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The Official Voice of Emergency Medicine

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WASHINGTON STATE BEST PRACTICES

7 TIPS TO REDUCE ED MISUSE

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SOUND ADVICE

ULTRASOUND-ASSISTED LUMBAR PUNCTURE

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**LAC attendees
(left to right)
Douglas Richmond,
MD, Chad Griffith,
DO, Miranda Phil-
lips, DO, Shawn
Radford, MD, John
DeTrolio, MD, and
Matt Roberts, MD.**

An Effective Voice for EM

Highlights from the 2014 ACEP Leadership and Advocacy Conference

Nearly 550 attendees at Leadership and Advocacy Conference (LAC) this year explored major issues of health care reform implementation that impact the emergency medicine. In addition to getting up to speed on the issues, practicing physicians, residents, and medical students also learned how to be more effective advocates for our patients, our specialty, and the public. The highlight of the meeting is always ACEP Lobby Day, when conference attendees descend on Capitol Hill to discuss our issues and concerns with congressional leaders. The bills discussed by ACEP during our visits to the Hill this year propose real solutions to real problems that we face every day in caring for patients in the ED. This year's

**by KATHRYN DIERKS, MD,
AND L. ANTHONY
CIRILLO, MD, FACEP**

CONTINUED on page 4

by KATHRYN DIERKS, MD,
AND L. ANTHONY
CIRILLO, MD, FACEP

CONTINUED on page 4



ACEP POLL SHOWS ED VISITS ON THE RISE

ACEP MEMBERS ARE
URGED TO
TAKE ACTIONS TO
ACCOMMODATE
GROWING NEEDS

by KAREN APPOLD

An online poll of emergency physicians conducted by ACEP showed that 86 percent of respondents expect emergency department visits to rise over the next three years. This could be due, in part, to the Jan. 1, 2014, implementation of the Affordable Care Act (ACA). Additionally, 77 percent reported that their EDs are not equipped for such significant increases. (You can view the complete poll results at <http://newsroom.acep.org/ACEP-Emergency-Visits-Up-Since-Implementation-of-ACA>.)

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ONE STEP CLOSER TO THE STAR TREK TRICORDER

Google Glass debuts in the ED, helping EPs streamline patient care

by CAROL PATTON

SEE PAGE 10

THE BREAK ROOM

Criticism over HRT Coverage

As a practicing, board-certified emergency physician, I wanted to respond to the recent May 2014 issue in regards to the cover stories “The Battle for Youth” and “Is Hormone Replacement Therapy Too Good to Be True?” I was under the impression that ACEP was the official voice of emergency medicine and not current trends in anti-aging. I look forward to the latest articles in regards to controversies over TPA use, managing sepsis, or even documentation. I don’t think anti-aging warrants front-page coverage on *our* monthly newsletter. Place it in the back or even link to the webpage.

Secondly, as a 45-year-old male who uses HRT personally, I don’t believe Eric G’s results are only because of HRT. He either benefitted from a combination of HRT, diet management, and exercise or was using supratherapeutic doses, which are dangerous and have severe side effects. To drop 17 percent body fat in six months by only using HRT is highly improbable and most likely impossible. The article as written is misleading and places HRT in the category of a “quick fix” versus a lifestyle change.

—George Davis, MD
The Woodlands, Texas

Bring Simple Language to End-of-Life Decisions

In response to “How to Approach End-of-Life Care Discussions, Determine Treatment Goals for Patients Near Death in the Emergency Department,” May 2014] The conversation changes completely if one uses “allow natural death” in the family discussion instead of the clinical terms “no CPR,” “do not resuscitate,” “no code,” etc.

I have had patients and families respond as if all the weight in the world was lifted from their shoulders when I have asked, “If while you are here in the hospital your heart or breathing stops *and you die a natural death*, do you want us to do anything about that?”

The usual response, no matter what their advance directive may say, is, “Oh, no. I’ve always wanted to die a natural death, not hooked up to any tubes or machines.”

There’s a wealth of resources on this available. Just search for “allow natural death.” ☛

—Chuck Pilcher, MD, FACEP
Kirkland, Washington

SEND YOUR THOUGHTS AND
COMMENTS TO
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CONGRESS NEEDS TO HEAR FROM EMERGENCY PHYSICIANS

Help us call for a congressional hearing to protect emergency care!

- ✓ Enact federal liability protections for emergency physicians
- ✓ Promote solutions for emergency department boarding of psychiatric patients
- ✓ Invest in graduate medical education and EM research
- ✓ Enhance patient care through stabilized reimbursement

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The Official Voice of Emergency Medicine

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A NEW SPIN

From the Medical Editor in Chief: This is an important issue for our College, worthy of our attention and discussion. The ACEP Council has previously considered alternative membership categories for physicians practicing emergency medicine who do not meet the current membership criteria. In the past, such resolutions were not adopted but were not unanimously rejected either. I have spoken to several emergency physicians on both sides of this issue. It appears that it is time to continue this discussion. The following is the first formal submission I have received on the topic. It is published not as an endorsement of the position but as the beginning of a very important discussion. I certainly don't know what the right answer is, but I hope through this discussion we will find clarity. Agree? Disagree? Either way, we want your input. **Send your comments to acepnow@acep.org.**

—Kevin M. Klauer, DO, EJD, FACEP

THE DEBATE CONTINUES

Don't miss next month's issue, where we will bring you a pro-con debate on alternative membership categories from both sides of the field!

Strength in Numbers: A Call to Action

by RICHARD STENNES, MD, MBA, FACEP

When the same question continues to be asked, this might mean that the answers lacked solutions.

I have advocated for an expanded ACEP membership since day one. The argument has failed based primarily on "exclusivity in the club."

Although recognizing residency training and board certification in emergency medicine as the standard is important, the masses seem to disregard the fact that vast numbers of physicians working as emergency physicians have no EM training but receive all of the educational and financial benefits that ACEP and the American Medical Association (AMA) provide for them.

Historical Perspective

I joined ACEP in the early 1970s. In California, we needed a mechanism to go to Sacramento to lobby for money for Medi-Cal; Bill O'Riordan, Walt Edwards, I, and others did just that.

We realized early on that our efforts would require more sophistication, like the big boys in Sacramento, and so CAL/ACEP hired a lobbyist, Jim Randlett. Often, our legislative efforts did not bear fruit, but they did stop some bad things from happening—a continued theme today.

We also realized that money talks (and bullshit walks) and that a political action committee (PAC) would be necessary to prompt legislators to listen more closely, and so EM-PAC was formed.

John McDade, president in about 1975, asked me to assume the chair of the Government Finance Committee during the Nexus 75 meeting in Palm Springs. I started marching on Washington, DC, with our part-time lobbyist, Terry Schmidt, again looking for money in some direct or indirect fashion.

Jack Wood of Wood, Lucksinger, and Epstein in Houston was one of the nation's recognized experts in Medicare rules and reimbursement and was retained to accompany me to the Medicare offices in Baltimore to look for improved reimbursement. We won.

During the winter ACEP Symposium meeting in Bermuda in the '70s, the option for independent contractor status for emergency physicians was being contested. I asked the Board for \$20,000 to march on Washington, and we prevailed. This was a money issue,

and this recurrent theme continues in present time.

It became apparent that our efforts to protect the practice of emergency medicine and the interests of emergency physicians needed full-time lobbying, and the College opened its own office in Washington.

We realized that a good message couldn't reach the ears, hearts, and minds of legislators without numbers and money. This was the birth of NEMPAC.

What was, and remains, largely unknown to most physicians is the incredible effect that the Relative Value Scale Update Committee (RUC) of the AMA has on directing money to emergency medicine. Mike Bishop, MD, FACEP, and others before him have represented EM at the RUC and have done an outstanding job.

As ACEP president, I was at the Reagan White House for the signing of EMTALA into law in 1986. In theory, EMTALA was to protect patient access to emergency care. The net effect to us has been more patients, and that means more opportunity.

We passed a law in California that precluded nonemergency physicians from testifying against emergency physicians in medical-malpractice cases. This was an effort to reduce risk and malpractice costs—again, a money issue.

The EM Landscape Today

One must ask who has benefited from all of these efforts. Arguably, society has as we have improved emergency care immensely, but more specifically, all physicians (and advanced practice providers) who work in emergency medicine have benefitted. Of note, in approximately 40 percent of visits to California EDs, patients are reportedly seen by physician assistants (PAs). They are clearly practicing EM and are not physicians, but PAs do a fine job and are a permanent piece of our workforce.

My experience suggests that, at least outside of major metropolitan areas, most emergency care is delivered by non-EM-trained physicians. Interestingly, they all have the benefits provided by ACEP but contribute nothing when it comes to "carrying the water" on regulatory and legislative matters. Free-loaders? I don't think so. We've refused their help and their participation.

I work in a rural Minnesota ED with up to three physicians and a nurse practitioner on duty at many times. I started staffing my hometown ED in 1992, with the objective of staffing it with residency-trained emergency physicians. Even today, with a pay scale at the 90th percentile, there are only two American Board of Emergency Medicine-certified physicians working there. The rest are family practice trained and do a wonderful job. They may not possess all the knowledge of those trained in EM in recent years, but this situation illustrates two points: there is an ongoing shortage of residency-trained emergency physicians in rural America, and emergency care is delivered effectively every day by those not trained in emergency medicine.

Imagine our membership and lobbying numbers if we somehow included these physicians as members of ACEP in some unique category. We have many sections within ACEP, but they don't add numbers or dollars because existing members are the only pool for section membership. A new section/category could be a substantive portion of ACEP membership. When Washington or Sacramento looks out on the horizon and sees a bigger group of physicians all rowing the boat together, our strength and influence will be notably enhanced while ACEP's mission of continuing to improve emergency care will be more completely actualized.

We are recognized as a big player in the house of medicine as evidenced by the recent election of an emergency physician, Steven Stack, MD, FACEP, as president-elect of the AMA.

Any fear that we would lose what we have achieved by adding members who practice our specialty but are not EM trained is no longer applicable, in my opinion. Quite the contrary, I think our stature and effectiveness would grow.

As a past president, I'm often silent on such issues as I watch the College and specialty grow and develop. It's time to break the silence. I ask that you consider my thoughts carefully as we move into the future as an established, well-respected specialty. We are only benefited by strength in numbers. ☛

DR. STENNES was ACEP president from 1985 to 1986.



Imagine our membership and lobbying numbers if we somehow included these physicians as members of ACEP in some unique category.

key issues were psychiatric patient boarding, the lack of resources for mental health care, the lack of funding for graduate medication education, and the need for liability protection for EMTALA care provided in the ED. (See sidebar for more information.)

This conference may seem quite intimidating to those who don't consider themselves political experts. You might think that the conference is really only for the "club" of political geeks who have been attending since the conference first started back in the 1990s. It's natural to feel that a member of Congress will recognize inexperience and eat you alive in a discussion about health care policy. Well, you would be *completely* wrong.

This conference is designed for everyone, from the political novice to the crustiest political wonk in the specialty. Perhaps that is the best thing about it. Beyond the issues, data,



Before meeting with Members of Congress and their staffs, emergency physicians from Delaware prepare their message and organize their visit schedules.

and charts, politics is really about building relationships. The strength of LAC is that it brings together residents, students, and young physicians who are new to the game and full of new ideas and incredible energy with others who are more seasoned in the specialty in order to network and learn from one another. During the first two days, there are great presentations about current health care policy issues and building leadership skills. In addition to focusing on national-level policies and health care reform, we must realize that each of us is a leader every time we don our stethoscopes and pick up a chart. The leadership development sessions and experiences are designed to nurture skills and techniques that can be used at the chapter and national levels of ACEP—and help you in your professional and private life.

Highlights of this year's lectures included a very informative and entertaining opening presentation titled "The Gift of Leadership" by Mark Levin, BAI, Inc. president, and a luncheon talk by Patrick Conway, MD, MSc, who is the deputy administrator for innovation and quality and chief medical officer at the Centers for Medicare & Medicaid Services. Dr. Conway highlighted the challenges and opportunities of creating new paradigms for the delivery and financing of health care as our population grows and ages.

In addition to the educational programs, there are great social events including opportunities to network with emergency physician leaders from throughout the country at the Opening Reception and the Congressional Reception. This year, ACEP's National Emergency Medicine Political Action Committee (NEMPAC), had a reception for VIP donors

at the United States Botanic Garden just outside the Capitol. NEMPAC and the Emergency Medicine Physicians Political Action Committee (EMP PAC) cohosted fund-raisers for two emergency physicians in Congress, Rep. Joe Heck (R-NV) and Rep. Raul Ruiz (D-CA).

The high point of the conference is the visit to Capitol Hill. The opportunity to have your voice heard by your elected officials is one of the most exciting things an emergency physician can ever experience, especially for the first-timers. Physicians are grouped by state and by district. The afternoon is spent in a small group with colleagues from your state, traveling from office to office to meet with the

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ACEP SUPPORTED ISSUES AND BILLS AT THE 2014 LEADERSHIP AND ADVOCACY CONFERENCE

BY K. KAY MOODY, DO, MPH

Mental Health

The Helping Families in Mental Health Crisis Act of 2013 (H.R. 3717)

This bill proposes to improve research and data collection of existing mental health programs, promote evidence-based medicine systems of care for patients with mental health issues, remove regulations that prohibit same-day billing under Medicaid for treatment of physical and mental health issues, and establish federal liability protections for health professionals who volunteer at community health centers or behavioral health centers.

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IMPORTANT SAFETY INFORMATION ABOUT PRADAXA

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

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

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

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

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

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients who are or will be anticoagulated.

Please see boxed WARNING and accompanying brief summary of full Prescribing Information.

NVAF=non-valvular atrial fibrillation; DVT=deep venous thrombosis; PE=pulmonary embolism.



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EMTALA Medical Liability Reform

The Health Care Safety Net Enhancement Act of 2013 (H.R. 36/S. 961)

Co-sponsored by multiple members of the House and Senate and passed in the House by voice vote in 2012, this bill would provide liability protection for EMTALA-related services in the emergency department to emergency physicians and on-call specialists as federal employees under the Public Health Safety Act.

Graduate Medical Education

The Resident Physician Shortage Reduction Act of 2013 (H.R. 1180/S. 577)

This bill would expand the current cap, in place since 1997, on the number of Medicare-supported graduate medical education slots in the United States. It would create 15,000 new training slots over five years with one-third of the positions each year directed to hospitals already operating over their resident limits and half of the positions dedicated to training physicians in specialty shortages. ACEP also supports funding for the National Health Care

Workforce Commission that was authorized under the Affordable Care Act in 2010 but remains unfunded.

Medicare Reimbursement

The SGR Repeal and Medicare Provider Payment Modernization Act of 2014 (H.R. 4015)

Although Congress averted a 24 percent cut in Medicare reimbursement to physicians this year, the latest patch still does not address the flaws with the SGR payment formula. This bill would completely repeal the SGR and replace it with a workable formula.

Safe Harbor Liability Protections

The Saving Lives, Saving Costs Act (H.R. 4106)

This bill would provide increased liability protection in the form of legal safe harbors to physicians who demonstrate they followed clinical guidelines developed by a multidisciplinary panel of experts. These safe harbors would provide physicians the opportunity to have their case heard in federal court, making the case subject to mandatory alternative dispute resolution rather than trial. ☺

DR. MOODY is an emergency physician and ED medical director for Mountain States Health Alliance in Norton, Virginia; president-elect for Tennessee ACEP; and an ACEP Councillor since 2011.



IMPORTANT SAFETY INFORMATION ABOUT PRADAXA (cont'd)

CONTRAINDICATIONS

PRADAXA is contraindicated in patients with:

- active pathological bleeding;
- known serious hypersensitivity reaction (e.g., anaphylactic reaction or anaphylactic shock) to PRADAXA;
- mechanical prosthetic heart valve

WARNINGS & PRECAUTIONS

Increased Risk of Stroke with Discontinuation of PRADAXA

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

Risk of Bleeding

- PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding.
- Risk factors for bleeding include concomitant use of medications that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment.
- *Reversal of Anticoagulant Effect:* A specific reversal agent for dabigatran is not available. Hemodialysis can remove dabigatran; however clinical experience for hemodialysis as a treatment for bleeding is limited. Activated prothrombin complex concentrates, recombinant Factor VIIa, or concentrates of factors II, IX or X may be considered but their use has not been evaluated. Protamine sulfate and vitamin K are not expected to affect dabigatran anticoagulant activity. Consider administration of platelet concentrates where thrombocytopenia is present or long-acting antiplatelet drugs have been used.

