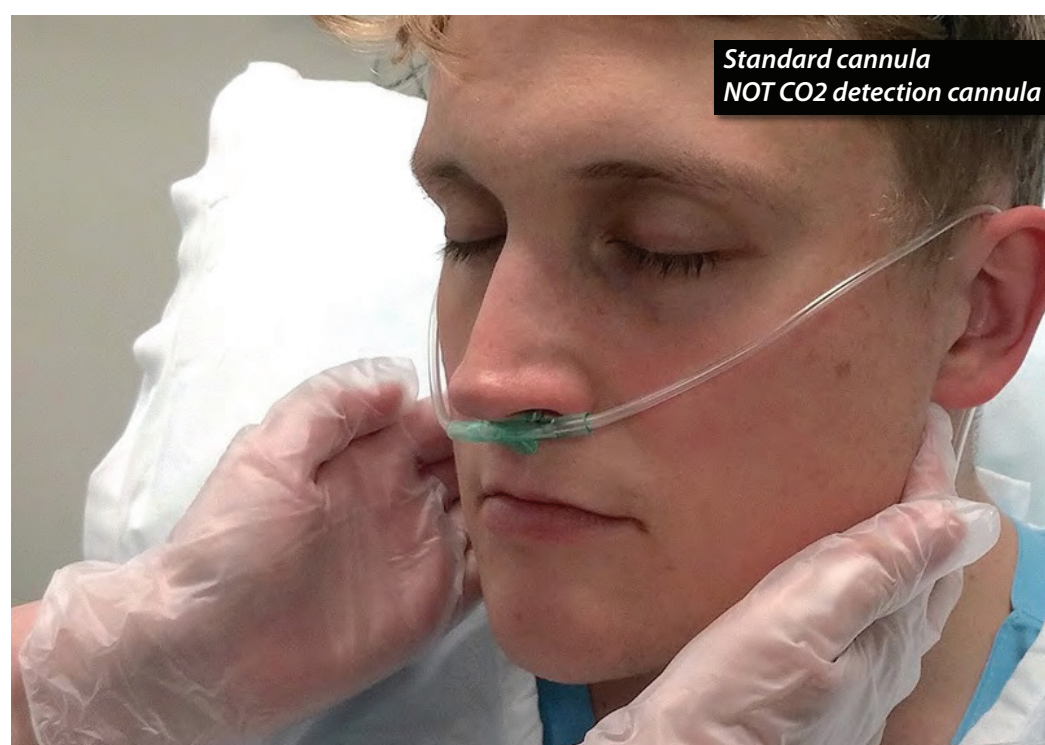


Figure 2 (left): A standard nasal cannula, shown here, can be paired with a low-flow cannula with end-tidal CO₂ detection to avoid affecting CO₂ detection when higher flows are needed.

PHOTO: RICHARD LEVITAN

respiratory depression or poor tone, but an oral airway may still trigger a gag response and vomiting, risking aspiration. Although mask ventilation techniques emphasize jaw thrust, struggling to maintain upper airway patency in a supine position is intrinsically self-defeating. It is also ergonomically difficult and frequently a multi-person task, especially in large patients.

Supine positioning runs counter to lower airway (alveolar) patency. In the supine position, the lung's upper areas compress the dependent alveoli, and abdominal contents push the diaphragm up, significantly reducing lung volume. Changing position from upright to supine reduces functional residual capacity (FRC) by as much as one liter. Because estimated FRC in adults measures approximately 2,400 ml, a reduction of 1,000 ml reduces FRC by 42 percent. Loss of tone (as occurs with anesthetic induction) or over-sedation further reduces FRC by 400 ml.

Collectively, then, FRC reduction from standing to supine plus loss of tone results in a reduction of roughly 52 percent! This reduction's impact on alveolar gas absorption is dramatic, especially in patients who already have compromised lung function.

Sit Them Up

The first and most important technique for boosting oxygen absorption is to apply high oxygen concentration with high flow as a means of augmenting the patient's negative inspiratory efforts. But beyond the application of 100 percent oxygen, and shy of extracorporeal membrane oxygenation or using hyperbaric oxygenation, clinicians have only two methods of further improving oxygenation across the alveoli: 1) positioning, and 2), positive end-expiratory pressure (PEEP).

