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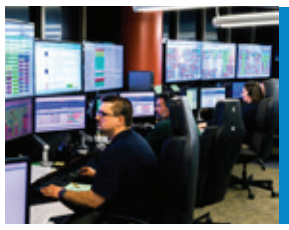

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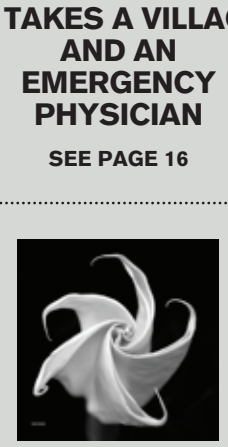

TOXICOLOGY Q&A

WHAT WILL TEA MADE FROM THIS PLANT YIELD?

SEE PAGE 13

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MEET THE ACEP BOARD OF DIRECTORS CANDIDATES

The candidates discuss major issues facing emergency medicine

Each October at ACEP's annual Council meeting, the ACEP Council elects new leaders for the College. The Council, which represents all 53 chapters, 37 sections of membership, the Association of Academic Chairs in Emergency Medicine, the Council of Emergency Medicine Residency Directors (CORD), the Emergency Medicine Residents' Association (EMRA), and the Society for Academic Emergency Medicine, will elect the College's President-Elect, four members to the ACEP Board of Directors, and the Council Vice Speaker. This month, we'll meet the Board of Directors candidates, and in October, we'll meet the Council Officer candidates.

CONTINUED *on page 10*

EM CASES

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

MEDICAL CLEARANCE OF THE PSYCHIATRIC PATIENT

Determining if a psychiatric emergency is the result of organic disease or psychological illness

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

The emergency department serves as both the lifeline and the gateway to psychiatric care for millions of patients suffering from acute behavioral or mental health emergencies. As ED providers, in addition to assessing the risk of suicide and homicide, one of our most important responsibilities is to determine whether the patient's behavioral emergency is the result of an organic disease process, as opposed to a psychological one; there is no standard process for this.

EM CASES

On the one hand, these psychiatric patients are high-risk medical patients. They not only have a higher incidence

CONTINUED *on page 25*

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

Think ELIQUIS for the treatment of DVT/PE.

DVT: deep vein thrombosis; PE: pulmonary embolism.

INDICATIONS

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

  The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS.

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(apixaban) tablets 5mg 2.5mg

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

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

1-855-ELIQUIS

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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

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

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

ADVERSE REACTIONS

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

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

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

Bristol-Myers Squibb Pfizer

IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS

- **Strong Dual Inhibitors of CYP3A4 and P-gp:** Inhibitors of cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are strong dual inhibitors of CYP3A4 and P-gp (e.g., ketoconazole, itraconazole, ritonavir, or clarithromycin). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with strong dual inhibitors of CYP3A4 and P-gp.
- **Strong Dual Inducers of CYP3A4 and P-gp:** Avoid concomitant use of ELIQUIS with strong dual inducers of CYP3A4 and P-gp (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban and increase the risk of stroke and other thromboembolic events.
- **Anticoagulants and Antiplatelet Agents:** Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

PREGNANCY CATEGORY B

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

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

ELIQUIS® (apixaban) tablets, for oral use

℞ ONLY

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

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

(B) SPINAL/EPIDURAL HEMATOMA

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

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

(B) SPINAL/EPIDURAL HEMATOMA

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

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

[see Warnings and Precautions]

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

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

INDICATIONS AND USAGE

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

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

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

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

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

DOSAGE AND ADMINISTRATION (Selected information)

Temporary Interruption for Surgery and Other Interventions

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

CONTRAINDICATIONS

ELIQUIS is contraindicated in patients with the following conditions:

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

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation

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

Bleeding

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

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

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

Reversal of Anticoagulant Effect

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

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

Spinal/Epidural Anesthesia or Puncture

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

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

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

Patients with Prosthetic Heart Valves

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

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

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

ADVERSE REACTIONS

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

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

Clinical Trials Experience

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

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

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

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

Bleeding in Patients with Nonvalvular Atrial Fibrillation in ARISTOTLE and AVERROES

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

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

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

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

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

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

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

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

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

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

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

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

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

Other Adverse Reactions

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

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

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

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

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

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

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

* All bleeding criteria included surgical site bleeding.

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

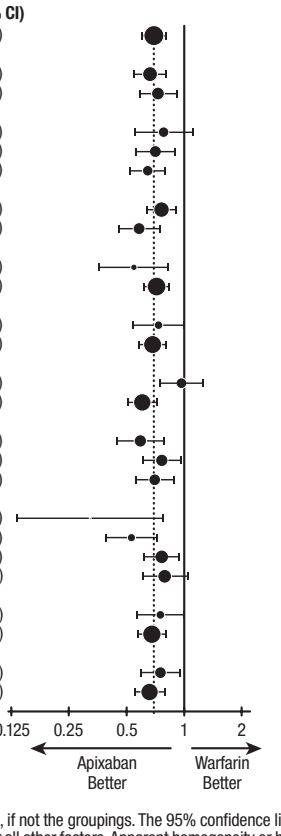
‡ Includes 5 subjects with major bleeding events that occurred before the first dose of apixaban (administered 12 to 24 hours post surgery).

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

¶ CRNM = clinically relevant nonmajor.

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

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



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

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

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

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

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

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

Vascular disorders: hypotension (including procedural hypotension)

Respiratory, thoracic, and mediastinal disorders: epistaxis

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

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

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

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

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

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

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

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

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

AMPLIFY Study

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

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

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

Table 5: Bleeding Results in the AMPLIFY Study

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

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

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

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

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

AMPLIFY-EXT Study

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

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

Table 7: Bleeding Results in the AMPLIFY-EXT Study

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

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

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

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

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

Other Adverse Reactions

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

Blood and lymphatic system disorders: hemorrhagic anemia

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

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

Musculoskeletal and connective tissue disorders: muscle hemorrhage

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

Vascular disorders: hemorrhage

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

Eye disorders: conjunctival hemorrhage, retinal hemorrhage, eye hemorrhage

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

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

DRUG INTERACTIONS

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

Strong Dual Inhibitors of CYP3A4 and P-gp

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

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

Strong Dual Inducers of CYP3A4 and P-gp

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

Anticoagulants and Antiplatelet Agents

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

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

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

Labor and Delivery

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

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

Nursing Mothers

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

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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

Renal Impairment

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

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

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

Patients with End-Stage Renal Disease on Dialysis

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

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

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

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

Hepatic Impairment

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

OVERDOSAGE

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

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

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

PATIENT COUNSELING INFORMATION

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

Advise patients of the following:

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

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1356615A2 / 1356514A1 Rev July 2016

432US1603587-13-01

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THE BREAK ROOM

Too Tough on Steroids?

Dr. Radecki's article on steroids in sore throat [June 2017] is too quick to accept the study he cites about the increased risk of short term steroids (*BMJ*. 2017;357;j1415). In that study, the steroid-treated group was older and had more comorbidities than the group not treated with steroids. It is likely that the increased incidence of adverse events related more to those preexisting differences than to the steroids.

Waljee et al compared non-steroid users and users with matched ICD-9 diagnoses. However, there can be a wide disparity in the severity of symptoms and findings for patients assigned the same ICD-9 code. No severity index or rating was used. It may be that corticosteroids were prescribed to those with more severe symptoms or findings, which would again invalidate the comparison.

Waljee et al also used a self-controlled case series, stating that patients had more adverse events in the six months after receiving steroids than in the six months before. That methodology may be appropriate to track adverse events related to vaccines, since individuals receiving vaccines are presumably at their baseline and the vaccine introduces an isolated new variable. However, the patients in this study received steroids to treat symptoms, conditions, or specific illnesses. Those represent additional variables that completely invalidate the "self-control."

Walljee et al suggest "alternatives to corticosteroids (eg, non-steroidal anti-inflammatory drugs for acute gout or tricyclic antidepressants for neuropathic pain." The considerable adverse effects of NSAIDs and tricyclics are widely known. The authors provide no data that their alternatives are safer than corticosteroids.

The study cited found statistically significant increased risk for short-term steroid use, but even if the methodology and results were valid, the relevance of those differences would be questionable. For example, non-steroid user incidence of sepsis was 0.02 percent; for users, it was higher, 0.05 percent. Most individuals who were informed that taking a steroid would likely improve their symptoms, but (according to a flawed study) may increase the incidence of sepsis by three patients among 10,000, would likely still choose steroids.

- Cloyd Gatrell, MD, FACEP
Carlisle, Pennsylvania

Dr. Radecki Responds

Thank you for your comprehensive and insightful comments. I agree with your assessment of the limitations of the Waljee article, many of which impact the validity of the observations and their generalization to the treating population. However, in a Bayesian sense, some of these observations are consistent with expected effects and are reinforcing, even if far from reliable proof of causation.

The absolute risk increase is, indeed, quite small—particularly for younger patients. As the risks grow, however, it is reasonable to consider these adverse effects, along with the potential harms of alternative therapies, in the context of the expected magnitude of benefit. Even if the risk to an individual patient may be low, the cumulative effect of this practice will ultimately have population-level costs and harms to be weighed against the societal and personal costs of self-limited symptomatology.

- Ryan P. Radecki, MD, MS, FACEP
Portland, Oregon

Dual-Shock Dangerous to Defibrillators?

Having just read ["All Charged Up & No Place To Go," July 2017], and being the chair of the medical control board (MCB) for one of the larger EMS systems in the country, I have to take issue with item four in the article.

We have implemented dual defibrillation protocols within our EMS service, but only after getting input from the manufacturer, and engineers, of our cardiac monitor devices. They warned that "dual-shock" could damage the devices and would void the warranty. However, "dual-sequential" shocks would not. That means that instead of pushing both shock buttons simultaneously, we have a one second pause before the second shock button is pushed.

This warranty issue was a huge consideration in our EMS system, as it is with others, and having to replace monitors that have been rendered inoperable by "dual-shock" is not being fiscally responsible to the cities we serve and their citizens.

Having used this technique successfully myself on several patients in my ED, I am a firm believer in its efficacy. However, I wanted to share what our MCB learned when we chose to ask the device manufacturer about this new process.

- Michael S. Smith, MD, FACEP
Tulsa, Oklahoma

Dr. Helman Responds

Thanks for your comment. You are correct that the warranty does not cover simultaneous dual shocks.

Based on consultation with defibrillation researchers and experts Dr. Sheldon Cheskes and Dr. Paul Dorion, the probability of device damage is actually very small and has never been observed in the double defib studies they have done for atrial fibrillation and ventricular fibrillation (VF). That being said, for some manufacturers at least, there is a reasonable small risk, so they are concerned about warranty.

Drs. Cheskes, Dorion, and I are also skeptical about sequential (one second separation) shocks being different than a second shock 15 or 30 sec later. For double difib to be effective, the shocks must be as close as possible together without being simultaneous (this is guaranteed by having one person hit shock on both defibs as quickly as possible). A one-second gap is too long.

Of course, we do not know the true answer about simultaneous (where there are data) or sequential (where there is only speculation) being better than a shock for VF two minutes later.

- Anton Helman, MD, CCFP(EM), FCFP
Toronto, Canada

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OPINIONS FROM EMERGENCY MEDICINE

A NEW SPIN

INDEPENDENT EMERGENCY GROUP PRACTICE

How I found a practice setting that fits

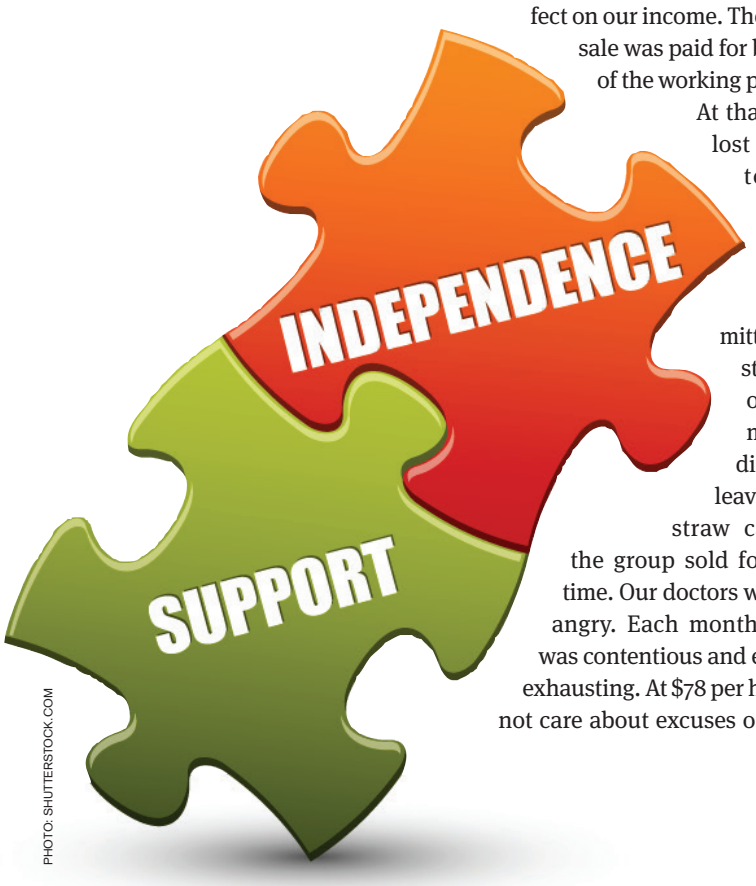
by RONEET LEV, MD, FACEP

There are many issues facing emergency medicine, but the biggest issue for me is physician satisfaction. Happy doctors make happy nurses and happy patients. There are many metrics that emergency physicians face, from door-to-doc to door-to-antibiotics and door-to-balloon.

I want emergency physicians to have the best door-to-home metrics, feeling after every shift that we made a difference—because we do.

There are many employment models in emergency medicine, and I want to share my story of going from a large group to an independent group to creating a setting that provided me with the best of both worlds. While I am protective of my practice model, I don't think it matters where emergency physicians work as long as they are highly satisfied.

I started my career in emergency medicine working for a large group practice at Mercy Hospital in San Diego. I felt like I won the lottery working at a community hospital with all the fixings of trauma, academics, inner city, and action. I was even given a special role as educational director. While I became very committed to my hospital and community, my colleagues and I became disillusioned with our management group. The group sold for several million dollars, and this had a negative effect on our income. The cost of the sale was paid for by the labor of the working physicians.



