Thursday, Sept. 17, 2020 marks the third annual National Physician Suicide Awareness (NPSA) Day. NPSA Day remains a day of reflection, dedicated to honor the memory of our colleagues who have died by suicide. The day raises awareness about physician suicide and should encourage discussion of how we can prevent it. This year’s theme is “One of Us,” and is meant to remind us that we, as a community, are at risk. The theme is also meant to remind us that we all have a part to play in preventing suicide among our colleagues. Suicide is preventable if we take the time to care for one another and destigmatize the issues that underlie it by being vulnerable and open to conversations about them.

A Year of Challenges

This year, in the shadow of the COVID-19 pandemic’s dramatic arrival in New York, we lost Lorna Breen, MD, FACEP, to suicide. Dr. Breen was one of us. She was radiant, charismatic, powerful, interesting, kind, and adored by those around her. She was an adventurer and snowboarder. She was a friend who loved and was loved by so many. She was the director of a major New York City emergency department. She led her department with every fiber of her being. She was an educator and mentor to colleagues, residents, and students. She was also a longtime ACEP and New York ACEP member who participated in committees and Scientific Assemblies. She was optimistic and had even taken on the challenge of starting a new educational path in 2019, studying for an MBA. She had no history of mental health issues and, though she was a colleague and friend, she revealed no signs to suggest she was at risk.2,3 She was an incredibly strong and effective person. She was the epitome of emergency medicine. She was one of us.

Dr. Breen’s death, as well as the deaths of so many others, reminds us that many...
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**COVID-19 Severity Calculation Tool Now Available**

ACEP and EvidenceCare created a seven-step triage process for emergency physicians to better classify COVID-19 patients and inform next steps. This new and evolving pathway integrates into many electronic health record systems and also can be downloaded for offline use. Learn more at www.acep.org/covid-19-severity-tool.

**ACEP20 Announces Dr. Fauci as Special Guest**

National Institute of Allergy and Infectious Diseases Director Anthony Fauci, MD, will provide his unique perspective from the epicenter of the pandemic to kick off the ACEP20 opening session. Following Dr. Fauci’s remarks, a panel of international emergency physicians will present “Lessons Learned: Global Response to COVID-19.” Learn more at www.acep.org/acep20-special-guests.

**ACEP20 CME: Gain Access to Hundreds of Courses for Three Years**

Have questions about how ACEP20 CME will work? Here’s what you need to know.

- The cost is less than $1.80 per CME hour for ACEP members.
- The 250 on-demand CME hours can be claimed based on what sessions you attend. You’ll be able to claim all of these hours at one time at the end of ACEP20. To view a schedule of the live content, visit www.acep.org/sa/education/schedule.
- The 250 on-demand CME hours can be claimed for the next three years. You claim the hours for individual courses after watching on demand. This option is added as courses are finished.
- The ACEP CME Tracker will keep all of these hours documented for members.

**Survey Results Show Financial Impact of COVID-19 on Group Practices and Individual Physicians**

ACEP has been actively advocating on your behalf to provide the tools and resources you need to safely do your job during the COVID-19 public health emergency. To inform our advocacy strategy, ACEP staff, in conjunction with a subgroup of the ACEP Reimbursement Committee, designed a survey that included 24 questions about the financial impact COVID-19 has had on emergency medicine group practices and individual emergency physicians. We received 197 responses representing EM teams across the country. The data confirmed many respondents reporting issues with the lack of or decreased volume and revenue. View the full article with the survey results and analysis at www.acepnow.com.

**Get Your X-Waiver Through Zoom This Fall**

ACEP, in partnership with Providers Clinical Support System, is hosting Medications for Addiction Treatment (MAT) X-Waiver (DEA DATA 2000) trainings this fall and in early 2021. These are free virtual live trainings done through the Zoom platform. Attendees who sign up for this training will attend a live four-hour webinar taught by clinical experts. Once completed, participants will receive the second half of the course, a four-hour online self-study portion. Participants are required to pass an exam to complete the training, and the course completion certificate does not expire. Sign up at acep.org/ed-x-waiver.

**Virtual Grand Rounds to Continue Throughout 2021**

ACEP’s Academic Affairs and Education Committee created the monthly Virtual Grand Rounds program in April as a way to provide free education for emergency physicians and residency programs during this time of social distancing. It allows you to track learner participation while engaging in Q&As with course faculty on different monthly topics. Once the sessions are complete, they are posted in the ACEP eCME catalog for online learning. The following sessions are coming up. Register at www.acep.org/virtualgrandrounds. Past recordings on COVID-19, airway, physician wellness, ultrasound, and pediatrics are free for ACEP members.

- **Sept. 23:** International
- **Oct. 16:** None—ACEP20 instead
- **Nov. 18:** Neurology
- **Dec. 16:** Cardiology
- **Jan. 27:** Vulnerable Populations/Social Determinants of Health

**Feb. 24:** Simulation: OR Emergencies with EMRA

**Improve Your ED’s Pain and Addiction Care**

We may be in the midst of a global pandemic, but the opioid epidemic isn’t going away. ACEP newest accreditation program, Pain and Addiction Care in the ED (PACED), is the nation’s only specialty-specific program that allows emergency departments to improve pain and addiction care. Elevate the quality of patient care with innovative treatments, alternative modalities, and impactful risk reduction strategies in a collaborative team setting, resulting in positive outcomes for your patients, families, and communities. Learn more at www.acep.org/paced.

**Exclusive Online-Only Content**

Every month, ACEP Now publishes additional content online. Here’s what we have in store for September:

- **Ethics:** Research and Information Sharing in a Pandemic
- **Clinical:** How to Manage Maritime Environments
- **And more!**
Speaking the Unspeakable

After Dr. Lorna Breen died by suicide in April, her family took up a cause they never wanted

by JORDAN GRANTHAM

It was less than 24 hours after Lorna Breen, MD, FACEP, died by suicide when The New York Times published the news. There it was, a headline the Breen family could have never imagined for their beloved sister, daughter, aunt: “Top ER Doctor Who Treated Virus Patients Dies by Suicide.”

Their world had been capsized by shock and grief, and the Breen family was huddled together in Charlottesville, Virginia, holding this horrific, unthinkable news as their own tragic truth. The Breens did not want to tell anyone about Lorna’s death, and they certainly did not want to announce it to the Times’ 47 million Twitter followers. But the news was out there, and there was nothing they could do about it.

As the family cried together, they tried to figure out what to do next. “Jennifer and I had this incredible moment of clarity,” said Corey Feist, Lorna’s brother-in-law. “We needed to lean into this conversation, and we needed to shine a light on it.”

The Breen Bond

Jennifer and Lorna Breen were “soul mates,” according to Corey. Jennifer was younger than Lorna by 22 months, and they were inseparable. The sisters developed their own language as children and kept it going into adulthood, often switching into it for secret sister chats. To Corey, a health care executive, Lorna was a “big sister” who shared his passion for running and was his favorite person to talk to about the quirks of working in the medical industry. To the Feist children and her other nieces and nephews, Lorna was “the cool aunt,” a status she greatly treasured.

The Feist family had just wrapped up their annual vacation with Lorna when she returned to unfamiliar territory at the emergency department at NewYork-Presbyterian Allen Hospital. COVID-19 had dramatically changed the landscape while she was traveling, and she immediately started sprinting to keep up with the increasing patient loads and rapidly changing protocols. It was March 18—only four days after returning to work—when she experienced her first COVID-19 symptoms.

The Feists spoke with Lorna daily as she tried to manage the illness alone at her home. Feverish and weak, she expressed concern for her colleagues and their safety, worrying about the personal protective equipment shortages and many staffers who had also fallen ill. She tried to help with a group project for the MBA program that she was enrolled in and kept in touch with her Bible study friends. Gifted with an incredible motor and work ethic, resting didn’t come naturally for her. The woman who regularly ran marathons was now winded by doing the dishes. Still, she knew she was urgently needed back at work.

She returned to work in the emergency department on April 1. The stress and workload had only mounted while she was sick, but she could

CONTINUED on page 6
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- LPs in Febrile Infants 29-60 Days Old?
- Suicidal Risk: Assessment and Intervention
- Cardiovascular Pearls, 2019
- DKA and Hyperglycemia Update
- Sore Throat: Still Trying to Get It Right
- Sexual/Racial/Ethnic Disparities in the ED
- ACS & PE – ACEP 2019 Guidelines
- Psychiatric Patients: Medical Evaluation
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*Topics listed with an asterisk (*) are 90-minute faculty panel discussions; all other topics are 30 minutes.

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ADVANCING EMERGENCY CARE

Physician wellness is a complicated concept. Emergency medicine comes with unique challenges, and all emergency physicians cope in their own ways. There is one thing most ACEP members agree on, though: It helps to talk to someone who “gets it.”

If you’d like to be that peer who gets it and recognizes when a colleague is needs extra support, we encourage you to check out ACEP’s new Peer Support Project. You’ll receive peer support resources and tips, plus monthly prompts that encourage you to check on your colleagues—and yourself. Sign up at acep.org/peer-support-project.

As most families, the Breen family shared a special bond, and they often reflected on what Lorna’s personal story and on to the solutions they are dedicated to shifting the focus off Lor- na’s personal story and on to the solutions they are dedicated to shifting the focus off—Lorna’s legacy. Once the family decided to share their story, they set a movement in motion.

The Cause

The first thing the Breen family did was set up the Lorna Breen Heroes’ Fund to provide mental health support to health care professionals. Soon that grew into a foundation dedicated to protecting and preserving the wellbeing of health care workers while des- tigmatising mental health support for cli- nicians. The Lorna Breen Heroes’ Foundation has told her story to many audiences over the last three months, furthering its mission to pri- oritize the protection and well-being of health care workers while breaking down barriers that prevent clinicians from seeking mental health support.