The immediate and easiest positioning fix to open the lower airway? Sit the patient up. This causes the abdominal contents to move caudad, the diaphragm to drop, and lung volume to rapidly expand. The area for gas absorption across the alveoli dramatically increases with proper positioning.

Middle airway obstruction is an infrequent clinical problem because the three-dimensional shape of laryngeal cartilages and the cartilaginous rings of the trachea maintain patency regardless of positioning or muscular tone. An orally placed tracheal tube traverses the upper airway and reaches the mid-trachea level. When the middle airway obstructs due to intrinsic laryngeal-tracheal pathology (eg, tumors, angioedema about the larynx, blood clots, etc.) or trauma (eg, laryngeal fracture, direct tracheal injury, etc.), patients can die precipitously.

With an awareness of gravity and positioning, and an understanding of the three airway components, engineering airway interventions that augment patency and gas absorption makes sense. Here's my stepwise approach to hypoxia with procedural sedation or in an initial emergency department presentation:

1. Sit the patient up, allowing the diaphragm to drop and the alveoli volume to expand, and pull on the mandible. This opens the upper airway.
2. Send O₂ up the nose—blast open the soft palate and shoot oxygen into the trachea up to and beyond 15 lpm.
3. Add PEEP with a bag valve mask (BVM) and a PEEP valve, or a continuous positive airway pressure system. PEEP is absolutely necessary when high-flow oxygen (with cannula plus mask) does not achieve high oxygen saturations (ie, >98 percent).

To desaturate after the tracheal tube has been placed, first examine the system to ensure the tube is at right depth, the oxygen is connected, and the cuff is up. Suction through the tube to remove mucous plugs, clots, etc. If high-pressure alarms go off or bagging difficulty persists (that is not consistent with the patient's pathology, ie, COPD, asthma, etc.), pull the tracheal tube. It is quite common to experience ball-valve obstructions from mucous plugs or clots that suctioning alone doesn't resolve.

Plan to maximize oxygenation in every instance of procedural sedation. Use gravity to reduce the risk of aspiration, and always ask, "Do you need the patient flat?" We rarely do, and head elevation adds tremendously to patient safety.

The highest-risk patients may be those sedated for hip reduction because they need to be lying flat. Even a slight amount of head elevation (ie, 10 degrees) tilts the pannus down and improves lung function tremendously. Once the hip reduction is complete, bring the head higher and pull on the mandible with the nasal cannula on. Often the most dangerous part of sedation occurs after the reduction because pain input drops but the drugs haven't worn off.

If positioning, pulling on the mandible, and nasal oxygen at high flow does not resolve hypoxia, add PEEP by using a BVM