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At that point, we lost a few doctors, but there was a core of us who were committed to the institution and our community; we didn't want to leave. The final straw came when the group sold for a second time. Our doctors were beyond angry. Each monthly meeting was contentious and emotionally exhausting. At $78 per hour, we did not care about excuses of bad payer mix, improved productivity, or future solutions. We hated the current buyer, whoever it may be, as we lost faith and wanted no part of any more sales.

It was Dec. 31, 2004, and each doctor was told to either sign a contract with the new buyer or get replaced. I didn't want to sign. However, at the last moment, and after some sweet phone calls from trusted colleagues, I was the last to sign, but there was a catch. My colleagues and I added a clause that would free us in one year and would allow us to compete for the business—and compete we did. We spent the year creating a business plan and securing our future. We won our bid for independence. It was like the Fourth of July, breaking off from the taxing king to form our own country. Overnight, we went from the most disgruntled group of doctors to the happiest group ever. We all agreed to go without pay until our accounts receivable came through, and in a short time, we were making much more money and were more productive.

As a new independent group, we learned about the business of emergency medicine and the art of negotiations. We are a much more lean and efficient organization than when we were under a large group. We have no recruiters, regional directors, or layers of management. Being cost-conscious is crucial, as we have a very poor payer mix and resist taking hospital stipends. Our expenses are minimal, and our provider salaries are not considered a line-item expense but group profit. We know that no one cares more about our money than we do.

We do not have service lines and official vertical integration like large groups have, but we have the best working relationship with our hospitalists and specialists. In the middle of the night, I can call Seth, my trauma surgeon, and Mark, my urologist, for a dual consultation for possible Fournier gangrene and have the patient in the operating room within an hour. I think an important indicator of quality medical care is collaboration of the medical professionals. Unfortunately, there is no Centers for Medicare & Medicaid Services measure for that.

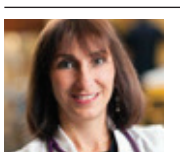
We are forever grateful to our administration that gave us the opportunity to create our group and makes it a point to respond quickly to various requests from the hospital or medical staff, as they are not just business collaborators but friends.

My physicians still hold resentment to the large group we broke off from. The experience was like going through a divorce, and their blood would boil at a suggestion of joining a large group again. Yet there was something about the large group that I missed. I enjoyed the collaboration between emergency physicians from different hospitals. If only independent emergency physicians could get together, then we would have the best of both worlds, small group independence plus large group collaboration. Emergency groups are resistant to sharing anything with one another due to competition and fear of "stealing" contracts. That's how the idea for Independent Emergency Physicians Consortium (IEPC) was born.

IEPC was established in 2012 and brings stability and support to more than 30 emergency departments in California. IEPC assists independent emergency physicians with sharing best clinical and business practices, annual surveys, marketing, recruitment, producing individual ED annual reports, human resources information, confidential consultation from hired hospital administrator and collective shared expertise. Our members believe in preserving their independent status and sign strong nondisclosure agreements that allow for trust in sharing sensitive business and clinical data. IEPC does not do any individual group management. Each group preserves its own billing, malpractice, pay model, and culture.

Some believe that independent physician groups will be extinct and cannot adapt to the ever-changing health care environment. My colleagues and I at IEPC disagree. We are well-established emergency physicians and hire some of the brightest residents. Our groups have survived managed health care, the Affordable Care Act, hospital name changes, several administrations, and the consolidation craze. Our emergency department is our home away from home, our business.

All emergency physicians need to decide for themselves what practice setting they enjoy the most. The business side of emergency medicine is a fraction of the total picture of what we do, and I realize that some doctors do not want the responsibility of being a business owner. The most important factor for the survival of our specialty and the groups within it is physician satisfaction. We need happy doctors.



DR. LEV is president of IEPC.

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

NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP

Satisfy ABEM's MOC Part 4 Requirement with CEDR

Physicians who participate in the Clinical Emergency Data Registry (CEDR) can now meet their Part IV requirement, which contributes to better patient care through ongoing assessment and improvement in the quality of care provided in the emergency department.

A systems integration between ACEP and the American Board of Emergency Medicine (ABEM) allows participants in CEDR to easily fulfill their Maintenance of Certification (MOC) requirement in a few simple steps:

Sign into ACEP's website to see your CEDR dashboard and "opt-in" to share your CEDR activity with ABEM.

Allow six months to ensure any substantive changes in your clinical practice have been accounted for in CEDR reporting.

Review your performance on the CEDR dashboard a second time to compare your performance.

Six months must elapse between your opt-in and performance review CEDR dashboard sign-ins, so ABEM diplomates who need Part IV credit within a calendar year must sign into CEDR prior to June 30 of that year.

ABEM will receive notification each time you review your data but will not have access to your individual performance on any CEDR measure. ABEM will not use these data to analyze individual performance.

If you have any questions about how participation in CEDR gives you credit for your Part IV requirement, please call ABEM at 517-332-4800, ext. 383.

ACEP Executive Director Joins Foundation for Advancing Alcohol Responsibility Board

ACEP Executive Director Dean Wilkerson has joined the national advisory board for the Foundation for Advancing Alcohol Responsibility. Responsibility.org is a nonprofit organization funded by distillers that leads the fight against drunk driving and underage drinking. Mr. Wilkerson will bring a wealth of insight to this position, in consideration of his years of service to ACEP and his previous position as national executive director and CEO of Mothers Against Drunk Driving.

"Drunk driving is a serious, preventable issue," Mr. Wilkerson said. "I admire the foundation's innovative and effective campaigns to make our roadways safe for everyone, and I look forward to working with the national advisory board to make these initiatives even stronger."

CONTINUED FROM PAGE 1

MEET THE ACEP BOARD OF DIRECTORS CANDIDATES

PLATFORM STATEMENTS

The following members are candidates for Board of Directors. They responded to this question:

How will your skills, background, knowledge, or unique abilities help you as a member of the Board to address the major issues facing emergency medicine in the next three years?

Stephen Huntley Anderson, MD, FACEP (incumbent, Washington)

Current Professional Positions: staff emergency department physician, MultiCare Auburn Medical Center, Auburn, Washington

Internships and Residency: internship/residency, general surgery, University of Michigan, Ann Arbor; chief resident, University of Michigan; University of Washington, Seattle

Medical Degree: MD, University of Michigan (1981)

Response

Experience, passion, and a commitment to the future define my skills set for the Board. For over 30 years, I've practiced emergency medicine and devoted myself as a department chairman, chair of education, and chief of staff at my hospital. I honed the abilities to prove the value of emergency medicine to my partners and colleagues. Leadership in your own shop focuses your commitment while teaching you the value of teamwork that works across all lines of service. What's best at the gurney needs to be the easy solution hospital-wide (be it EHRs, boarding, or continuity of care). I'm grounded in my patients' best interests.

With many of our strategic battles now being waged on the state level with Medicaid and insurance companies, I've fought and won against flawed policy at that level. Having found win-win solutions by developing a care coordination program in Washington that is now a blueprint nationally for other state programs, I understand how to stand up for prudent layperson access to care while achieving better health outcomes, increased provider satisfaction, and *saving money*. We don't need more roadblocks or revolving doors; we need more tools like we created with the Washington State 7 Best Practices that I co-wrote.

That experience and passion got me elected to the Board three years ago. There, we created the Clinical Emergency Data Registry (CEDR) (to augment reimbursement while owning our metrics), created a Diversity and Inclusion Task Force (to remove obstacles to success), and fought balance billing and the flawed policies of the American Health Care Act. I was honored to give the Colin Rorrie Health Policy lecture on coordinating care at ACEP15. Through these and countless other battles, I worked tirelessly to find solutions for over the last three years on the Board.

I don't feel my work is done.

So my focus is still three to 10 years down the line, through advocacy, mentoring, and creating a structure within ACEP to continue to keep us at the head of the table in the house of medicine. "Been there, done this. Proud but not satisfied," yet I'm still passionate about continuing to help lead for years to come.

Kathleen Clem, MD, FACEP (American Association of Women Emergency Physicians Section)

Current Professional Positions: professor of emergency medicine, University of Central Florida College of Medicine, Orlando; chief medical officer, vice president, Florida Hospital East Orlando
Internships and Residency: emergency medicine residency, Loma Linda University, Loma Linda, California
Medical Degree: MD, Loma Linda University School of Medicine (1989)

Response

I recognize that the current challenges facing our specialty, and indeed the entire house of medicine, are unprecedented. ACEP needs experienced leaders to lead through this critical time in health care. I have been an involved ACEP member since 1991 and have over 20 years of experience as a leader for both community and academic emergency medicine. I know how to work within and for complex systems as we shape the future of emergency medicine.

I have served as a medical director; tackled reimbursement issues for my group, tort reform at the state level, and residency support issues; and understand that unnecessary requirements of our time and energy matter. I also understand the challenges associated with addressing these issues. As a past academic chair, current chief medical officer, and health system vice president, I bring additional experience to navigate challenges for our specialty. I have led efforts for hospitals to be incentivized to rapidly admit patients, supported resources for timely consults, and worked to build bridges with other specialties. I value, seek out, and treasure opportunities to listen to physicians. The importance of listening-to-understand cannot be overstated. I would continue to seek these opportunities as a member of the Board of Directors and then collaborate with the Board to incorporate the concerns and solutions offered by our members into the work we do at ACEP.

I would continue ACEP's focus on specific strategies to recruit and retain young physicians by increasing designated chapter leadership positions for residents and leadership development tracks. I would continue to work with CORD and EMRA to bring synergy around these efforts as well.

I spent 18 years as an academic chief and chair at Level 1 trauma centers, started the emergency medicine residency at Duke University, and was the chair at Loma Linda during the San Bernardino mass shootings. I have worked my share of nights, weekends, and holidays, and I have worked in small single-coverage emergency departments, too. My current employer has enthusiastically endorsed my involvement with ACEP. I recognize that emergency departments and the physicians who staff them are crucial to America's health care. I want the opportunity to be at the forefront of ACEP's work to promote our core values and continue to deliver the highest quality of care for our patients.

Carrie de Moor, MD, FACEP (Freestanding Emergency Centers Section)

Current Professional Positions: chairman, president, and CEO, Code 3 Emergency Partners, LLC; chairman/founder, Code 3 Emergency Physicians
Internships and Residency: emergency medicine residency, Texas Tech University/Thomason Hospital, El Paso; internship, department of pediatrics, University of Texas Medical Branch Children's Hospital, Galveston
Medical Degree: MD, Texas Tech University Health Sciences Center School of Medicine, Lubbock/El Paso (2005)

Response

Although I have an early career background in academics and as a medical director at a Level 1 trauma center, what differentiates me as a candidate and where I can fill a void on the ACEP Board right now is my significant experience in not only starting, managing, and growing a physician-owned business but also my experience in both facility-based and physician billing. We all know that the insurance industry has taken aim at emergency medicine.

Despite this assault, I have devoted a large amount of my administrative time to protecting and defending my group's independent practice by carefully studying insurance company behavior, learning their games, and devising strategies to overcome their predatory practices. I don't have all the answers, and at times, I have had occasional setbacks and challenges. I have learned a lot of things along the way.

I am proud to say I have created a practice environment that allows physicians to be back in the driver's seat and in control of their practice. It is possible to stand up to the insurance industry that doesn't want to appropriately pay us. It is possible, no matter what your practice environment, to have a career that you enjoy and where you have a sense of ownership or control. I will bring the business know-how, resiliency, strategic thinking, negotiation skills, and a deep understanding of payer behavior to the Board. But more important, I will bring optimism. The future can be better than the present for *all* emergency physicians, and we have the ability to make certain that it is so. I will not represent one type of practice, I will represent all emergency physicians and do so without influence and will be fearless in the pursuit of a better tomorrow for all of us.

John T. Finnell, MD, MSc, FACEP (Indiana)

Current Professional Positions: fellowship program director, clinical informatics, Indiana University, Indianapolis; president, American Medical Informatics Association (AMIA) Academic Forum; member, AMIA Board of Directors; member, AMIA Education Committee; American Board of Emergency Medicine (ABEM) senior case examiner reviewer; ABEM item writer; ABEM oral examiner; ABEM case development panel
Internships and Residency: emergency medicine residency, University of California, San Francisco–Fresno
Medical Degree: MD, University of Vermont, Burlington (1991)

Response

I am a practicing emergency physician and ACEP member for over 22 years. I work in Indianapolis at Eskenazi Health. Our hospital is a Level 1 trauma center and one of the teaching facilities for Indiana University's emergency medicine residency program. My primary role is to lead the clinical informatics fellowship program. I am also a research scientist at the Regenstrief Institute. There are three major issues that currently impact the practice of emergency medicine: psychiatric boarding, the opiate epidemic, and reimbursement.

As a *research scientist*, I will bring wisdom and analytic skills to help your Board provide solutions for these problems. Regarding psychiatric boarding, how is this defined? Each of us, in our own facilities, uses different terminology to define this common problem. We should aim to find a common definition. Regarding opiates, while we are often able to identify patients, we have few treatment options. Resources should be pooled and patients prioritized. As a research scientist, I've led many similar projects and have made critical decisions to help us think strategically about our future.

As an *educator* with a subspecialization in informatics, I will provide your Board with the relevant expertise it needs to help lead us forward. Data is the cornerstone in providing relevant clinical care. We need data to help us make more informed treatment decisions at the bedside. This same clinical data, when aggregated, can be used to help inform others of the value of emergency medicine. These types of data will allow us to better demonstrate how minor complaints can be true emergencies. We have a duty to educate payers of a patient's fundamental right to access care.

As a *mentor*, I've been fortunate to have great mentors that have allowed me to grow. A great mentor doesn't tell you what needs to be done or how to do it; he or she is a good listener. A great mentor asks you questions and poses challenges designed to help you see problems that you may have not identified, to look further ahead than you may be currently looking, or to encourage a different perspective. I will draw upon my unique skills as a research scientist and informatician to help lead your ACEP Board and offer a sounding board to test your ideas and your concerns.

Alison Haddock, MD, FACEP (Texas)

Current Professional Positions: assistant professor of emergency medicine, director of health policy: advocacy, department of emergency medicine, Baylor College of Medicine, Houston
Internships and Residency: emergency medicine residency, University of Michigan, Ann Arbor
Medical Degree: MD, Cornell Medical College (2007)

Response

The biggest issues that emergency medicine will face in the coming years are policy and reimbursement issues. For the past several years, emergency medicine has faced an increasingly hostile environment in many states due to the actions of insurers, regulators, and legislators. We must be prepared to defend our value as a specialty and our patients' right to access emergency care. We have been challenged on prudent layperson, out-of-network billing, and our commitment to providing universal access to emergency care. My strongest skills set is in this policy world.