In June, Jennifer and Corey submitted writ- ten testimony to a Congressional hearing ex- amining the pandemic’s toll on the mental well being of clinicians. The Feits included multiple calls to action imploring the various entities involved in the clinician wellness cri- sis—the health care industry, federal and state governments, health care rating agencies, and the clinicians themselves—to each do their part to chip away at the harmful stigmas that keep clinicians from seeking support.

In late July, Sen. Tim Kaine (D-VA), Sen. Mark Warner (D-VA), and Sen. Mark Warner (D-VA), and Sen. Bill Cassidy, MD (R-LA), introduced S. 4339: The Dr. Lorna Breen Health Care Provid- er Protection Act to honor Dr. Breen and pre- vent suicide and mental health issues among health care professionals amid the COVID-19 pandemic and beyond. The movement was gaining momentum.

For the Breen’s, the cause is equal parts personal and professional. Jennifer and Corey explained, so she was particularly passionate about that project."

Powered by the same problem-solving instincts that fed Lorna’s drive, the Breen’s are dedicated to shifting the focus off Lor- na’s personal story and on to the solutions needed to protect and prioritize the emotion- al well being of health care workers. “That’s the way [Lorna] would have operated,” Corey explained.

As the public and medical community mark Suicide Prevention Week (Sept. 6–12) and National Physician Suicide Awareness Day (Sept. 12) during this pandemic that has only compounded the nation’s mental health crisis, the Breen family said they will continue to speak to the unspeakable in Lorna’s honor. “She cared so deeply about her col- leagues. ...We feel like this work is spreading her,” Corey explained. “It’s the hardest thing I’ve ever done in my life. And it’s the most rewarding.”

MS. GRANTHAM is ACEP’s communications manager.
among us as at risk and struggle to process and vocalize our own emotions. Though each story varies, we physicians tend to have a problem acknowledging our own mental health struggles and we need to make concerted efforts to change that. While we have always been the safety net for our communities, we lack our own safety net to effectively deal with the barrage of psychological injuries that our jobs confer.

2020 has given emergency physicians front-row seats to one of the most tumultuous periods in generations. The COVID-19 pandemic has put the spotlight squarely on the health care system, medicine, and, in particular, on us as the front lines of our communities. The record number of unemployed due to furloughs and layoffs has given way to social and economic strife, even affecting emergency physicians. Our communities have also seen increasing numbers of opioid-related deaths, domestic violence, and gun violence. It would be ignorant to assume that we are all somehow psychologically insulated from our environments.

How We Can Help Prevent Suicide

Though there is a need for broader systemic change to improve the physician experience, changes are occurring. For example, as a result of Dr. Breen’s suicide, her family helped push the State of Virginia to make changes to several laws to better protect physicians seeking mental health care.1 (See page 4 to read about how Dr. Breen’s family is honoring her legacy.) Similarity, on July 29, 2020, the U.S. Senate introduced bipartisan legislation, the Dr. Lorna Breen Health Care Provider Protection Act, that aims to reduce and prevent suicide, burnout, and mental and behavioral health conditions among health care professionals.2

1. Recognizing the need to minimize barriers to obtaining help, the Federal Communications Commission (FCC) unanimously voted to create a national three-digit suicide prevention hotline, 988, which will be implemented on July 16, 2022.6 Organizations like the Joint Commission, the Federation of State Medical Boards, and the American Medical Association have released statements to aimed at making it easier for physicians to access mental health services without deleterious effects on their own ability to practice medicine.7 ACEP has expanded its offerings for mental health and well-being support by compiling wellness resources and even offering three free confidential counseling or wellness coaching sessions.8

Locally, there are actions within our grasp that can help create the safety net we need. Starting with empathy and kindness, we can create supportive workplace environments that promote a willingness to share experiences and permit both cognitive and emotional unloading. Just as we rally when critical patients arrive and support one another with treatment recommendations and procedural support, we must do the same when we are ourselves at risk. Over time, once momentum and buy-in from leadership is assured, operational changes can be implemented to better safeguard physicians.

We urge emergency physicians across the country and around the globe to mark Sept. 17 on your calendars as NPSA Day and to take the following steps at your home institutions:

1) Create a safe space by dedicating time to talk about mental health and suicide. Set aside time at your morning report, morning huddle, or faculty meeting to discuss physician mental health, depression, and suicide. More participation will allow individuals in your group to speak freely about these issues without creating a spotlight on any one person.

2) Speak the names of your colleagues who have died by suicide. Remember them, honor their memory, and share stories and lessons learned.

3) Be vulnerable and be a role model for your colleagues and trainees. Physicians are notoriously constricted in sharing their own emotions and experiences, which may contribute to higher rates of burnout, depression, and suicide. We need courageous individual leaders to start the conversation and break the ice. By modeling vulnerability, you are helping to change the culture in medicine.

4) Support access to mental health. This may take a little preparation, but review and share how mental health care and resources are accessed locally. As you are doing the research, look for the barriers to access care. How easy is it to access care? How long does it take to get an appointment? Is confidentiality protected? Does your employer provided insurance plan have adequate mental health options?

If you would like to donate to Dr. Lor- na Breen’s Heroes Foundation, visit www. drlorbnreem.com.

If you would like to purchase National Physi cian Suicide Awareness Day pins, visit www. corem.org/npsa.

If you are having thoughts of suicide or self-harm, please call a friend or a loved one or the National Suicide Prevention Lifeline at 1-800-273-8255 (TALK).

References
emergency physicians have experienced a 20 percent wage decrease. Lower rates will drive a reduction in the cost of care. Some members are already facing furloughs and burnout. Lower volumes and increased workloads will fall on the physician. Emergency physician assistants who must be adequately supervised and trained.

ACEP must connect with members and support them in the workplace during this challenging time.

The candidates for the Board responded to the following question:

What are the two greatest opportunities and threats to ACEP?

**Michael J. Baker, MD, FACEP (Michigan)**

*Current Professional Positions:* director of telehealth, EPMG/Envision; medical director, Munson Healthcare Cadillac Hospital; clinical assistant professor, Michigan State University College of Osteopathic Medicine, East Lansing; ED informatics representative on the clinical excellence committee and chairperson for optimizing information technology, Trinity Health; adjunct clinical instructor, University of Michigan College of Medicine, Ann Arbor; core faculty, University of Michigan/St. Joseph Mercy Hospital emergency medicine residency; attending physician, member of the telemedicine clinical quality committee, and Cerner physician liaison, St. Joseph Mercy Hospital, Ann Arbor

*Internships and Residency:* emergency medicine residency, University of Michigan

*Medical Degree:* MD, Ohio State University, Columbus (1993)

**Response**

ACEP’s strategic plans revolve around both threats and opportunities. The unpredictability of the COVID-19 health emergency represents a threat to ACEP. ACEP risks losing members due to furloughs and burnout. Lower volumes and reimbursement will drive a reduction in the cost of care. Some emergency physicians have experienced a 20 percent wage drop. Cutting CME benefits will drive our members to low-cost options for education. As hospitals cut positions to save money, more work will fall on the physician. Emergency physician positions might be filled with nurse practitioners or physician assistants who must be adequately supervised and trained. ACEP must connect with members and support them in the workplace during this challenging time.

The second threat is the consolidation of insurers, health systems, and physician groups to establish fair work environments and wellness are assured.” ACEP leaders can work with payers, health systems, and physician groups to establish fair workplace policies, promote appropriate reimbursement, and encourage competition.

One of ACEP’s most significant opportunities is to create and analyze big data through CEDR, E-QUAL, and EMF-sponsored research. Reliable data can support the adoption of new concepts, such as telemedicine and electronic records systems. The consolidation of health systems provides opportunities to collect data in a standardized way. For example, I worked to convince a 35-hospital health system to support CEDR reporting for any participating emergency center. Lastly, EMF must be strongly supported in its vital support of independent research efforts and developing future researchers.

ACEP’s other opportunity is to push for insurance reforms. The COVID-19 pandemic demonstrated the value of emergency medicine to the health care system. Our work with disaster preparedness and ACEP’s quick development of COVID resources such as the ACEP COVID-19 Field Guide (acep.org/corona/covid-19-field-guide) stunned many outsiders who portrayed the emergency center as a high-priced place to receive medical care. ACEP can use that realization to push for fair payment, end narrow networks and surprise billing, and identify mechanisms to ensure adequate health care coverage. ACEP continues to push for a fair resolution to the surprise billing issue and advocates alongside state chapters advocacy, emergency physician groups, and other medical organizations. ACEP can re-affirm its commitment to its vision that “All patients have access to full and adequate health care coverage.” Legal mandated health care services are fully funded.” ACEP needs Board members who can quickly recognize and respond to new threats and opportunities.