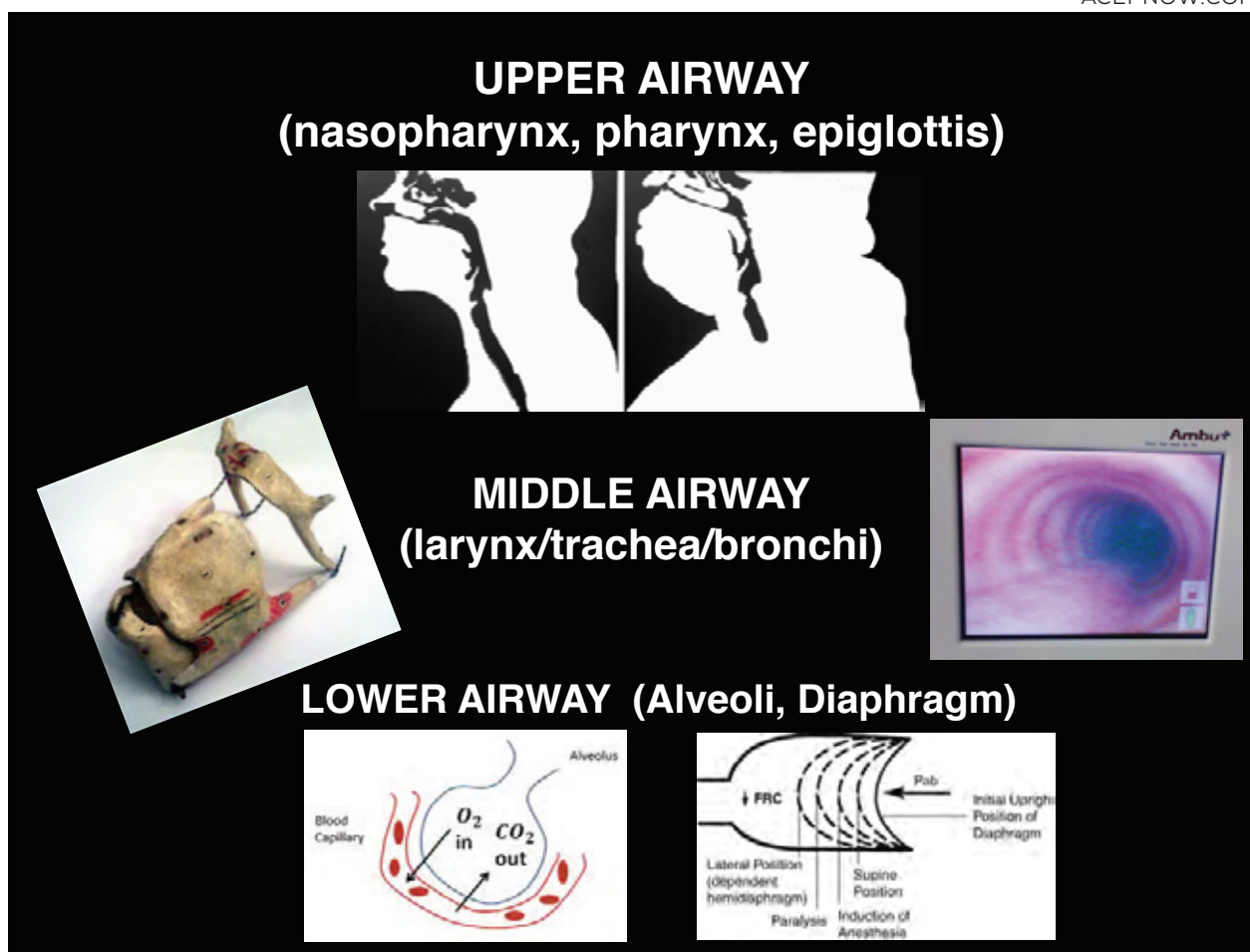


Figure 3: Think of the airway in these three sections.

PHOTO: RICHARD LEVITAN

with a PEEP valve. Install PEEP valves on every BVM in your department so when PEEP is needed, you don't need to locate one.

Be mindful of patients at high risk of desaturation due to alveolar disease (ie, heart failure, acute respiratory distress syndrome, multi-lobar pneumonia, aspiration, etc.). The sickest of the sick may require combining both upright positioning and PEEP for pre-oxygenation, and also during the onset phase of

muscle relaxation when performing rapid sequence intubation. Even after successful intubation, these patients can prove difficult to oxygenate. Increase the fraction of inspired O₂, increase PEEP, lower tidal volumes, and increase the ventilator rate in these challenging cases.

Finally, consider prone positioning if upright positioning doesn't allow for sufficient oxygenation. +

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About This Series

Welcome to this CME/CE video series on infection control. Although institutions and infection control experts have made significant progress in preventing some types of infections, there is still a great deal of work to be done. This series will feature discussions with top faculty on infection transmission and healthcare-associated infections. We will take a look at the healthcare environment and touch on medical equipment, injection safety, risk recognition, glove use, and hand hygiene.

Activity 1

Learn how to recognize and mitigate the risk of infection transmission CME/ABIM MOC/CE

Learn how to reduce infection transmission and healthcare-associated infections

Faculty: Michael Bell, MD; Lisa Maragakis, MD, MPH; Peter Pronovost, MD, PhD

Activity 2

Healthcare-associated infections and the role of the healthcare environment CME/ABIM MOC/CE

Healthcare-associated infections and how to prevent them in healthcare settings.