On the national level, I have many years of experience with the Federal Governmental Affairs Committee and am serving my second term on the NEMPAC Board. As of late, we have seen our biggest challenges on the state level, and having spent the past several years serving as chair of the State Legislative/Regulatory Committee, I have been engaged with leaders from states around the country as they have fought to defend their patients' right to access emergency care. I have developed relationships with Emergency Department Practice Management Association (EDPMA) leaders by serving on the ACEP-EDPMA Joint Task Force. As we continue our legislative and regulatory work around the country, my knowledge and experience can help us gather the data and choose the tactics that we need to protect patients and demonstrate the value of emergency care.

Additionally, I have lived and worked in different states, from Michigan to Washington to California to Texas, and practiced in different environments, from working single-coverage for a small democratic group to large communi-

CONTINUED *on page 12*

ty sites for a big group to an academic urban county hospital. This breadth of experience helps me to understand the challenges that our members face wherever they may work.

I would bring generational diversity to the Board as a current member of the Young Physicians Section, which is a perspective not currently represented on the ACEP Board. Earlier in our careers, emergency physicians often have a different outlook and emphasis, and I am excited to bring that fresh perspective to the Board.

I also have a solid breadth of experience with different aspects of the College. I have been involved in the activities of three different chapters and am currently serving on the Board of Directors of the Texas College of Emergency Physicians. Within the national organization, I not only have policy experience, but I have served on the EMRA Board of Directors, have completed a term on the Steering Committee, and have served several times on Council Reference Committees. My time on the Education Committee gave me an inside look at our annual meeting, a large event that has a huge impact on our membership and our budget. My varied experience within ACEP has developed my leadership skills, and I am now ready to be a focused, passionate, collaborative Board member in service of all aspects of our College.

Jon Mark Hirshon, MD, FACEP (incumbent, Maryland)

Current Professional Positions: professor, department of emergency medicine and department of epidemiology and public health, University of Maryland School of Medicine, Baltimore; senior vice-chair of the University of Maryland, Baltimore Institutional Review Board

Internships and Residency: emergency medicine residency, Johns Hopkins Hospital, Johns Hopkins University, Baltimore; preventive medicine residency, Johns Hopkins Bloomberg School of Public Health

Medical Degree: MD, University of Southern California School of Medicine, Los Angeles (1990)

Response

✔ Board service isn't a hobby; it is a serious commitment of thought, energy, time, and passion. ACEP's mission is to promote the highest quality of emergency care. We are the leading advocate for emergency physicians, our patients, and the public. As a member of the ACEP Board of Directors for the past three years, I have been and remain passionately dedicated to improving access to high-quality emergency care in the United States and globally for you, our colleagues, and our patients.

For over 25 years, I have been a clinician, an educator, and a physician leader. Whether treating a patient with a STEMI, teaching wide-eyed interns the finer points of a lung exam, or speaking to unseen thousands through the television, I tirelessly advocate for our specialty. The key traits of an outstanding emergency physician—the abilities to work together as a team leader, to communicate clearly and effectively, and to make thoughtful decisions based upon the available data—are all necessary aspects to being a valuable member of ACEP's Board.

As a physician board-certified in both emergency medicine and preventive medicine, as well as having a doctorate in epidemiology, I bring an exceptionally strong background in understanding data and the impact of data-driven policy on populations. My background, rich in data analysis and interpretation, is an incredibly important asset to the Board, as it will assure that we can have strong, effective public policy based upon high-quality science.

In our current environment of health policy uncertainty, my passion shines through, whether at the bedside, in the boardroom, or in front of policymakers and the public. I will continue to thoughtfully, passionately, and tirelessly advocate for you and our profession as I continue to advocate for my patients to address the many challenges we face.

Aisha Liferidge, MD, MPH, FACEP (Washington, D.C.)

Current Professional Positions: assistant professor, department of emergency medicine, and director, emergency medicine health policy fellowship, George Washington University School of Medicine and Health Sciences, Washington, D.C.; assistant professor, department of health policy, Milken Institute of Public Health, George Washington University

Internships and Residency: emergency medicine residency, University of Maryland Medical System department of emergency medicine, Baltimore

Medical Degree: MD, University of North Carolina School of Medicine, Chapel Hill (2003)

Response

✔ Driven by purpose and passion, I have a proven track record of leadership that results in organizational growth and the advancement of landmark issues. While I was EMRA president, its budget hit the $1 million mark, which was unprecedented at the time. As President of the District of Columbia Chapter ACEP, I led revitalization efforts that resulted in doubled revenue and a 50 percent increase in membership. While I was chair of the ACEP Associate Membership Task Force, significant progress was made on the delicate topic of membership for non-board-certified providers. Currently, I serve as the chair of the trailblazing Diversity and Inclusion Task Force, which sets ACEP apart as a courageous champion of this important initiative. Additionally, I've served on ACEP's Public Health and Injury Prevention, CEDR, and Steering committees.

The challenges that we face are far more complex than our founders could have ever imagined. Crucial issues such as the devaluation of emergency care as an essential service, the devastating opioid crisis, and the daunting challenge of sustainable health care financing beg our immediate attention and creativity. The approach must be strategic and skilled through effective health policy. As a senior leader in health policy at George Washington University in Washington, D.C., I have been uniquely prepared to do just this. I understand how the federal government, agencies, private entities, and think tanks operate and how they are most effectively influenced. I also understand the implementation of change through policy. Having forged beneficial relationships with key stakeholders, my skills set additionally includes the ability to effectively employ health policy strategy that utilizes myriad collaborative approaches.

As ACEP charts crucial territory, now is the time to promote experienced leadership that is purposeful, passionate, *and* policy-minded to ensure that our voice is not only heard but also respected and heeded.

Virgil W. Smaltz, MD, MPA, FACEP (New York)

Current Professional Positions: self-employed emergency physician working as an independent contractor at Arnot Ogden Medical Center, Elmira, New York, and Oswego Hospital, Oswego, New York

Internships and Residency: emergency medicine residency, West Virginia University, Morgantown

Medical Degree: MD, Marshall University School of Medicine, Huntington, West Virginia (1993)

Response

✔ Insurance companies, the government, and others are affecting our ability to care for patients. My experience in small (West Virginia) and large (New York) chapters allows me to have a broad perspective on the issues. I was involved in passing the prudent layperson standard in West Virginia and continue to be involved in fighting for patient protections in New York. I will bring to the ACEP Board of Directors someone who has worked in many aspects of emergency medicine.

I started my career as a clerk and then as a manager in the emergency department. I have volunteered as an EMT, firefighter, paramedic, and flight medic. I have worked as a staff physician and as a director. My work background has been as a hospital employee, small and large contract group employee, and now as a locum tenen. This varied employer background gives me insight into how issues affect the delivery of care in varied situations. I am currently working with residents in a community-based emergency medicine residency, and my daughter is a second-year medical student. I have definitely become more aware of the issues facing our residents and students and how we must address them to ensure their success in their future careers. I have an excellent perspective on the issues that we are faced with. It would be easy to say I have all of the answers or even some of them.

In reality, these issues are complex, and only through collaboration will ACEP be able to effectively address them. Among my ACEP accomplishments, I have been a Reference Committee chair and chair of the Bylaws Committee. This allowed me to polish the skills necessary to work with other like-minded and strong-willed individuals. My ability to work collaboratively with other team members will be an important asset.

TOXICOLOGY Q&A


PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

Tea Anyone?

A dangerous brew

by JASON HACK, MD

QUESTION: What will this beautiful plant yield when used for an herbal tea?

ANSWER *on page 17*

ABEM's New President on the Benefits of Certification

Dr. Terry Kowalenko tackles today's EM issues for *ACEP Now*

Medical certification organizations should be "relevant, responsive, and innovative," according to Terry Kowalenko, MD, FACEP, new President of the American Board of Emergency Medicine (ABEM), who was elected in July and will serve for the 2017–2018 term.

Dr. Kowalenko is professor and chair of emergency medicine at the Oakland University William Beaumont School of Medicine in Rochester, Michigan; president and chief medical officer of the Beaumont Medical Group; and senior vice president of Beaumont Health. He has been a member of the ABEM Board of Directors since July 2010 and was elected to the Executive Committee in 2014.

Dr. Kowalenko recently responded in writing to *ACEP Now*'s questions on his goals as ABEM President and the organization's approach to certification.

PHOTO: ACEP NOW

Q: What do you anticipate will be your biggest challenge as ABEM President this coming year?

A: The biggest challenge ABEM faces will be directing a focused conversation about the importance of certification for emergency physicians. ABEM certification is the most valuable professional credential an emergency physician can obtain. Leveraging the strength of that credential to limit "merit badge" requirements and to optimize physician reimbursement through the Medicare Access and CHIP Reauthorization Act of 2015 are high priorities for me and the ABEM Board.

ABEM is committed to remaining relevant, responsive, and innovative. To that end, we are convening a special Board retreat and a maintenance of certification (MOC) summit of emergency medicine stakeholder organizations to explore the development of alternative approaches to MOC and, in particular, the ConCert Examination. ABEM needs to guide the emergency medicine community through a conversation about offering a sound option while still allowing emergency physicians to take the current ConCert Examination if they prefer. Any option must be sufficiently rigorous while also addressing concerns that emergency physicians have expressed. The ABEM MOC program has never been static. It has been constantly revised to increase the relevance and value to emergency physicians while adhering to the American Board of Medical Specialties (ABMS) requirements. I think ABEM has been very successful in doing that. Part of that success has come from emergency physicians providing constructive feedback to ABEM about the program. We really need the specialty and emergency physicians to be partners in this process of revision and innovation.

Q: MOC has been under fire in some states and at the American Medical Association (AMA) House of Delegates. What's ABEM's take?

A: I think what has been lost in the discussion about state legislative initiatives is that the importance of certification has held up incredibly well. States where the anti-MOC faction has had success usually involve a physician leading the movement. Interestingly, many of the anti-MOC arguments made by physicians, such as the amount of time spent on MOC, have been rejected by public lawmakers. I'm not saying these are not valid concerns. It's just that, as physicians, we need to be careful about how we come across to the public and to policymakers. We don't want to create the impression of a battle between medical self-interests and the public's best interests.

There's also very little discussion about states such as Oklahoma, which last year passed an anti-MOC bill that was unenforceable. When the bill was reintroduced this year, it was soundly defeated. In Michigan, anti-MOC bills were unsuccessful last year and have been reintroduced this year but are losing ground. Finally, the degree to which the bill passed in Texas will affect emergency medicine is uncertain.

Within the AMA, the Emergency Medicine Section has been a strong supporter of ABEM certification. Unfortunately, what's been driving many of the AMA resolutions is not the desire to innovate or improve MOC but to return to lifetime certification. I think that sends a terrible message to the public, especially when research demonstrates that self-directed CME is largely ineffective. A big risk here is our ability to self-regulate. Medicine has lost its battles over cost control, access to care, and quality. We have been slow to address the issue of the aging physician, and now, some hospitals have started mandatory testing programs and making policies aimed at age-based forced retirement. Many of the anti-MOC initiatives surrender professional self-regulation to the government. That's a horrible precedent. I think our best defense against government control is effective self-regulation through ongoing certification. That's not just an ABEM concern; it should be a concern of every physician in every specialty.

Q: In what way is ABEM responding? Do you see changes coming to the ABEM MOC program, especially to the ConCert Exam?

A: What's important to ABEM, and the specialty, is that ABEM wants to get any option or innovation right the first time. ABEM is actively exploring an option to the ConCert Exam, though I suspect that many physicians will still want to take the exam. During the past two years, several ideas have been floating around within our specialty about revising the ConCert, and we need to look closely at these ideas. ABEM has been actively examining pilots being conducted by other ABMS boards. Keeping in mind that ABEM certification will be time-limited and require episodic recertification, any changes will be a topic for open discussion with the entire emergency medicine community.

It's helpful to remember that ABEM has a role in protecting professional self-regulation through certification. Certification only has value when physicians meet a standard. The rigor of the standard determines the strength of the credential.

Q: There still seems to be substantial frustration about MOC in other specialties. How is ABEM different than other specialty boards?

A: There is a great deal of frustration about MOC in some of the other specialties, and it sometimes spills over into our conversations about emergency medicine. There are a few big differences between the ABEM MOC program and programs in other specialties. ABEM never offered lifetime certification ever. Most other boards have lifetime certificate holders, which has created some factionalism. The notion that ABEM diplomates needed to periodically recertify has always been a part of our professional culture. In many ways, ABEM got the MOC program right the first time. After Lifelong Learning and Self Assessment was introduced in 2004, several changes were made to improve the relevancy and lessen the burden of the activity. Having the American Academy of Emergency Medicine and ACEP provide CME credit added value to the process. Soon, we will be providing rationales for the answers to the questions, offering a choice about which articles you can read, and delivering optional prereading questions that have been shown to enhance learning.

The Part IV Improvement in Medical Practice (IMP) requirement is seamless for most emergency physicians. That's because ABEM designed the requirement to allow you to get credit for work that you are already doing. ABEM recently finished a project with ACEP to provide IMP credit for physicians participating in the Clinical Emergency Data Registry. We also approved the ACEP E-QUAL Sepsis activity for IMP credit.

Q: To many physicians, especially community physicians, ABEM seems like a closed group. What do you think ABEM can do to be seen as more transparent by emergency physicians?

A: I think that's an old impression that is no longer warranted. ABEM directors are nominated by every emergency medicine organization and are usually well-known physicians in our specialty. As a sponsor, ACEP has three positions on the ABEM Board for which they nominate directors. ABEM has always had a strict policy that anybody who serves on the Board or is a volunteer must be clinically active. ABEM values community physician input, and we make certain to include community physicians when setting passing scores for any ABEM examination. Also, last year's Chair of the Test Administration Committee and former ABEM president, Barry N. Heller, MD, is a community physician, as is last year's President, Michael L. Carius, MD, FACEP.

Q: You are a well-known leader in our specialty, but could you share something personal about you so we can know you even better?

A: I'm a professor and the chairman of the Oakland University William Beaumont School of Medicine department of emergency medicine. I oversee three emergency departments (one academic and two community hospitals). I am the first son of immigrants and grew up with real blue-collar values. I enjoy spending time with my family and friends. I also enjoy just about every outdoor activity regardless of the season. I encourage emergency physicians to talk to me and provide constructive feedback on how to improve ABEM-related programs.