**Allison Haddock, MD, FACEP (incumbent, Texas)**

*Current Professional Positions:* assistant professor of emergency medicine, director of health policy; advocacy, assistant director of faculty development, department of emergency medicine, Baylor College of Medicine, Houston

*Internships and Residency:* emergency medicine residency, University of Michigan Medicine, Houston

*Medical Degree:* MD, Cornell Medical College (2007)

**Response**

ACEP has 41,435 members, and while our membership is growing, our rate of growth is declining. The growing number of EM residencies in the United States has brought an increase in our candidate membership, but we are seeing a drop in the percentage of graduating residents who retain their membership in ACEP. ACEP must ensure that we are the premier source of opportunities—for networking, education, and personal development—for emergency physicians. We must demonstrate that we share our members’ values and are advocates for them and their most vulnerable patients. While some will dedicate the time and effort required to be councillors and committee members, we must also offer smaller innovative opportunities.
for members to get involved with issues that are critical to them personally to support their growth as educators and advocates. As a Board member, I have been involved in our efforts to trial new membership models that meet member needs at every career stage. The picture isn’t grim—our overall membership is still up 5 percent this year—but we should embrace this opportunity to ensure that residency-trained emergency physicians look to ACEP first as an advocate for their specialty. We must show our members that we are not afraid to put the needs of the individual emergency physician first—advocating for physician-led teams with no absentee chart signing when working with NPs and PAs, and paid parental leave.
EMF GRANT HELPED PHYSICIAN STUDY Bystander CPR DISPARITIES

For Dr. Comilla Sasson, early career research funding helped launch a career investigating health disparities

When Comilla Sasson, MD, PhD, FACEP, was an emergency medicine resident, she couldn’t understand why so many cardiac arrest patients were coming into her emergency department without having any CPR performed. The issue occupied her mind so much that she decided to apply for a grant with the Emergency Medicine Foundation (EMF) to study it.

EMF is a nonprofit organization whose mission is to fund research that “develops career emergency medicine researchers, improves patient care, and provides the basis for effective health policy.” Since its founding in 1972, EMF has awarded more than $17 million in research grants.

Today, Dr. Sasson is associate clinical professor of emergency medicine at the University of Colorado Denver and author of more than 90 research papers. Dr. Sasson recently spoke with EMF about how the grant she received more than a decade ago propelled her career.

CS: I got an EMF grant to look at racial and health disparities and who is getting bystander CPR. This involves looking at data to actually figure out where in neighborhoods people are getting CPR done or not getting it done. We looked at Denver data, and were able to see that if your heart stopped on one side of the street, your chances of getting CPR were 40 percent less than on the other side of the street. This actually changed the entire trajectory of my career.

EMF: How did this grant change the trajectory of your career?

CS: I've always had an interest in looking at why there are differences in how people do in the emergency department. I did my training at Grady Hospital, which is a Level 1 trauma center in Atlanta, and saw that time and time again, patients primarily who were African American were not having CPR done before they got to the hospital or to the emergency department. We know that time is essential for the brain and heart muscle. For every one minute that you don’t have CPR performed, your chances of surviving go down by about 10 percent. You only have this 10-minute window.

EMF: What was the most significant impact of your EMF research grant?

CS: We’ve been able to work with community groups, police, fire, EMS, hospital systems, nonprofit organizations, community-based organizations. We've been able to take that data that I got from the EMF grant and do actionable change. We’re making improvements in neighborhoods because of the work that I did through the EMF grant, and now we’re taking that research, turning it into real-world outcomes, and saving more lives by teaching people CPR and then, more importantly, when to call 911.

EMF: Since receiving your EMF grant, what other research awards and achievements have you received?

CS: I’ve gotten a career development award and have an additional $1.5 million of funding to work on opioids, overdose deaths, and how that relates to cardiac arrest. You need somebody to believe in you, and then I think that sets you up to make a huge impact.

EMF: What breakthrough treatments or protocols resulted from your research?

CS: We’ve been able to completely change the way in which we were looking at how to go into communities and do targeted training. It sounds like a really simple concept. We were the first ones that really launched this idea, and since that time, we’ve been going out to more than 10 major urban cities to do the same type of program and we’re working on scaling up to a national program as well.

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BROOKS F. BOCK, MD, FACEP

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The Wiegenstein Legacy Society is named after Dr. John Wiegenstein, the founding president of ACEP.
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(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:
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• Active pathological bleeding
• Severe hypersensitivity reaction to ELIQUIS (e.g., anaphylactic reactions)

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ARISTOTLE study design1,2
A phase III, double-blind, randomized trial designed to compare the effects of ELIQUIS 5 mg twice daily* (n=9120) and warfarin (n=9081) (target INR range: 2.0-3.0) in reducing the risk of stroke and systemic embolism in 18,201 patients with NVAF and ≥1 additional risk factor for stroke: prior stroke or transient ischemic attack (TIA); prior systemic embolism; age ≥75 years; arterial hypertension requiring treatment; diabetes mellitus; heart failure ≥New York Heart Association (NYHA) Class 2; or left ventricular ejection fraction (LVEF) ≤40%. Patients were followed for a median of ≈1.7 years. The 2 treatment groups were well balanced with respect to baseline characteristics, including age, stroke risk at entry as measured by CHADS2 score,* and prior vitamin K antagonist (VKA) experience. The primary efficacy endpoint was stroke/systemic embolism, and the primary safety endpoint was major bleeding. Patients who needed aspirin >165 mg/day or needed aspirin plus a thienopyridine (eg, clopidogrel) were excluded from ARISTOTLE.

AVERROES study design1,3
AVERROES was a phase III, double-blind, randomized trial designed to compare the effects of ELIQUIS 5 mg twice daily* (n=2807) and aspirin (81 mg–324 mg once daily) (n=2791) in reducing the risk of stroke and systemic embolism in 5598 patients with NVAF who had not been candidates for warfarin therapy, and with ≥1 additional risk factor for stroke: prior stroke or TIA; age ≥75 years of age; arterial hypertension (receiving treatment); diabetes mellitus (receiving treatment); heart failure (≥NYHA Class 2 at the time of enrollment); LVEF ≤35%, or documented peripheral artery disease. Patients could not be receiving VKA therapy (eg, warfarin), either because it had already been demonstrated to be or was expected to be unsuitable for them. The 2 treatment groups were well balanced with respect to baseline characteristics, including age, stroke risk at entry as measured by CHADS2 score,* and prior use of a VKA within 30 days before screening. The mean follow-up period was approximately 1.1 years. The primary efficacy endpoint was stroke/systemic embolism, and the primary safety endpoint was major bleeding.

SELECTED IMPORTANT SAFETY INFORMATION
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, SSRI s, SNRIs, and NSAIDs.
  – Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room.
  – Discontinue ELIQUIS in patients with active pathological hemorrhage.
  – The anticoagulant effect of apixaban can be expected to persist for at least 24 hours after the last dose (ie, about two half-lives). An agent to reverse the anti-factor Xa activity of apixaban is available. Please visit www.andexxa.com for more information on availability of a reversal agent.

• Spinal/Epidural Anesthesia or Puncture: Patients treated with ELIQUIS undergoing spinal/epidural anesthesia or puncture may develop an epidural or spinal hematoma which can result in long-term or permanent paralysis.
  The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS. The next dose of ELIQUIS should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of ELIQUIS for 48 hours. Monitor patients frequently and if neurological compromise is noted, urgent diagnosis and treatment is necessary. Physicians should consider the potential benefit versus the risk of neuralaxial intervention in ELIQUIS patients.

• Prosthetic Heart Valves: The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves and is not recommended in these patients.

• Acute PE in Hemodynamically Unstable Patients or Patients who Require Thrombolysis or Pulmonary Embolectomy: Initiation of ELIQUIS is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

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

ADVERSE REACTIONS
• The most common and most serious adverse reactions reported with ELIQUIS were related to bleeding.

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

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

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

**ARISTOTLE: ONLY ELIQUIS demonstrated superiority in BOTH stroke/systemic embolism and major bleeding vs warfarin**¹

ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding²:

- Superiority to warfarin was primarily attributable to a reduction in hemorrhagic stroke and ischemic strokes with hemorrhagic conversion compared to warfarin. Purely ischemic strokes occurred with similar rates on both drugs³.
- In another clinical trial (AVERROES), ELIQUIS was associated with an increase in major bleeding compared with aspirin that was not statistically significant (1.41%/yr vs 0.92%/yr, HR=1.54 [95% CI: 0.96–2.45]; P=0.07)¹.
- The most common reason for treatment discontinuation in both ARISTOTLE and AVERROES was 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, respectively¹.

Major bleeding was defined as clinically overt bleeding accompanied by ≥1 of the following¹:

A decrease in hemoglobin of ≥2 g/dL over 24 hours; transfusion of 2 or more units of packed red blood cells; bleeding that occurred in at least one of the following critical sites: intracranial, intraspinal, intracranial, pericardial, intra-articular, intramuscular with compartment syndrome, retroperitoneal; and fatal bleeding.

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**SELECTED IMPORTANT SAFETY INFORMATION**

**DRUG INTERACTIONS (cont’d)**

- **Combined P-gp and Strong CYP3A4 Inducers:** Avoid concomitant use of ELIQUIS with combined P-gp and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John’s wort) because such drugs will decrease exposure to apixaban.

- **Anticoagulants and Antiplatelet Agents:** Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk postacute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

**PREGNANCY**

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

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

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Acute PE in hemodynamically unstable Patients or Patients who Require Thrombolyis or Pulmonary Embolectomy

Initiation of ELIQUIS (apixaban) is not recommended as an alternative to unfractionated heparin for the initial treatment of acute PE in patients with hemodynamic instability or who may require thrombolysis or pulmonary embolectomy.

Increased Risk of Thrombosis in Patients with Triple Positive Antiphospholipid Syndrome

Clinical- or oral anticoagulant therapy with DOACs, including ELIQUIS, are not recommended for use in patients with triple-positive antiphospholipid syndrome (APS). For patients with APS who are triple-positive for lupus anticoagulant, anti-cardiolipin antibodies, and anti-β2-glycoprotein I antibodies, treatment with DOAKs has been associated with increased rates of moribund thrombotic events compared with vitamin K antagonist therapy.

ADVERSE REACTIONS

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

GI bleeding includes upper GI, lower GI, and rectal bleeding. The table includes only events that contributed to death.