Authors: Patti Costello; Ruth Carrico, PhD, MSN, FNP; Russell N. Olmsted, MPH, CIC

Activity 3

Recognizing Infection Risks in Medical Equipment CME/ABIM MOC/CE

Medical equipment and devices pose infection risks: a look at their use, maintenance, and reprocessing

Faculty: Michael Bell, MD; Daniel Diekema, MD; J. Hudson Garrett, Jr, PhD, MSN, MPH, FNP-BC

Activity 4

Infection Transmission Risks Associated with Nonsterile Glove Use CME/ABIM MOC/CE

Handle with care: hand hygiene and nonsterile glove use.

Faculty: Michael Bell, MD; Ruth Carrico, PhD, MSN, FNP; J. Hudson Garrett Jr, PhD, MSN, MPH, FNP; Sujun C. Reddy, MD

Activity 5

Infection Prevention: A Hierarchy of Controls Approach CME/ABIM MOC/CE

Learn how this "prevention through design" strategy can reduce or prevent illness, fatalities, and occupational injuries.

Faculty: Vineet Chopra, MD, MSc; Bryan Christensen, PhD, MEPC; Lynn Janssen, MS, CIC, CPHQ

Activity 6

Learn how to implement a system-wide approach to prevent breaches in injection safety CME/ABIM MOC/CE

Learn how to decrease use of syringes and misuse of medical vials.

Faculty: Joseph Perz, DrPH, MA; Marion A. Kainer, MD, MPH, FRACP, FSHEA; Timothy Wiemken, PhD, MPH, CIC

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MYTHS

IN EMERGENCY MEDICINE

Rooted in culture, based on tradition

by KEVIN M. KLAUER, DO, EJD, FACEP

Myth: Normal Saline Is the IV Fluid of Choice

Which fluid is superior, normal (0.9%) saline or balanced crystalloids (ie, lactated Ringer's)? Balanced fluids, in theory, are defined as fluids that are more physiologic in several parameters when compared to normal saline (NS).

It appears we have a critical mass of sufficient evidence suggesting NS needs to take a back seat to lactated Ringer's (LR).

LR has been criticized for being physiologically hypotonic, (reduced "actual osmolality" or tonicity) and thus may diffuse to extravascular spaces too quickly, limiting their effectiveness for volume expansion. Such diffusion results from osmotic pressure (ie, solutes and their associated osmotic coefficients).¹ As an example, sodium and chloride only partially dissociate when dissolved and thus the solutes are only partially osmotically active (osmotic coefficient 0.926). The osmolality of NaCl 0.9% is 308 mOsmol/L, but its actual osmolality is

286 mOsmol/kg H₂O. The osmolality of LR is 273 mOsm/L, but its osmolality is 254 mOsm/kg.¹ This difference in tonicity may result in a shorter half-life for LR.

Hahn et al reported, "The T_{1/2} for crystalloids is usually 20 to 40 min in conscious humans but might extend to 80 min or longer in the presence of preoperative stress, dehydration, blood loss of <1 l or pregnancy."² Drobin and Hahn published data from 10 healthy male subjects, noting the half-life for NS and LR was 110 min and 50 min, respectively.³ The data is

not without significant limitations. However, it does imply a longer half-life for NS, which is theorized to be, in part, from the renal vasoconstriction from the high chloride content of NS.^{1,2}

If you are buying that half-life, as a function of tonicity, predicts outcomes, I'd be cautious. Although the individual properties of the fluids (ie, tonicity) cannot be isolated, outcomes appear to be better with balanced fluids. For instance, a meta-analysis of 14 randomized controlled trials including 18,916 patients treated for sepsis noted a mortality benefit from LR compared to NS (odds ratio 0.78).⁴

Some critics of LR have proposed that the infusion of lactate may worsen metabolic acidosis. However, much like the concern over lower tonicity, this concern is also a physiologic argument as opposed to evidence-based. Sodium lactate, the additive in LR, is hepatically metabolized to bicarbonate and is not an acid.