Prudent Layperson Standard Under Attack

ILLUSTRATION: CHRIS WHISSEN PHOTOS: SHUTTERSTOCK.COM

This foundation of emergency medicine is being challenged in several states

by L. ANTHONY CIRILLO, MD, FACEP

In the history of the specialty of emergency medicine, there have been landmark pieces of legislation that have significantly changed the paradigm of how we practice. Perhaps the two most important have been EMTALA and the prudent layperson standard. EMTALA mandates the evaluation and stabilization of all patients who present to the emergency department, and the prudent layperson standard gives patients the protection to seek emergency care and provides hospitals and emergency physicians the assurance of payment for those services. While our obligation under EMTALA hasn't lessened, the protection for patients and providers under the prudent layperson standard has come under increasing attack by government and private payers. Just like the fight to enact it 25 years ago, the need to protect the prudent layperson standard today is now a rallying point for the specialty of emergency medicine and the larger house of medicine.

History of Prudent Layperson

In 1986, EMTALA created a mandate that all patients be seen in the emergency department regardless of insurance status or ability to pay. Under EMTALA, hospitals could no longer deny people at least an initial evaluation and stabilizing treatment when they presented for care. Today, we understand why it was important to have EMTALA: to ensure that patients got treated fairly.

Although well-intentioned, EMTALA had a secondary and much more negative effect. Once health insurance companies realized that hospitals and emergency physicians were required by law to see all patients, the insurance companies, especially in the heyday of HMOs, began implementing policies that were harmful to patients and providers. Patients were required to get prior authorization approval *before* going to the emergency department. If, after an appropriate evaluation in the emergency department, the patient's final diagnosis was felt to be "nonemergent" by the insurer, payments to the hospital and providers were retrospectively denied.

For several years, things were bad for patients and providers. Then, in 1992—according to Cal Chaney, former ACEP Director of State and Chapter Relations—Maryland emergency physician David S. Davis, MD, while pursuing his law degree, learned about the concept of "the prudent layperson" as it related to a consumer protection case. Under that precedent, if consumers used a product in a manner consistent with a prudent layperson, then they would be afforded protections if injured, even if they used it in a way that was not its original purpose. Dr. Davis contacted ACEP, and the movement to get the prudent layperson standard extended to ED patients was born. At the "twelfth hour" of the 1993 session, the Maryland General Assembly became the first state legislature to pass the prudent layperson standard for emergency department visits.

The passage of the prudent layperson standard in Maryland became a rallying point for other ACEP chapters. The push for passage of the standard in other states served as the impetus for many ACEP chapters to hire professional lobbyists, create chapter health policy committees, and sponsor emergency medicine "Days on the Hill" to advocate for the standard.

Mr. Chaney also tells a story of his presenting this issue at a meeting of the National Council of State Legislators in 1994. At that time, no other medical specialty or group representing the larger house of medicine, including the American Medical Association (AMA) or the American Hospital Association (AHA), had any policy or official position on the issue. Understanding that building a coalition behind an issue is critical to successful advocacy, ACEP began working through ACEP's delegates in the AMA Young Physicians Section and AMA Council on Medical Service, resulting in the passage of an AMA resolution in support of the prudent layperson standard. Both the AHA and AARP subsequently developed similar policies in support of the standard.

As other ACEP chapters were having success at the state level, success at the federal level came in 1997 with the passage of the federal Balanced Budget Act (BBA) of 1997. With then-Rep. Ben Cardin of Maryland as the primary sponsor, the BBA extended the standard to all Medicare plans and Medicaid managed care plans (but not Medicaid fee-for-service). The BBA included the language that we all recognize today:

The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,
ii) serious impairment to bodily functions, or
iii) serious dysfunction of any bodily organ or part.

The standard was extended to all federal health plans in 1998 by executive order of President Bill Clinton. With the passage of the Affordable Care Act in 2010, the standard was extended to all insurance plans regulated under the Employee Retirement Income Security Act (ERISA) and qualified health plans in the state Exchanges. To date, 47 states (all except Mississippi, New Hampshire, and Wyoming) have passed laws making some kind of prudent layperson standard mandatory in their state. Together, these laws protect almost all patients. The only patients who are not covered by the combination of law, regulation, and executive order are those patients in Medicaid fee-for-service.

Latest Attacks on Prudent Layperson

Despite the multiple layers of federal and state protection, patients and providers have been under increasing attack by government and private health care insurers. In 2011–2012, the Washington State Medicaid agency attempted to limit access to emergency care for Medicaid beneficiaries by limiting the number of allowed ED visits and denying payments based upon a long list of "nonemergent" diagnoses. Most recently, Anthem BlueCross BlueShield has begun enforcing statewide policies in Georgia, Missouri, and Indiana that deny coverage for care provided in the emergency department based upon the "patient's presenting symptoms and the final diagnosis."

This practice of denying coverage based upon anything other than the patient's perception of a medical emergency would be dangerous for patients and devastating to the practice of emergency medicine. ACEP is working with a number of external stakeholder groups, including Consumers for Quality Care, the Emergency Department Practice Management Association, and the AMA to mount a response to this latest threat. After 25 years of tireless work to protect our patients and our practice, we cannot allow insurers or regulators to undo the critical protections granted by the prudent layperson standard. These latest attacks should once again serve as a rallying point for the entire house of medicine to fight to make sure that the federal and state laws are enforced to keep our patients and the specialty of emergency medicine safe.

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

PHOTO: FLOATING DOCTORS AND MATTHEW PARENT

Patients line up to receive care in La Sabana, the most remote community served by Floating Doctors. Volunteers travelled there by boat, bus, and a three-hour hike.

"IT TAKES A VILLAGE" & AN EMERGENCY PHYSICIAN

Floating Doctors provides not just care but education and sustainable change to communities

There are many volunteer programs that bring physicians from industrialized nations to developing or underserved areas to provide periodic medical care or care in times of crisis. However, not many are designed to provide ongoing care to communities in need—and that's where Floating Doctors comes in. Through health professional volunteers, Floating Doctors provides ongoing primary health care services to communities in Panama while working with community members to improve health education and help reduce burdens on local health systems.

PHOTO: FLOATING DOCTORS AND JONAS NEICHIN

PHOTO: RYAN MCCORMICK

PHOTO: MATT DAYKA/VITAMIN ANGELS

ABOVE: Floating Doctors has partnered with Clean the World to promote the use of soap, resulting in a huge decrease in scabies in the communities it serves. **RIGHT:** Dr. Ryan McCormick. **FAR RIGHT:** Dr. Benjamin LaBrot in a boat running from a storm, en route to see patients.

Recently, two physicians from Floating Doctors—Benjamin LaBrot, MD, and Ryan McCormick, MBBS, BAO—sat down with *ACEP Now* Medical Editor in Chief Kevin Klauer, DO, EJD, FACEP, to discuss the genesis and ongoing mission of the Floating Doctors program. Dr. LaBrot is the founder of Floating Doctors and the medical director and co-founder of RemoteCare Education, a tropical medicine competence and medical mission performance CME program held at Floating Doctors' mission headquarters. Dr. McCormick is vice president of Floating Doctors and CEO of RemoteCare Education. Here are some highlights from their discussion.

KK: Where did Floating Doctors come from conceptually, and how did it get started?

BL: Floating Doctors is a nonprofit medical team providing primary health care, emergency care, and community development assistance to remote rural populations. The idea came from an impromptu accidental clinic that I ended up conducting while I was traveling in Tanzania in 2006.

I attended the Royal College of Surgeons in Ireland. One of my classmates suggested that I visit Tanzania. On my way out to the Serengeti, the guy driving suggested that we stop in a small Maasai village to see it, and I said, "Sure, that sounds very interesting." When we got to the village and they found out that I was a doctor they said, "Oh, you're a doctor! Do you mind having a look at this thing on my arm?" Ironically, the very first time that happened to me as a qualified doctor was in a tiny Maasai village in the middle of nowhere in East Africa. I saw one person, and then I saw another, and then I saw another, and pretty soon I ran out of everything I had with me in my own medical kit. I was like, "Oh, resource-limited health care." Fifty or 60 patients and seven hours later, I finished up and got back into the car and had a moment of clarity. I'm going to come back to this village or any of the hundreds of thousands of communities just like this, but I'm going to bring a much bigger backpack. Floating Doctors is really a much bigger backpack with way more effective tools. The epilogue is that eight years later on my honeymoon, my wife and I went back to that village, and it was actually the highlight of our entire honeymoon, especially because they said, "What? You came back?" No doctor had visited since.

KK: How many communities are you serving at this point?

BL: At the moment, there's a network of about 27 communities in western Panama that we visit every three months in rotation. In total, it's probably closer to 35 or 40 communities. Some of the communities that we've chosen are strategically located so that when we're there, people from neighboring communities can have access, too.

KK: Ryan, what are some of the things Floating Doctors is doing that are most impactful for these patients?

RM: Well, one of the best parts of Floating Doctors is that, as opposed to other organizations, we don't just go in for short-term fixes. We focus on making sustainable changes to the communities, providing not just health care but also a lot of education. We don't just work in our clinics; we actually live beside a lot of these people. We live in the village for three or four days. We get to know them, and it's through those personal relationships that we're actually able to make the type of change that you can see as the months and the years go by.

KK: This sounds like third-world population health.

BL: Yeah. It could be functionally the same

CONTINUED *on page 18*

Toxicology Q&A Answer

QUESTION ON PAGE 13

ANSWER: Anticholinergic toxicity—this brew can be eye-opening.

Toxins

Atropine, hyoscyamine, hyoscine, and scopolamine. All are belladonna alkaloids and possess strong anticholinergic/antimuscarinic properties.

Mechanism

Toxins block acetylcholine at peripheral and central muscarinic receptors from attaching to their binding site.

Anticholinergic Toxidrome

The mnemonic for anticholinergic symptoms is, "Blind as a bat (big pupils), mad as a hatter (altered mental status, hallucinations, delirium), red as a beet (dry flushed skin), hot as a hare (fever), dry as a bone (dry mouth), full as a flask (full bladder and can't urinate), silent as a mouse (no bowel movements)."

Death can result from very high fever, dysrhythmias, and seizures.

Facts

They are called anticholinergic because they block the action of acetylcholine, a neurotransmitter substance that controls the contraction of skeletal muscles and also plays an important role in the chemistry of the brain.

For thousands of years, belladonna alkaloids have been used by shamans to induce sensations of leaving their bodies, flying, or changing into an animal.

Jimsonweed is a contraction of "Jamestown weed." Its effects were first described in 1676 in Jamestown, Virginia. British troops sent to halt Bacon's Rebellion inadvertently added the locally growing plant to salads. Many became acutely intoxicated and unfit for duty.

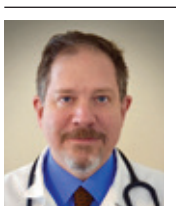
Treatments for mild to moderate systemic symptoms of the anticholinergic toxidrome are primarily supportive and include time, benzodiazepines, and an evaluation for alternative causes of altered mental status (eg, glucose, central nervous system infection, etc.).

Severe systemic symptoms may be treated with judicious administration of intravenous physostigmine, an acetylcholinesterase inhibitor.

Belladonnas were named for their use by Italian women to dilate their pupils.

Ocular toxicity has been well-described in gardeners who inadvertently inoculate their eyes after working with Datura plants. This topical administration of alkaloids is absorbed from the lachrymal, inducing parasympathomimetic effects resulting in mydriasis (unilateral or bilateral). Ocular exposures can also result in systemic symptoms. Usual therapy for ocular toxicity is supportive and time.

If the etiology of large pupil is uncertain, pilocarpine instillation will decrease pupil size with central etiology but not with Datura exposure.



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

PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

JIMSONWEED

Datura stramonium

COMMON NAMES: **locoweed, angel's trumpet, thorn apple, devil's trumpet, mad apple, stinkweed, sacred datura, green dragon, and devil's trumpet**

as an indigent population in Los Angeles. It really has a lot of the very same challenges. The most terrifying thing that our patients can hear is, "Hi, I'm from the government, and I'm here to help you." Outside groups of any kind are something that the indigenous people in Panama have not had the greatest luck with since Columbus's first voyage.

There were a lot of communities when we first went there that believed what we were doing was incomprehensible. It did not compute that we did not have some other kind of agenda. The assumption was that we must be spies for a hydroelectric or a mining concern or that we were working with the government against them in some way. Often, it would be one particular patient in which we've invested a huge amount of time and resources that would really let the community know, "Man, they're really serious."

KK: Is this one way that your organization is different than others?

BL: Doctors Without Borders' greatest strength is that they are able to deploy very large and efficient resources in a very short time. When the cholera epidemic came to Haiti, two days later they're on the ground with cholera treatments and tents and camps all set up, but doing essentially ongoing primary care is much more unusual. A lot of what we do is geared toward trying to reduce the burden on the local health service, not just treating disease and the illnesses of our patients. We have data for about 40,000 patients in our database. We're able to target the microclimates of health, and better yet, we're then able to say this is an intervention that would work in this context of this health landscape.

KK: How many clinicians, physicians, nurses, physician assistants, etc. are actually working with you?

BL: Last year, we had something like 550 or 600 volunteers pass through from nine countries. People from 16 different countries have come to work with us.

KK: If ACEP members or others want to get involved, how would they do it?

BL: On our website's volunteer page [FloatingDoctors.com], there's some info about volunteering and also the application. They can email us and contact us if they have questions before they choose to apply. I would say another thing that really sets us apart is that one of my volunteers a couple of years ago said, "You know, [for other organizations] it's much harder to volunteer than you would think. There's a minimum requirement of two years, or it costs $2,000 for 10 days of a boondoggle where you do half a day of clinical work or you get there and the standard of care is poor." How difficult volunteering for some organizations may be hadn't really occurred to me, and one of the things that's hard for US doctors is getting even one week off. We accept volunteers for shorter amounts of time. It's a little bit different for ER doctors because ER doctors can actually take more than one week off.

KK: Are there suggestions that you offer to defray some of the costs so it's not an obstacle or barrier to participating?

BL: For our volunteer fees? I guess if people can come longer. From our point of view, it's much more desirable if people can come longer, and we do the weekly volunteer contribution, which we really use to run our entire program. That rate drops for each week that people can stay longer.

KK: So when they're going to participate, they're helping fund the mission and they're also going to participate by donating their time. Is that how it works?

BL: Correct. I teach a course at the University of Southern California in their global health department, and one of the lesser-known tenants of mission work is that mission work needs to give benefit both to the recipients of care and also the participants.

KK: What's the minimum amount of time that you would expect someone to put in, and what would be the contribution you would expect?