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

<table>
<thead>
<tr>
<th>Event</th>
<th>All Patients</th>
<th>N=9088</th>
<th>Warfarin</th>
<th>N=9052</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major†</td>
<td>327(2.1)</td>
<td>462(5.9)</td>
<td>0.69 (0.60, 0.80)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Intracranial (ICH)</td>
<td>52 (0.53)</td>
<td>125 (1.64)</td>
<td>0.41 (0.34, 0.49)</td>
<td>≤0.0001</td>
<td></td>
</tr>
<tr>
<td>Hemorrhagic stroke</td>
<td>36 (0.4)</td>
<td>74 (0.9)</td>
<td>0.53 (0.47, 0.60)</td>
<td>≤0.0001</td>
<td></td>
</tr>
<tr>
<td>Other ICH</td>
<td>51 (0.34)</td>
<td>141 (1.80)</td>
<td>0.29 (0.26, 0.31)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Hemorrhagic GI</td>
<td>126 (0.53)</td>
<td>141 (1.42)</td>
<td>0.86 (0.67, 1.13)</td>
<td>0.22</td>
<td></td>
</tr>
<tr>
<td>Fatal†</td>
<td>100 (0.67)</td>
<td>270 (2.90)</td>
<td>0.28 (0.23, 0.36)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Intracranial</td>
<td>40 (0.4)</td>
<td>90 (0.9)</td>
<td>0.43 (0.35, 0.53)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Non-intracranial</td>
<td>6 (0.06)</td>
<td>7 (0.07)</td>
<td>0.84 (0.28, 2.15)</td>
<td>0.77</td>
<td></td>
</tr>
</tbody>
</table>

Note: The figure above presents effects in various subgroups, all of which are baseline characteristics and all of which were prespecified, if not the groupings. The 95% confidence limits that are shown may not reflect the rates observed in practice.

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

In ARISTOTLE, the results for major bleeding were generally consistent across subgroups including age, weight, CHADS2, score (0 to 6 used to estimate thromboembolic risk), gender, current smoking status, history of stroke, or aspirin use at randomization (Figure 1). Subjects treated with ELIQUIS with diabe (3% per year) than did subjects without diabetes (1.3% per year).

Table 2: Bleeding During the Treatment Period in Patients Undergoing Knee Replacement Surgery

Table 3: Bleeding During the Treatment Period in Patients Undergoing Knee Replacement Surgery
Minor
Major
Bleeding results from the AMPLIFY-EXT study are summarized in Table 7.

- In the 1 Phase II study and the 3 Phase III studies are listed in Table 4.

- Patients receiving anticoagulants, including pregnant women, are at risk for bleeding.

- Pregnancy confers an increased risk of thromboembolism that is higher for women with

- The estimated background risk of major birth defects and miscarriage for the indicated

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

- Some patients with moderate hepatic impairment (Child-Pugh class B) may have

- In ARISTOTLE, concomitant use of aspirin increased the bleeding risk on ELIQUIS from 1.8% per

- Anticoagulants and Antiplatelet Agents

- Inhibitors of CYP3A4 and P-gp increase

- Apixaban is a substrate of both CYP3A4 and P-gp. Inhibitors of CYP3A4 and P-gp increase

- For patients receiving ELIQUIS 5 mg or 10 mg twice daily, the dose of ELIQUIS should be

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

- Gastrointestinal disorders:

- Aspartate aminotransferase increased

- Drug interaction:

- AIB), because patients with moderate hepatic impairment (Child-Pugh class B) may have

- The recommended dose is 2.5 mg twice daily in patients with at least two of the following

- The milk to plasma AUC (0-24) ratio is 30:1 indicating that apixaban can

- Maximal plasma concentrations were observed after 30 minutes following a single oral

- Animal Data

- Breastfeeding is not recommended during treatment with ELIQUIS (apixaban).

- Protein binding:

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

- In controlled clinical trials, orally administered apixaban in healthy subjects a 50 mg daily for 3 to 7 days (25 mg twice daily for 7 days or 50 mg once daily for

- Risk Summary

- Pregnancy

- Pregnancy confers an increased risk of thromboembolism that is higher for women with

- Femoral/femoral access

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

- Active lesions

- The recommended dose is 2.5 mg twice daily in patients with at least two of characteristics

- Pregnancy

- Anticoagulants and Antithrombotic Agents

- Coagulation parameters:

- ELIQUIS (apixaban), in

- The MRHD was not associated with reduced maternal mortality or reduced causes

- Lactation

- Sedative hyponatremia (including procedural hypovolemia)

- Bleeding disorders:

- Menorrhagia

- Gingival bleeding, hemoptysis, hypersensitivity, muscle hemorrhage, ocular hemorrhage (including

- Skin and subcutaneous tissue disorders:

- Eye disorders:

- Gastrointestinal disorders:

- Hypersensitivity

- Musculoskeletal and connective tissue disorders: muscle hemorrhage

- Renal and urinary disorders:

- Hematuria

- Hematological disorders:

- Epistaxis

- Asparaginase, and proteinase inhibitors.

- General information:

- Animal Data

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy

- Pregnancy
Emergency Medicine
Gains Ground in 2021

by MICHAEL GRANOVSKY, MD, FACEP, DAVID MCKENZIE, CAE

The Centers for Medicare & Medicaid Services (CMS) has released the 2021 Physician Fee Schedule (PFS) proposed rule, which will affect emergency medicine reimbursement significantly. Following a commentary period lasting until Oct. 5, 2020, CMS is expected to issue its final PFS rule, which will impact services beginning Jan. 1, 2021.

Here are some highlights from this year’s PFS rule. A longer summary is available at www.acep.org/globalassets/new-pdfs/advocacy/summary-of-the-cy-2021-pfs-and-gpp-proposed-rule.pdf.

2021 RVUs Increase for ED E/M Services
Acting to protect the safety net, ACEP asked CMS to recognize the intensity of ED services and maintain the relativity between the ED evaluation and management (E/M) codes and the new patient office codes. Even though the ED codes received increases of about 5 percent for code levels 1–5 in 2020, CMS has accepted our arguments and agreed to increase the ED relative value units (RVUs) for 99283–99285 again in 2021 (see Table 1).

2021 Conversion Factor Decrease
For 2021, CMS proposes a Medicare PFS conversion factor of $32.26, a 10.6 percent decrease from the 2020 conversion factor of $36.09. This historic decrease was due to the CMS decision to increase reimbursement for the office visit codes, a boon for urgent care (which reports using office codes). However, this increased spending triggered a significant “budget neutrality adjustment,” as required by law. However, in light of the COVID-19 pandemic and the stresses placed on the whole house of medicine, Congress may waive the budget neutrality requirements, which could shield us from this significant potential decrease.

Due to the budget neutrality adjustment in the conversion factor for the whole house of medicine, emergency medicine could see as much as a 6 percent net decrease. ACEP has mounted a vigorous campaign to protect the safety net and is urges Congress to support the conversion factor at current levels (see “Advocate to Waive Budget Neutrality” for more on this effort).

ED Continued Traction with Telehealth Services
CMS is examining which of the codes that are temporarily on the list of approved Medicare telehealth services during the COVID-19 public health emergency will remain on the list permanently. CMS is proposing to keep ED E/M code levels 1–3 (CPT codes 99281–99283) on the approved telehealth list for the remainder of the year after the public health emergency expires. However, CMS is not proposing to include

Table 1: 2021 Proposed Increases to ED Work RVUs

<table>
<thead>
<tr>
<th>CODE/ED VISIT LEVEL</th>
<th>2020 WORK RVUS</th>
<th>2021 PROPOSED WORK RVUS</th>
<th>% INCREASE IN WORK RVUS IN 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>99281/Level 1</td>
<td>0.48</td>
<td>0.48</td>
<td>0%</td>
</tr>
<tr>
<td>99282/Level 2</td>
<td>0.93</td>
<td>0.93</td>
<td>0%</td>
</tr>
<tr>
<td>99283/Level 3</td>
<td>1.42</td>
<td>1.60</td>
<td>12.68%</td>
</tr>
<tr>
<td>99284/Level 4</td>
<td>2.60</td>
<td>2.74</td>
<td>5.38%</td>
</tr>
<tr>
<td>99285/Level 5</td>
<td>3.80</td>
<td>4.00</td>
<td>5.26%</td>
</tr>
</tbody>
</table>

Table 2: MIPS Performance Category Weighting in Final Score

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>45%</td>
<td>40%</td>
</tr>
<tr>
<td>Cost</td>
<td>15%</td>
<td>20%</td>
</tr>
<tr>
<td>Improvement Activities</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Promoting Interoperability</td>
<td>25%</td>
<td>25%</td>
</tr>
</tbody>
</table>

WHAT CAN YOU DO?

Advocate to Waive Budget Neutrality

Efforts are under way to ask Congress to waive budget neutrality for 2021 and maintain the Medicare payment per RVU close to current levels.


Less than 24 hours after CMS released the proposed rule, ACEP sent a letter to Congress expressing our strong concerns on this proposed cut, noting the unprecedented strain emergency physician practices already are facing due to the ongoing COVID-19 pandemic.

Congress has the power to fix this by waiving the budget neutrality requirement. If Congress acts, emergency medicine reimbursement could actually increase by about 3 percent instead of decreasing by 6 percent.

2021 CMS PROPOSED RULES WILL INCREASE RVUS AND RELAX MIPS REQUIREMENTS

Table 2: MIPS Performance Category Weighting in Final Score

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</tr>
<tr>
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<td>25%</td>
</tr>
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</table>

MIPS Value Pathways (MVPs): CMS is committed to developing MVPs, which would combine all four categories of MIPS reporting into a single, more harmonized process. However, due to COVID-19, the implementation of MVPs is being delayed until 2022. ACEP is working with CMS on developing an MVP for emergency medicine and is examining how ACEP’s qualified clinical data registry, the Clinical Emergency Data Registry (CEDR), can help emergency physicians participate in an MVP.