So, what happens when lactate is infused? Despite the limitations of the study, Ross et al found no such effect in 157 blood donors (500 ml) with an estimated less than 15 percent blood loss. Post-donation, all groups had lactate levels between 1.05 and 1.10. However, post infusion, the picture changed. After 2 L of intravenous fluid, the lactate was higher in the LR group (1.46), compared to both the NS and no infusion groups, which were 1.0 and 1.36, respectively. The base deficit for NS was 10 times that of LR, and the pH was the lowest for NS (7.32 for NS, 7.34 for LR, 7.36 for the controls).⁵ While not definitive, the study suggests buffers in fluids may positively impact acid-base status.

Quite the contrary, it is NS that has been proved to promote metabolic acidosis. Although theories vary, the dilutional effect on bicarbonate concentrations and an increase in unpaired anions (Cl⁻) resulting in a non-gap acidosis are two common explanations.¹

On March 1, 2018, Self et al published two studies from Vanderbilt on this topic, one focusing on the critically ill and the second on those not critically ill but admitted from the emergency department. Although un-blinded, the studies provide valuable insights. The first found that, "Among critically ill adults, the use of balanced crystalloids for intravenous fluid administration resulted in a lower rate of the composite outcome of death from any cause, new renal-replacement therapy, or persistent renal dysfunction than the use of saline."⁶ Although there was no difference in the hospital-free days in the non-critically ill study, the authors found that, "balanced crystalloids resulted in a lower incidence of major adverse kidney events within 30 days than saline (4.7 percent vs. 5.6 percent; adjusted odds ratio, 0.82; 95 percent CI, 0.70 to 0.95; P=0.01)."⁷

In most cases, it may be time to check your saline at the door in favor of LR.

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

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

Student Loan Forgiveness

How physicians can use a federal program to reduce their debt burden

by **JAMES M. DAHLE, MD, FACEP**



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Q. I understand there's a way to get my student loans forgiven if I work for a non-profit hospital. How does that work?

A. You're referring to the Public Service Loan Forgiveness (PSLF) program. This federal program allows you to have the remainder of your federal direct student loans forgiven, tax-free, if you make 120 monthly payments under an eligible payment plan while being employed full-time by the military, Veterans Administration, or a 501(c)3 employer (ie, a non-profit employer).

Eligible payment plans include the standard 10-year repayment plan along with three income driven repayment (IDR) programs: Income Based Repayment (IBR), Pay As You Earn (PAYE), and Revised Pay As You Earn (RePAYE). These IDR plans also have a forgiveness component to them, which doesn't require you to work for a 501(c)3, but they require 20–25 years of payments, after which most emergency physicians (EPs) would have paid their loans off anyway. The amount forgiven is taxable. Thus, PSLF is really the only federal forgiveness program that most EPs should consider.

Most residency and fellowship programs qualify as non-profit employers, as do many academic positions and some community emergency physician positions. Bear in mind that working in a non-profit hospital doesn't necessarily allow you to qualify. You must be an employee of the hospital, not a partner or employee of a private group that contracts with the hospital.

A typical EP with a typical medical school debt burden wouldn't have any debt left to forgive after making 120 monthly payments under the standard 10-year repayment plan. The secret to actually receiving economic benefit

under this program lies in enrolling in one of the other programs. PAYE and RePAYE have the lowest required payments—10 percent of discretionary income, which is defined as the difference between your income and 150 percent of the poverty line for your geographic area and family size. Note that the payments have nothing to do with the amount or interest rate of your debt. During residency, RePAYE is often the best program to enroll in because it may actually subsidize the loan, lowering your effective interest rate. PAYE is usually the best program after residency because, unlike RePAYE, it caps payments at the 10-year standard repayment plan amount.

The amount left to be forgiven after 10 years of payments turns out to be essentially the difference between what you would've paid under the standard repayment plan and what you did pay under an IDR plan. So, a typical medical student may graduate with \$200,000 in debt, which grows to \$250,000 during residency (IDR payments don't even cover the interest on the debt). The student then pays it down to perhaps \$150,000 as an attending, at which point the rest is forgiven. The more payments you make that are less than the standard payments, the more debt is left to be forgiven after 120 payments.

This leads doctors to use a few strategies to try to maximize the amount forgiven. First, some types of loans (eg, Federal Family Education Loans and Federal Perkins Loans) don't qualify for forgiveness unless they are consolidated into a Federal Direct Loan. Second, you can enroll in an IDR program and start making payments late in your fourth year of medical school, essentially increasing the percentage of payments you make while your income, and thus your payments, remain low.