BL: The minimum that we really require is one week, but we sometimes will take people for one day. In general, our volunteers seem to indicate that three weeks is a really good minimum time. The one-week rate is $700, and that includes accommodation and meals. Ryan, what is it for two weeks?
RM: I want to say it's either $600 or $650.

KK: With charging that amount for a week and providing food and accommodations, there's clearly no room for profit. What percentage do you think goes to funding the mission beyond making sure that you're housing and feeding the volunteers?

BL: That's a good question. When we broke it down from our taxes last year, I think 6 percent went to administrative costs, and then pretty much everything else drove the clinical program itself.

KK: I think it's important for people to hear that because there may be some degree of skepticism.

BL: Oh, yeah, I can't stand when I get dozens and dozens of high-gloss, laminated mailings from organizations. Come on, this looks like it costs $10,000 to actually develop.

KK: The altruistic reasons that your organization exists are the same reasons why you probably are limited on how well you can get your message out. You're not going to spend those dollars because those dollars come from the mission and your patients.

BL: Yeah. Literally every time you have to spend money on something that's not actually related to driving the delivery of care, it hurts. All you can think of is the patients that we have on our advanced follow-up list who need open heart surgery and so many other services. Ryan, did you want to highlight the particular value of ER doctors in this kind of mission?
RM: They're the jack-of-all-trades and the master of when everything falls apart.

KK: If you had a dream for how this story would end for Floating Doctors, what would be your hope for this program?

RM: That it wouldn't end.
BL: Or I guess that it would end only when it was no longer needed.

KK: It's really amazing that the two of you have done that, and I'm really honored to call you my colleagues.

TAKE COMMAND OF YOUR ED

Hospital command centers can be a critical factor in improving access and patient outcomes

by PAUL A. HASKINS, MD

For the past four years, I have had the honor of serving as the medical director of Carilion Clinic's Transfer and Communications Center (CTaC), based in Roanoke, Virginia, where we are responsible for facilitating patient transfers into and out of our system, ensuring the ease of patient admissions, addressing EMTALA issues, and spearheading the policies that improve patient flow and communications through the system. We are the only Level 1 trauma center for 150 miles in any direction, and we also have a pediatric emergency department.

Command Center Overview

A command center helps break down system-wide silos and brings together disparate groups. For example, the CTaC is composed of patient placement, transfer center, case management, patient transport, environmental services, behavioral health call intake, and ambulance/helicopter dispatch, all staffed 24-7-365 under one roof. This strategic approach is based on principles from the distributive situational awareness theory, which high-reliability organizations like NASA implement to facilitate successful outcomes.

From a physical perspective, a command center is an actual space that brings together hardware and software to provide system-wide visibility and transparency. This comprehensive system replaces what were previously manual tasks (eg, white boards, phone calls, and paper orders). We are structured like something from NASA, where banks of computer screens in one room allow teams to easily determine what patients are coming into the system, what rooms are available at each hospital, and where each patient should be moved to or placed in order to receive the care required (see photo).

The center operates 24 hours a day, with clinical and non-clinical staff serving as the system's eyes and ears. The level of responsiveness with this structure is unprecedented, with everything occurring in real time. This type of transparency makes it possible to always know when patients are coming in and going out; it's also possible to predict the times that will be busier in order to effectively staff for them. Changes can be easily communicated across departments, and we know that when patients receive more rapid placement, care commences sooner, leading to better overall outcomes.

With this type of integrated approach, and the extensive data driving it, the command center serves as the source of truth for data and analytics for the entire health system. It also helps to resolve competing departmental priorities with the situational awareness it provides. It is a truly synergistic approach between people, process, and technology.

Pre-CTaC: Barriers to Access and Throughput

Carilion Clinic is responsible for serving the health care needs of more than 1 million Virginians. Prior to the implementation of the CTaC, we were dealing with barriers to access and throughput that impacted our ability to serve our population. We were experiencing increasing patient volumes but did not have enough beds to accommodate them. We were also dealing with length-of-stay issues, which were inhibiting our ability to bring in new patients. This, in turn, created a stressed, overextended workforce as well as dissatisfied patients and families due to inefficiencies

One component of this challenge that needed to be addressed included determining what services could be provided on an outpatient versus inpatient basis, thus freeing up capacity. In addition, there were a variety of different portals leading into the system. When a hospital is between 95 and 98 percent capacity, this can be extremely dangerous, especially with time-sensitive medical issues.

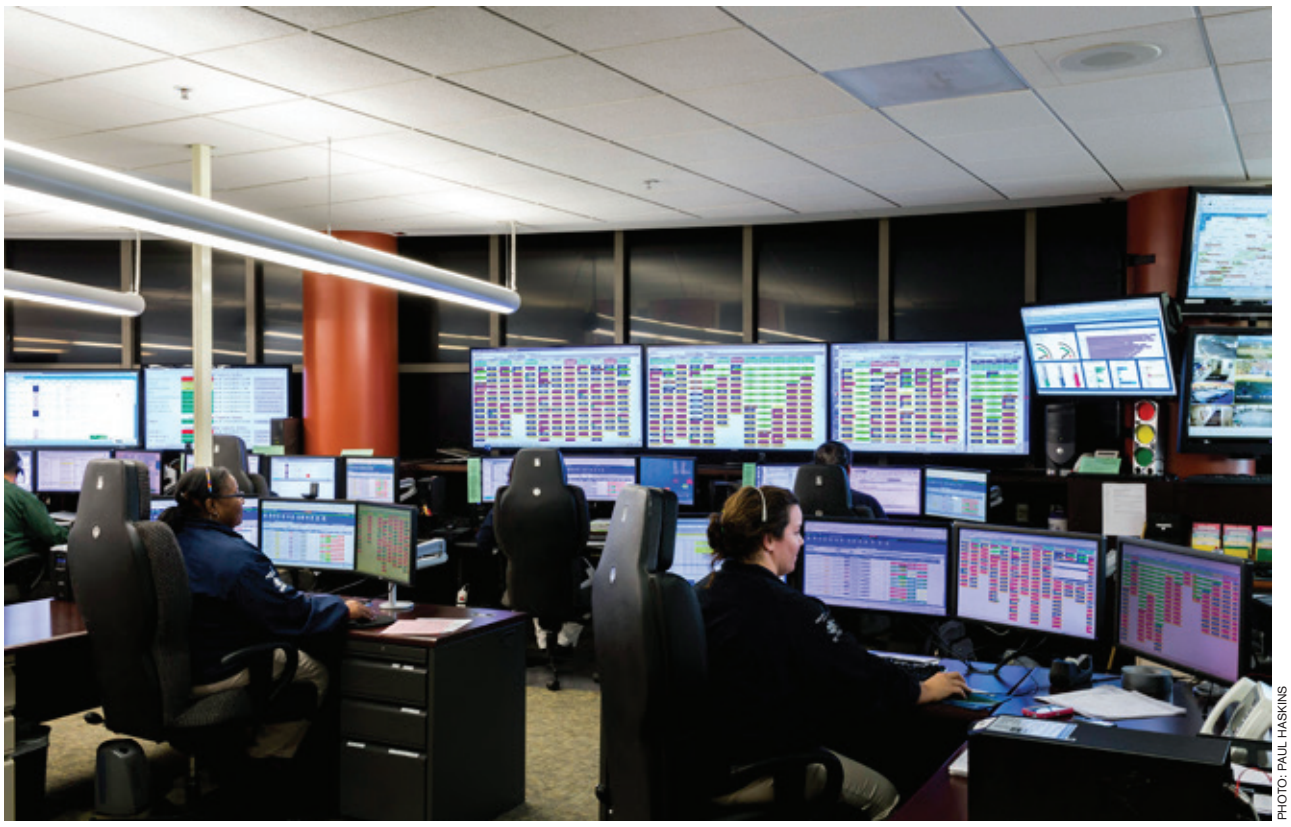


PHOTO: PAUL HASKINS

The Carilion Clinic's Transfer and Communications Center has banks of computer screens, allowing teams to easily determine available resources and patient needs.

Center Goals and Implementation

In 2011, the decision was made to create a centralized command center to address the access and throughput issues. With that decision, three core goals were established:

- Seamless entry of patients into the health system.
- Coordination of the safest, most appropriate transport of patients.
- Efficient management of hospital throughput needs.

We were fortunate to be given the physical space previously occupied by the hospital library, which is a

CONTINUED *on page 21*

FAST FACTS: CARILION CLINIC

Provide quality care for nearly 1 million Virginians

Hospitals: 7

Licensed beds: 1,026

Annual admissions: 50,399

ED visits: 167,211

Physicians: 696

Specialties: 76+

Practice sites: 209

Employees: 12,800

Accredited by The Joint Commission

Top 5 Hospital in Virginia by U.S. News & World Report (Carilion Roanoke Memorial Hospital)

Consumer Choice No. 1 by National Research Corporation (ninth consecutive year, Carilion Roanoke Memorial Hospital and Carilion Roanoke Community Hospital)

Driving Innovation at CMS

CMMI DIRECTOR DR. PATRICK CONWAY ON COSTS OF CARE, BUNDLED PAYMENTS, AND HEALTH TECHNOLOGY

Patrick H. Conway, MD, MSc, has had an interesting journey. He is a Texas resident who became a pediatrician after his residency at Harvard Medical School at Boston Children's Hospital and is still practicing clinically. He was a White House fellow and then worked his way up through the federal government.

He is currently the deputy administrator for innovation and quality at the Centers for Medicare & Medicaid Services (CMS) and director of its Center for Medicare & Medicaid Innovation (CMMI). He also sees patients as a pediatric hospital medicine attending, and his clinical work helps shape his policy work at CMS.

PHOTO: RICARDO MARTINEZ

Dr. Ricardo Martinez

In his various roles, he keeps four important job criteria in mind:

1. Family
2. Impact (the Triple Aim)
3. Learning
4. People, which originally meant mentorship but has grown to encompass the people and culture of the organization

Dr. Conway recently sat down with *ACEP Now* editorial board member Ricardo Martinez, MD, FACEP, chief medical officer for Adeptus Health in Lewisville, Texas, and assistant professor of emergency medicine at Emory University in Atlanta, to discuss his role at CMS and what the future may hold for emergency medicine.

RM: Patrick, you've had a very interesting journey, both in health care and in government. What drives you?

PC: What drives me, and has for probably the last 20 years, is trying to have the largest positive impact on the US health system possible. I know that sounds like a bold goal, and I certainly struggle to achieve it at times, but I've been really focused on better care, better health, and lower cost throughout my career. As you've mentioned, I've been in government through a couple tours of duty and probably would not have predicted that when I was in my first job at McKinsey Consulting before I went to medical school. The core of what I'm passionate about is how to deliver better care to people and to populations of patients.

RM: You're at the Department of Health and Human Services during a very interesting time. In truth, government work gives you low pay and long hours but an opportunity to make a great difference. One of the roles you have is director of CMMI. Can you tell us a little bit about that organization and some of the innovations that you've seen?

PC: I came in originally to CMS as the chief medical officer and ran our quality center. Don Berwick was the administrator at the time and then, over four years ago, he was asked to run CMMI, the innovation center. The whole point of the innovation center is to test new payment and service delivery models like accountable care organizations, bundled payments, primary care medical homes, and state-based innovation. If those models improve quality and lower cost for patients, then we're able to scale those models up nationally. The innovation center is really an exciting sort of innovation engine. It's funded at $10 billion over every 10 years, but the scale of change can be enormous. Just to give you a few numbers, we put out a report to Congress at the end of last year, and we now are working with over 200,000 providers—and even more physicians because a provider can be a hospital, a physician group, or a post-acute facility. Those providers are serving about 27 million patients directly and over 200 million Americans indirectly.

RM: Kaiser has an acute care strategy that actually sends more patients to the emergency department than it does to urgent care because it allows them to get a diagnosis quickly and put that patient in the right cost of care and the right place of care. Does CMMI have any programs that begin to follow patients across their continuum and that may help put a greater focus on that, or do you see that as something we need to do as a profession?

PC: That's a great question. The vast majority of our models actually look at total cost of care as a metric, which I think is the right metric. We sometimes get pushback on this that physicians or clinicians only want to be responsible for their niche of care, but I think we're trying to build a system with physicians, clinicians, and providers that is highest quality at lower cost for the total patient experience. Our focus is really on quality outcomes over time for patients and total cost of care for patients in the health care system.

RM: What do you see as the biggest changes in health care systems over the next five to eight years?

PC: I think we are seeing accountable care organizations (ACOs) continue to grow. We have over 500 now for over 12 million Medicare beneficiaries. Even more important, we have about 120 two-sided risk ACOs, whereas we had about 20 just a couple of years ago. Increasingly, those ACOs are realizing emergency care, urgent care, and acute care are critical pieces of their success. I think you'll see that grow in the bundled payment and episode-based payment arena. We certainly have inpatient bundles now, but I think you're going to see even more outpatient bundles, and you should see bundles around emergency care as well.

As for the state- and community-based programs, we're seeing states like Vermont develop a program that is an all-payer ACO putting all of its patients, beneficiaries, and people into care systems often anchored with a hospital with its associated emergency network and clinics. In state-based innovation, you'll see the critical role for emergency care grow. In the last year, I'd call out the telehealth, remote monitoring, and patient engagement technology arenas. Increasingly, we're going to see a focus on consumer-driven care and how you manage the patients outside of the hospital, the clinic, etc. How do you manage them at home? How do you keep them healthy and avoid admissions? You're going to see growth in emergency medicine using remote technology and other electronic means of communicating and interacting with patients, including telehealth.

RM: We're proud of your success as a clinician leader and not only with what you believe but what you do. I will tell you, for all the emergency physicians out there, we're the only place in the health care system that's open 24 hours a day and takes care of everyone. We really look forward to working together with you and your team. Thank you, Patrick.

PC: Thank you, Ric.

Editor's Note: *After this interview was conducted, it was announced that Dr. Conway is leaving CMS to become president and CEO of Blue Cross Blue Shield of North Carolina, starting Oct. 1.*

PHOTO: PATRICK CONWAY

ACOs are realizing emergency care, urgent care, and acute care are critical pieces of their success. I think you'll see that grow in the bundled payment and episode-based payment arena. We certainly have inpatient bundles now, but I think you're going to see even more outpatient bundles, and you should see bundles around emergency care as well.