Spinal/Epidural Anesthesia or Puncture

When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulants are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis. To reduce potential risk of bleeding with concurrent use of dabigatran and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of dabigatran. Placement/removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of dabigatran is low but exact timing to reach a sufficiently low anticoagulant effect in each patient is unknown. If anticoagulation is administered with epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently for signs/symptoms of neurological impairment, i.e., midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs/symptoms. If spinal hematoma is suspected, initiate urgent diagnosis and treatment; consider spinal cord decompression even though it may not prevent or reverse neurological sequelae.

Thromboembolic and Bleeding Events in Patients with Prosthetic Heart Valves

The safety and efficacy of PRADAXA in patients with bileaflet mechanical prosthetic heart valves (recently implanted or implanted more than 3 months prior to enrollment) was evaluated in the phase 2 RE-AUGN® trial. RE-AUGN was terminated early because of significantly more thromboembolic events (valve thrombosis, stroke, transient ischemic attack, and myocardial infarction) and an excess of major bleeding (predominantly post-operative pericardial effusions requiring intervention for hemodynamic compromise) for PRADAXA vs warfarin. Therefore, the use of PRADAXA is contraindicated in patients with mechanical prosthetic valves. Use of PRADAXA for the prophylaxis of thromboembolic events in patients with AFib in the setting of other forms of valvular heart disease, including bioprosthetic heart valve, has not been studied and is not recommended.

Effect of P-gp Inducers & Inhibitors on Dabigatran Exposure

Concomitant use of PRADAXA with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. P-gp inhibition and impaired renal function are major independent factors in increased exposure to dabigatran. Concomitant use of P-gp inhibitors in patients with renal impairment is expected to increase exposure of dabigatran compared to either factor alone.

Reduction of Risk of Stroke/Systemic Embolism in NVA

- For patients with moderate renal impairment (CrCl 30-50 mL/min), consider reducing the dose of PRADAXA to 75 mg twice daily when dronedarone or systemic ketoconazole is coadministered with PRADAXA.
- For patients with severe renal impairment (CrCl 15-30 mL/min), avoid concomitant use of PRADAXA and P-gp inhibitors.

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

- For patients with CrCl <50 mL/min, avoid use of PRADAXA and concomitant P-gp inhibitors

ADVERSE REACTIONS

The most serious adverse reactions reported with PRADAXA were related to bleeding.

NVA

- Most frequent adverse reactions leading to discontinuation of PRADAXA were bleeding & gastrointestinal (GI) events
- PRADAXA 150 mg resulted in higher rates of major and any GI bleeds compared to warfarin.
- In patients ≥75 years of age, the risk of major bleeding may be greater with PRADAXA vs warfarin.
- Patients on PRADAXA 150 mg had an increased incidence of GI adverse reactions. These were commonly dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including GERD, esophagitis, erosive gastritis, gastric hemorrhage, hemorrhagic gastritis, hemorrhagic erosive gastritis, and GI ulcer).

DVT/PE

- Rates of any GI bleeds were higher in patients receiving PRADAXA 150 mg vs warfarin and placebo
- In the active-controlled studies, there was a higher rate of clinical myocardial infarction (MI) in PRADAXA patients [20 (0.66/100 patient-years)] vs warfarin [5 (0.17/100 patient-years)]. In the placebo-controlled study, there was similar rate of non-fatal and fatal clinical MI PRADAXA patients [1 (0.32/100 patient-years)] vs warfarin [1 (0.34/100 patient-years)].
- GI adverse reactions were similar in patients receiving PRADAXA 150 mg vs warfarin. They were commonly dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including gastritis, GERD, esophagitis, erosive gastritis and gastric hemorrhage).

Drug hypersensitivity reactions were reported in ≤ 0.1% of patients receiving PRADAXA.

Other Measures Evaluated

In NVA patients, a higher rate of clinical MI was reported in patients who received PRADAXA (0.7/100 patient-years for 150 mg dose) than in those who received warfarin (0.6).

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US representative from your home district and with your US senators.

During the Capitol Hill visits, you meet with staffers and, in most cases, the members of Congress themselves. In a congressional office, staffers work closely with the elected official and do a great deal of the grunt work in developing and reviewing the myriad health care-related bills introduced each year. During a congressional office visit, you have roughly 30 minutes to discuss what bills you deem most important and why you would like your member of Congress to support them. As a physician, constituent, and American citizen, this may be the most important meeting you can have. This is more important than



Congressmen and ACEP members Dr. Raul Ruiz (D-CA; left image, on right) and Dr. Joe Heck (R-NV; above right) talk with ACEP members during fundraisers held for them by NEMPAC and EMP PAC at LAC.

voting because you actually talk to the people who can effect change.

Members of Congress and staffers don't have firsthand knowledge of what affects

our patients every day; they depend on our opinions to influence their positions on bills. Being emergency physicians gives us a unique perspective on medicine and soci-

ety. We have "street cred," and no one else understands health care better than we do. Staffers and members of Congress will listen intently to what you have to say and sometimes challenge your positions while you get to challenge theirs. Although you might not agree on all issues, it is the best opportunity to educate them about the critical role that emergency medicine plays in the US health care system. ☺

DR. DIERKS is an emergency physician at Genesis Medical Center in Davenport, Iowa. **DR. CIRILLO** is director of health policy and legislative advocacy for Emergency Medicine Physicians in Canton, Ohio.

Pradaxa® (dabigatran etexilate mesylate) capsules for oral use
BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see package insert for full Prescribing Information.

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

(A) PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS
Premature discontinuation of any oral anticoagulant, including PRADAXA, increases the risk of thrombotic events. If anticoagulation with PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see Dosage and Administration (2.4, 2.5, 2.6) and Warnings and Precautions (5.1)].

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

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- a history of traumatic or repeated epidural or spinal punctures
- a history of spinal deformity or spinal surgery
- optimal timing between the administration of PRADAXA and neuraxial procedures is not known [see Warnings and Precautions (5.3)].

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary [see Warnings and Precautions (5.3)].

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated [see Warnings and Precautions (5.3)].

INDICATIONS AND USAGE: Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation: PRADAXA is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. **Treatment of Deep Venous Thrombosis and Pulmonary Embolism:** PRADAXA is indicated for the treatment of deep venous thrombosis and pulmonary embolism in patients who have been treated with a parenteral anticoagulant for 5-10 days. **Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** PRADAXA is indicated to reduce the risk of recurrence of deep venous thrombosis and pulmonary embolism in patients who have been previously treated.

CONTRAINDICATIONS: PRADAXA is contraindicated in patients with: Active pathological bleeding [see Warnings and Precautions and Adverse Reactions]. History of a serious hypersensitivity reaction to PRADAXA (e.g., anaphylactic reaction or anaphylactic shock) [see Adverse Reactions]. Mechanical prosthetic heart valve [see Warnings and Precautions].

WARNINGS AND PRECAUTIONS: Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including PRADAXA, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. If PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant. **Risk of Bleeding:** PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding. Risk factors for bleeding include the concomitant use of other drugs that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment. **Reversal of Anticoagulant Effect:** A specific reversal agent for dabigatran is not available. Hemodialysis can remove dabigatran; however the clinical experience supporting the use of hemodialysis as a treatment for bleeding is limited [see Overdosage]. Activated prothrombin complex concentrates (aPCCs, e.g., FEIBA), or recombinant Factor VIIa, or concentrates of coagulation factors II, IX or X may be considered but their use has not been evaluated in clinical trials. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of dabigatran. Consider administration of platelet concentrates in cases where thrombocytopenia

is present or long-acting antiplatelet drugs have been used. **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis [see Boxed Warning]. To reduce the potential risk of bleeding associated with the concurrent use of dabigatran and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of dabigatran. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of dabigatran is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae. **Thromboembolic and Bleeding Events in Patients with Prosthetic Heart Valves:** The safety and efficacy of PRADAXA in patients with bileaflet mechanical prosthetic heart valves was evaluated in the RE-ALIGN trial, in which patients with bileaflet mechanical prosthetic heart valves (recently implanted or implanted more than three months prior to enrollment) were randomized to dose adjusted warfarin or 150, 220, or 300 mg of PRADAXA twice a day. RE-ALIGN was terminated early due to the occurrence of significantly more thromboembolic events (valve thrombosis, stroke, transient ischemic attack, and myocardial infarction) and an excess of major bleeding (predominantly post-operative pericardial effusions requiring intervention for hemodynamic compromise) in the PRADAXA treatment arm as compared to the warfarin treatment arm. These bleeding and thromboembolic events were seen both in patients who were initiated on PRADAXA post-operatively within three days of mechanical bileaflet valve implantation, as well as in patients whose valves had been implanted more than three months prior to enrollment. Therefore, the use of PRADAXA is contraindicated in patients with mechanical prosthetic valves [see Contraindications]. The use of PRADAXA for the prophylaxis of thromboembolic events in patients with atrial fibrillation in the setting of other forms of valvular heart disease, including the presence of a bioprosthetic heart valve, has not been studied and is not recommended. **Effect of P-gp Inducers and Inhibitors on Dabigatran Exposure:** The concomitant use of PRADAXA with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. P-gp inhibition and impaired renal function are the major independent factors that result in increased exposure to dabigatran. Concomitant use of P-gp inhibitors in patients with renal impairment is expected to produce increased exposure of dabigatran compared to that seen with either factor alone. **Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation:** Consider reducing the dose of PRADAXA to 75 mg twice daily when dronedarone or systemic ketoconazole is coadministered with PRADAXA in patients with moderate renal impairment (CrCl 30-50 mL/min). Avoid use of PRADAXA and P-gp inhibitors in patients with severe renal impairment (CrCl 15-30 mL/min) [see Drug Interactions and Use in Specific Populations]. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** Avoid use of PRADAXA and concomitant P-gp inhibitors in patients with CrCl <50 mL/min [see Drug Interactions].

ADVERSE REACTIONS: The most serious adverse reactions reported with PRADAXA were related to bleeding [see Warnings and Precautions]. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. **Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation:** The RE-LY (Randomized Evaluation of Long-term Anticoagulant Therapy) study provided safety information on the use of two doses of PRADAXA and warfarin. The numbers of patients and their exposures are described in Table 1. Limited information is presented on the 110 mg dosing arm because this dose is not approved.

Table 1 Summary of Treatment Exposure in RE-LY			
	PRADAXA 110 mg twice daily	PRADAXA 150 mg twice daily	Warfarin
Total number treated	5983	6059	5998
Exposure			
> 12 months	4936	4939	5193
> 24 months	2387	2405	2470
Mean exposure (months)	20.5	20.3	21.3
Total patient-years	10,242	10,261	10,659

Drug Discontinuation in RE-LY: The rates of adverse reactions leading to treatment discontinuation were 21% for PRADAXA 150 mg and 16% for warfarin. The most frequent adverse reactions leading to discontinuation of PRADAXA were bleeding and gastrointestinal events (i.e., dyspepsia, nausea, upper abdominal pain, gastrointestinal hemorrhage, and diarrhea). **Bleeding [see Warnings and Precautions]:** Table 2 shows the number of patients experiencing serious bleeding during the treatment period in the RE-LY study, with the bleeding rate per 100 patient-years (%). Major bleeds fulfilled one or more of the following criteria: bleeding associated with a reduction in hemoglobin of at least 2 grams per deciliter or leading to a transfusion of at least 2 units of blood, or symptomatic bleeding in a critical area or organ (intraocular, intracranial, intraspinal or intramuscular with compartment syndrome, retroperitoneal bleeding, intra-articular bleeding, or pericardial bleeding). A life-threatening bleed met one or more of the following criteria: fatal, symptomatic intracranial bleed, reduction in hemoglobin of at least 5 grams per deciliter, transfusion of at least 4 units of blood, associated with hypotension requiring the use of intravenous inotropic agents, or necessitating surgical intervention. Intracranial hemorrhage included intracerebral (hemorrhagic stroke), subarachnoid, and subdural bleeds.

Table 2 Bleeding Events* (per 100 Patient-Years)			
	PRADAXA 150 mg twice daily N (%)	Warfarin N (%)	Hazard Ratio (95% CI**)
Randomized patients	6076	6022	
Patient-years	12,033	11,794	
Intracranial hemorrhage	38 (0.3)	90 (0.8)	0.41 (0.28, 0.60)
Life-threatening bleed	179 (1.5)	218 (1.9)	0.80 (0.66, 0.98)
Major bleed	399 (3.3)	421 (3.6)	0.93 (0.81, 1.07)
Any bleed	1993 (16.6)	2166 (18.4)	0.91 (0.85, 0.96)

*Patients contributed multiple events and events were counted in multiple categories.
**Confidence interval

The risk of major bleeds was similar with PRADAXA 150 mg and warfarin across major subgroups defined by baseline characteristics, with the exception of age, where there was a trend towards a higher incidence of major bleeding on PRADAXA (hazard ratio 1.2, 95% CI: 1.0 to 1.4) for patients ≥75 years of age. There was a higher rate of major gastrointestinal bleeds in patients receiving PRADAXA 150 mg than in patients receiving warfarin (1.6% vs. 1.1%, respectively, with a hazard ratio vs. warfarin of 1.5, 95% CI, 1.2 to 1.9), and a higher rate of any gastrointestinal bleeds (6.1% vs. 4.0%, respectively). **Gastrointestinal Adverse Reactions:** Patients on PRADAXA 150 mg had an increased incidence of gastrointestinal adverse reactions (35% vs. 24% on warfarin). These were commonly dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including GERD, esophagitis, erosive gastritis, gastric hemorrhage, hemorrhagic gastritis, hemorrhagic erosive gastritis, and gastrointestinal ulcer). **Hypersensitivity Reactions:** In the RE-LY study, drug hypersensitivity (including urticaria, rash, and pruritus), allergic edema, anaphylactic reaction, and anaphylactic shock were reported in <0.1% of patients receiving PRADAXA. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** PRADAXA was studied in 4387 patients in 4 pivotal, parallel, randomized, double-blind trials. Three of these trials were active-controlled (warfarin) (RE-COVER, RE-COVER II, and RE-MEDY), and one study (RE-SONATE) was placebo-controlled. The demographic characteristics were similar among the 4 pivotal studies and between the treatment groups within these studies. Approximately 60% of the treated patients were male, with a mean age of 55.1 years. The majority of the patients were white (87.7%), 10.3% were Asian, and 1.9% were black with a mean CrCl of 105.6 mL/min. Bleeding events for the 4 pivotal studies were classified as major bleeding events if at least one of the following criteria applied: fatal bleeding, symptomatic bleeding in a critical area or organ (intraocular, intracranial, intraspinal or intramuscular with compartment syndrome, retroperitoneal bleeding, intra-articular bleeding, or pericardial bleeding), bleeding causing a fall in hemoglobin level of 2.0 g/dL (1.24 mmol/L or more, or leading to transfusion of 2 or more units of whole blood or red cells). RE-COVER and RE-COVER II studies compared PRADAXA 150 mg twice daily and warfarin for the treatment of deep vein thrombosis and pulmonary embolism. Patients received 5-10 days of an approved parenteral anticoagulant therapy followed by 6 months, with mean exposure of 164 days, of oral only treatment; warfarin was overlapped with parenteral therapy. Table 3 shows the number of patients experiencing bleeding events in the pooled analysis of RE-COVER and RE-COVER II studies during the full treatment including parenteral and oral only treatment periods after randomization.