Third, contributing to tax-deferred retirement accounts during residency further lowers your income and your required payments. Finally, some physicians married to high earners find it advantageous to file their taxes as "married filing single" while enrolled in an IDR program. Even though this often increases their combined tax burden, it can also reduce the borrower's income (at least in the IBR and PAYE programs) and thus their spouse's required payments.

A longer training period can also help maximize forgiveness. A physician who spends seven years in residency and fellowship may need to make full payments for only three years as an attending before receiving forgiveness.

Private student loans are never eligible for PSLF, and the best strategy for managing those usually involves refinancing to a lower rate as soon as possible (usually shortly after medical school graduation) and paying them off early in your career. Several lenders allow very low payments during training, just like the federal IDR programs.

Caution: Refinancing your federal direct loans can be a big mistake if you later end up working for a 501(c)3 after residency graduation. Another common error is putting your loans into forbearance or deferment during training, which prevents the accumulation of lower IDR payments that would later allow for significant forgiveness under PSLF. If you make IDR payments throughout residency and work full-time for a 501(c)3 after residency, going for PSLF instead of refinancing the loans generally works out better mathematically than refinancing, even if the interest rate is higher.

Many students, residents, and attendings

worry Congress will change the rules and take PSLF away. That is a significant risk—both the Obama Budget of 2013 and the Trump Budget of 2018 proposed doing away with the program as we know it. The Prosper Act, currently in House committee, would also cause significant changes to the federal loan programs if it becomes law in its current form.

However, in the past, when federal student loan programs were changed, those currently in the program were usually grandfathered into the old program. A good way to hedge this legislative risk is to make large student loan payments as an attending that would allow you to pay off your loans within two to five years after residency completion, but make those payments to your own investing account. Then, if something happens to PSLF, you can simply take those funds and pay off the loans. If you do receive forgiveness, you can use that money to bolster your retirement nest egg or other savings goals.

Some worry about the morality of not paying back borrowed money when you have the means to do so. My response? Hate the game, not the player. I see loan forgiveness no differently than using a tax-advantaged retirement savings account or taking the child tax credit. We have no duty to leave money on the table that we legally qualify for, even if we disagree with federal student loan policy.

Since PSLF was instituted in 2007, the first borrowers are just now starting to receive forgiveness after making their 120 monthly payments. As the years go by, you'll see more and more physicians receiving this federal benefit. Managing your student loans well will increase your financial security and allow you to take better care of your family and patients. ➤



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Safe Discharge in Non-low Risk Chest Pain

Risk stratify for follow-up intensity as opposed to discharge

by RYAN PATRICK RADECKI, MD, MS

There's been a clear shift in the emergency medicine mindset toward chest pain over the past few years, including an explosion of literature and professional guidance in support of the history, electrocardiogram, age, risk factors, and troponin (HEART) score.¹ The primary application of this and other similar rules is to support risk-stratification and the early discharge of patients with chest pain at low risk for acute coronary syndrome (ACS).

In fact, various strategies for early discharge have been enshrined in the guidelines

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from the American College of Cardiology since 2014.² These guidelines support the use of not only such stalwarts as the Thrombolysis in Myocardial Infarction (TIMI) and Global Registry of Acute Coronary Events (GRACE) scores, but HEART, a modification of HEART called HEARTS₃, and the Vancouver Rule. Suffice it to say, if you're not at least risk-stratifying patients for early discharge using clinical judgement or an objective tool, you're lagging.

However, this article isn't about discharging patients with low-risk chest pain. This article discusses discharging the other 40–50 percent of emergency department patients with chest pain who don't fall into such an optimal classification. For instance, a septuagenarian with non-obstructive coronary artery disease on a previous cardiac catheterization, a couple seconds of atypical chest pain, and an undetectable troponin I counts as a “moderate” risk by HEART. Or a 65-year-old male

without any known risk factors and non-specific pain who falls into the “not low risk” classification of the Emergency Department Assessment of Chest Pain Score (EDACS).³ How should we manage the vast heterogeneous cohort of patients like these who aren't in the low-risk strata?