- Dr. Patrick Conway

Breaking Bread with a Champion of Prudent Layperson

ACEP and NEMPAC create opportunities for leaders to meet with key legislators regardless of party affiliation—as when we recently shared ACEP's vision with Sen. Cardin (D-MD)

PHOTOS: ACEP NOW

From left: Dr. Drew White, Dr. Jon Mark Hirshon, Sen. Ben Cardin, Dr. Hugh Hill, and Dr. Laura Pimentel.

by JON MARK HIRSHON, MD, PHD, MPH

The fierce snowstorm that occurred during this year's ACEP's Leadership & Advocacy Conference cancelled multiple meetings with senators and representatives, including one of our scheduled NEMPAC Dine-Arounds (which offer ACEP members the opportunity to engage and support federal legislators) with the senior senator from Maryland, Ben Cardin (D). However, we were able to arrange another time to meet with Sen. Cardin, a man of his word. Recently, several ACEP colleagues and I sat down with him at the Monocle Restaurant, a Capitol Hill favorite for decades, located in a 130-year-old brick building just down the street from the Dirksen Senate Office Building.

The close, intimate meeting in a small, private dining room was a wonderful opportunity to break bread together, further develop our relationship with Sen. Cardin, and hear his thoughts about the current political environment, especially related to health care. The conversation ranged from lighthearted banter about the weather to serious, in-depth discussions about topics important to emergency physicians and our patients. The topics included the then-upcoming Affordable Care Act repeal vote, out-of-network and balance billing issues, and Maryland's global budget revenue hospital payment model.

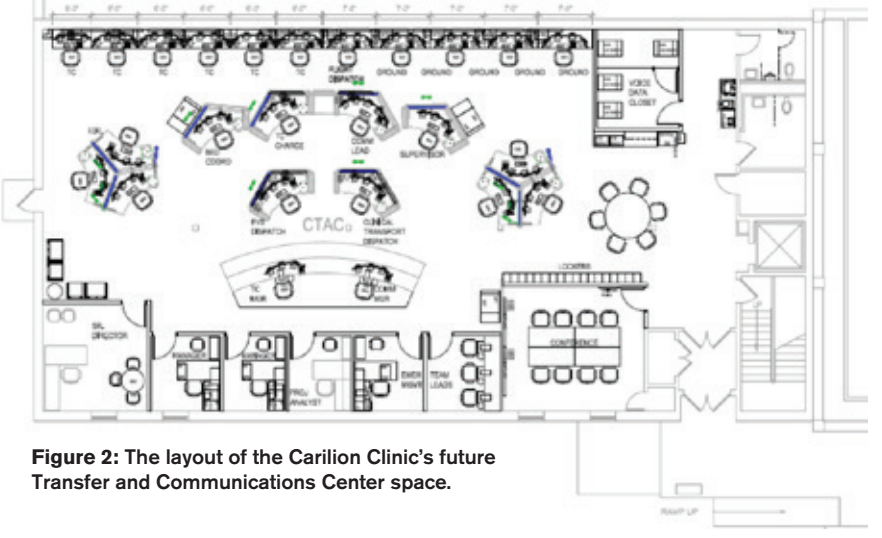
Sen. Cardin brought the prudent layperson standard from Maryland to the national stage, and he has been a fierce champion for this standard for decades. He was surprised to hear that it is again under assault in a number of states by Anthem's newly announced policy to deny coverage for emergency department visits it deems nonemergent retrospectively. (See page 15 for more on the ongoing assaults to the prudent layperson standard.)

We had a great time with Sen. Cardin, and he gave us excellent insights to the current dynamics and politics of the Senate. Included at the luncheon from Maryland ACEP were President Drew White, MD, FACEP; Past President Laura Pimentel, MD, FACEP; Hugh Hill, MD, JD, FACEP; and I. Additional ACEP participants included Laura Wooster, MPH, associate executive director for public affairs; Brad Gruehn, congressional affairs director; and Jeanne Slade, political action director.

DR. HIRSHON is professor of emergency medicine at the University of Maryland School of Medicine and an ACEP Board member.

CARILION CLINICS | CONTINUED FROM PAGE 19

Figure 1: The current layout of the Carilion Clinic's Transfer and Communications Center.



ILLUSTRATIONS: PAUL HASKINS

Figure 2: The layout of the Carilion Clinic's future Transfer and Communications Center space.

semicircle layout that works perfectly from a collaboration standpoint (see Figure 1). We worked with a space planner and were able to maximize the floor area to create strong partnerships between nurses and dispatchers as well as allow for the proper space for monitors and dashboards. Due to the success of the center and increasing needs, we are in the process of moving to a new, larger 4,400-square-foot off-site space (see Figure 2).

Engaging the staff was also a critical part of the implementation. Open communication, including having everyone who would be impacted involved in the planning, was an important first step. Transparent communications were also essential to overcoming other adoption challenges.

Benefits

The CTaC went live in 2012, and the benefits were felt almost immediately. First, it only takes one call to place a patient. The ability to have real-time capacity updates across all areas, in addition to being able to predict discharge dates based on historical data, had a positive impact on throughput and customer service.

The benefits were especially significant for the emergency department, which had been the biggest point of conflict, and include:

- Ability to see exactly how many patients are in the emergency department and where they're going, making it possible to know if the department will be ahead on beds and staffing or needs to add more resources.
- Ability to instantly queue a helicopter to launch in order to transport a critically ill patient from a referring hospital.
- Real-time estimated time of arrival and patient updates during transport.
- Ability to launch preplanning before a patient arrives in order to make sure the hospital has the right bed type, leading to better overall outcomes as the right treatment starts sooner.
- Ability to provide the acceptance, as well as the mode of transport, thus removing the burden of transfer logistics.

Outcomes

The outcomes to date have also been significant:

- Eliminating 30 minutes of wasted time per patient means beds become available 30 minutes quicker and overall length of stay decreases.
- Using the metric of 1,900 admitted patients per month moving through the emergency department via the CTaC translates to approximately 60,000 hours saved per month to care for even more critically ill patients and 720,000 hours per year.
- Real-time emergency department alerts make it possible to precisely place patients and free up space to treat more people, resulting in a 50 percent reduction in the time it takes to place a patient in a room.
- There are year-over-year increases in transfer volumes, including a 40 percent increase in transfer admissions to the secondary campus.
- There is a decrease of 0.3 days in intensive care length of stay.
- The CTaC plays a central role in emergency operations and disaster management logistics at both the local and regional levels.
- The six dimensions of quality outlined by the Institute of Medicine are positively impacted.
- A real-time dashboard for senior leadership helps them monitor patient flow and make short- and long-term strategic decisions.

Conclusion

Providing exceptional care to patients and their families is at the heart of what we do—the CTaC helps us maximize our capacity to do that. By providing us with highly accurate real-time data, it enables us to drive systematic change at our organization.

DR. HASKINS is an emergency physician, medical director of Carilion Clinic's Transfer and Communications Center (CTaC), and assistant professor of emergency medicine at Virginia Tech Carilion School of Medicine and Research Institute.

PAs *IN EM:* A CAREER PERSPECTIVE

Mr. Terry Carlisle reminisces about his long EM PA career and offers a vision for the future of PAs in EM

PHOTOS: TERRY CARLISLE

ABOVE: Mr. Terry Carlisle today.
LEFT: Mr. Terry Carlisle at his emergency medicine physician assistant residency graduation in 1987.

Physician assistants (PAs) have partnered with emergency physicians almost since the birth of emergency medicine as a specialty. Terry Carlisle, PA-C, who has worked for more than 30 years as an emergency medicine physician assistant (EM PA), recently sat down with Chadd K. Kraus, DO, DrPH, a physician in the department of emergency medicine at Geisinger Health System in Danville, Pennsylvania, to discuss his thoughts on the evolution of PAs in emergency medicine. Carlisle is an original member of the Society of Emergency Medicine Physician Assistants (SEMPA), and in 2014, he was recognized as a diplomat of SEMPA for his contributions to emergency medicine. He retired from his career in the emergency department in August. Here are some highlights from their conversation.

CK: What is your background, and how did you become an EM PA?

TC: I started out as an EMT, became a paramedic, and then went to physician assistant school. After I graduated as a PA from Alderson Broaddus University in 1985, I began training in one of the first post-graduate EM training programs specifically designed for PAs at LA County/University of Southern California (USC) in Los Angeles. I completed that program in 1987. While at LA County/USC, I worked with Dr. Gail Anderson, a founding father of emergency medicine, who was the chair of the department of emergency medicine at USC. It was always interesting to hear him talk about emergency medicine and the value he thought PAs could offer to the specialty and to the delivery of emergency care. After my training at LA County/USC, I began my EM PA career, working for five years in the Washington, D.C.–metro area and then for the past 26 years at the University of Missouri-Columbia.

CK: Tell me about your experience and role with SEMPA.

TC: While at LA County in 1986, I wrote a letter to ACEP asking about PA membership. I was told that ACEP was only for physicians so I wasn't eligible to become member. Around the same time, Arnold Zigman, RN, PA-C, who was the program director of the EM PA residency at LA County, had the idea of creating a professional society for PAs in emergency medicine. In 1990, a group of us met in Los Angeles, and SEMPA was born. It was exciting to be at that first meeting and to be one of the founding members of SEMPA. Over the years, I have been on the Board of Directors of SEMPA and served as Vice President. SEMPA continues to be an excellent professional group for networking, education, and advocacy for EM PAs. Although EM PAs are not eligible for ACEP membership, the relationship between ACEP and SEMPA has always been, and I hope will continue to be, a cooperative, collegial, and productive one.

CK: What do you think has changed since the 1980s and what role do you see EM PAs having in the future?

TC: The acceptance of PAs as important members of the ED team has grown among emergency physicians and among physicians from other specialties. In the clinical setting, more EM PAs are working in the main emergency department and not exclusively in the fast track or urgent care areas of the department. In some facilities, the EM PA plays an active role in trauma and medical resuscitations. As emergency care is found in non-hospital venues, such as satellite or freestanding emergency departments, there might be a role for EM PAs to work in those settings with close collaboration and input from EM attendings at a tertiary facility. Teaching by EM PAs is an area that is vastly overlooked. Many EM PAs have years of experience working in a variety of EM settings and could be utilized as teaching faculty that contribute to the educational missions of EM residency programs as well as EM PA training programs. Finally, there is a great opportunity for EM PAs to take on administrative and leadership roles, such as managers of emergency departments and EMS administrators, and to participate in research endeavors.

CK: There are currently approximately 30 EM PA post-graduate residency/fellowship training programs. Is that going to be the future for PAs in emergency medicine?

TC: As a graduate of one of the first EM PA residencies and as the current program director of an EM PA fellowship for PAs, I have a bias in favor of these training programs. There are many excellent EM PAs out there who have learned on the job. However, as emergency medicine has grown as a specialty, and as EM PA roles continue to evolve, these training programs provide a solid academic foundation in a supervised, clinical environment that gives EM PAs an advantage going into the job market by providing additional focused training in emergency medicine. Additionally, most of these programs are in institutions with EM residencies, giving EM PAs the opportunity to participate in lectures, simulation, journal clubs, and research projects and to gain procedural competencies alongside EM residents, residents who someday will be EM attendings. In the future, I could foresee these programs adopting a standardized curriculum for training EM PAs that could even result in a PA equivalent to EM board certification.

BRINGING DATA TO THE BEDSIDE

BENCHMARKING ALLIANCE

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

All Hands on Deck!

Staffing mix: advanced practice providers in the ED

PHOTO: SHUTTERSTOCK.COM

by JAMES J. AUGUSTINE, MD, FACEP

The management of patients in the emergency department requires skilled staff members working as a team to navigate the complex flow with high quality and patient safety. The growth in ED volumes that is continuing in America (and around the globe) requires constant update on the most effective staffing mix to accomplish operational goals.

The Emergency Department Benchmarking Alliance (EDBA) has developed the definitions and descriptors of ED staffing and markers of performance. The definitions are completed and published and are being used in the annual EDBA survey.[1] The definitions developed by the EDBA consider four classes of ED staff: physicians, advanced practice providers (APPs), nurses (not differentiating the various levels of staff nurses), and the group composed of personnel who function in technical and clerical roles.

The latest EDBA survey compiled data from more than 1,500 emergency departments that saw more than 60 million patients in calendar year 2016. The EDBA collects data on daily staffing to provide performance comparisons. A trend that is reportable is the increasing mix of APPs providing service in emergency departments that see more than 20,000 patients per year.

As the EDBA began its work in 1994, it was necessary to develop a formula that allowed comparison of staffing ratios where APPs were working in collaboration with emergency physicians. At that time, the shared role of ED patient management by physicians and APPs did not allow the same level of productivity of APPs as physicians. Emergency physicians at the time managed all patients in the emergency department independently, while APPs needed physician oversight of all work and typically were limited to seeing a low-acuity mix of patients. The EDBA has consistently assigned APPs a factor of 0.5 the number of physician hours to calculate the overall "professional productivity" (physicians plus APPs) in an emergency department. The EDBA calculation of the professional productivity for an emergency department that sees an average of 100 patients a day using 40 scheduled physician hours and 20 scheduled APP hours would result in a figure of 2.0 patients seen per hour. That is 100 patients divided by (40 physician hours + [20 APP hours multiplied by a factor of 0.5]), or 100 divided by (40 + 10), equals 2.0 patients per hour.

Table 1. Professional Productivity Changes Minimally Through the Years

ED TYPE	2011 Physicians + APPs	2012 Physicians + APPs	2013 Physicians + APPs	2014 Physicians + APPs	2015 Physicians + APPs	2016 Physicians + APPs
All EDs	**2.2**	**2.1**	**2.1**	**2.0**	**2.1**	**2.1**
Under 20K	1.5	1.4	1.4	1.3	1.3	1.3
20–40K	2.1	2.1	2.1	2.1	2.1	2.2
40–60K	2.7	2.3	2.4	2.2	2.3	2.4
60–80K	2.3	2.4	2.3	2.4	2.5	2.4
80–100K	2.3	2.4	2.3	2.4	2.3	2.3
Over 100K	2.2	2.4	2.4	2.4	2.5	2.4
Pediatric EDs	1.9	2.0	2.1	2.0	2.0	2.1
Adult EDs	2.2	2.1	2.1	2.2	2.1	2.1

Table 2. APP Utilization in the Emergency Department

CALENDAR YEAR	NUMBER OF EDS REPORTING USE OF APPS	% OF EDBA EDS USING APPS	APP HOURS AS % OF DOCTOR HOURS
2010	117	23%	53%
2011	224	27%	54%
2012	533	51%	57%
2013	627	54%	57%
2014	610	54%	61%
2015	791	58%	63%
2016	911	62%	64%

The six-year trend results of professional productivity from the EDBA data surveys are shown in Table 1. Across all the ED cohorts, productivity appears to be flat. Emergency physician staffing produces an average of 2.55 patients seen per hour. When attending physician coverage was supplemented by APPs, the professional productivity averaged 2.1 patients seen per hour.