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Seven Best Practices to Reduce ED Misuse

IN WASHINGTON STATE, POLITICIANS AND PROVIDERS COLLABORATE TO REDUCE COSTS AND IMPROVE CARE

BY STEPHEN H. ANDERSON, MD, FACEP, AND NATHAN SCHLICHER, MD, JD, FACEP

Table 3 Bleeding Events in RE-COVER and RE-COVER II Treated Patients

	Bleeding Events-Full Treatment Period Including Parenteral Treatment		
	PRADAXA 150 mg twice daily N (%)	Warfarin N (%)	Hazard Ratio (95% CI)*
Patients	N=2553	N=2554	
Major bleeding event*	37 (1.4)	51 (2.0)	0.73 (0.48, 1.11)
Fatal bleeding	1 (0.04)	2 (0.1)	
Bleeding in a critical area or organ	7 (0.3)	15 (0.6)	
Fall in hemoglobin ≥2g/dL or transfusion ≥2 units of whole blood or packed red blood cells	32 (1.3)	38 (1.5)	
Bleeding sites for MBE*			
Intracranial	2 (0.1)	5 (0.2)	
Retroperitoneal	2 (0.1)	1 (0.04)	
Intraarticular	2 (0.1)	4 (0.2)	
Intramuscular	2 (0.1)	6 (0.2)	
Gastrointestinal	15 (0.6)	14 (0.5)	
Urogenital	7 (0.3)	14 (0.5)	
Other	8 (0.3)	8 (0.3)	
Clinically relevant non-major bleeding	101 (4.0)	170 (6.7)	0.58 (0.46, 0.75)
Any bleeding	411 (16.1)	567 (22.7)	0.70 (0.61, 0.79)

Note: MBE can belong to more than one criterion.
*Patients with at least one MBE.
*Bleeding site based on investigator assessment. Patients can have more than one site of bleeding.
*Confidence interval

The rate of any gastrointestinal bleeds in patients receiving PRADAXA 150 mg in the full treatment period was 3.1% (2.4% on warfarin). The RE-MEDY and RE-SONATE studies provided safety information on the use of PRADAXA for the reduction in the risk of recurrence of deep vein thrombosis and pulmonary embolism. RE-MEDY was an active-controlled study (warfarin) in which 1430 patients received PRADAXA 150 mg twice daily following 6 to 18 months of oral anticoagulant regimen. Patients in the treatment studies who rolled over into the RE-MEDY study had a combined treatment duration of up to more than 3 years, with mean exposure of 473 days. Table 4 shows the number of patients experiencing bleeding events in the study.

Table 4 Bleeding Events in RE-MEDY Treated Patients

	PRADAXA 150 mg twice daily N (%)	Warfarin N (%)	Hazard Ratio (95% CI)*
Patients	N=1430	N=1426	
Major bleeding event*	13 (0.9)	25 (1.8)	0.54 (0.25, 1.16)
Fatal bleeding	0	1 (0.1)	
Bleeding in a critical area or organ	7 (0.5)	11 (0.8)	
Fall in hemoglobin ≥ 2g/dL or transfusion ≥2 units of whole blood or packed red blood cells	7 (0.5)	16 (1.1)	
Bleeding sites for MBE*			
Intracranial	2 (0.1)	4 (0.3)	
Intraocular	4 (0.3)	2 (0.1)	
Retroperitoneal	0	1 (0.1)	
Intraarticular	0	2 (0.1)	
Intramuscular	0	4 (0.3)	
Gastrointestinal	4 (0.3)	8 (0.6)	
Urogenital	1 (0.1)	1 (0.1)	
Other	2 (0.1)	4 (0.3)	
Clinically relevant non-major bleeding	71 (5.0)	125 (8.8)	0.56 (0.42, 0.75)
Any bleeding	278 (19.4)	373 (26.2)	0.71 (0.61, 0.83)

Note: MBE can belong to more than one criterion.
*Patients with at least one MBE.
*Bleeding site based on investigator assessment. Patients can have more than one site of bleeding.
*Confidence interval

In the RE-MEDY study, the rate of any gastrointestinal bleeds in patients receiving PRADAXA 150 mg was 3.1% (2.2% on

warfarin). RE-SONATE was a placebo-controlled study in which 684 patients received PRADAXA 150 mg twice daily following 3 to 6 months of oral anticoagulant regimen. Patients in the treatment studies who rolled over into the RE-SONATE study had combined treatment duration up to 9 months, with mean exposure of 165 days. Table 5 shows the number of patients experiencing bleeding events in the study.

Table 5 Bleeding Events in RE-SONATE Treated Patients

	PRADAXA 150 mg twice daily N (%)	Placebo N (%)	Hazard Ratio (95% CI)*
Patients	N=684	N=659	
Major bleeding event*	2 (0.3)	0	
Bleeding in a critical area or organ	2 (0.3)	0	
Gastrointestinal*	2 (0.3)	0	
Clinically relevant non-major bleeding	34 (5.0)	13 (2.0)	2.54 (1.34, 4.82)
Any bleeding	72 (10.5)	40 (6.1)	1.77 (1.20, 2.61)

Note: MBE can belong to more than one criterion.
*Patients with at least one MBE.
*Bleeding site based on investigator assessment. Patients can have more than one site of bleeding.
*Confidence interval

In the RE-SONATE study, the rate of any gastrointestinal bleeds in patients receiving PRADAXA 150 mg was 0.7% (0.3% on placebo). **Clinical Myocardial Infarction Events:** In the active-controlled VTE studies, a higher rate of clinical myocardial infarction was reported in patients who received PRADAXA [20 (0.66 per 100 patient-years)] than in those who received warfarin [5 (0.17 per 100 patient-years)]. In the placebo-controlled study, a similar rate of non-fatal and fatal clinical myocardial infarction was reported in patients who received PRADAXA [1 (0.32 per 100 patient-years)] and in those who received placebo [1 (0.34 per 100 patient-years)]. **Gastrointestinal Adverse Reactions:** In the four pivotal studies, patients on PRADAXA 150 mg had a similar incidence of gastrointestinal adverse reactions (24.7% vs. 22.7% on warfarin). Dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) occurred in patients on PRADAXA in 7.5% vs. 5.5% on warfarin, and gastritis-like symptoms (including gastritis, GERD, esophagitis, erosive gastritis and gastric hemorrhage) occurred at 3.0% vs. 1.7%, respectively. **Hypersensitivity Reactions:** In the 4 pivotal studies, drug hypersensitivity (including urticaria, rash, and pruritus), allergic edema, anaphylactic reaction, and anaphylactic shock were reported in 0.1% of patients receiving PRADAXA. **Postmarketing Experience:** The following adverse reactions have been identified during post approval use of PRADAXA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following adverse reactions have been identified during post approval use of PRADAXA: angioedema, thrombocytopenia, esophageal ulcer.

In RE-LY, a higher rate of clinical myocardial infarction was reported in patients who received PRADAXA (0.7 per 100 patient-years for 150 mg dose) than in those who received warfarin (0.6).

DRUG INTERACTIONS: Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation: The concomitant use of PRADAXA with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. P-gp inhibition and impaired renal function are the major independent factors that result in increased exposure to dabigatran. Concomitant use of P-gp inhibitors in patients with renal impairment is expected to produce increased exposure of dabigatran compared to that seen with either factor alone. In patients with moderate renal impairment (CrCl 30-50 mL/min), consider reducing the dose of PRADAXA to 75 mg twice daily when administered concomitantly with the P-gp inhibitor dronedarone or systemic ketoconazole. The use of P-gp inhibitors (verapamil, amiodarone, quinidine, and clarithromycin) does not require a dose adjustment of PRADAXA. These results should not be extrapolated to other P-gp inhibitors [see Warnings and Precautions and Use in Specific Populations]. The concomitant use of PRADAXA and P-gp inhibitors in patients with severe renal impairment (CrCl 15-30 mL/min) should be avoided [see Warnings and Precautions and Use in Specific Populations]. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** Avoid use of PRADAXA and P-gp inhibitors in patients with CrCl <50 mL/min [see Warnings and Precautions and Use in Specific Populations].

USE IN SPECIFIC POPULATIONS: Pregnancy: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Dabigatran has been shown to decrease the number of implantations when male and female rats were treated at a dosage of 70 mg/kg (about 2.6 to 3.0 times the human exposure at maximum recommended human dose [MRHD] of 300 mg/day based on area under the curve [AUC] comparisons) prior to mating and up to implantation (gestation Day 6). Treatment of pregnant rats after implantation with

dabigatran at the same dose increased the number of dead offspring and caused excess vaginal/uterine bleeding close to parturition. Although dabigatran increased the incidence of delayed or irregular ossification of fetal skull bones and vertebrae in the rat, it did not induce major malformations in rats or rabbits. **Labor and Delivery:** Safety and effectiveness of PRADAXA during labor and delivery have not been studied in clinical trials. Consider the risks of bleeding and of stroke in using PRADAXA in this setting [see Warnings and Precautions]. Death of offspring and mother rats during labor in association with uterine bleeding occurred during treatment of pregnant rats from implantation (gestation Day 7) to weaning (lactation Day 21) with dabigatran at a dose of 70 mg/kg (about 2.6 times the human exposure at MRHD of 300 mg/day based on AUC comparisons). **Nursing Mothers:** It is not known whether dabigatran is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from PRADAXA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness of PRADAXA in pediatric patients have not been established. **Geriatric Use:** Of the total number of patients in the RE-LY study, 82% were 65 and over, while 40% were 75 and over. The risk of stroke and bleeding increases with age, but the risk-benefit profile is favorable in all age groups [see Warnings and Precautions and Adverse Reactions]. **Renal Impairment: Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation:** No dose adjustment of PRADAXA is recommended in patients with mild or moderate renal impairment. Reduce the dose of PRADAXA in patients with severe renal impairment (CrCl 15-30 mL/min). Dosing recommendations for patients with CrCl <15 mL/min or on dialysis cannot be provided. Adjust dose appropriately in patients with renal impairment receiving concomitant P-gp inhibitors [see Warnings and Precautions and Drug Interactions]. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** Patients with severe renal impairment (CrCl <30 mL/min) were excluded from RE-COVER. Dosing recommendations for patients with CrCl <30 mL/min or on dialysis cannot be provided. Avoid use of PRADAXA with concomitant P-gp inhibitors in patients with CrCl <50 mL/min [see Warnings and Precautions and Drug Interactions].

OVERDOSAGE: Accidental overdose may lead to hemorrhagic complications. There is no reversal agent for dabigatran. In the event of hemorrhagic complications, initiate appropriate clinical support, discontinue treatment with PRADAXA, and investigate the source of bleeding. Dabigatran is primarily eliminated by the kidneys with a low plasma protein binding of approximately 35%. Hemodialysis can remove dabigatran; however, data supporting this approach are limited. Using a high-flux dialyzer, blood flow rate of 200 mL/min, and dialysate flow rate of 700 mL/min, approximately 49% of total dabigatran can be cleared from plasma over 4 hours. At the same dialysate flow rate, approximately 57% can be cleared using a dialyzer blood flow rate of 300 mL/min, with no appreciable increase in clearance observed at higher blood flow rates. Upon cessation of hemodialysis, a redistribution effect of approximately 7% to 15% is seen. The effect of dialysis on dabigatran's plasma concentration would be expected to vary based on patient specific characteristics. Measurement of aPTT or ECT may help guide therapy [see Warnings and Precautions].

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PXD-BS (4-14)

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R_x only



1. Tracking of ED visits, with an automated notification sent to providers of any patient visiting five or more times in the last 12 months. All hospitals have adopted the program. This tracking includes a summary of prior visits, care plans from any facility in the state, and safety warnings such as violence or radiation alerts.

2. Implementation of an education program for all providers, administrators, and patients via forums, webinars, handouts, and posters in ED waiting rooms (see the January 2014 issue of ACEP Now for more on these posters).

3. Identification of the highest utilizers, along with follow-up and care plans for them. This population had significant issues, including 86 percent with mental health issues and 41 percent with addiction issues. The key for these patients was an emphasis on case management with care plans and coordination with primary care.

4. A requirement that "frequent flyers," or overutilizers, are seen by primary care within 72 hours.

5. Creation of a statewide narcotics program. A 17-point program was adopted by all ED providers that created a statewide standard for prescribing opioids for chronic, noncancer pain.

6. A requirement that providers enroll in the prescription-monitoring program (PMP). Despite 96 percent enrollment, the reality is that the current data pull system is difficult to use. Thus, this sum-

mer, the PMP data will be pushed through the Emergency Department Information Exchange system. This eliminates the pull method and the inherent bias in provider selection.

7. Creation of a feedback system to track success for both the HCA and individual departments and their providers.

The first-year results of this effort exceeded everyone's expectations. A full report is available at <http://www.hca.wa.gov/Documents/EmergencyDeptUtilization.pdf>. Highlights include a 9.9 percent reduction in overall ED Medicaid visits and a 10.7 percent reduction among frequent utilizers. The ER is for Emergencies campaign resonated, and our low-acuity visits dropped 14.2 percent.

What about opioid-overdose deaths? We reduced narcotic prescriptions from the EDs 24 percent! This contributed to Washington being one of several states to

decrease opioid-related deaths annually for the last three years. Finally, in what began as a budget-generated policy, we saved the state more than \$34 million and counting.

The economics of health care are changing, but the foundation of preserving access to care should remain paramount. With expanding Medicaid enrollment, many states will be trying to rein in costs, and Washington's solution is an option for significant savings. The Centers for Medicare & Medicaid Services recently moved to protect

CONTINUED on page 26

Rate of ED Visits per 1000 Medicaid Clients



Emergency Department Utilization:
Update on Assumed Savings from Best Practices Implementation, March 20, 2014

Rate of Frequent Client Visits per 1000 Medicaid Clients



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ED VISITS RISE IN THE WAKE OF THE ACA IMPLEMENTATION

CONTINUED FROM PAGE 1

“We conducted the poll to be sure that emergency departments had an understanding of future needs and that they will have the resources to meet the demand,” said Alex M. Rosenau, DO, FACEP, president of ACEP and senior vice chair of the department of emergency medicine at Lehigh Valley Health Network in Allentown, Pennsylvania.

The Issues at Hand

Although more Americans now have health care coverage, being covered doesn’t necessarily guarantee access. “Some people will have difficulty finding a primary care physician [PCP] because many have full schedules,” Dr. Rosenau said. “A delay in addressing chronic care can lead to acute emergencies.” Medicaid patients also commonly present to the ED because many PCPs, specialists, and urgent care centers typically don’t accept them due to low reimbursement. In fact, according to the poll, more than 35 percent of respondents are now seeing more Medicaid patients.



“ACEP’S POLL SHOULD BE VIEWED AS AN ALARM AND A CALL TO ACTION.”

—Alex M. Rosenau, DO, FACEP, ACEP President

By 2020 there may be a shortage of up to 91,500 physicians; about half of these will be PCPs.¹ The projected number of physicians will be insufficient to meet the needs of an aging population requiring more care. One factor creating this problem, Dr. Rosenau said, is that “the number of graduate medical education slots has been frozen for almost two decades.”

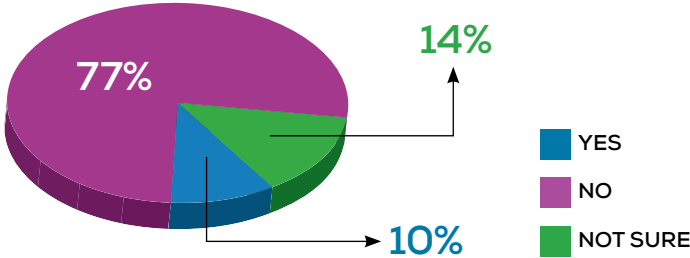
Care of patients with acute psychiatric illness is another growing problem. In the poll, 84 percent of respondents reported that these patients linger for days in the ED, waiting for a hospital bed—which clogs the ED system. “This is cruel and can lead to violent episodes,” Dr. Rosenau said. This occurs, in part, because few psychiatrists accept Medicaid or private insurance.