It's Two Questions

This question basically breaks down into two components, which people frequently stick together and address singly when evaluating the performance of these algorithmic approaches. These approaches try to pare down the cohort by defining certain discharge criteria in the emergency department, and they measure success by remaining free of major adverse cardiac events (MACE) for a certain period of time.

This approach seeks to prevent the dreaded, “Hey, remember that guy with chest pain you sent home last week?” follow-up conversation on a future shift. However, assessing safety for discharge truly breaks down into these two questions: 1) “Have I adequately ruled-out an acute coronary syndrome on today's visit,” and 2) “What follow-up or additional testing will prevent a future MACE?”

To answer question one, we rely upon the relevant presenting features of the chest pain, the electrocardiogram, and biomarker testing. In the vast majority of cases in which acute ischemia is not apparent or highly suspected, the limiting factor becomes biomarkers. In the past, concern over the relative lack of early sensitivity to cardiac ischemia led clinicians to routinely refer patients for admission or observation for repeat biomarker testing. However, in recent years, an explosion of new literature describes the early test characteristics of both conventional and highly-sensitive troponins, and it's clear the biomarker rule-out can be

performed entirely within the emergency department.⁴

These accelerated diagnostic protocols may involve one-hour or two-hour repeat testing, or, if the time of onset of the more recent symptoms is adequately remote, a single troponin on arrival may prove sufficient. Protocol sensitivity typically exceeds 95 percent, with negative predictive values in excess of 99 percent, even in patients with known coronary disease or coronary risk factors.⁵

Determining the best next step fundamentally asks the purpose of admission or observation. For an admission or observation to have value, whether on a health-system level or to a patient on a deductible health insurance plan, the intervention should offer a reasonable expectation of identifying a problem potentially amenable to treatment. Unfortunately, despite our reliance on various stress tests and the increasing prevalence of CT coronary angiography, population-based and claims-based data find no clear benefit signal.^{6,7} These data don't rule out individual benefit to intelligently-selected downstream testing, but the premise that admission or observation will benefit patients with known cardiac disease remains unproven.

However, the risk score data does make clear non-low risk patients are precisely that. These patients *do* have elevated risk for serious outcomes, some preventable, some not. When assessing whether a non-low risk patient is safe for discharge after accelerated biomarker rule-out, the key element is follow-up. Many patients have well-established coronary anatomy and disease, and the benefit from subsequent invasive or non-invasive testing ranges may easily be zero for a patient who's primarily medically-managed. This follow-up can occur via established primary care or a cardiologist, depending on the complexity of the

subsequent decision-making process—or, better yet, prior to disposition, if a specialist familiar with the patient's management can be looped in contemporaneously.

The bottom line: A diagnosis of ACS can be rapidly excluded in the emergency department in most patients, and we can think of our various decision instruments for risk-stratification as tools not to determine which patients we should discharge, but tools to help us triage patients for varying follow-up intensity. Anecdotally, at my institution, with well-integrated follow-up, more than 85 percent of biomarker-negative chest-pain presentations are discharged directly from the emergency department without untoward patient safety. It might seem implausible, but it can be done! ➔

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Going Old School with Alcohol Withdrawal Treatment

Brining back phenobarbital monotherapy for alcohol withdrawal

by JEREMY SAMUEL FAUST, MD, MS;
AND LAUREN WESTAFER, DO, MPH

Shortening the time window of research knowledge to clinical application is one of the major aims of the Free Open-Access Medical Education (FOAMed) movement. When new research is published, it often takes years, and sometimes decades, for that information to trickle out into mainstream practice. That's where FOAMed shows some of its greatest promise. In fact, FOAMed junkies might occasionally be accused of being the opposite of late-adaptors; many of our



most enthusiastic FOAMed consumers have been criticized for adopting new ideas too quickly, based solely on a podcast or a blog that may have been based on a body of low quality research.