Additional information on MIPS is available at https://gpp.cms.gov/mips/overview.

Other Resources

Resources for these and other topics can be found on the reimbursement section of the ACEP website. ACEP Director of Reimbursement David McKenzie, CAE, is also available to field your questions at 800-708-1822, ext. 3233. Finally, ACEP offers well-attended and highly recommended coding and reimbursement educational conferences annually. Visit www.acep.org/rc for more information.

DR. GRANOVSKY is president of LogixHealth, an ED coding and billing company, and currently serves as the course director of ACEP’s Coding and Reimbursement courses. He may be reached at mgranovsky@logixhealth.com.

MR. MCKENZIE is ACEP director of reimbursement.

Urges your member of Congress to waive the budget neutrality requirement for calendar years 2021 and 2022 at https://p2a.co/SzSIVU.

Congress is already juggling many other priorities as a result of the pandemic and pressure from the upcoming November elections. It is essential that they hear directly from emergency physicians in their district just how devastating these cuts could be for access to emergency care for patients across the country.
COVID-19 and Children

by JOSHUA NIFORATOS, MD, MTS

With thousands of articles published weekly on COVID-19, navigating the literature on this emerging infectious disease can be daunting. To help health care professionals and the general public keep up and to fight medical misinformation, a group of emergency physicians started the website Brief19.com, which publishes analysis of COVID-19 research and policy five days a week, all for free. Here are highlights from recent Briefs. (Note: ACEP Now’s medical Editor in Chief, Jeremy Samuel Faust, MD, MS, MA, FACEP, is also Editor in Chief of Brief19.)

For the first few months of the COVID-19 pandemic, it was thought that children were not important vectors of transmission of the SARS-CoV-2 virus. Early data reported from the Centers for Disease Control and Prevention (CDC) in April found that children only accounted for 1.7 percent of positive tests in the United States.1 By the middle of August, we now know that children account for approximately 7.3 percent of all positive cases in the United States.2

ACE2 Gene and Viral RNA

Biological hypotheses have emerged to account for these trends in transmission as it varies by age group. A paper published in late May in the JAMA was among the first to show that levels of ACE2 gene expression of cells lining the airway of humans differ by age: ACE2 is one of the receptors that SARS-CoV-2 binds to enter cells of the upper and lower airways. In that study, ACE2 gene expression was lowest in younger children with levels of gene expression and it rose with increasing age. A few months later, research published in JAMA Pediatrics found quantitative differences of viral genetic material among different age groups.4 In young children (under age 5), older children (age 5–17), and adults who had mild or moderate COVID-19 illnesses, young children had between 10 and 100 times the amount of SARS-CoV-2 RNA in their upper airways as compared to older children and adults. However, those studies do not directly report on replication-competent virus, so it is not necessarily the case that contagiousness correlates with these figures.

This research suggests that children may have fewer receptors for SARS-CoV-2 to bind, but when a child does become infected, the amount of viral RNA in the upper airways appears to be significantly greater than in adults, which further suggests that children may, in fact, play a role as important vectors of transmission. However, these are still hypotheses that have yet to be demonstrated causally.

Severity and Disparities

What about asymptomatic infection in children? The epidemiology of COVID-19 among children suggests, at least in the United States, that the rate of asymptomatic carriers is relatively low. A robust study in JAMA Pediatrics revealed that asymptomatic children presenting for elective medical and surgical care had a pooled prevalence of 0.65 percent out of 33,041 children in tests conducted across 28 children’s hospitals.5 That said, the incidence of SARS-CoV-2 is not random and this may not be an accurate reflection of the entire country.

Recent data published in Pediatrics reveals racial/ethnic and socioeconomic disparities of COVID-19 among children.6 Among 1,000 children tested at a drive-through/walk-up testing site within one mile of Children’s National Hospital in Washington D.C., the demographic breakdown of children who tested positive was 46 percent Latinx, 30 percent Black, and 7 percent white. Of the children who tested positive, 9 percent were Latinx, 30 percent Black, and 7 percent white. Of the children who tested positive, 9 percent were children from families in the highest income quartile and 38 percent were in the lowest income quartile. These results corroborate findings published in JAMA from the Johns Hopkins Health System, which found that of 37,727 patients tested for COVID-19, the positivity rate was 4.6 percent for Latinx patients and 3.9 percent Black patients. To date, no data suggest that presenting symptoms of COVID-19 among children differ by race/ethnicity or socioeconomic status.

Children tend to have less severe disease compared to
adults. The CDC estimates the rate of hospitalization among children at 8.0 per 100,000 compared to adults at 164.5 per 100,000 population, with similar lower rates of mechanical ventilation and death. Children with symptomatic COVID-19 often have nonspecific symptoms, including vague respiratory or only gastrointestinal symptoms. The most common presenting symptoms are cough and/or fever. However, almost one-third of children admitted to the hospital are admitted to intensive care units.

Multisystem Inflammatory Syndrome

A new complication of COVID-19 that is particularly devastating is the multisystem inflammatory syndrome in children (MIS-C). While rare, it has received attention. The American College of Rheumatology defines MIS-C as an postinfectious inflammatory syndrome characterized by fever, inflammation, and multiorgan dysfunction that occurs late in the course of COVID-19 in children.11 The new FOAMed website and podcast The Cribsiders (https://thecurbsiders.com/thecribsiders), led by internists and pediatricians from 15 different institutions across the country, recently published an episode dedicated to MIS-C. In brief, the presentation of MIS-C seems to have three common phenotypes: Kawasaki-like, gastrointestinal, and neurologic. In Figure 1, the signs and symptoms, evaluation, and management of MIS-C are summarized. Interestingly, data from the CDC reveals that MIS-C is more prevalent among Latinx (38 percent) and Black (33 percent) children compared to white (15 percent) children.2

Finally, with respect to COVID-19 treatment, the evidence for children in the United States (and elsewhere) is an evolving area of research. Treatments for moderate-to-severe COVID-19, such as remdesivir and dexamethasone, have not been fully evaluated in children of different age groups. What is clear, however, is that children are vectors of the SARS-CoV-2 virus. They may be asymptomatic or have nonspecific symptoms, and a smaller subset can become quite ill from the acute illness or later as a result of MIS-C.

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The Columbia University Department of Emergency Medicine

11. Berk J. #5 MIS-C: when COVID affects kids. The Cribsiders website. Available at: https://thecurbsiders.com/thecribsiders. Published an episode dedicated to MIS-C.

DR. NIFORATOS is an emergency medicine resident at The Johns Hopkins School of Medicine in Baltimore and research editor of Brief19.com. Follow him @RevEvenDoIt and follow Brief19 @Brief_19.
Updates from the Gut

Latest research on when to do an endoscopy and administer tranexamic acid

by RYAN PATRICK RADECKI, MD, MS

When COVID-19 reached the United States, emergency departments had one of two experiences. In places with large outbreaks, every ounce of energy went into taking care of critically ill patients. Everywhere else, emergency visits plummeted by 42 percent. It was actually a quiet time.

Now, patient volumes are starting to return to normal in many areas. That means that the usual culprits are back in steady force. Depending on whether your emergency department is in a COVID-19 hotspot, you may feel the need either to rush patients to endoscopy (ie, keeping the emergency department and observation units as empty as possible) or delay the procedures out of a concern for the safety of everyone involved. Regardless of COVID-19, where do we stand on the question of how quickly patients with suspected upper gastrointestinal bleeding (UGIB) must have an endoscopy?

Best Timing for Endoscopy

The first of two important related articles released during the COVID-19 pandemic (and perhaps flying under the radar) looks at this.2 Do GI consultants really need to answer our 2 a.m. pages and rally the team of nurses and equipment for endoscopy immediately?

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The answer is surprising, especially consid-
ering that all the patients enrolled in the first 
trial we discuss were. The authors recruited 
and enrolled patients with Glasgow-Blatch-
ford Bleeding Scores (GBS) of 12 or above, 
which is considered “high risk” for an UGB 
likely to require a medical intervention (trans-
fusion, endoscopy, or surgery). The 
median enrolled hemoglobin level was 7.4 g/dL, a third had tachycardia, and about 
a sixth were already hypotensive. Virtually all 
(90 percent) received a transfusion of packed 
red blood cells, with a mean requirement of 
2.4 units. Patients were excluded if they were 
in hypotensive shock and unstable despite 
initial resuscitation (i.e., the need for a proce-
dure meant that waiting was not an option). In 
short, these were genuinely the sort of patients 
who are worrying to emergency physicians 
but not clearly in extremis.

The 516 patients randomized in this 
trial were sorted to either an “urgent endoscopy,” 
endoscopy within six hours, or “early endos-
copy,” an endoscopy within 24 hours. All pa-
tients were treated with continuous infusion 
of high-dose proton-pump inhibitors, while 
those suspected of having variceal bleeding 
received vasoactive agents and antibiotics. The 
primary outcome of the study was mor-
tality at 30 days following enrollment, with 
secondary measures of clinical progression, 
recurrence, and resource utilization.

The quick answer: Mortality was not sig-
nificantly different between groups. The dif-
ference favored waiting for endoscopy, but the 
trial was not large enough to claim any sort of 
hidden trend. As might be expected, delaying 
endoscopy meant fewer patients with active 
bleeding identified and subsequently fewer in-
terventions. Neither transfusion requirements 
or occurrences of rebleeding were different, and 
there were no signs of potential hazard 
associated with waiting.