Why the lack of improvement? The application of information technologies appears to have stalled the improvement in professional productivity, and the overall ability to see patients has been stable over the last six years. The technology must be simplified to place medical orders in the hospital systems, provide past medical records, and assist in documentation on patient care to improve the work capabilities of emergency physicians.

However, the mix is changing. Very few emergency departments that see less than 20,000 annual volume have APPs in their staffing mix. But above that number, most emergency departments now have APPs as a growing percentage of the professional hours. Table 2 shows that over the last seven years, the professional mix has increasingly featured work hours by APPs.

Emergency departments that use APPs for staffing now comprise 62 percent of all EDBA emergency departments. More important, in 2010, the APPs worked about 53 percent of the physician staffing hours. That means an emergency department that had an average of 60 emergency physician hours a day also had about 32 APP hours. In 2016, the APP hours comprised 64 percent of the emergency physician hours. That means that today, the same emergency department would now have 38 APP hours accompanying the 60 physician hours.

The most effective patient flow appears to increasingly favor the team use of emergency physicians and APPs to manage ED patients in emergency departments that see more than 20,000 patients per year. The EDBA data have followed the trend toward increasing use of APPs in the emergency department.

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DOGMA FEELS RIGHT UNTIL YOU STEP IN IT

SKEPTICS' GUIDE TO EMERGENCY MEDICINE

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

PATCH Me Up?

Platelets in patients with nontraumatic ICH

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

The Case

A 67-year-old woman presents with sudden onset of right-sided hemiparesis and facial droop. She takes aspirin daily. The noncontrast head CT shows a hemorrhagic stroke. Would a platelet transfusion be of benefit?

Background

Antiplatelet therapy prior to a hemorrhagic stroke raises the risk of death by 27 percent, and more than 25 percent of patients with intracerebral hemorrhages (ICHs) were taking antiplatelet therapy.[1]

Reversal of antiplatelet medications in patients with ICH was addressed in a publication by Martin and Conlon.[2] They stated, "None of these studies showed a mortality benefit or improved functional outcome with platelet transfusion in patients with spontaneous or traumatic intracerebral hemorrhage who were receiving antiplatelet medications."

They also said there are "no compelling data currently supporting the use of platelet transfusion" and that "it would be within the standard of care to withhold platelet transfusion in patients with either spontaneous or traumatic intracerebral hemorrhage who are receiving antiplatelet therapy." The review did note that the existing evidence at the time was all based on relatively small retrospective studies.

The recommendation from the neurosurgical perspective states, "At present, the literature contains insufficient information to establish any guidelines or treatment recommendations. Considering this, the current authors have proposed a protocol for antiplatelet reversal in both spontaneous and traumatic acute ICH."[3]

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Clinical Question

In patients with acute nontraumatic hemorrhagic stroke, does platelet transfusion reduce death or disability?

Reference

Baharoglu MI, Cordonnier C, Al-Shahi Salman R, et al. Platelet transfusion versus standard care after acute stroke due to spontaneous cerebral haemorrhage associated with antiplatelet therapy (PATCH): a randomised, open-label, phase 3 trial. *Lancet*. 2016;387(10038):2605-2613.

- **Population:** Adults 18 years or older with nontraumatic ICH with a Glasgow Coma Scale rating of greater than 7 in whom platelets could be transfused within six hours of symptom onset and who used antiplatelet therapy for at least seven days.
- **Exclusions:** Epidural or subdural hematoma, underlying aneurysm or arteriovenous malformation, planned surgery within 24 hours, intraventricular blood more than sedimentation in the posterior horns, previous adverse reaction to platelet transfusion, known use of vitamin K antagonists or history of coagulopathy, known thrombocytopenia, lacking mental capacity, or death appeared imminent. **Intervention:** Platelet transfusions within six hours of supratentorial ICH symptom onset and within 90 minutes of diagnostic brain imaging.
- **Comparison:** Standard care.
- **Outcomes:**
  - » **Primary:** A shift toward death or dependence scored with the modified Rankin Scale (mRS) at three months.
  - » **Secondary:** Survival, poor outcome (mRS 4–6), poor outcome (mRS 3–6), hemorrhage growth after 24 hours, transfusion issues (reactions and thrombotic complications), and other serious adverse events.

ILLUSTRATION: CHRIS WHISSEN PHOTO: SHUTTERSTOCK.COM

Authors' Conclusion

"Platelet transfusion seems inferior to standard care for people taking antiplatelet therapy before intracerebral hemorrhage. Platelet transfusion cannot be recommended for this indication in clinical practice."

Key Results

The study included 190 patients randomized, with 97 in the platelet transfusion group and 93 in the standard care group. The mean patient age was 74 years.

Primary Outcome:

- Odds of death or dependence (mRS 4–6) were greater in the platelet transfusion group.
- Unadjusted odds ratio of mRS 4–6 was 1.84 (95% CI; 1.10–3.08, P=0.02) in the platelet transfusion group.
- Adjusted odds ratio of mRS 4–6 was 2.05 (95% CI; 1.18–3.56, P=0.0114) in the platelet transfusion group.

Secondary Outcomes:

- Alive at three months: 68% in the platelet transfusion group versus 77% in the standard care group; odds ratio 0.62 (95% CI; 0.33–1.19, P=0.15).
- mRS 4–6 at three months: 72% versus 56%; odds ratio 2.04 (95% CI; 1.12–3.74, P=0.0195).
- mRS 3–6 at three months: 89% versus 82%; odds ratio 1.75 (95% CI; 0.77–3.97, P=0.18).
- Median ICH growth at 24 hours (mL): 2.01 (0.32–9.34) in the platelet transfusion group (n=80) versus 1.16 (0.03–4.42) in the standard care group (n=73) (P=0.81).

Transfusion Issues: One patient had a minor transfusion reaction; there was no difference in thrombotic complications (four in platelet transfusion group versus one in standard care).

Serious Adverse Events: 42% in the platelet transfusion group versus 29% in the standard care group; odds ratio 1.79 (95% CI; 0.98–3.27) in the intention-to-treat analysis.

Evidence-Based Medicine Commentary

Emergency Department Patients: It is not clear if these patients were ED patients as it was not explicitly stated in the paper. It seems likely that they were given the nature of the complaint.

Consecutive Recruitment: There was no documentation on whether the patients were recruited consecutively. The publication does say that PATCH investigators did not need to keep a screening log. Therefore, we are unable to know if there was selection bias.

Additional Data: The authors say in their discussion that a similar randomized control trial is nearing completion. ClinicalTrials.gov shows that no results are available, and the page says, "The recruitment status of this study is unknown. The completion date has passed, and the status has not been verified in more than two years."[4]

Bottom Line: Transfusion of platelets in patients with nontraumatic intracerebral hemorrhage cannot be recommended based on the available evidence.

Case Resolution

You discuss the care with the patient and her family. Neurosurgery is contacted, no platelets are transfused, and she is transferred to the intensive care unit.

Thank you to Dr. Robert Edmonds, an emergency medicine staff physician in Newport News, Virginia, and a recent graduate of the University of Missouri-Kansas City emergency medicine residency. (Disclaimer: The views and opinions of this article do not reflect the views and opinions of the US Air Force, the United States government, or Langley Air Force Base.)

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

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of chronic medical conditions, but they're at greater risk of injury, including serious head injury, than the general population. The rate of missed medical diagnoses in the emergency department ranges from 8 to 48 percent, with the highest missed diagnosis rate among first presentations. Any and all acute medical emergencies need to be identified. The admitting psychiatric team certainly shouldn't be burdened with a missed medical emergency.

On the other hand, psychiatric patients can stress the emergency department, with the average length of stay ranging from 15 to 30 hours, depending on the whether they require medical clearance and whether they are admitted.[1,2] Lack of agreement between the emergency department and the psychiatric department can lead to the adoption of arbitrary exclusionary criteria, which delay admissions even further. In one study, the total costs were $17,240 per patient requiring medical screening.[3] So, having these patients who are at high risk for acute medical problems that need to be dealt with before their disposition while at the same time wanting to move them through the system efficiently poses significant challenges. An appropriate and accurate medical clearance process is imperative for decreasing length of stay in the emergency department and the cost of care as well as for identifying medical issues that may be causing or exacerbating the patients' presentation.

General Approach to Behavioral Complaints

Overall, the approach to patients presenting with behavioral complaints should be the same as the approach to those with general medical conditions: ABCs, a thorough history (including collateral history) and physical, and *selective* testing.

History and physical exam remain the mainstays of evaluation; the minimum data set should include full vital signs, history including record of mental illness, medications, substances, mood and thought content, mental status exam, and further examination as indicated by the presentation. In a 1997 study by Olshaker et al of 345 patients presenting to an emergency department with psychiatric complaints, a complete history was the most sensitive, at 94 percent, for identifying a common medical condition compared to physical and lab tests.[4] If you are unable to obtain a history from an altered patient, the risk for missing an important medical illness goes up significantly.

Historical Clues to Differentiate Organic Versus Psychiatric Illness

Patients who present with an altered level of awareness or a dramatic change in behavior often end up getting extensive and expensive workups that could be avoided by asking them a few simple questions: Where do you live? Who do you live with? How do you support yourself? Do you have any outstanding charges you're facing? Have you ever been in jail? What substances do you regularly use? Where were you just before you came to the emergency department?

Several factors favor psychiatric illness including history of psychiatric illness, younger age, and onset over weeks to months. Factors favoring organic illness include no history of psychiatric illness, age older than 40 years, onset over hours to days, complaint of headache, and any recent new medication.[5]

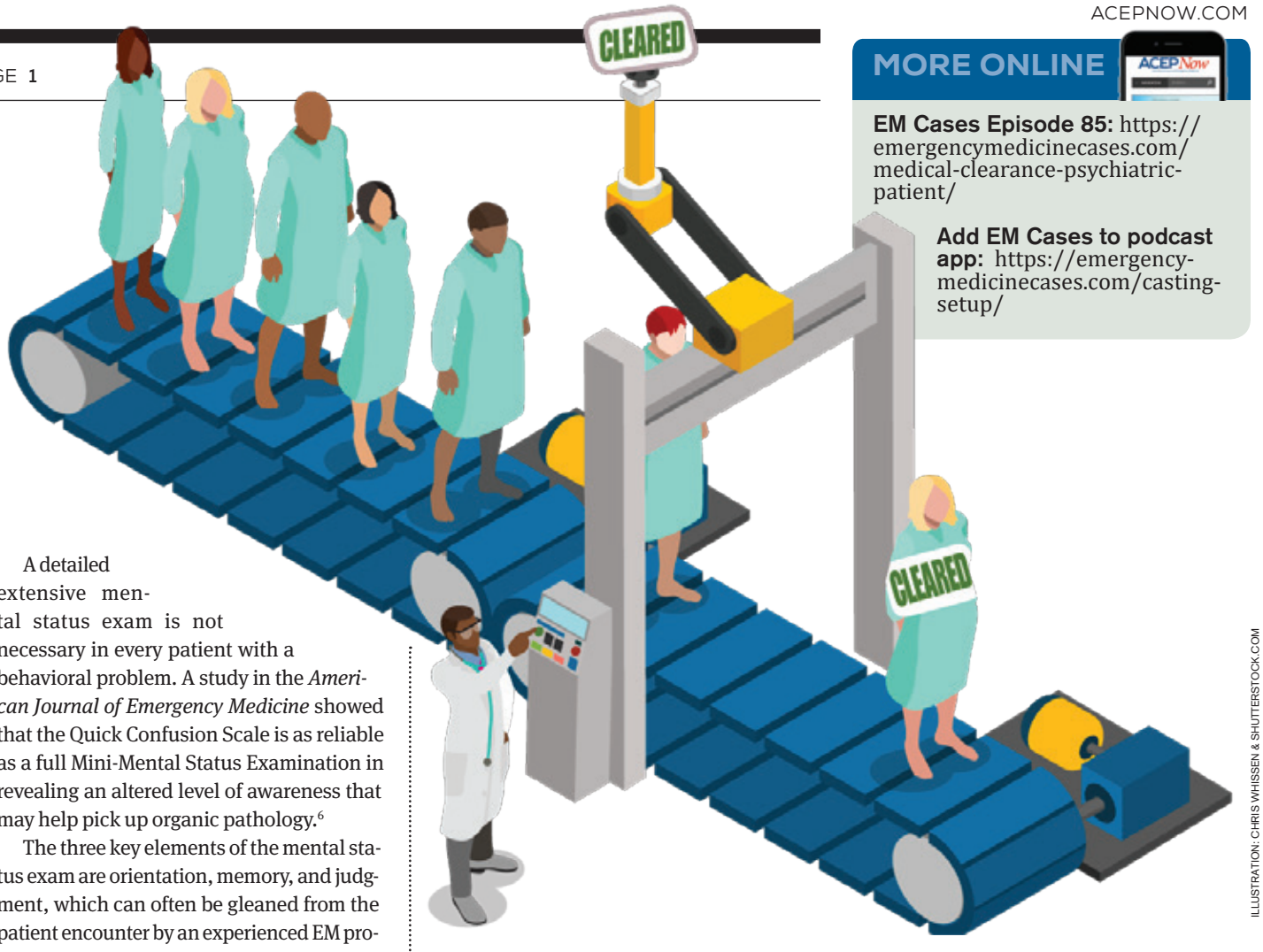

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

A detailed extensive mental status exam is not necessary in every patient with a behavioral problem. A study in the *American Journal of Emergency Medicine* showed that the Quick Confusion Scale is as reliable as a full Mini-Mental Status Examination in revealing an altered level of awareness that may help pick up organic pathology.[6]

The three key elements of the mental status exam are orientation, memory, and judgment, which can often be gleaned from the patient encounter by an experienced EM provider without using a validated scale.

Generally speaking, auditory hallucinations are more indicative of a psychiatric illness, whereas visual hallucinations are more indicative of an organic illness. While about 15 percent of patients with schizophrenia are said to experience visual hallucinations, these tend to occur in those schizophrenics with severe illness and usually in addition to auditory hallucinations.

Physical Exam Clues to Differentiate Organic Versus Psychiatric Illness

As always, vital signs are vital! Any abnormality in vital signs should be addressed and accounted for.

Hypoglycemia can mimic many psychiatric illnesses, from catatonic schizophrenia to severe depression, and could be considered as "the sixth vital sign": *blood glucose (**ABC** **D**on't **E**ver **F**orget **G**lucose*).