There's probably some truth to that, but in reality, we haven't heard too many stories about cases gone wrong because a physician was blindly following the advice of some joker with a blog or a podcast available on iTunes. In fact, we've found that FOAMed consumers tend to be the ones who are likely to be among the most informed

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when it comes to journals and text books, not just what’s free online. We’d like to think that’s because FOAMed encourages its users to go deeper than one podcast or a blog and inspires them to look carefully into a topic being discussed. Sometimes you find that what passes for “cutting-edge FOAMed” is actually a venerable treatment that, for some reason, has been supplanted by something shiny and new. In that spirit, in a recent episode of FOAMcast, we covered some FOAMed that advocated for the return of a tried-and-true treatment masquer-

ading as progressive medicine for an emergency medical condition that we treat all the time: alcohol withdrawal.

Treatment History

After the 1950s, benzodiazepines became the mainstay treatment for alcohol withdrawal and delirium tremens. However, a recent blog post on the Pulmcrit/Emcrit.org website, written by critical care physician Joshua Farkas, MD, made a fairly convincing argument for bringing back the previous mainstay of al-

cohol withdrawal treatment, phenobarbital. Many alcohol withdrawal protocols in use today include phenobarbital when the benzos just aren’t working. What Dr. Farkas is talking about is phenobarbital as monotherapy for alcohol withdrawal. Cool!

The beauty of using phenobarbital is that its dosing is far easier to keep straight. Rather than deciding among diazepam, lorazepam, or midazolam—perhaps after a failed trial of chlordiazepoxide (Librium)—and trying to guess how large a dose to give and how of-

ten, the phenobarbital monotherapy protocol seems to have an easier opening gambit. In patients with moderate to severe alcohol withdrawal who have not yet received benzodiazepines (or other sedatives) and appear to have alcohol withdrawal alone (ie, no other active neurologic problem), simply give 10 mg/kg (ideal body weight) intravenously over 30 minutes. Then wait 30 minutes. If after one hour, the patient still requires more medication, you can give 130 mg (for mild symptoms) or 260 mg (for moderate to severe symptoms)

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IV given over three to five minutes, as needed every 30 minutes. As long as the cumulative dose does not exceed 20 mg/kg IV, there is little risk. There are also oral and intramuscular strategies for maintenance. For that, check out emcrit.org/pulmcrit/phenobarbital-reloaded.

This protocol is certainly easier than many of the benzodiazepine-based protocols. Better yet, some recent data suggest that this approach may even decrease intubation rates. This was suggested (though hardly proven) in a study published in *Critical Care Medicine*.¹

On our recent show, we discussed why the lower intubation rates might be occurring in the patients getting phenobarbital only. While we can't be sure, it is a distinct possibility that

phenobarbital isn't better than the fairly aggressive diazepam-based protocol suggested in *Goldfrank's Toxicology Emergencies*. Sure, phenobarbital hits NMDA receptors in addition to GABA and that might confer some advantage over benzos. However, it might just be that people aren't that comfortable following the Goldfrank-inspired protocol—which is a shame because it works well. Many facilities feel uneasy giving escalating doses of diazepam (starting from 5 mg and rising to 10 mg, 20 mg, 40 mg, and even 80 mg per dose) every five minutes to a patient in alcohol withdrawal. Instead, the patients get under-dosed, and they end up progressing to delirium tremens and, not infrequently, require intubation for

airway protection.

Interestingly, after we published our podcast, the feedback we got was divergent. Younger physicians tended to find the idea of ditching benzodiazepines in favor of phenobarbital monotherapy to be sort of crazy, but kind of awesome. As usual, the up-and-comers are excited by anything that sounds edgy, especially when it involves controlled substances, but the more seasoned emergency physicians were less impressed, albeit somewhat enthusiastic. One of the more experienced critical care physicians we spoke to said, "Yeah, we used to use phenobarbital monotherapy all the time, and it was easy and worked great. We should definitely consider

going back to that. I hate CIWA scores [Clinical Institute Withdrawal Assessment for Alcohol scale, a tool to assess withdrawal severity]!"

So, we guess what's old again is new again. FOAMed has many faces and facets, and we at FOAMcast are pleased to bring it to our listeners.

Do you have any effective old-school treatments that make you feel like a dinosaur? Let us know, and as always, share any evidence and your experience. We'd love to cover it in a future show. ➕

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