It should be noted there were 20 patients in 
the “early” endoscopy cohort who converted 
to “urgent” as a result of new hypotension, he-
matemesis, melena, or otherwise failing to 
respond to initial resuscitation. While these data 
dicate it is clearly safe to delay endoscopic 
evaluation, vigilance regarding possible deter-
rioration is required. A little fewer than one in 
10 patients may necessitate a change in plans.

When to Give Tranexamic Acid

The second new article on this topic repre-
sents a possible change in practice many of 
us have likely adopted or considered adopt-
ing already. Should emergency physicians 
be giving tranexamic acid (TXA) to patients 
with acute gastrointestinal bleeding? After 
all, we’ve been giving it to patients with ma-
jor bleeding in trauma, as well as considering 
it to be likely beneficial for those with severe 
head injuries and postpartum hemorrhage.**

Like other TXA trials, this latest trial was a 
massive undertaking, enrolling nearly 12,000 
patients over six years across 164 hospitals. 
Patients were eligible for inclusion based on 
pragmatic, subjective clinical assessment. To 
be included, patients simply needed to 
be judged likely to have a significant or life-
threatening gastrointestinal bleed. Disease se-
verity was assessed using the Rockall Score, 
which differs from the GBS as it incorporates 
findings identified at endoscopy as well as 
clinical presentation. Overall, however, pa-
tients appeared similarly ill as the endoscopy 
study above when accounting for tachycardia, 
melena, and signs of shock.

In contrast to the other TXA trials, unfortu-
nately, there is simply no way to parse these 
results in a fashion favoring the intervention. 
Whether measured in deaths due to bleeding, 
recurrent bleeding, or all-cause mortality, outcomes 
were virtually identical. A major-
ity of patients required transfusion, and 
these transfusion requirements were not altered by 
whether TXA was given. Adverse events were 
rare, but a small excess of venous thrombo-
embolic events was seen in the cohort receiv-
ing TXA. The absolute difference, even in this 
study of 12,000 patients, was just a handful but 
likely does reflect an increased risk for venous 
thromboembolism in those receiving TXA.

Considering neither the CRASH-2 nor 
WOMAN trial detected an increase in throm-
boembolic events, the risk seen with TXA 
here is likely related to this specific popula-
tion enrolled with gastrointestinal bleeding. 
Conceptually, this makes sense. Nearly half 
the patients enrolled were described as hav-
ing liver disease severe enough to be judged 
to potentially result in variceal bleeding. Pa-
tients with advanced liver disease maintain 
a balance of deranged hemostasis, with relative 
excess and absence of coagulation factors and 
components. It is likely that hypofibrinolysis 
underlying states tipped off-balance by TXA 
resulted in the observed increases in venous 
thromboembolism. Regardless of liver func-
tional status, however, absent a detectable 
benefit for TXA in gastrointestinal bleeding, 
this trial reveals that this medication has no 
apparent role in the treatment of GIB.

Conclusions

In sum, we have two potentially practice-
changing conclusions. First, even a very ill 
patient with UGIB undergoing transfusion 
treatment may be managed medically for an 
extended period of time prior to a decision to 
perform an endoscopy, rather than requiring urgent inter-
vention, provided they are hemodynamically 
stable. Second, if you’ve been extrapolating 
the potential advantage of TXA from other 
clinical applications to your gastrointestinal 
bleeding patients, it seems clear this is un-
likely to help and may even result in a small 
amount of harm in a subset of patients.

The opinions expressed here are solely those 
of Dr. Radkei and do not necessarily reflect 
those of his employer or academic affiliates. 

References

A Patient Transfer Leads to a Lawsuit

This case reminds us we can be sued for anything

by ERIC FUNK, MD

Difficult airway is every emergency physician’s worst nightmare. The decision to intubate a patient needs to be coupled with adequate preparation, good communication with nurses and other team members, and a backup plan for possible complications. These situations require rapid decision making under stress. The case below depicts a real-life situation that resulted in a medical malpractice lawsuit. The description and figures shown are the actual evidence used in the lawsuit.

The Case

A 52-year-old woman presented to the emergency department with shortness of breath. She was brought to the emergency department in a wheelchair by her husband. The triage nurse immediately recognized that she was in severe respiratory distress. Her respirations were noted to be rapid and labored, and she had an audible gurgle. She was assigned a triage Level 1.

There were no available rooms, so she was put in a hallway bed. The physician was immediately at the bedside. He noted that she was cool, clammy, and grossly cyanotic. The patient was able to state that she did not have asthma or chronic obstructive pulmonary disease but did note a history of congestive heart failure. After a very limited history, the patient’s respiratory status declined into complete apnea. The physician made an initial attempt at blind nasal intubation while the nurses started an IV, but he was unsuccessful. A second attempt was made, also with no success. By that time, the nurses had cleared a room and she was brought into the resuscitation bay. The patient’s heart rate declined to 40 bpm on the monitor, a pulse could not be palpated, and chest compressions were started immediately at the bedside. He noted that she had a coronary artery bypass graft approximately 18 months earlier.

Obtaining a Transfer

With her oxygen saturation holding in the 80s, the physician began the process to transfer her to a hospital with ICU capabilities. This process was unfortunately fraught with unnecessary delays. An emergency physician (Dr. H) at a regional medical center recommended that the patient be transferred to his facility after numerous challenges of working in a small hospital with limited resources. There have been numerous lawsuits that involved determining precisely when a consulting or receiving physician establishes a patient-doctor relationship. The issue is murky and can vary in different states and by the facts of the case.

Finally, this case involved an alleged EMTALA violation as opposed to standard medical negligence. As demonstrated in this instance, an EMTALA lawsuit brought by a patient against an individual physician is unlikely to succeed. However, this does not mean that doctors are free from punishment for EMTALA violations. The Centers for Medicare and Medicaid Services and the Office of the Inspector General have enforcement powers that include fines up to $50,000 for physicians.

Learning Points

The initial approach to intubation was challenging due to a precipitous arrival to the emergency department, with the final diagnosis shown in Figure 2.

The Lawsuit

The patient’s family was understandably upset and contacted the hospital’s risk management department. They were assigned an outpatient cardiologist who worked at a nearby academic center was called, took down the patient’s information, and said they would call back, but 30 minutes later there was still no response. The doctor then tried a third hospital, and the cardiologist on call declined the admission until the emergency physician consulted the patient’s outpatient cardiologist. The outpatient cardiologist worked at the first hospital that had been called, and he ultimately accepted the patient.

The patient departed the emergency department via helicopter with an oxygen saturation of approximately 80 percent. On arrival to the receiving hospital, her oxygen saturation was noted to be 40 percent. The anesthesia team was waiting for the patient at the bedside in the ICU, removed the King airway, and intubated the patient.

The patient’s status continued to decline. She sadly passed away five days after going into the emergency department, with the final diagnoses shown in Figure 2.

The Lawsuit

The patient’s family was understandably upset and contacted the hospital’s risk management department. They were assigned an outpatient cardiologist who worked at a nearby academic center was called, and he ultimately accepted the patient.

The patient was transferred to his facility after numerous phone calls. In addition to an alleged EMTALA violation, the lawsuit also alleged that he was negligent in his responsibility to the patient. Dr. H was deposed (see Figure 3). He stated that he did not explicitly decline the transfer but that he was helping the sending physician brainstorm the best arrangement for the transfer.

Ultimately, Dr. H’s attorneys filed for summary judgment. The lawsuit was dismissed because EMTALA allows for legal action against hospitals but not against individual physicians. Further, the defense asserted that Dr. H could not be personally liable for negligence because he did not establish a relationship with the patient solely on the basis of taking a phone call about her possible transfer.

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Institutional Elder Abuse

Early recognition in the ED is a key factor in stopping abuse

by HEATHER ROZZI, MD, FACEP; AND RALPH RIVIELLO, MD, FACEP

The Case
A 74-year-old female nursing home resident with moderate dementia presents with her daughter for evaluation of rash on the mother’s face and arms (see Figure 1). The daughter has not seen her mother for several weeks due to COVID-19 visitation restrictions. The nursing home nurse cannot explain how the resident got the bruises. There were no reports of a fall. The last time the daughter video-chatted with her mom was about two weeks ago. The daughter also says her mom seems quieter and more withdrawn than usual. Her mother seemed fearful of the male medic who transported her to the emergency department.

Discussion
The Centers for Disease Control and Prevention defines elder abuse as “an intentional act or failure to act that causes or creates a risk of harm to an older adult. An older adult is someone age 60 or older. The abuse often occurs at the hands of a caregiver or a person the elder trusts.” Legal definitions vary from state to state. Elder abuse can be further divided into neglect (the most common form of abuse), physical abuse, sexual abuse, financial abuse, and emotional/psychological abuse. Elder abuse is a serious problem and a public health emergency. It is estimated that one in 10 people older than 60 who live at home are abused.2,3 This is likely a substantial underestimation as studies often only look at ED visits and not other sites of care like primary care offices and clinics. A high number of cases are thought to go unreported because patients do not have someone who can advocate on their behalf.

There are numerous physical and emotional effects of elder abuse. Physical injuries can be minor or severe and can cause lasting or permanent disabilities. These injuries can lead to premature death and worsen existing health problems. There are also immediate and long-term emotional effects. Victims are often fearful and anxious. They may have problems trusting others and are wary around them.