Look for fluctuating level of awareness as it is rare in isolated psychiatric illness and often signifies delirium with an underlying toxin, metabolic abnormality, or central nervous system lesions. Scrutinize the patient's eyes. Any abnormality in gaze, nystagmus, pupillary dilation, etc. may signify organic pathology. Ask the patient to protrude their tongue. If you see a laceration, think about a postictal state. Take a moment to look up the patient's nose; you might be surprised to find cocaine, crushed bupropion, or any number of toxins that the patient has insufflated.

Screening Lab Tests or Head CT Scan?

There is no evidence-based list or panel of investigations or order set that can be applied to all psychiatric patients requiring medical clearance.

Routine lab test screening: Several retrospective studies suggest that for psychiatric patients presenting to the emergency department with a behavioral chief complaint, almost all acute medical illnesses requiring treatment could have been identified if a thorough history and physical were performed and that routine laboratory screening has a very low yield for clinically significant acute medical illness.[7-9]

Urine drug screens are not required routinely in the psychiatric patients, as supported by the ACEP guidelines. Most patients, if asked in a nonaccusatory manner, will tell you what drugs they have recently taken. Olshaker et al found that the reliability of self-reported drug use had a sensitivity of 92 percent and specificity of 91 percent.[4] The reliability of self-reported alcohol use was 96 percent sensitive and 87 percent specific. In addition, urine drug screens have many false positives and negatives, which can be misleading.

Literature suggests a very low rate of clinically significant imaging findings in psychiatric patients without risk factors for organic illness. The yield of a clinically significant finding on a CT of the head in uncomplicated schizophrenia patients with normal vital signs and an otherwise normal physical exam (even if it is a first-time presentation) was published in a *Canadian Journal of Emergency Medicine* study.[10] From three Ontario hospitals, the yield was one in 300. Another review of five studies from 2009 showed the diagnostic yield to be only 1.3 percent for CTs and 1.1 percent for MRIs in 384 CTs and 184 MRIs of first episode psychosis patients. CT is clinically indicated in psychiatric patients with altered mental status, trauma, immunodeficiency, or focal neurological findings.

Three Main Take-Home Points in Medical Clearance

1. Approach to psychiatric patients should be the same as your approach to any medical patient. An adequate history and physical are essential.
2. Know which patients are at high risk for an organic cause of their behavioral presentation so that you have a heightened awareness for organic pathology in these patients.
3. There is no evidence for benefit of routine diagnostic screening; tests should be ordered just as you would for medical patients, guided by the presenting complaint and findings on a thorough history and physical examination.

Thanks to Howard Ovens, Ian Dawe, and Brian Steinhart for their expert contributions to the EM Cases podcast that inspired this article.

MORE ONLINE

EM Cases Episode 85: https://emergencymedicinecases.com/medical-clearance-psychiatric-patient/

Add EM Cases to podcast app: https://emergencymedicinecases.com/casting-setup/

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SPECIAL OPs

DR. WELCH is a practicing emergency physician with Utah Emergency Physicians and a research fellow at the Intermountain Institute for Health Care Delivery Research. She has written numerous articles and three books on ED quality, safety, and efficiency. She is a consultant with Quality Matters Consulting, and her expertise is in ED operations.

Hard at Work

"Dealing" with heavy workloads in the emergency department

by SHARI WELCH, MD, FACEP

ILLUSTRATION: CHRIS WHISSEN PHOTOS: SHUTTERSTOCK.COM

At this very minute in emergency departments across the country, physicians and nurses are working hard, trying to manage patient loads and workloads that are both unsafe and unsustainable. How patients are assigned to providers and how workloads of clinicians are managed has implications in terms of worker satisfaction, patient safety, efficiency, and flow. Yet, most departments do not have a clearly articulated strategy for making equitable assignments and particularly for determining when an individual provider is overloaded.

A few goals should be articulated for designing the best model for patient assignments and managing the workload within a department:

1. Models that utilize teams are superior because they enhance communication and improve workflow; in turn, this improves efficiency.[1]
2. Models that utilize geographic zones are superior because they also enhance communication, teamwork, and efficiency.[2]
3. Models that empower providers with regard to workload are preferred.[3]
4. A patient flow coordinator overseeing patient flow for the department is an integral role and part of a patient assignment system. The traditional charge nurse role has morphed into an effective coordinator, policing the department and each zone for inefficiencies, backlogs, delays, and workloads.[4]
5. Patient segmentation, grouping patients according to resources needed and anticipated length of stay, is an innovative new concept and part of the best patient assignment models.[5]
6. The move toward objective measures of workloads for physicians and nurses will continue and aid in patient assignments.[6]
7. Load leveling, balancing the workloads of clinicians, is an important concept in ED workflow for both physicians and nurses.

Patient Staffing/ Assignment Models

An informal telephone survey of members of the Emergency Department Benchmarking Alliance (EDBA), a nonprofit organization with more than 1,000 ED members, identified the following models of patient assignments. It quickly becomes clear that the vocabulary and language don't fully exist to even discuss the topic, and you will likely hear terms that are entirely unfamiliar. A department may use combination strategies.

For Nurses

Primary Care Nursing: One nurse cares for the patient.

Assembly Line Nursing: One nurse performs one task.

Zone Nursing: A nurse is assigned to a geographic zone.

Cross-Cover Nursing: A group of nurses covers all rooms/tasks within the department (most often seen in very small departments).

Team Nursing: A nurse is assigned to a physician/team for a shift and cares for that physician's patients.

For Physicians

Free-Range Staffing: The physician (or nurse) *self-assign*s to the patient (the most common patient assignment strategy).

By Assignment: Patients are assigned to an area by a designated provider in charge.

Rotational: This employs a rotation system with patient assignments made in a planned sequence.

Zone Assignments: Analogous to zone nursing, the physician staffs a zone. Zones can receive distributed patients by rotation, acuity, or chief complaint.

Team Assignments: A team including a physician, nurse(s), tech(s), PAs (in some models), a health unit coordinator, and a scribe inhabits a geographic zone and receives patients into that zone.

Workload Feeding: One of the newest and most innovative systems for patient assignment, this is currently being studied at several sites. It involves sophisticated information technology with a "smart tracker" forecasting the workload and assigning patients accordingly.[7]

Most departments have no real-time mechanisms for identifying when the workload

challenging providers is unsafe or for physicians to indicate their work threshold. The system has no means for recognizing and responding to the changing conditions of patients, such as when patients unexpectedly become unstable.

One intriguing solution has been employed by Intermountain Medical Center in Salt Lake City. It developed the ability for providers to communicate on the ED tracking system (by a physician or a nurse) when a zone is "at capacity," regardless of bed vacancy. An icon on the tracking system suggests to the triage nurse and the patient flow coordinator that the staff in that area feel it would be unsafe to send another patient to their zone or team.

These are the types of technology tools that all physicians will employ in the future. Ultimately, physicians will have the capability to objectively calculate, using Emergency Severity Index scales, chief complaint data, and utilization measures, the work being done in a zone by a team or a provider and manage workloads more effectively. Workloads should never be unsafe or unsustainable!

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Most departments have no system in place for physicians to indicate their work threshold.

CODING WIZARD

NAVIGATE THE CPT MAZE, OPTIMIZING YOUR REIMBURSEMENT

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

CODING FOR PULSE OXIMETRY

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

Question: Can I bill for pulse oximetry in the emergency department?

Answer: The short answer is no. Even though you cannot bill for the pulse ox CPT code, you frequently can use the information obtained from pulse oximetry as part of your medical decision making. Considering the pulse oximeter readings and incorporating that information into the data that you are utilizing to fully evaluate and manage a patient definitely demonstrate an increased complexity of medical decision making. Although a pulse oximeter reading is frequently obtained on many ED patients, your charting should demonstrate the medical necessity of obtaining and interpreting the reading on that particular patient.

To find out more about why you cannot routinely bill the pulse ox CPT code in the emergency department, visit the pulse ox FAQ at www.acep.org/reimbursement.

Brought to you by the ACEP Coding and Nomenclature Committee.

DR. LEMPERT is chief medical officer, health care financial services„ at TeamHealth, based in Knoxville, Tennessee.

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Academic Faculty & Clinical Faculty Opening

The Department of Emergency Medicine at Baylor College of Medicine is looking for Faculty who are interested in a career in Academic Emergency Medicine. We are currently hiring faculty of all ranks commensurate with prior experience and seeking applicants who have demonstrated a strong interest and background in medical education, simulation, ultrasound, or research. Clinical opportunities are also available at our affiliated hospitals.

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

Our academic program is based out of Ben Taub General Hospital and Baylor St. Luke's Medical Center. Ben Taub General Hospital is the largest Level 1 trauma center in southeast Texas with certified stroke and STEMI programs that sees nearly 100,000 emergency visits per year. Baylor St. Luke's Medical Center is home to the Texas Heart Institute and with freestanding Baylor St. Luke's Emergency Centers offers multiple additional practice sites for Baylor faculty. BCM has a collaborative affiliation with eight world-class hospitals and clinics in the Texas Medical Center. These affiliations, along with the medical school's preeminence in education and research, help to create one of the strongest emergency medicine experiences in the country.

Those interested in a position or further information may contact Dr. Dick Kuo via email dckuo@bcm.edu or by phone at 713-873-7044. Please send a CV and cover letter with your past experience and interests.

ASSISTANT/ASSOCIATE PROGRAM DIRECTOR OPENING

The Department of Emergency Medicine at Baylor College of Medicine in Houston, TX is seeking outstanding candidates for the **position of Assistant/Associate Program Director**.

Applicants should have a strong background in medical education with a career path directed towards graduate medical education. Duties of this position will include a focus on developing and implementing innovative educational strategies in the CLER pathways (Patient Safety, Health Care Quality, etc.) that meet and exceed the ACGME accreditation standards. In addition, we are searching for applicants who will contribute to our missions of promoting academic excellence, diversity, and teamwork in service to our patients.

Interested applicants should submit a CV, letter of intent, and 1 letter of recommendation to the Program Director, Dr. Tyson Pillow (**pillow@bcm.edu**).

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EMERGENCY MEDICINE RESEARCHER POSITIONS

The Emergency Medicine Department at Penn State Health Milton S. Hershey Medical Center seeks energetic, highly motivated and talented physicians to join our Penn State Hershey family. Opportunities exist in both teaching and community hospital sites. This is an excellent opportunity from both an academic and a clinical perspective. As one of Pennsylvania's busiest Emergency Departments treating over 75,000 patients annually, Hershey Medical Center is a Magnet® healthcare organization and the only Level 1 Adult and Level 1 Pediatric Trauma Center in PA with state-of-the-art resuscitation/trauma bays, incorporated Pediatric Emergency Department and Observation Unit, along with our Life Lion Flight Critical Care and Ground EMS Division. We offer salaries commensurate with qualifications, sign-on bonus, relocation assistance, physician incentive program and a CME allowance. Our comprehensive benefit package includes health insurance, education assistance, retirement options, on-campus fitness center, day care, credit union and so much more! For your health, Hershey Medical Center is a smoke-free campus. Applicants must have graduated from an accredited Emergency Medicine Residency Program and be board eligible or board certified by ABEM or AOBEM. We seek candidates with strong interpersonal skills and the ability to work collaboratively within diverse academic and clinical environments. Observation experience is a plus.

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

PennState Health

Susan B. Promes, Professor and Chair, Department of Emergency Medicine, c/o Heather Peffley, Physician Recruiter, Penn State Health Milton S. Hershey Medical Center, 500 University Drive, PO Box 855 Mail Code A595, Hershey PA 17033, Email: hpeffley@pennstatehealth.psu.edu

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RONALD O. PERELMAN DEPARTMENT OF EMERGENCY MEDICINE

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MORE INFORMATION: Silas W. Smith, MD, FACEP, FACMT, silas.smith@nyumc.org

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THE FELLOWSHIP IN EMERGENCY ULTRASOUND, established in 2012, aims to prepare graduates to pursue academic or community leadership positions in emergency ultrasound, education and research. This 1- or 2-year postgraduate program focuses on developing educational, administrative and research skills through formal didactics, hands-on experiential scanning shifts, simulation sessions, journal review, image review and participation in division research projects. The Ultrasound Division has five dedicated ultrasound faculty members participating in fellow education and scholarly activities. The Division places particular emphasis on undergraduate medical education (UME) and the fellow has the opportunity to participate in all UME ultrasound curricular innovations and teaching opportunities. Interested candidates may have the opportunity to pursue an advanced degree in Masters of Health Professions Education (MHPE).

MORE INFORMATION: Uché Blackstock, MD, RDMS, uche.blackstock@nyumc.org and Kristin Carmody, MD, MHPE, kristin.carmody@nyumc.org

PEDIATRIC EM

THE FELLOWSHIP IN PEDIATRIC EMERGENCY MEDICINE was established in 1987 and is an ACGME accredited, three year program (pediatric trained fellows) or two year program (emergency medicine trained fellows) focusing on education and experience in patient care, research, teaching, and administration. The goal of the fellowship program is to produce physicians who are clinically proficient in the practice of Pediatric Emergency Medicine, especially in the management of the acutely ill and injured child. In addition, fellows are given the opportunity to become skilled teachers, knowledgeable investigators and competent administrators. With the unique resources of Bellevue Hospital Center and NYU Langone Medical Center, we are able to offer a fellowship of the highest caliber. Interested candidates may have the opportunity to pursue advanced degrees in Masters of Health Professions Education or Masters Programs in Clinical Investigation.

MORE INFORMATION: Michael Mojica, MD, michael.mojica@nyumc.org

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MORE INFORMATION: Rana Biary, MD, rana.biary@nyumc.org

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This position provides competitive compensation and an excellent benefits package. Those interested must apply by uploading a cover letter and current CV online at academiccareers.uchicago.edu/applicants/Central?quickFind=55160. Review of applications will continue until all available positions are filled.

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Toldeo, Ohio

The Emergency Department at the University of Toledo Medical Center is seeking an energetic, highly motivated and talented physician to join the University of Toledo Emergency Medicine Department Residency Program as a curriculum/didactic Director and Core Faculty.

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For further information call the Department of Emergency Medicine Administrator, Hesham Youssef at 419-383-4439 or email him at Hesham.Youssef@utoledo.edu.

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Contact Information:
Kumar Alagappan, MD, FACEP, FAAEM, FIFEM
Professor and Chair
Department of Emergency Medicine
Unit 1468
The University of Texas MD Anderson Cancer Center
PO Box 301402
Houston, TX 77030-1402
Email: kalagappan@mdanderson.org

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