According to Michael J. Gerardi, MD, FACEP, President-Elect of ACEP, senior vice president of Emergency Medical Associates, and director of pediatric emergency medicine at Morristown Medical Center in Morristown, New Jersey, many more psychiatric patients could go home if more acute care options, such as intensive outpatient programs, were available. In addition,

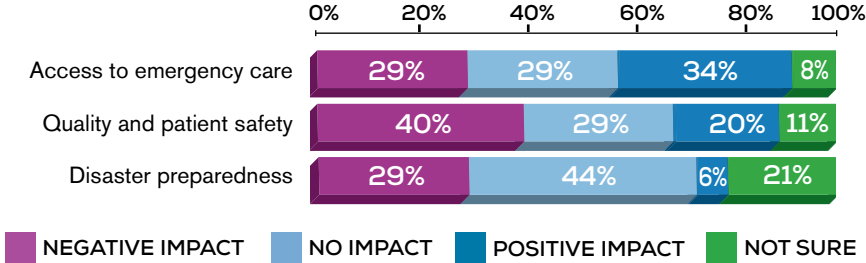
he said, “Physicians are hesitant to discharge many patients who would be fine as an outpatient due to liability concerns.”

To resolve these issues, Dr. Rosenau and Dr. Gerardi advise:

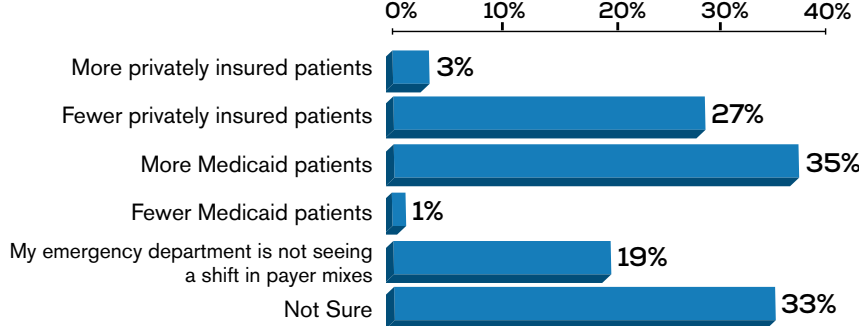
- Enacting liability reform (which the poll ranked as the most important solution to improving emergency care)
- Urging the government to increase the number of paid slots for physician training
- Enticing psychiatrists to see more patients by increasing Medicaid rates to Medicare rates
- Using telemedicine to increase access to psychiatrists who have inadequate availability due to manpower shortages and limited insurance/federal/state program participation
- Increasing the number of intensive outpatient treatment centers and programs
- Increasing inpatient capacity
- Addressing unfunded mandates, such as EMTALA



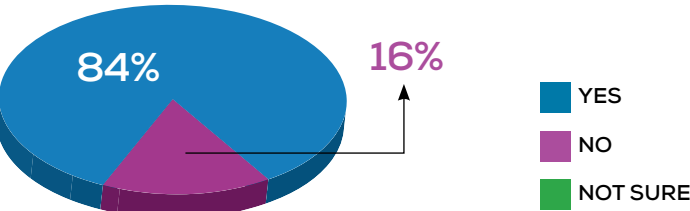
In your opinion, what type of long-term impact will the Affordable Care Act have on...?



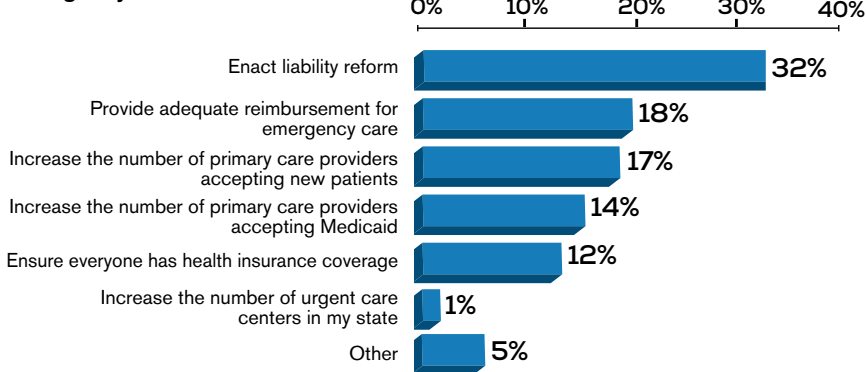
Are you seeing any of the following shifts in payer mixes? (Check all that apply.)



Do psychiatric patients “board” in your emergency department?



What is the most important issue policy makers should address to improve emergency care?



Action Needed

Armed with the poll’s results, Dr. Rosenau and Dr. Gerardi urge ACEP members to share the information with individuals who have decision-making power (eg, state and federal legislators, medical societies, and hospital administrators). For an even greater impact, Dr. Rosenau and Dr. Gerardi recommend becoming involved in local politics or supporting your state’s medical society chapter.

Dr. Gerardi said that congressional representatives are willing to listen because emergency physicians care for many of their constituents. “Stories illustrating the data win the day inside the halls of Congress,” he said. “If you can’t visit your congressman, share your stories with ACEP, and we will take them to Washington, D.C., for you.”

ACEP is urging Congress to make a firm commitment to emergency medicine patients by holding a hearing to examine whether additional strains are occurring in the ED safety net as a consequence of ACA.



“STORIES ILLUSTRATING THE DATA WIN THE DAY INSIDE THE HALLS OF CONGRESS.”

—Michael J. Gerardi, MD, FACEP, ACEP President-Elect

Future Outlook

Dr. Rosenau maintains that all U.S. citizens deserve health care coverage. Of those polled, 34 percent believed that the ACA will have a positive impact on access to emergency care in the long term.

But in the near and middle term, there is a danger that there won’t be adequate infrastructure to ensure adequate care. “We need Congress to act,” Dr. Rosenau said. “Many politicians think emergency medicine contributes to the high cost of medical care, but ultimately, it is a valuable service for a reasonable price for 136 million people per year.”

“ACEP’s poll should be viewed as an alarm and a call to action,” Dr. Rosenau concluded. ☺

Reference

1. Association of American Medical Colleges. GME funding: how to fix the doctor shortage. Available at: https://www.aamc.org/advocacy/campaigns_and_coalitions/fixdocshortage/. Accessed June 10, 2014.

KAREN APPOLD is a writer in Pennsylvania

Last September, emergency physicians at Beth Israel Deaconess Medical Center in Boston began testing a new technology that may forever change the way they deliver patient care. It weighs less than a pound, instantly retrieves critical patient data and clinical information, and takes pictures and records videos that other physicians can see in real time.

Google Glass made its debut last year and is already in the hands of emergency physicians at Beth Israel, Rhode Island Hospital in Providence, and Brigham and Women's Hospital in Boston. The wearable technology is a touch- or voice-activated computer featuring an optical face-mounted display. Emergency physicians believe the device can serve as an effective diagnostic, decision-support, and patient-tracking tool, but just like with any new technology, they say it needs to evolve to reach its full potential.

At Beth Israel, a handful of emergency physicians are integrating the HIPAA-compliant device into patient care, said Terrance Lee, MD, a resident physician in emergency medicine at Beth Israel. Dr. Lee and others worked with San Francisco-based Wearable Intelligence to develop an application that would display everything from patient triage vitals to lab and radiology results on Glass.

Just as impressive, the device's camera scans QR (quick response) codes displayed on the outside of every patient room. The patient's information instantly pops up on Glass. Although the technology enables physicians to quickly access data between patient rooms and spend more time at the patient's bedside, Dr. Lee said reactions have been mixed.



Google Glass.

"Some [physicians] need to be more familiar with the device, especially those not tech-savvy or comfortable with computers, while others are trying it out and making it work for them," he said. "Anecdotally, we've had great responses from patients of all ages ... they're intrigued by Glass and how we're using it."

PREDICTING PLENTY OF POTENTIAL

Before it was used in a live clinical setting, Google Glass was tested at the simulation center at Brigham and Women's Hospital for five months. Charles Pozner, MD, an



Rhode Island Hospital emergency physicians Peter Chai, MD, Paul Porter, MD, and Roger Wu, MD, (left to right) test Google Glass's real-time video capabilities.

emergency physician who runs the center, and other emergency physicians have been working with several IT partners and universities, including MIT, in hopes of introducing a more mature product to the clinical environment.

"We want to be able to integrate it with some of the equipment that we use within the [emergency] department," he said. "We're trying to figure out what is im-

portant to put on the screen in order to make [it] the most efficient ... if you put too much on the screen, ultimately, you will overwhelm the clinician and maybe make things even worse."

Likewise, Mike Stone, MD, FACEP, chief of the division of emergency ultrasound in the department of emergency

medicine at Brigham and Women's, has been working with another software developer to display ultrasound images on Glass while performing ultrasound procedures. While physicians must use both hands to perform ultrasounds, he explains that they also switch their gaze multiple times from the procedure to an ultrasound screen.

"A real-time, heads-up display during the procedure enables you to continue looking at the patient while performing the procedure," said Dr. Stone, adding that accurate hand placement is critical for obtaining quality images. With Google Glass,



"THERE'S NOTHING MORE DISCOURAGING TO PATIENTS THAN WATCHING A DOCTOR'S FACE BURIED IN A KEYBOARD"

—Paul Porter, MD

he said, a physician can see what trainees in another room are seeing and help guide their hands.

Meanwhile, integrating the device with existing technology is proving challenging, said Dr. Pozner. He said "thoughtful development" of Google Glass is critical, especially where doctor-patient interactions are concerned.

"If we approach it strictly from a technology [perspective], we will fail," Dr. Pozner said. "If we approach it from how

the technology can make things better and how it can improve the doctor-patient relationship, we'll have much more chance of success."

Since February, Rhode Island Hospital has been testing a HIPAA-compliant stripped-down version of Google Glass for real-time audio-visual dermatology consults with patients. This study is part of a larger program at Brown University to train the next generation of doctors in the safe and appropriate use of technology in health care, said Paul Porter, MD, a physician in the emergency departments of Rhode Island, Hasbro Children's, and The Miriam hospitals and associate professor of emergency medicine at Brown University.

"There's nothing more discouraging to patients than watching a doctor's face buried in a keyboard," he said, adding that another study will investigate the efficacy of emergency medical service providers using Google Glass with stroke victims.

Other than a short battery life, occasional overheating, and a handful of dropped calls, Dr. Porter said physicians and patients have been extremely satisfied with Google Glass. So far, only one patient declined its use during her care for reasons unknown.

He said the technology helps emergency physicians put their eyes back on the patient instead of a desktop screen, which enhances physician-patient relations. "And that's good," Dr. Porter said. "That's very good." ☺

CAROL PATTON is a freelance journalist based in Las Vegas.



DR. WEINGART is an ED intensivist. This column is a distillation of the best material from the EMCrit Blog and Podcast (<http://emcrit.org>).



DR. HINDS is an intensivist and an Irish Road Racing Doctor. Follow him on twitter @DocJohnHinds.

Should We Use Cricoid Pressure During RSI?

If an assistant's hand is placed on the patient's neck, it should be for the sole purpose of assisting with external laryngeal manipulation to allow better glottic exposure.

by SCOTT D. WEINGART, MD, FCCM, AND JOHN D. HINDS, MB BCH, BAO

Note to readers: The following piece is a tongue-in-cheek condemnation of the evidentiary base for the use of cricoid pressure for emergency airway management. Cricolol is an imaginary medication, but all of the references quoted below actually refer to cricoid pressure rather than Cricolol. Dr. Hinds uses the artifice of this fabricated drug to demonstrate how poor the evidentiary support is for the use of cricoid pressure for airway management.—SDW

Recently, I was at the Social Media and Critical Care (SMACC) conference in the Gold Coast of Australia. I looked forward to attending a debate on cricoid pressure for rapid sequence intubation (RSI) in the emergency department and ICU. The speaker was an Irish anaesthetist, intensivist, and prehospital doctor named John Hinds. I looked forward to this lecture because I have always believed the evidence does not support the use of cricoid pressure and that it should not be used for emergency airway management.¹

In an inexplicable turn of events, this lecturer got up and, instead of discussing cricoid pressure, used his allotted time to push a brand-new medication called Cricolol. I still remember Dr. Hinds' pitch for the drug. It was apparently invented as an herbal remedy by an Irish chap called O'Monroe in 1774, then refined and rebranded by O'Sellick in 1961. O'Sellick performed a non-randomized trial of just 26 patients in a single hospital.² Even more

worrisome for this new medication, there was no standardizing of dose—they just pushed what looked like a good amount. Somehow, based on this, the drug not only got approved, but it was incorporated into national guidelines throughout Ireland. Dr. Hinds indicated that we should be administering it for all of our emergent intubations.

The way Cricolol is administered requires a dedicated and trained assistant to start pushing the medication at the beginning of airway management and continue administration throughout the entire process of securing the airway. The problem is that even though dosing guidelines are included on the package insert, the ampule itself is unmarked and contains variable amounts of drug. When they did postmarketing surveillance, it turns out that the correct dose of the drug was given only 5 percent of the time.³

Aside from that initial small trial, Dr. Hinds tried to convince his audience of the merits of the drug with additional support from BSE

data. I'd have to watch the video of the lecture (see below) to remember what that stands for, but I remember the evidentiary level was not very impressive—something about corpses and magnetic resonance imaging (MRI) scanners.

To his credit, Dr. Hinds did admit to some problems with the medication. Cricolol may make airway management more difficult.⁴⁻⁶ It can prevent endotracheal tube placement once you visualize the cords.⁷ It lowers the esophageal sphincter tone and increases the potential for regurgitation.^{8,9} If the medication is dosed too high (a significant risk given the lack of ampule standardization), side effects can include airway fracture and esophageal rupture.^{10,11}

Dr. Hinds stressed again that the medication must be administered by your trained airway assistant throughout the whole procedure. He wanted to make sure we understood that the assistant's full attention must be devoted to medication administration at the exclusion of any other assistance during RSI. He did mention that Cricolol will soon be available in suppository form, which may aid administration.

Anticipating audience questions, Dr. Hinds addressed whether it would be reasonable to start administering Cricolol at the beginning of an intubation and, if it made the airway more difficult, we could simply stop administering it. He strongly warned against this plan, explaining that the drug's creator had the highest incidence of regurgitation ever reported when he used that strategy.

I don't think I will be pushing for my hospital to add Cricolol to the formulary.

Message Behind the Joke

All kidding aside, Dr. Hinds' lecture is a must-watch. You can see it at <http://emcrit.org/wee/cricolol>.

In summary, cricoid pressure, considered an essential aspect of rapid sequence tracheal intubation when it was first conceived, has come under increasing scrutiny within critical care and emergency medicine.¹ Computed tomography and MRI scanning have shown that cricoid pressure causes tracheal compression in 80 percent of patients. Numerous studies have

found that cricoid pressure hinders bag-valve-mask device ventilation, increases peak inspiratory pressure, and reduces tidal volumes.¹ For the same reasons that the airway obstruction induced by cricoid pressure may preclude effective manual ventilation, it may limit the effectiveness of apneic oxygenation as well. If an assistant's hand is placed on the patient's neck, it should be for the sole purpose of assisting with external laryngeal manipulation to allow better glottic exposure.¹²

I do not believe in the use of cricoid pressure for RSI for all of the reasons mentioned above. However, I don't think you should make this call as an individual doc but instead make a departmental guideline stating that, after a review of the evidence, cricoid pressure seems not helpful and possibly harmful. This will protect all members of your department while allowing excellent patient care. ☺

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Cricolol!

"For all the good it does, you might as well just stick it up your Arse"



CHRONIC PAIN: THEIR PAIN OR YOURS?



DR. DUCHARME is editor in chief of the *Canadian Journal of Emergency Medicine*, clinical professor of medicine at McMaster University, and chief medical officer of McKesson Canada.



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Decriminalizing Chronic Pain: How to Approach Those Without Adequate Follow Up

by JIM DUCHARME, MD, CM, FRCP

SCENARIO 1: Mr. Smith is a 42-year-old male who has come to the ED because he is in severe pain from a chronic low back condition lasting at least 10 years. He cannot stand upright. He moved into town when his company closed two months ago so he could stay with his sister. He is unemployed. He says his meds—duloxetine, tramadol, and celecoxib—are running out. There is no pain clinic in the community, and he has no family physician.