There are several identified risk and protective factors for elder abuse perpetration. Risk factors can be divided as individual, relationship, institutional, and societal. Individual factors include: current diagnosis of mental illness, alcohol or drug abuse, high levels of hostility, poor or inadequate preparation or training for caregiving responsibilities, early age assumption of caregiving responsibilities, inadequate coping skills, and exposure to abuse as a child. Relationship factors include: high financial and emotional dependence upon a vulnerable elder, past experience of disruptive behavior, lack of social support, and lack of formal support. Institutional factors include: unsympathetic or negative attitudes toward residents, chronic staffing problems, and lack of administrative oversight, staff burnout, and stressful working conditions. Societal factors include a culture where there is high tolerance and acceptance of aggravating behavior; health care personnel, guardians, and other agents are given greater freedom in routine care and decision-making; family members are expected to care for elders; and elders, healthy, strong relationships.

In additional to the protective factors and elder abuse prevention strategies, one of the key factors in stopping abuse is early recognition by health care workers. Elders should be screened for abuse using any of several validated tools. In the emergency department, there are several red flags that should alert the care team to the possibility that an elder is being abused. These include a lack of basic hygiene, food, medical aids, and clean and appropriate clothing; a person with dementia left unsupervised; a bed-bound person without care; untreated or unusual pressure sores/ulcers; a caregiver who isolates the elder; a caregiver who is verbally aggressive or demeaning to the elder; inadequately explained fractures, bruises, welts, cuts, sores, or burns; a delay in seeking care for obvious injuries or conditions; unexplained sexually transmitted infections; and behavioral changes.4

Health care workers in most states are mandated reporters of elder abuse and should alert the proper authorities and adult protective services when abuse or neglect is suspected. Patients may require additional workup to determine abuse from progression of chronic diseases, as well as admission to the hospital for the patient’s protection.

Case Outcome
The emergency physician was concerned that the rash was actually bruising and suspected elder abuse. Labs, X-rays, and CT scans were negative. A forensic nurse examiner was consulted. On exam, in addition to the bruises, there was evidence of genital injury and vaginal discharge, which subsequently tested positive for chlamydia. Based on the concern for abuse, police and adult protective services were consulted. An investigation identified a dietary worker at the nursing home as the perpetrator.

References

KEY POINTS
• Elder abuse is a serious health problem.
• Any elder is potentially at risk.
• Elder abuse may not always be readily evident.
• The risk factors for elder abuse are contributing factors, not direct causes.
• Health care workers should screen elders and have a high index of suspicion when red flags are present.
• Treatment includes a multidisciplinary approach including geriatric medicine, social services, law enforcement, and adult protective services.
To All People Staying Neutral About Black Lives Matter

An eight-minute video caused me to question my neutrality
by AL GIWA, LLB, MD, MBA, MBE

Just when we thought life in 2020 couldn’t get any worse after the COVID-19 pandemic began to wreak havoc, social unrest broke out all over country. Some saw yet another series of lynchings. Others saw just another round of uprising. And some just didn’t want to be bothered, did not want to take a stand, let alone voice an opinion. It is you, my fellow “stay out of it” colleagues, whom I’d like to address. At first, I was like so many of you when it came to people crying injustice at the hands of the police. I refused to fall prey to the cop bashing or twisting the narrative from an unarmed person being shot to it being justice for a “bad hombre.” Personally, I think I was in denial because, in my mind, that was “their” problem. But in reality, I am one of them.

These last few years (and months) have revealed the continued racial disharmony that exists in America, most pronounced between Blacks and whites. (Many briefly focused their hate on Asians during the initial outbreak of the COVID-19 pandemic, but that seems to have faded now.)

When the Black Lives Matter movement emerged after the killing of unarmed Black people, I must confess that I was initially conflicted about it. After all, I had drank the Kool-Aid; I was “a good Negro.” I moved to the suburbs and did all the necessary things to be accepted by white America. Most important, I never brought attention to my Blackness; nor involved myself in anything that could be considered divisive or offensive, lest I offended anyone’s sensibilities. I supported arguments that seemed, on the surface, to make sense, and even echoed that “all lives matter.” Why were those Black “troublemakers” being so divisive and running counter to becoming a more united people?

So when reports of unarmed Black men and women dying at the hands of police officers started appearing in the media again and again, I largely avoided discussing it. I listened to the narrative that discouraged second-guessing police officers who must make life-or-death decisions in a split second, which is hard for the media to capture. However, I began to ruminate out loud about my own—and most especially my kids’—safety at the hands of a police officer. I reassured myself that those Black people were different. After all, why were they struggling with an officer to begin with? Why were they running away if they were innocent? Why were they speaking back to the officers so rudely? Innocent people don’t do that. Or do they?

Then George Floyd was killed. And it was there on tape. Almost eight minutes of it. And it became painfully clear. I am one of them.

Despite my being part of a respected profession, when I enter a convenience store, no one seems to recognize my education or multiple advanced degrees. Instead, I become just another Black man. Apparently, that means I require additional scrutiny afforded only to people of color in the United States and many other places. Once you have been profiled and assumed to be a criminal just because of the color of your skin, it is very hard to say things are “fair” or that one should be “grateful” for the opportunities and “privilege” to be in this country. One thing that white privilege has made painfully obvious is a lack of awareness of racial injustices that are everyday realities for people of color. So despite my upbringings, education, and current living circumstances, I am one of them.

One of my proudest accomplishments was becoming an officer in the U.S. Armed Forces. I work alongside courageous men and women from all socioeconomic, racial, and national origins. My desire to serve was born out of an upbringing that prioritized hard work, dedication, and responsibility, as well as a belief in the duty to serve to one’s nation. I accepted the calling and now proud...
By taking care of the men and women of the Armed Forces, who ensure the liberties for each and every one of us in this country. My military service has taken me to many parts of the country where race relations are not always the best. But wearing this uniform has given me access and exposure to people I would normally never be able to speak to personally. I am happy that I have been able to be a real-life person who shatters negative preconceptions of Black people to those willing to listen. But at the end of the day, I am still one of them.

As a soldier and officer in the U.S. Army, I am aware and appreciate the daily sacrifices of the women and men who serve and protect the public in this country. The job is unenviable and often thankless, and I truly salute their service. However, just like there are bad apples in the U.S. military (eg, some of those who served at Abu Ghrain), we, as a people, should demand accountability from our police and military service members. Law enforcement agencies need to institute protective measures for the public through better and accountable reporting mechanisms, ensuring leaders have zero tolerance for the “fraternity of silence” that keeps the actions of bad cops hidden. We need to improve neighborhood outreach through education and immersion. We need to evaluate the processes and procedures that lead to the clear racial disparities around when force is used disproportionately on people of color. I am a Black man who supports accountable policing and Black lives, as I am one of them.

For me, it took accidentally stumbling across comedian Trevor Noah’s poignant discussions on what the Black Lives Matter movement truly meant to me to finally understand that unless Black lives matter, “all lives matter” carries no meaning. Until then, I missed that in the screaming and protesting by angry Black people was not just their anger but my suppressed anger, too. Their screams were my screams. Their sense of betrayal and injustice were the same as mine even in the ivory towers of academic medicine. I could have been George Floyd; in fact, I was George Floyd. Each and every person of color in America is George Floyd; all of us are just an incident away from having our breath permanently taken away for doing nothing except living Black in America.

So, yes, all lives matter—but only when every life is respected or cared for like every other life. For too long, we’ve ignored that the most urgent work in this area, the opportunity for the most improvement, is to first insist that Black lives matter.

Let’s start to fix it. Let’s ensure that Black lives, brown lives, and all other lives really do matter the same. Let’s stop just watching others’ lives being subjugated to unfair treatment, hoping to avoid controversy. Let’s stop pretending that a good education and a house in the suburbs are the cure. They aren’t. That realization finally hit home for Americans of all colors this summer. Continuing to ignore it is not much better than someone kneeling on a Black man’s neck for eight minutes. It is time we realize WE are all one of them.

As Desmond Tutu said, “If you are neutral in situations of injustice, you have chosen the side of the oppressor.”
And Then There Were None

Randomized controlled trials show lack of efficacy of tPA in acute ischemic stroke

by KEN MILNE, MD

The Case

A 71-year-old woman arrives to the ED by EMS with right-sided weakness beginning 7 hours prior. Immediate neuroimaging demonstrates she does not qualify for endovascular clot retrieval. She has a National Institutes of Health Stroke Scale (NIHSS) score of 12 and no contraindications for systemic thrombolyis.

Clinical Question

Is tissue plasminogen activator (tPA) safe and effective 3–4.5 hours after onset of symptoms in patients with acute ischemic stroke (AIS)?

Background

One of the most debated subjects in EM over the years is the use of thromblytics in AIS. The controversy goes back to 1995 when the National Institute of Neurological Disorders and Stroke (NINDS) trial was published. This was the first randomized controlled trial (RCT) to claim efficacy for tPA in patients presenting with stroke symptoms of less than 3 hours. The authors of NINDS reported a 12 percent absolute benefit (good neurological outcome on the modified Rankin Scale [mRS]) at 90 days, with a 6 percent absolute increase in harm (bleeding).

A reanalysis of the NINDS data published in 2009 revealed that a baseline imbalance in stroke severity at presentation likely led to the difference in outcomes. After controlling for these baseline differences, the claimed efficacy of tPA was no longer statistically significant.

There’s only one other RCT claiming benefit for the primary outcome of thromblytics in AIS—the ECASS-III trial that gave tPA 3–4.5 hours after stroke symptom onset. ECASS-I and -II did not show a benefit with thrombolysis but did find an increase in harm (7 percent increase in mortality and 7 percent increase in intracranial hemorrhage, respectively).

The ECASS-III trial reported a 7 percent absolute benefit of improved mRS at 90 days compared to placebo, 9 percent increase in intracranial hemorrhage, 2 percent increase in symptomatic intracranial hemorrhage, and no significant difference in mortality.

NINDS and ECASS-III informed the ACP clinical policy statement on the issue. The policy looked at the less than 3-hour time frame and the 3–4.5-hour time frame and made no level A recommendations, but it did make level B and C recommendations:

- Is IV tPA safe and effective for patients with AIS if given within 3 hours of symptom onset?
- Level B Recommendations: With a goal to improve functional outcomes, IV tPA should be offered and may be given to selected patients with AIS within 3 hours after symptom onset at institutions where systems are in place to safely administer the medication. The known risk of symptomatic intracranial hemorrhage (sICH) should be considered when deciding whether to administer IV tPA to patients with AIS.

- Level C Recommendations: When feasible, shared decision-making between the patient (and/or their surrogate) and a member of the care team should include a discussion of potential benefits and harms prior to the decision whether to administer IV tPA for AIS. (Consensus recommendation.)

Now, 12 years after the publication of ECASS-III, a reanalysis of the RCT—similar to the reanalysis of the NINDS trial 14 years after it was published—has been published.


- Population: Adult patients age 18–80 years with at least 90 minutes of AIS symptoms presenting between 3–4.5 hours after onset of symptoms with no significant improvement.
- Main Exclusion: Multiple exclusions were listed in the manuscript.
- Intervention: tPA 0.9 mg/kg; initial 10 percent bolus, remainder given over 60 min.
- Comparison: Placebo.
- Outcomes: Primary: mRS score 0–1 (favorable) versus >2–6 (unfavorable) at 90 days.
- Secondary: Global outcome measure

Table 1: Trials Involving Thrombolytics for Acute Ischemic Stroke

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>NUMBER OF PATIENTS</th>
<th>REFERENCE</th>
<th>TIME TO TREATMENT</th>
<th>THROMBOLYICS</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAST-Italy</td>
<td>622</td>
<td>Lancet. 1995;346:1509-1514.</td>
<td>&lt;6 hours</td>
<td>Streptokinase</td>
<td>No difference in primary benefit, increased chance of early death.</td>
</tr>
<tr>
<td>ECASS-I</td>
<td>620</td>
<td>JAMA 1995;274:1017-1025.</td>
<td>&lt;6 hours</td>
<td>tPA</td>
<td>No difference on disability scores and 7% increase in mortality.</td>
</tr>
<tr>
<td>NINDS-I</td>
<td>291</td>
<td>N Engl J Med. 1995;333:1581-1588.</td>
<td>&lt;3 hours</td>
<td>tPA</td>
<td>No difference in symptoms or 3-month outcomes.</td>
</tr>
<tr>
<td>NINDS-II*</td>
<td>333</td>
<td>Ann Emerg Med. 2009;54:329-336</td>
<td>&lt;3 hours</td>
<td>tPA</td>
<td>No difference in favorable mRS at 90 days, 6% absolute increase in brain bleeds, and no mortality difference.</td>
</tr>
<tr>
<td>MAST-Europe</td>
<td>310</td>
<td>N Engl J Med. 1996;335:145-150.</td>
<td>&lt;6 hours</td>
<td>Streptokinase</td>
<td>No difference in death or disability at 3–6 months, 18% increase in brain bleed, and stopped early due to harm.</td>
</tr>
<tr>
<td>ASK</td>
<td>340</td>
<td>JAMA. 1996; 276:961-966.</td>
<td>&lt;4 hours</td>
<td>Streptokinase</td>
<td>No difference in death or disability at 3 months, 10% increase in brain bleeds, and stopped early due to harm.</td>
</tr>
<tr>
<td>ECASS-II</td>
<td>800</td>
<td>Lancet. 1998;382:1245-1251.</td>
<td>&lt;6 hours</td>
<td>tPA</td>
<td>No difference in outcomes on the mRS or mortality, and 7% increase in brain bleeds.</td>
</tr>
<tr>
<td>ATLANTIS-B</td>
<td>613</td>
<td>JAMA. 1999; 282:2019-2026.</td>
<td>3–5 hours</td>
<td>tPA</td>
<td>No difference in neurologic recovery and stopped early because <em>unlikely to prove beneficial.</em></td>
</tr>
<tr>
<td>ATLANTIS-A</td>
<td>142</td>
<td>Stroke. 2000; 31:811-816.</td>
<td>&lt;6 hours</td>
<td>tPA</td>
<td>No benefit in NIH stroke scale at 30 days, 18% greater risk of mortality, and stopped early due to harm.</td>
</tr>
<tr>
<td>ECASS-III **</td>
<td>821</td>
<td>BMJ Evid Based Med. 2020. doi: 10.1136/bmjebm-2020-111386.</td>
<td>3–4.5 hours</td>
<td>tPA</td>
<td>No difference in favorable mRS score after 90 days, and 9% increased rate of brain bleed.</td>
</tr>
<tr>
<td>DIAS-2</td>
<td>193</td>
<td>Lancet Neurol. 2009;8:141-150.</td>
<td>3–9 hours</td>
<td>Desmoteplase</td>
<td>No difference in clinical response, and increased rate of brain bleed.</td>
</tr>
<tr>
<td>IST-3</td>
<td>3058</td>
<td>Lancet. 2012; 379:2352-2363.</td>
<td>&lt;6 hours</td>
<td>tPA</td>
<td>No difference in mortality or independence after 6 months, 4% increase in death at 1 week, and 6% increase in fatal or non-fatal brain bleeding.</td>
</tr>
<tr>
<td>DIAS-3</td>
<td>492</td>
<td>Lancet Neurol. 2015;14:575-584.</td>
<td>3–9 hours</td>
<td>Desmoteplase</td>
<td>No difference in unfavorable mRS at 90 days, and no difference in major adverse events.</td>
</tr>
</tbody>
</table>

* Reanalysis of NINDS II ** Reanalysis of ECASS III Red indicates trials that were stopped before completion.
combining 90-day outcomes of mRS 0–1, 295 Barthel Index, NIHSS score 0–1, score of 1 Glasgow Outcome Scale; mortality at 90 days; any ICH, sICH, symptomatic edema, and other serious adverse events.

Authors’ Conclusions

“Reanalysis of the ECASS III trial data with multiple approaches adjusting for baseline imbalances does not support any significant benefits and continues to support harms for the use of alteplase 3–4.5 hours after stroke onset.”

Key Results

ECASS-III included 821 patients with a mean age of 65 years and 60 percent male. After adjusting for baseline imbalances, multiple methods failed to find statistically significant benefits with thrombolysis given 3–4.5 hours after stroke onset and confirmed the significant increase in harm.

Evidence-Based Medicine Commentary

1. Inter-rater reliability (IRR): The outcome assessment used mRS. The IRR for mRS is moderate at best. A clinical trial has internal validity only if imbalances between groups and bias in the assessment of outcome and chance have been excluded as possible explanations for the observed difference in outcomes.

2. Fragility index (FI): The FI is another way to represent the data, and it’s statistically reproducible. FI is the minimum number of patients who would need to have a different outcome to change the P value from <0.05 to >0.05, although the 0.05 threshold as a measure of statistical significance has its own problems. A low FI means only a small number of patients would need to have their outcome change for the trial to lose statistical significance. The FI of the original ECASS-III data is 1, meaning only one patient would need to have a different outcome to change the result. This is consistent with the reanalysis study by Alper et al, which found no significant benefit for tPA.

Other data for this time window support the fragility of ECASS-III data. IST-3 was the largest RCT investigating tPA for AIS in treated patients up to 6 hours. It didn’t show a benefit for its primary outcome. The pre-specified 3–4.5 hour subgroup was around double that of ECASS-III (n=1,177 versus n=821). IST-3 had a significant decrease in good neurologic outcome in patients randomized to tPA (32 percent) versus placebo (38 percent).

3. Baseline imbalances: A strong predictor of stroke outcome is severity of symptoms at presentation. There was an important baseline imbalance in stroke between the two groups in the ECASS-III trial. Those randomized to placebo had a worse median and mean baseline NIHSS score. Another difference between the two groups was that double the number of patients with a history of a previous stroke (7.7 percent tPA versus 14.1 percent placebo; \( P = 0.003 \)) appeared in the placebo arm. Recurrent strokes have a worse outcome than first strokes. The statistical difference in outcome favoring tPA over placebo could be explained by the baseline imbalance.

Bottom Line

Reanalysis of the original ECASS-III data does not support a patient-oriented benefit of tPA given 3–4.5 hours after onset of stroke symptoms and confirms the known potential harm.

Summary of Thrombolytics for AIS

There are 13 RCTs of thrombolytics for AIS (see Table 1). Four were stopped early for harm (bleeding) or futility, and all 13 failed to show a statistical benefit after the reanalysis of NINDS-2 and ECASS-III.

The table does not include two newer RCTs looking at extending the therapeutic window to 4.5–9 hours. These newer trials were done with more advanced brain imaging, selecting patients with a perfusion mismatch. Both RCTs were stopped early, which can introduce bias toward efficacy. In addition, the majority of patients included in these trials would now qualify for endovascular therapy (EVT) clot retrieval. EVT has more evidence for efficacy than systemic thrombolysis and a recent RCT has shown that EVT alone is noninferior to EVT plus tPA.

Case Resolution

You provide the patient with the latest information on thrombolytics for stroke. Her mental status is intact and she clearly understands the information as presented. She elects not to move forward with systemic tPA administration.

Thank you to Prof. Daniel Fatovich, an emergency physician at Royal Perth Hospital in western Australia and the head of the Centre for Clinical Research in EM, for his help with this review.

Remember to be skeptical of anything you learn, even if you heard it on the Skeptics’ Guide to Emergency Medicine. Visit ACEPNow.com for references and additional reading recommendations for this article.

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FOR MORE INFORMATION PLEASE CONTACT:
Heather Peffley, PHR FASPR at: hpeffley@pennstatehealth.psu.edu