SCENARIO 2: Mrs. Smith is a 51-year-old female with 15 years of chronic neuropathic leg pain. She has been discharged by her family physician because her urine tested positive for cocaine twice—she admits this because she is desperate to get care. The physician rapidly tapered her off opioids (in 10 days), and she has just finished a horrible week of withdrawal. She comes into the ED with severe pain and has no analgesic prescriptions.

These types of scenarios are not rare in emergency medicine. After all, we are the safety net for health care. Patients with varying types of chronic medical conditions and nowhere else to go end up in the

emergency department and are routinely seen in county hospitals. Emergency physicians have had no training in any chronic medical condition, including chronic pain with its inherent biases and risks of opioid misuse. Just as we do not provide ongoing care for patients with insulin-dependent diabetes, we should not provide ongoing care for patients with chronic pain. There is a difference, however: patients with the former can continue to receive insulin and can often be cared for in hospital or community clinics, whereas the latter are shunned. Further, emergency phy-

sicians have received zero training in chronic pain and so often have a starting viewpoint that this is “not our problem.”

When you talk to patients with chronic pain who have been successfully managed, they will usually state how they have learned to deal with their problem and how their coping skills have improved. They will tell you that medications ultimately played a minor role—essential for getting the pain under control at the start but less important as other steps are taken. The American Pain Society will tell you that mindfulness is an essential primary aspect of care for

these patients. Patients with fibromyalgia will experience a 75 percent decrease in pain if they complete and maintain a four-day-a-week exercise program for at least four to six weeks. How does this help us in the ED? We need to sit down with these patients and help them review how they are in charge of their illness; dependency on others is a sign of failure. Specifically, areas patients need to work on include:

1. Learning about their illness/condition. We need to help educate them about the (minimal) role of the ED as well as what their condition is and why they have pain.

ADASUVE® (loxapine) inhalation powder 10 mg

THE FIRST
AND ONLY...

Orally inhaled medicine indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults



When agitation escalates...

**HOW LONG
CAN YOU WAIT?**

INDICATIONS AND USAGE

ADASUVE® (loxapine) inhalation powder, for oral inhalation use, is a typical antipsychotic indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. Efficacy was demonstrated in 2 trials in acute agitation: one in schizophrenia and one in bipolar I disorder.

Limitations of Use: As part of the ADASUVE Risk Evaluation and Mitigation Strategy (REMS) Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare facility.

⚠ IMPORTANT SAFETY INFORMATION

WARNING: BRONCHOSPASM and INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Bronchospasm

ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Administer ADASUVE only in an enrolled healthcare facility that has immediate access on-site to equipment and personnel trained to manage acute bronchospasm, including advanced airway management (intubation and mechanical ventilation). Prior to administering ADASUVE, screen patients regarding a current diagnosis, history, or symptoms of asthma, COPD and other lung diseases, and examine (including chest auscultation) patients for respiratory signs. Monitor for signs and symptoms of bronchospasm following treatment with ADASUVE. Because of the risk of bronchospasm, ADASUVE is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ADASUVE REMS.

Increased Mortality in Elderly Patients With Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ADASUVE is not approved for the treatment of patients with dementia-related psychosis.

- ADASUVE is contraindicated in patients with the following:
 - Current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD), or other lung disease associated with bronchospasm
 - Acute respiratory signs/symptoms (eg, wheezing)
 - Current use of medications to treat airways disease, such as asthma or COPD
 - History of bronchospasm following ADASUVE treatment
 - Known hypersensitivity to loxapine or amoxapine. Serious skin reactions have occurred with oral loxapine and amoxapine
- ADASUVE must be administered only by a healthcare professional
- Prior to administration, all patients must be screened for a history of pulmonary disease and examined (including chest auscultation) for respiratory abnormalities (eg, wheezing)
- Administer only a single 10 mg dose of ADASUVE within a 24-hour period by oral inhalation using the single-use inhaler

2. Developing coping skills. Catastrophizing, social isolation, and despair all lead to marked worsening of the pain. Dealing with flare-ups in their pain by coming to the ED demonstrates a failure to understand their condition and how to deal with the worse days. You might want to ask a social worker to get involved for this discussion, as well.

3. Learning what the community has to offer. That means the staff in the ED needs to know what is available: social work, support groups for fibromyalgia, etc.

It is my experience that this type of discussion rarely takes more than 10 to 15 minutes and is worth every minute. If we do not take the time to explain their responsibilities and

We are all responsible for every script we write. No physician in the ED should initiate opioids for patients with chronic pain, renew prescriptions of opioids for such patients, or provide short-acting opioids to “get them out of the ED.”



the role of the ED, these patients will keep re- turning, expecting to get a prescription and developing an ever-increasing institutional dependency—a poor coping trait and a grow- ing burden on the ED.

Managing Medications

We are all responsible for every script we write. No physician in the ED should initiate opioids for patients with chronic pain, renew prescriptions of opioids for such patients,

or provide short-acting opioids to “get them out of the ED.” The latter creates institutional dependency and also accelerates tolerance. There is no positive for patients other than

CONTINUED on page 14

ADASUVE® (loxapine) inhalation powder
HELP DEFUSE THE SITUATION BEFORE AGITATION ESCALATES FURTHER

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ORAL INHALATION

Breath-actuated, single-use, ready-to-use inhaler¹

FAST ONSET

Statistically significant reduction in agitation at **2 hours**, with improvement rapidly achieved at **10 minutes** post-dose¹

Reduction from baseline in agitation symptoms^{2,3}

ENDPOINT	SCHIZOPHRENIA		BIPOLAR I DISORDER	
	ADASUVE	PLACEBO	ADASUVE	PLACEBO
AT 2 HOURS (PRIMARY)	49%	33%	53%	27%
AT 10 MINUTES (SECONDARY)	19%	10%	23%	10%

The mean baseline PEC scores in all treatment groups were 17.3 to 17.7.

PEC—Positive and Negative Syndrome Scale-Excited Component. Intent-to-treat population with last observation carried forward. Agitation symptoms measured: tension, excitement, poor impulse control, uncooperativeness, hostility. Each item is scored on a scale from 1 to 7 (1=absent, 4=moderate, 7=extreme). Patient total PEC scores ranged from 14 to 31 out of a possible 35. The efficacy of ADASUVE 10 mg in the acute treatment of agitation associated with schizophrenia or bipolar I disorder was established in a short-term (24-hour), randomized, double-blind, placebo-controlled, fixed-dose trial including 344 patients who met DSM-IV criteria for schizophrenia and in another study, 314 patients who met DSM-IV criteria for bipolar I disorder, manic or mixed episodes with or without psychotic features.

- ⚠ IMPORTANT SAFETY INFORMATION (continued)**
- After ADASUVE administration, patients must be monitored for signs and symptoms of bronchospasm at least every 15 minutes for at least 1 hour
 - ADASUVE can cause sedation, which can mask the symptoms of bronchospasm
 - Antipsychotic drugs can cause a potentially fatal symptom complex called Neuroleptic Malignant Syndrome (NMS), manifested by hyperpyrexia, muscle rigidity, altered mental state, irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia. Associated features can include elevated serum creatine phosphokinase (CPK) concentration, rhabdomyolysis, elevated serum and urine myoglobin concentration, and renal failure. If NMS occurs, immediately discontinue antipsychotic drugs and other drugs that may contribute to the underlying disorder, monitor and treat symptoms, and treat any concomitant serious medical problems
 - ADASUVE can cause hypotension, orthostatic hypotension, and syncope. Use with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that would predispose patients to hypotension. In the presence of severe hypotension requiring vasopressor therapy, epinephrine should not be used
 - Use ADASUVE with caution in patients with a history of seizures or with conditions that lower the seizure threshold. ADASUVE lowers the seizure threshold. Seizures have occurred in patients treated with oral loxapine and can also occur in epileptic patients
 - Use caution when driving or operating machinery. ADASUVE can impair judgment, thinking, and motor skills
 - The potential for cognitive and motor impairment is increased when ADASUVE is administered concurrently with other CNS depressants
 - Treatment with antipsychotic drugs caused an increased incidence of stroke and transient ischemic attack in elderly patients with dementia-related psychosis; ADASUVE is not approved for the treatment of patients with dementia-related psychosis
 - Use of ADASUVE may exacerbate glaucoma or cause urinary retention
 - The most common adverse reactions (incidence ≥2% and greater than placebo) in clinical studies in patients with agitation treated with ADASUVE were dysgeusia, sedation, and throat irritation
 - Pregnancy Category C. Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk of extrapyramidal and/or withdrawal symptoms after delivery. ADASUVE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus
 - Nursing mothers: Discontinue drug or nursing, taking into account the importance of the drug to the mother
 - The safety and effectiveness of ADASUVE in pediatric patients have not been established

References: 1. ADASUVE [package insert]. Horsham, PA: Teva Select Brands, a division of Teva Pharmaceuticals USA, Inc.; December 2013. 2. Data on file. Clinical Study Report 004-301. Teva Pharmaceuticals. 3. Data on file. Clinical Study Report 004-302. Teva Pharmaceuticals.

Please see Brief Summary of Prescribing Information, including Boxed Warnings, on following pages.

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(loxapine) inhalation powder

perhaps a two-hour decrease in pain, a pain they have had for years. Opioids should be reserved in opioid-dependent patients for acute breakthrough pain or for acute new injuries or conditions, such as a new fracture.

Other medications for pain, such as a tricyclic or gabapentinoid for new zoster-related neuropathic pain, may be of benefit and worth initiating. A SSRI, such as duloxetine for chronic osteoarthritis or low back pain, combined with acetaminophen or a NSAID may provide valid relief. Patients can follow up in a medical clinic without fear of bias and start on the long road to stabilization. We do the same for patients with hypertension, so why not for chronic pain? To do so, however, means we

It is not our role to care for them on an ongoing basis but to educate them and start them in the right direction.

have to learn more about chronic pain conditions and the medications and doses required. Dosing for chronic pain may be very different than for other indications, for example:

- 300 mg gabapentin a day for seizure disorders but up to 3,600 mg for pain
- 25–75 mg nortriptyline for depression but

up to 250 mg for neuropathic pain

Still, all patients with chronic pain are treated the same way with medications: “start low and go slow,” avoiding adverse effects and identifying the lowest effective dose possible. The starting dose you are comfortable prescribing will be the same starting dose a

pain physician would use, but they then take up to three months to get to the right dose and combination of medications.

It is up to the ED group as a whole to work with the hospital and community to identify potential resources for patients with chronic pain; that way, the nursing staff and the physicians can guide the patients properly. It is not our role to care for them on an ongoing basis but to educate and start them in the right direction. We are also there for acute worsening of their pain and to identify other pathologies as causes of new or worsening pain. In the end, our role for patients with chronic pain is almost the same as for every other chronic medical condition. ➔

BRIEF SUMMARY

ADASUVE® (loxapine) inhalation powder, for oral inhalation use
The following is a brief summary only; see full prescribing information, included Boxed Warnings for complete product information.

WARNING: BRONCHOSPASM and INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Bronchospasm
ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Administer ADASUVE only in an enrolled healthcare facility that has immediate access on-site to equipment and personnel trained to manage acute bronchospasm, including advanced airway management (intubation and mechanical ventilation) [see Warnings and Precautions (5.1, 5.2)]. Prior to administering ADASUVE, screen patients regarding a current diagnosis, history, or symptoms of asthma, COPD and other lung diseases, and examine (including chest auscultation) patients for respiratory signs. Monitor for signs and symptoms of bronchospasm following treatment with ADASUVE [see Dosage and Administration (2.2, 2.4) and Contraindications (4)].

Because of the risk of bronchospasm, ADASUVE is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ADASUVE REMS [see Warnings and Precautions (5.2)].

Increased Mortality in Elderly Patients with Dementia-Related Psychosis
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ADASUVE is not approved for the treatment of patients with dementia-related psychosis [see Warnings and Precautions (5.3)].

1 INDICATIONS AND USAGE
ADASUVE is a typical antipsychotic indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. “Psychomotor agitation” is defined in DSM-IV as “excessive motor activity associated with a feeling of inner tension.” Patients experiencing agitation often manifest behaviors that interfere with their care (e.g., threatening behaviors, escalating or urgently distressing behavior, self-exhausting behavior), leading clinicians to the use of rapidly absorbed antipsychotic medications to achieve immediate control of the agitation [see Clinical Studies (14)]. The efficacy of ADASUVE was established in one study of acute agitation in patients with schizophrenia and one study of acute agitation in patients with bipolar I disorder [see Clinical Studies (14)].

Limitations of Use:
As part of the ADASUVE REMS Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare facility [see Warnings and Precautions (5.2)].

4 CONTRAINDICATIONS
ADASUVE is contraindicated in patients with the following:

- Current diagnosis or history of asthma, COPD, or other lung disease associated with bronchospasm [see Warnings and Precautions (5.1)]
- Acute respiratory symptoms or signs (e.g., wheezing) [see Warnings and Precautions (5.1)]
- Current use of medications to treat airways disease, such as asthma or COPD [see Warnings and Precautions (5.1)]
- History of bronchospasm following ADASUVE treatment [see Warnings and Precautions (5.1)]
- Known hypersensitivity to loxapine or amoxapine. Serious skin reactions have occurred with oral loxapine and amoxapine.

5 WARNINGS AND PRECAUTIONS
5.1 Bronchospasm
ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest [see Adverse Reactions (6.1)]. Administer ADASUVE only in an enrolled healthcare facility that has immediate access on-site to equipment and personnel trained to manage acute bronchospasm, including advanced airway management (intubation and mechanical ventilation) [see Boxed Warning and Warnings and Precautions (5.2)]. Prior to administering ADASUVE, screen patients regarding a current diagnosis or history of asthma, COPD, and other lung disease associated with bronchospasm, acute respiratory symptoms or signs, current use of medications to treat airways disease, such as asthma or COPD; and examine patients (including chest auscultation) for respiratory abnormalities (e.g., wheezing) [See Dosage and Administration (2.2) and Contraindications (4)]. Monitor patients for symptoms and signs of bronchospasm (i.e., vital signs and chest auscultation) at least every 15 minutes for a minimum of one hour following treatment with ADASUVE [see Dosage and Administration (2.4)]. ADASUVE can cause sedation, which can mask the symptoms of bronchospasm.

Because clinical trials in patients with asthma or COPD demonstrated that the degree of bronchospasm, as indicated by changes in forced expiratory volume in 1 second (FEV1), was greater following a second dose of ADASUVE, limit ADASUVE use to a single dose within a 24 hour period. Advise all patients of the risk of bronchospasm. Advise them to inform the healthcare professional if they develop any breathing problems such as wheezing, shortness of breath, chest tightness, or cough following treatment with ADASUVE.

5.2 ADASUVE REMS to Mitigate Bronchospasm
Because of the risk of bronchospasm, ADASUVE is available only through a restricted program under a REMS called the ADASUVE REMS. [see Boxed Warning and Warnings and Precautions (5.1)] Required components of the ADASUVE REMS are:

- Healthcare facilities that dispense and administer ADASUVE must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site access to equipment and personnel trained to provide advance airway management, including intubation and mechanical ventilation.
- Wholesalers and distributors that distribute ADASUVE must enroll in the program and distribute only to enrolled healthcare facilities.

Further information is available at www.adasuverems.com or 1-855-755-0492.

5.3 Increased Mortality in Elderly Patients with Dementia-Related Psychosis
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the cases of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies can be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. ADASUVE is not approved for the treatment of elderly patients with dementia-related psychosis [see Boxed Warning].

5.4 Neuroleptic Malignant Syndrome
Antipsychotic drugs can cause a potentially fatal symptom complex termed Neuroleptic Malignant Syndrome (NMS). Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Associated features can include elevated serum creatine phosphokinase (CPK) concentration, rhabdomyolysis, elevated serum and urine myoglobin concentration, and renal failure. NMS did not occur in the ADASUVE clinical program. The diagnostic evaluation of patients with this syndrome is complicated. It is important to consider the presence of other serious medical conditions (e.g., pneumonia, systemic infection, heat stroke, primary CNS pathology, central anticholinergic toxicity, extrapyramidal symptoms, or drug fever). The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs that may contribute to the underlying disorder, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems. There is no general agreement about specific pharmacological treatment regimens for NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

5.5 Hypotension and Syncope
ADASUVE can cause hypotension, orthostatic hypotension, and syncope. Use ADASUVE with caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease, or conditions that would predispose patients to hypotension (dehydration, hypovolemia, or treatment with antihypertensive medications or other drugs that affect blood pressure or reduce heart rate). In the presence of severe hypotension requiring vasopressor therapy, the preferred drugs may be norepinephrine or phenylephrine. Epinephrine should not be used, because beta stimulation may worsen hypotension in the setting of ADASUVE-induced partial alpha blockade. In short-term (24-hour) placebo-controlled trials of patients with agitation associated with schizophrenia or bipolar I disorder, hypotension occurred in 0.4% and 0.8% in the ADASUVE 10 mg and placebo groups, respectively. There were no cases of orthostatic hypotension, postural symptoms,

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POT OF GOLD FROM
BAD ADVICE

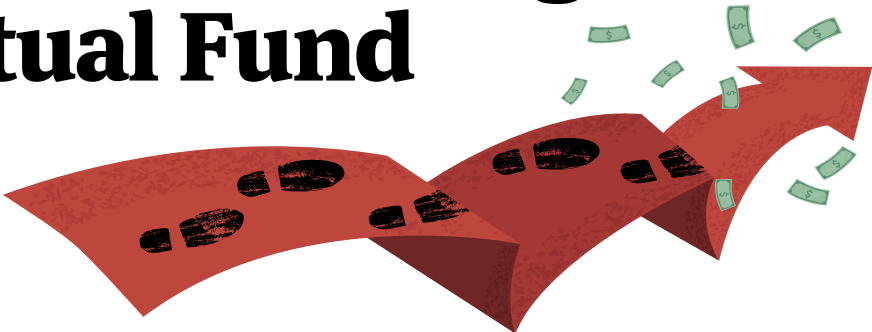
THE END OF THE RAINBOW



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

Five Steps to Choosing the Right Mutual Fund

by JAMES M. DAHLE, MD, FACEP



Question. I feel overwhelmed when I see all of the mutual funds available in my 401(k). How can I choose the right one?

Answer. Mutual funds are an excellent way to invest in stocks, bonds, and other securities. Mutual funds provide for broad diversification, economies of scale, and professional management not available to individual investors selecting securities on their own. This task can be delegated to a competent advisor, but

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presyncope or syncope. A systolic blood pressure ≤ 90 mm Hg with a decrease of ≥ 20 mm Hg occurred in 1.5% and 0.8% of the ADASUVE 10 mg and placebo groups, respectively. A diastolic blood pressure ≤ 50 mm Hg with a decrease of ≥ 15 mm Hg occurred in 0.8% and 0.4% of the ADASUVE 10 mg and placebo groups, respectively. In 5 Phase 1 studies in normal volunteers, the incidence of hypotension was 3% and 0% in ADASUVE 10 mg and the placebo groups, respectively. The incidence of syncope or presyncope in normal volunteers was 2.3% and 0% in the ADASUVE and placebo groups, respectively. In normal volunteers, a systolic blood pressure ≤ 90 mm Hg with a decrease of ≥ 20 mm Hg occurred in 5.3% and 1.1% in the ADASUVE and placebo groups, respectively. A diastolic blood pressure ≤ 50 mm Hg with a decrease of ≥ 15 mm Hg occurred in 7.5% and 3.3% in the ADASUVE and placebo groups, respectively.

5.6 Seizures

ADASUVE lowers the seizure threshold. Seizures have occurred in patients treated with oral loxapine. Seizures can occur in epileptic patients even during antiepileptic drug maintenance therapy. In short term (24 hour), placebo-controlled trials of ADASUVE, there were no reports of seizures.

5.7 Potential for Cognitive and Motor Impairment

ADASUVE can impair judgment, thinking, and motor skills. In short-term, placebo-controlled trials, sedation and/or somnolence were reported in 12% and 10% in the ADASUVE and placebo groups, respectively. No patients discontinued treatment because of sedation or somnolence. The potential for cognitive and motor impairment is increased when ADASUVE is administered concurrently with other CNS depressants [see *Drug Interactions* (7.1)]. Caution patients about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with ADASUVE does not affect them adversely.

5.8 Cerebrovascular Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis

In placebo-controlled trials with atypical antipsychotics in elderly patients with dementia-related psychosis, there was a higher incidence of cerebrovascular adverse reactions (stroke and transient ischemic attacks), including fatalities, compared to placebo-treated patients. ADASUVE is not approved for the treatment of patients with dementia-related psychosis [see *Boxed Warning and Warnings and Precautions* (5.3)].

5.9 Anticholinergic Reactions Including Exacerbation of Glaucoma and Urinary Retention

ADASUVE has anticholinergic activity, and it has the potential to cause anticholinergic adverse reactions including exacerbation of glaucoma or urinary retention. The concomitant use of other anticholinergic drugs (e.g., antiparkinson drugs) with ADASUVE could have additive effects.

6 ADVERSE REACTIONS

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

- Hypersensitivity (serious skin reactions) [see *Contraindications* (4)]
- Bronchospasm [see *Warnings and Precautions* (5.1)]
- Increased Mortality in Elderly Patients with Dementia-Related Psychosis [see *Warnings and Precautions* (5.3)]
- Neuroleptic Malignant Syndrome [see *Warnings and Precautions* (5.4)]
- Hypotension and syncope [see *Warnings and Precautions* (5.5)]
- Seizure [see *Warnings and Precautions* (5.6)]
- Potential for Cognitive and Motor Impairment [see *Warnings and Precautions* (5.7)]
- Cerebrovascular Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis [see *Warnings and Precautions* (5.8)]
- Anticholinergic Reactions Including Exacerbation of Glaucoma and Urinary Retention [see *Warnings and Precautions* (5.9)]

6.1 Clinical Trials Experience

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

The following findings are based on pooled data from three short-term (24-hour), randomized, double-blind, placebo-controlled clinical trials (Studies 1, 2, and 3) of ADASUVE 10 mg in the treatment of patients with acute agitation associated with schizophrenia or bipolar I disorder. In the 3 trials, 259 patients received ADASUVE 10 mg, and 263 received placebo [see *Clinical Studies* (14)].

Commonly Observed Adverse Reactions: In the 3 trials in acute agitation, the most common adverse reactions were dysgeusia, sedation, and throat irritation. These reactions occurred at a rate of at least 2% of the ADASUVE group and at a rate greater than in the placebo group. (Refer to Table 1).

Table 1. Adverse Reactions in 3 Pooled Short-Term, Placebo-Controlled Trials (Studies 1, 2, and 3) in Patients with Schizophrenia or Bipolar Disorder

Adverse Reaction	Placebo (n = 263)	ADASUVE (n = 259)
Dysgeusia	5%	14%
Sedation	10%	12%
Throat Irritation	0%	3%

Airway Adverse Reactions in the 3 Trials in Acute Agitation

Agitated patients with Schizophrenia or Bipolar Disorder: In the 3 short-term (24-hour), placebo-controlled trials in patients with agitation associated with schizophrenia or bipolar disorder (Studies 1, 2, and 3), bronchospasm (which includes reports of wheezing, shortness of breath and cough) occurred more frequently in the ADASUVE group, compared to the placebo group: 0% (0/263) in the placebo group and 0.8% (2/259) in the ADASUVE 10 mg group. One patient with schizophrenia, without a history of pulmonary disease, had significant bronchospasm requiring rescue treatment with a bronchodilator and oxygen.

Bronchospasm and Airway Adverse Reactions in Pulmonary Safety Trials

Clinical pulmonary safety trials demonstrated that ADASUVE can cause bronchospasm as measured by FEV1, and as indicated by respiratory signs and symptoms in the trials. In addition, the trials demonstrated that patients with asthma or other pulmonary diseases, such as COPD are at increased risk of bronchospasm. The effect of ADASUVE on pulmonary function was evaluated in 3 randomized, double-blind, placebo-controlled clinical pulmonary safety trials in healthy volunteers, patients with asthma, and patients with COPD. Pulmonary function was assessed by serial FEV1 tests, and respiratory signs and symptoms were assessed. In the asthma and COPD trials, patients with respiratory symptoms or FEV1 decrease of $\geq 20\%$ were administered rescue treatment with albuterol (metered dose inhaler or nebulizer) as required. These patients were not eligible for a second dose; however, they had continued FEV1 monitoring in the trial.

Healthy Volunteers: In the healthy volunteer crossover trial, 30 subjects received 2 doses of either ADASUVE or placebo 8 hours apart, and 2 doses of the alternate treatment at least 4 days later. The results for maximum decrease in FEV1 are presented in Table 2. No subjects in this trial developed airway related adverse reactions (cough, wheezing, chest tightness, or dyspnea).

Asthma Patients: In the asthma trial, 52 patients with mild-moderate persistent asthma (with FEV1 $\geq 60\%$ of predicted) were randomized to treatment with 2 doses of ADASUVE 10 mg or placebo. The second dose was to be administered 10 hours after the first dose. Approximately 67% of these patients had a baseline FEV1 $\geq 80\%$ of predicted. The remaining patients had an FEV1 60-80% of predicted. Nine patients (17%) were former smokers. As shown in Table 2 and Figure 7, there was a marked decrease in FEV1 immediately following the first dose (maximum mean decreases in FEV1 and % predicted FEV1 were 303 mL and 9.1%, respectively). Furthermore, the effect on FEV1 was greater following the second dose (maximum mean decreases in FEV1 and % predicted FEV1 were 537 mL and 14.7 %, respectively). Respiratory-related adverse reactions (bronchospasm, chest discomfort, cough, dyspnea, throat tightness, and wheezing) occurred in 54% of ADASUVE-treated patients and 12% of placebo-treated patients. There were no serious adverse events. Nine of 26 (35%) patients in the ADASUVE group, compared to one of 26 (4%) in the placebo group, did not receive a second dose of study medication, because they had a $\geq 20\%$ decrease in FEV1 or they developed respiratory symptoms after the first dose. Rescue medication (albuterol via metered dose inhaler or nebulizer) was administered to 54% of patients in the ADASUVE group [7 patients (27%) after the first dose and 7 of the remaining 17 patients (41%) after the second dose] and 12% in the placebo group (1 patient after the first dose and 2 patients after the second dose).

COPD Patients: In the COPD trial, 53 patients with mild to severe COPD (with FEV1 $\geq 40\%$ of predicted) were randomized to treatment with 2 doses of ADASUVE 10 mg or placebo. The second dose was to be administered 10 hours after the first dose. Approximately 57% of these patients had moderate COPD [Global Initiative for Chronic Obstructive Lung Disease (GOLD) Stage II]; 32% had severe disease (GOLD Stage III); and 11% had mild disease (GOLD Stage I). As illustrated in Table 2 there was a decrease in FEV1 soon after the first dose (maximum mean decreases in FEV1 and % predicted FEV1 were 96 mL and 3.5%, respectively), and the effect on FEV1 was greater following the second dose (maximum mean decreases in FEV1 and % predicted FEV1 were 125 mL and 4.5%, respectively). Respiratory adverse reactions occurred more frequently in the ADASUVE group (19%) than in the placebo group (11%). There were no serious adverse events. Seven of 25 (28%) patients in the ADASUVE group and 1 of 27 (4%) in the placebo group did not receive a second dose of study medication because of a $\geq 20\%$ decrease in FEV1 or the development of respiratory symptoms after the first dose. Rescue medication (albuterol via MDI or

even if you use an investment manager, understanding this process will allow for evaluation of an advisor’s advice and performance.

Prior to evaluating a mutual fund for inclusion in your portfolio, it is important to first complete several prerequisite tasks. These include setting appropriate goals, developing an overriding investment plan (asset allocation), and selecting the most appropriate and tax-efficient combination of investing accounts (such as 401(k), Roth IRA, or a taxable brokerage account). Deciding on an asset allocation (what percentage of your portfolio to invest in each asset class) can be a difficult decision, but once completed, selecting appropriate mutual funds

to fulfill the chosen asset allocation can be ridiculously easy.

STEP 1: Match Funds to the Asset Allocation

This might seem obvious, but many investors seem to get it wrong. If your hypothetical asset allocation plan calls for 30 percent of your portfolio to be invested in U.S. stocks, 30 percent in bonds, 20 percent in international stocks, 10 percent in real estate, and 10 percent in small value stocks, then you just need to select one fund for each of those categories.

When evaluating a mutual fund, the first consideration is to determine which assets the fund actually holds. If you are looking for a

fund for your U.S. stock allocation, you do not want to look at a balanced fund (contains both stocks and bonds) or an all-world fund (invests in both U.S. and international stocks). Likewise, if you want a broadly diversified international stock fund, you can eliminate funds that invest solely in Japanese stocks, European stocks, or Brazilian stocks. This information can easily be found in the first few pages of the prospectus, on the fund summary page on the fund’s website, or on an independent website like Morningstar.com.

STEP 2: Avoid Playing the Loser’s Game of Active Management

All mutual funds are managed by profession-

als. However, the mission of most mutual funds is to “beat the market,” outperforming an index composed of all of the stocks (or bonds) in a particular asset class. The managers of these active funds try to buy investments likely to go up in value and sell investments likely to go down in value. Although it seems intuitive that highly trained, hard-working professionals could easily do this, it turns out to be extraordinarily difficult to outperform the market in the long run. Very few active managers will do this over any given period, and there is no reliable way to select them in advance.

According to data published in Allan Roth’s *How a Second Grader Beats Wall Street*, a typical actively managed mutual fund has about a 38 percent chance of beating an appropriate index in any given year. Over five years, that falls to 22 percent, and after 25 years (a typical physician career length), it is just 1 percent. In a five-fund portfolio, the chances are even worse, about 20 percent in any given year and 7 percent after five years. The solution to this dilemma is to avoid playing the game at all despite all the time, effort, and money spent by financial institutions trying to get you to do so.

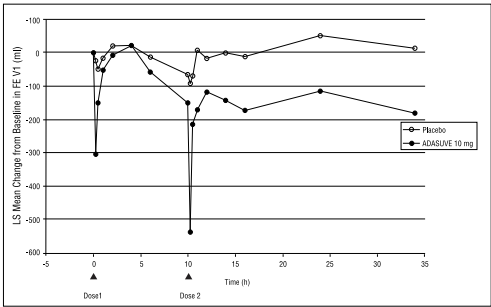
nebulizer) was administered to 23% of patients in the ADASUVE group: 8% of patients after the first dose and 21% of patients after the second dose, and to 15% of patients in the placebo group.

Table 2: Maximum Decrease in FEV1 from Baseline in the Healthy Volunteer, Asthma, and COPD Trials

	Healthy Volunteer		Asthma		COPD	
	Maximum % FEV1 ↓	Placebo n (%)	Placebo n (%)	Placebo n (%)	Placebo n (%)	Placebo n (%)
After any Dose		N=26	N=26	N=26	N=27	N=25
≥10	7 (27)	7 (27)	3 (12)	22 (85)	18 (67)	20 (80)
≥15	1 (4)	5 (19)	1 (4)	16 (62)	9 (33)	14 (56)
≥20	0	1 (4)	1 (4)	11 (42)	3 (11)	10 (40)
After Dose 1		N=26	N=26	N=26	N=27	N=25
≥10	4 (15)	5 (19)	2 (8)	16 (62)	8 (30)	16 (64)
≥15	1 (4)	2 (8)	1 (4)	8 (31)	4 (15)	10 (40)
≥20	0	0	1 (4)	6 (23)	2 (7)	9 (36)
After Dose 2		N=26	N=25	N=25	N=26	N=19
≥10	5 (19)	6 (24)	3 (12)	12 (71)	15 (58)	12 (63)
≥15	0	5 (20)	1 (4)	9 (53)	6 (23)	10 (53)
≥20	0	1 (4)	1 (4)	5 (30)	1 (4)	5 (26)

FEV1 categories are cumulative; i.e. a subject with a maximum decrease of 21% is included in all 3 categories. Patients with a ≥ 20% decrease in FEV1 did not receive a second dose of study drug.

Figure 7: LS Mean Change from Baseline in FEV1 in Patients with Asthma



Patients with a ≥ 20% decrease in FEV1 did not receive a second dose of study drug and are not included in the curves beyond hour 10.

Extrapyramidal Symptoms (EPS): Extrapyramidal reactions have occurred during the administration of oral loxapine. In most patients, these reactions involved parkinsonian symptoms such as tremor, rigidity, and masked facies. Akathisia (motor restlessness) has also occurred.

In the 3 short-term (24-hour), placebo-controlled trials of ADASUVE in 259 patients with agitation associated with schizophrenia or bipolar disorder, extrapyramidal reactions occurred. One patient (0.4%) treated with ADASUVE developed neck dystonia and oculogyration. The incidence of akathisia was 0% and 0.4% in the placebo and ADASUVE groups, respectively.

Dystonia (Antipsychotic Class Effect): Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during treatment with ADASUVE. Dystonic symptoms include spasm of the neck muscles, sometimes progressing to tightness of the throat, difficulty swallowing or breathing, and/or protrusion of the tongue. Acute dystonia tends to be dose-related, but can occur at low doses, and occurs more frequently with first generation antipsychotic drugs such as ADASUVE. The risk is greater in males and younger age groups.

Cardiovascular Reactions: Tachycardia, hypotension, hypertension, orthostatic hypotension, lightheadedness, and syncope have been reported with oral administration of loxapine.

7 DRUG INTERACTIONS

7.1 CNS Depressants

ADASUVE is a central nervous system (CNS) depressant. The concurrent use of ADASUVE with other CNS depressants (e.g., alcohol, opioid analgesics, benzodiazepines, tricyclic antidepressants, general anesthetics, phenothiazines, sedative/hypnotics, muscle relaxants, and/or illicit CNS depressants) can increase the risk of respiratory depression, hypotension, profound sedation, and syncope. Therefore, consider reducing the dose of CNS depressants if used concomitantly with ADASUVE.

7.2 Anticholinergic Drugs

ADASUVE has anticholinergic activity. The concomitant use of ADASUVE and other anticholinergic drugs can increase the risk of anticholinergic adverse reactions including exacerbation of glaucoma and urinary retention.

8 USE IN SPECIFIC POPULATIONS

In general, no dose adjustment for ADASUVE is required on the basis of a patient’s age, gender, race, smoking status, hepatic function, or renal function.

8.1 Pregnancy

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies of ADASUVE use in pregnant women. Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Loxapine, the active ingredient in ADASUVE, has demonstrated increased embryofetal toxicity and death in rat fetuses and offspring exposed to doses approximately 0.5-fold the maximum recommended human dose (MRHD) on a mg/m² basis. ADASUVE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Human Data

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorders in these neonates. These complications have varied in severity; in some cases symptoms have been self-limited, but in other cases neonates have required intensive care unit support and prolonged hospitalization.

Animal Data

In rats, embryofetal toxicity (increased fetal resorptions, reduced weights, and hydronephrosis with hydroureter) was observed following oral administration of loxapine during the period of organogenesis at a dose of 1 mg/kg/day. This dose is equivalent to the MRHD of 10 mg/day on a mg/m² basis. In addition, fetal toxicity (increased prenatal death, decreased postnatal survival, reduced fetal weights, delayed ossification, and/or distended renal pelvis with reduced or absent papillae) was observed following oral administration of loxapine from mid-pregnancy through weaning at doses of 0.6 mg/kg and higher. This dose is approximately half the MRHD of 10 mg/day on a mg/m² basis.

No teratogenicity was observed following oral administration of loxapine during the period of organogenesis in the rat, rabbit, or dog at doses up to 12, 60, and 10 mg/kg, respectively. These doses are approximately 12-, 120-, and 32-fold the MRHD of 10 mg/day on a mg/m² basis, respectively.

8.3 Nursing Mothers

It is not known whether ADASUVE is present in human milk. Loxapine and its metabolites are present in the milk of lactating dogs. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from ADASUVE, a decision should be made whether to discontinue nursing or discontinue ADASUVE, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

The safety and effectiveness of ADASUVE in pediatric patients have not been established.

8.5 Geriatric Use

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death [see *Boxed Warning and Warnings and Precautions* (5.3)]. ADASUVE is not approved for the treatment of dementia-related psychosis. Placebo-controlled studies of ADASUVE in patients with agitation associated with schizophrenia or bipolar disorder did not include patients over 65 years of age.

10 OVERDOSAGE

Signs and Symptoms of Overdosage

As would be expected from the pharmacologic actions of loxapine, the clinical findings may include CNS depression, unconsciousness, profound hypotension, respiratory depression, extrapyramidal symptoms, and seizure.

Management of Overdosage

For the most up to date information on the management of ADASUVE overdose, contact a certified poison control center (1-800-222-1222 or www.poison.org). Provide supportive care including close medical supervision and monitoring. Treatment should consist of general measures employed in the management of overdose with any drug. Consider the possibility of multiple drug overdose. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures.

Manufactured by: Alexza Pharmaceuticals, Inc., Mountain View, CA 94043

Manufactured for: Teva Select Brands, Horsham, PA 19044, Division of Teva Pharmaceuticals USA, Inc.

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Deciding on an asset allocation can be a difficult decision, but once completed, selecting appropriate mutual funds to fulfill the chosen asset allocation can be ridiculously easy.

However, because index fund managers just have to match the market return, they rarely have to buy or sell anything and certainly don’t need to spend money on analysts. It can be very inexpensive to run index funds, often less than 0.1 percent per year (\$10 on a \$1,000 investment). Index funds are also inherently tax-efficient due to their lower turnover. If the asset class you are trying to invest in is U.S. stocks, you want the investment that will best capture the return of that market—a passively managed fund that owns all of the publicly traded stocks in the United States or at least a

statistical representation of them. Accepting that market returns are likely the best you are going to get is the counterintuitive first step in becoming a successful long-term investor.

STEP 4: Keep Costs Low

Once you realize that active management is a loser's game, your focus should shift to those things you can control, like investment expenses. In investing, you get what you *don't* pay for. If you are paying 2 percent per year in advisory and management fees, that 2 percent is subtracted from the market return, and over the long run, expenses that high will transfer more than 50 percent of your eventual wealth from your pocket to Wall Street. A portfolio of index funds can be managed for just 0.05–0.20 percent per year. There is no reason to pay five times that much, much less 40 times. Mutual fund fees come in many flavors. The most visible one is the expense ratio, which is the cost of running the fund divided by the value of the assets in the fund. Every fund has an expense ratio, although they vary from 0.02 percent per year to more than 100 times as much. Many mutual funds also charge an additional marketing, or 12b-1 fee, which is often around 0.25 percent. There is no benefit to you to pay such a fee.

Mutual funds sold by mutual fund salespeople masquerading as financial advisors also have loads, or commissions. These range from 3–8 percent of your investment. Some are front-end loads (A shares), paid when the money is initially invested. If you invest \$1,000 in a mutual fund with a 5 percent front load, \$950 goes into the mutual fund and \$50 goes into the pocket of your advisor. There are also back-end loads (B shares), where the commission comes out when you sell the investment, and C shares, where the load is ongoing in the form of a higher expense ratio. However, because the best mutual funds have no load at all, there is really no reason to ever buy a loaded mutual fund. If you need investment assistance, pay a fee-only advisor for advice to minimize conflicts of interest. Be aware that most 401(k)s not only charge additional fees, they are often filled with loaded, high expense ratio, actively managed mutual funds. Do your best to avoid the most expensive options when selecting 401(k) funds. Remember that the very best predictor of future mutual fund performance is low fees.

STEP 5: Avoid Performance Chasing

Academic studies have demonstrated time and time again that there is no persistence in performance among active mutual fund managers. Actually, that is not entirely true as the worst managers do persist in being terrible. Investors are notorious for buying high and selling low, dramatically underperforming the funds they are invested in due to their terrible timing. The solution is to avoid timing the market at all. Rather than choosing a fund (or an asset class) based on its past performance, simply follow your written investing plan. If your plan says 30 percent of the portfolio should be invested in U.S. stocks and due to recent market changes your portfolio is only 25 percent U.S. stocks, then buy some more to rebalance the portfolio. This forces you to buy low and sell high.

Following these five steps when choosing a mutual fund will help you reach your retirement and other investing goals. ☺

AVOID THE HAZARDS
OF EM PRACTICE:
FAQs FROM YOUNG
PHYSICIANS

WHAT I
WISH
I KNEW...



DR. KLAUER is director of the Center for Emergency Medical Education (CEME) and chief medical officer for Emergency Medicine Physicians, Canton, Ohio; on the board of directors for Physicians Specialty Limited Risk Retention Group; assistant clinical professor at Michigan State University College of Osteopathic Medicine; and medical editor in chief of *ACEP Now*.

Make Sure a Prospective Job Is the Right One for You

Convincing someone to hire you or convincing someone to take a job based on inaccurate or incomplete information is a common mistake.

by KEVIN M. KLAUER, DO, EJD, FACEP

It has been reported that up to 70 percent of emergency physicians leave their first job within two years. It's in no one's interest to hire physicians they won't retain.

A bad fit isn't usually a reflection on the physician but the result of misaligned expectations and a lack of open communication during the interview process. Convincing someone to hire you or convincing someone to take a job based on inaccurate or incomplete information is a common mistake. Before signing, you should feel comfortable asking the difficult questions to make certain the position is right for you. Here are the 10 questions you should ask to make certain you aren't a square peg signing a contract for a round hole.

1. How many physicians have left in the past two years and why?

A revolving door may be a red flag you need to explore.

2. How can I develop professionally?

Any position you hold should help you develop professionally. Your director should be interested in your development as a person and as an emergency physician.

3. How long will you [the medical director] be staying in your position?

Most people identify with their boss and choose a position based on that relationship. If you are signing on to work with that person, make certain they'll be the person for whom you'll actually be working.

4. Is everyone paid the same?

You may or may not be interested in the nuts and bolts of how the compensation system works; however, you want it to be fair.

5. How is the relationship with the nurses, and how experienced are they?

Experienced nurses are a critical component of a well-run ED. Excessive turnover may result in less-experienced nurses working in the ED.

6. How many nurses have left in the past two years?

A revolving door on the nursing side may also be an indication of trouble.

7. Will I have an orientation? Will I be paid for any portion of the orientation?

A structured orientation is key for a successful start. It's optimal to have a well-defined orientation process, and it's a plus if when you start seeing patients, you are compensated for your time even during orientation shifts.

8. What performance expectations do you have?

Every medical director will have performance expectations. You need to know what they are before you accept the job. If you can meet or



The questions for "What I Wish I Knew..." come from Sarah Hoper, MD, and Jordan Celeste, MD. Dr. Hoper recently joined the staff at Vanderbilt University in Nashville, Tennessee. She is the legislative advisor for the Emergency Medicine Residents' Association (EMRA). Dr. Celeste is EMRA president, is a fourth-year resident at Brown University in Providence, Rhode Island, and will be heading to Florida this summer to begin practice.

exceed them, great! If not, think twice about signing on the dotted line.

9. Are there plans for the hospital to change ownership?

Although hospital restructuring can be positive, it may also signal more change, including who staffs the ED.

10. Do you think the CEO will be staying in the position?

Much like hospital ownership, when a new CEO is hired, you can expect that policy change will follow. This can also result in a change in ED staffing models and partners. ☺



DR. JEONG is an emergency medicine resident at St. Joseph's Regional Medical Center in Paterson, New Jersey.



DR. MCNAMEE is chief resident of the emergency medicine residency at St. Joseph's.



DR. ROSENBERG is chair of the department of emergency medicine, chief of geriatrics emergency medicine, and chief of palliative medicine at St. Joseph's.

Tips for Paracentesis Using Continuous Wall Suction

A quick and safe way to drain this fluid without tying up resources at the bedside.

by JORDAN JEONG, DO, JUSTIN MCNAMEE, DO, AND MARK ROSENBERG, DO, MBA, FACEP, FACOEP-D

A 55-year-old male with severe ascites secondary to chronic cirrhotic liver disease presents to the emergency department for shortness of breath secondary to fluid accumulation and abdominal distention. He routinely visits the ED for therapeutic

paracentesis, likely due to poor follow-up as a result of being uninsured. As usual, the department is very busy, and you have many critical patients who require your attention. Is there a quick and safe way to drain this fluid without tying up resources at the bedside?

You can use wall suction and several suction canisters to create a closed continuous drainage system for removing large amounts of ascitic fluid during a paracentesis.

Often, chronic liver failure patients will present to the ED for

symptomatic drainage of their ascites. Many of these patients need to have several liters drained, and this can become time-consuming in a busy emergency department. This technique allows for a quick, clean, and easy way to continuously remove this ascitic fluid.

EQUIPMENT NEEDED

- Wall suction unit
- 3-way stopcock
- Tubing elbow
- 3, 5, or 10 ml syringe
- Suction tubing
- Paracentesis tray
- Several suction canisters

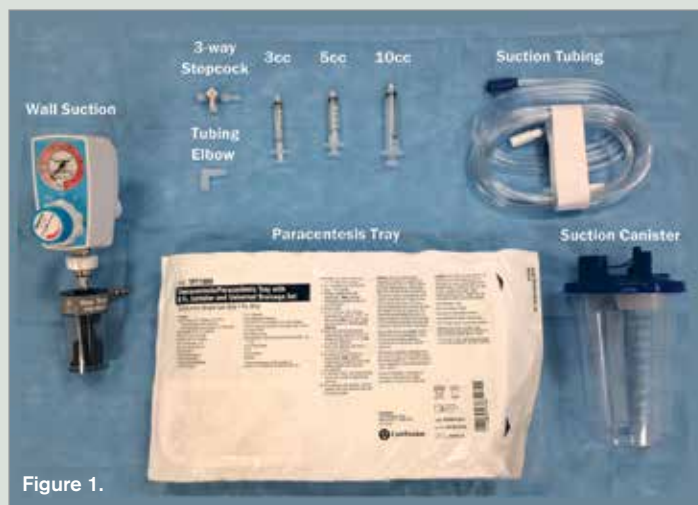


Figure 1.

TECHNIQUE

1. Prepare the patient for a standard paracentesis, and place the patient on a monitor.

2. Ensure that wall suction is available, and attach standard tubing to the wall, with the opposite end connected to the first suction canister.

3. Another piece of tubing is then used to attach the first canister to a second canister.

4. It is important to note that most canisters have one port with a self-sealing filter (see Figure 2). Using this port will close the system and prevent continuous flow, so it is necessary to avoid this port, except for first canister connected to the wall.



Figure 2.

5. Once all of the tubing is connected, ensure that all other ports are capped and sealed.

6. This process for adding canisters can be repeated several times, depending on the amount of fluid to be drained. This will effectively create a suction "train," as shown in Figure 3.



Figure 3.

TECHNIQUE (CONTINUED)

7. After you have the desired number of canisters in your “train,” take the final end of suction tubing and place it tightly into a syringe (you must first remove the plunger). Based on the size of suction tubing used and syringes at your hospital, this setup may vary, as shown in Figure 4.



Figure 4.

8. After successful insertion of the catheter into the peritoneal cavity, the suction syringe can be attached directly to the paracentesis catheter or first to a 3-way stopcock, as explained below in Step 10 (see Figure 5).



Figure 5.

9. Turn the paracentesis catheter valve to the open position, and turn on the wall suction. The fluid will begin to drain into the first canister of the “train.” After filling the first canister to capacity, the fluid will continue to drain into the adjacent canister(s) without any intervention.



Figure 6A.



Figure 6B.

10. If you find that the flow stops, presumably from siphoning a loop of bowel to the catheter tip, you can integrate a 3-way stopcock with a syringe into the system (Figure 6A). This will allow you to flush the catheter with sterile saline or, preferably, the patient's own ascitic fluid in order to push any bowel wall away from the catheter tip. If the flow stops, turn the 3-way stopcock to the off position to the suction syringe. Place the valve to the open position to a 10 ml or 50 ml syringe filled with the patient's ascitic fluid; then flush 5–10 ml at a time through the catheter in an attempt to restore flow to the suction tip (Figure 6B). Ultrasound may also be used to determine the location of the catheter tip while flushing the fluid. Return the valve to the open position to the suction syringe, and resume the removal of ascitic fluid once flow is restored.

11. Figure 7 shows your final setup.



Figure 7.

Patient Selection

This technique may be applicable for stable patients with a large amount of ascites, usually chronic liver failure patients, who regularly have a significant amount of ascitic fluid removed via paracentesis.

This may not be appropriate for patients with a small amount of ascites or unstable patients.

Cautions and Complications

Complications of paracentesis are infrequently encountered and have been reported as low as 1.6 percent in a 2009 study.¹ Most of the complications encountered, such as bleeding from the puncture site or a persistent leak of fluid from the punc-

ture site, are considered minor. Major complications are rarely encountered, and according to newer studies on paracentesis safety, coagulopathy does not seem to increase the risk of complications from a paracentesis.² It is imperative that all patients undergoing a paracentesis are placed on a cardiac monitor and IV access is established prior to starting the procedure. Fluid shifts from ascitic fluid removal render the patients at risk for post procedure hypotension, electrolyte abnormalities (most notably hyponatremia), and third spacing leading to the most feared complication, pulmonary edema.³ Cirrhotic liver disease is linked to hepatopulmonary syndrome and cirrhotic cardiomyopathy, placing patients at risk of pulmonary edema as a result of fluid shifts if a large volume of fluid is removed

during paracentesis.⁴ Recommended limits for total fluid removal vary depending on the source, but the consensus among guidelines is 5–6 liters without the need for volume expanders to lessen chances of major complications. ☺

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How to Perform an Ultrasound-Assisted Lumbar Puncture

by ARUN NAGDEV, MD, CHRISTINE RIGUZZI, MD, ORON FRENKEL, MD, AND DANIEL MANTUANI, MD

Integration of ultrasound when determining ideal needle entry in a difficult case can prevent repeated failed attempts and the overreliance on consultative services.

Ultrasound guidance is an accepted practice for many emergency medicine procedures (eg, central venous cannulation, joint aspiration, pericardiocentesis), but it is not commonly associated with benefit in lumbar punctures.^{1,3} Patients with nonpalpable bony landmarks and/or failed attempts can benefit from anatomical localization with ultrasound. Integration of ultrasound when determining ideal needle entry in a difficult case can prevent repeated failed attempts and the overreliance on consultative services (eg, interventional radiology or anesthesiology). A simplified two-step approach—defining the correct lumbar level and the true anatomic midline—can make this often-difficult “blind” procedure controlled and precise.

Patient Positioning

We recommend placing the patient in a sitting position, with feet supported and moderate neck flexion. The goal is to enlarge the interspinous distance; however, positioning should be determined by patient tolerance and comfort. The lateral decubitus position is also amenable to bony localization with ultrasound.

Probe Selection

The curvilinear low-frequency (5–2 MHz) transducer is ideal for imaging nonpalpable bony landmarks in the difficult adult patient. In our opinion, the linear high-frequency transducer (commonly recommended for ultrasound landmark identification) is limited in only identifying structures under 6–9 cm in depth and not ideal in a patient with a large body habitus.

Bony Landmark Identification with Ultrasound⁴

Set the ultrasound system to a depth of around 10–12 cm with presets for musculoskeletal imaging (the depth will have to be adjusted based on the patient). Position the curvilinear low-frequency transducer with probe marker cephalad near the presumed midline. Slowly slide the transducer in a lateral manner (left or right) until the facet joints are noted. A paramedian view will be obtained, allowing for imaging of

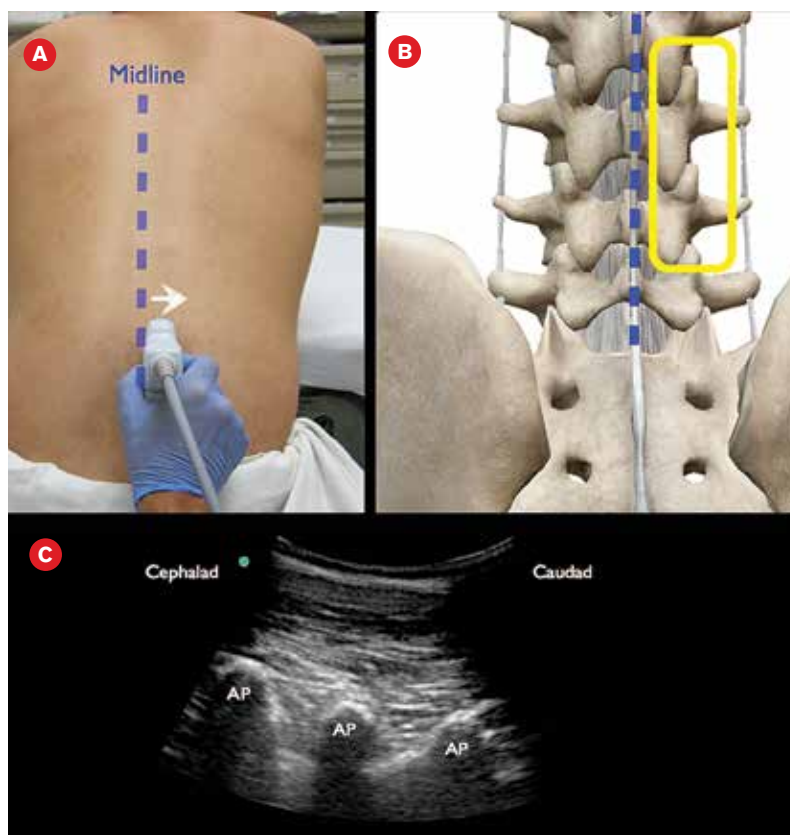


Figure 1A: A curvilinear transducer with marker cephalad is moved laterally from midline. 1B: The yellow box denotes the articular processes between adjacent lumbar vertebrae visualized by the ultrasound transducer. 1C: Corresponding ultrasound image noting the hump of the articular processes (AP).

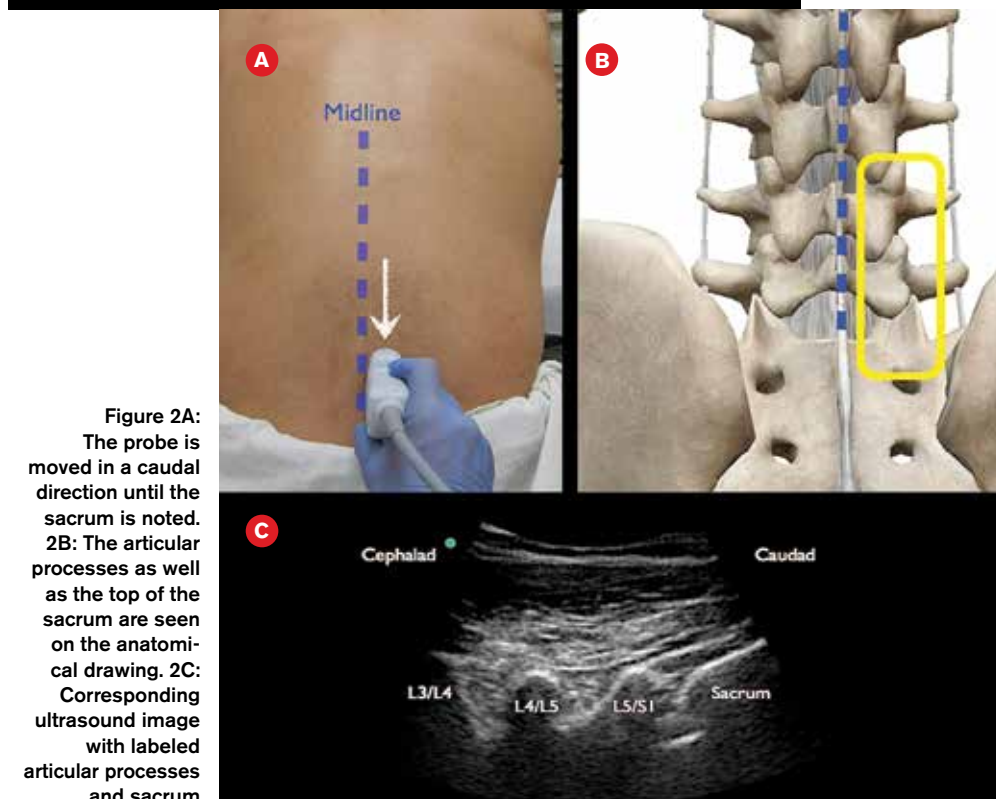


Figure 2A: The probe is moved in a caudal direction until the sacrum is noted. 2B: The articular processes as well as the top of the sacrum are seen on the anatomical drawing. 2C: Corresponding ultrasound image with labeled articular processes and sacrum

the inferior and superior articular processes of the adjacent lumbar vertebrae. These facet joints will look like humps on the ultrasound screen (see Figure 1). Then slide the probe caudad until the sacrum is visualized (horizontal hyperechoic line; see Figure 2). Delineating the most inferior aspect of the lumbar spine will allow for accurate locali-

zation of the L3-L4 and L4-L5 interspaces.

From this position, slide the probe cephalad (in a paramedian plane), counting the facet joints to ensure that the initial attempt is not too caudal. Sonographers can use either the ultrasound system's reference line or M-mode line to ensure that the center of the probe

corresponds to the center of the ultrasound image. Mark the L4 and L3 facet joints (corresponding to L4-L5 and L3-L4 interspaces, respectively) on the skin surface (see Figure 3).

Rotate the transducer to the patient's left in order to locate the true anatomic midline. Identify the bony spinous process, then slide the probe cephalad and caudad, mark-

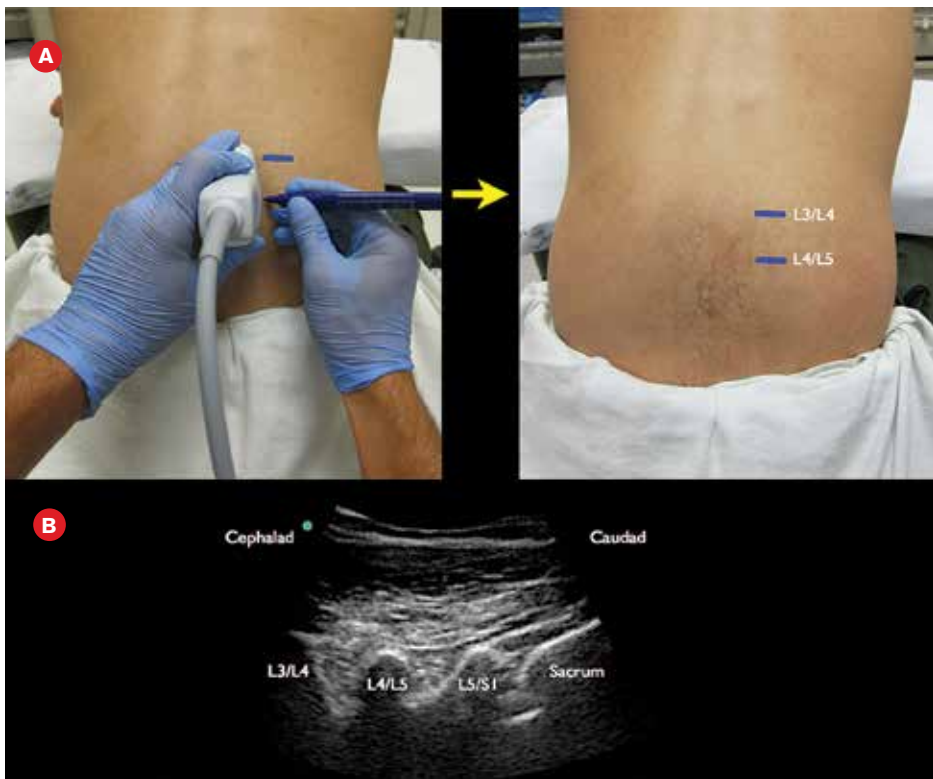


Figure 3A: Using a marker, the interspaces are labeled lateral to the probe. 3B: Ultrasound image with labeled articular processes.

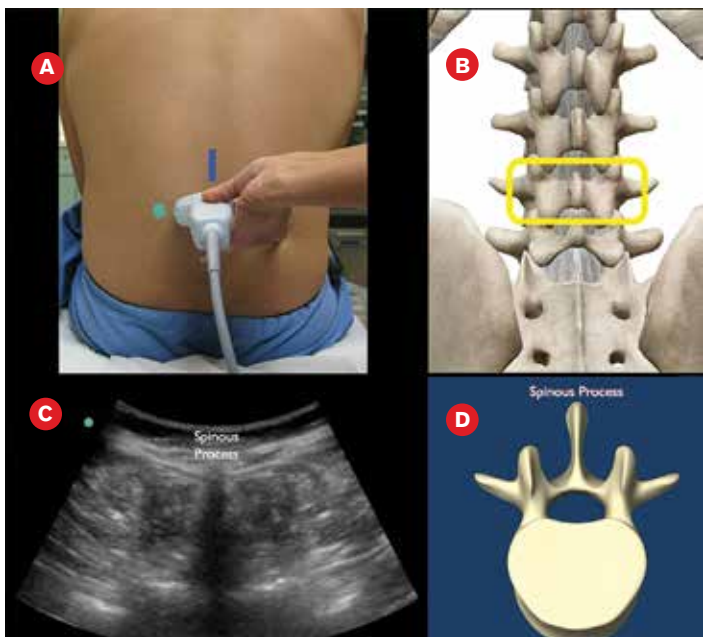


Figure 4A: Ultrasound transducer is rotated so the probe marker is to the patient's left. 4B: Schematic representation of the area imaged on the lumbar spine. 4C: Ultrasound image with spinous process and resultant shadow. 4D: Schematic that corresponds to the ultrasound image.

ing the direction of the bony midline (see Figure 4). Connect the surface markings from the midline and previously identified interspace levels for an ideal location for needle entry. We recommend marking and anesthetizing two interspace levels before performing standard aseptic technique for a lumbar puncture (ensuring that the patient does not make significant movements in between skin marking and lumbar puncture needle entry). Standard lumbar puncture technique should be followed, with the clinician aware that slight needle manipulations are to be expected even though the interspace has been visualized.

Summary

Ultrasound localization for lumbar puncture can be a useful adjunct when anatomic landmarks are not palpable and/or initial attempts fail. Difficult lumbar punctures are often due to nonpalpable bony anatomy, making ultrasound localization for lumbar puncture a useful adjunct for the emergency physician.⁵ Errors are often due to inferior estimation of Tuffier's line (a horizontal line connecting the top of the iliac crests that is thought to

represent the L4-L5 interspace) as well as not locating the true anatomic midline.⁶ A simplified two-step ultrasound localization method in which the L4-L5 or L3-L4 interspace and true anatomic midline are defined can help reduce procedural error in patients with nonpalpable anatomy. The reason for ultrasound localization of bony anatomy in the difficult patient is to reduce rates of failure and reliance on consultative services. ➔

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PEARLS FROM THE
MEDICAL LITERATURE

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Wise Choices from Beyond Emergency Medicine

by RYAN PATRICK RADECKI, MD, MS

Continual improvement of safe, effective care delivery is a goal of every clinician. Involving our patients in shared decision making and discussing the value of low-yield testing and therapeutics is a fundamental ethical responsibility. The Choosing Wisely campaign, launched by the American Board of Internal Medicine in 2012, aims to publicize and engage clinicians and patients in support of such discussions.¹

The initiative spans more than 30 specialties, including emergency medicine, and ACEP announced its first five recommendations at ACEP13 in Seattle. These recommendations, covered previously by *ACEP Now*, address imaging in minor head injury, urinary catheter placement, palliative and hospice care, abscess management, and fluid administration.² However, many other specialties have produced recommendations for care of patients within their purview that have substantial overlap with the spectrum of care provided in the emergency department. Here are a few of the highlights from across the rest of the medical community:

AMERICAN ACADEMY OF ALLERGY, ASTHMA & IMMUNOLOGY

Don't order sinus computed tomography (CT) or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis.

This very broad recommendation is supported in part by those from the American Academy of Family Physicians, the American Academy of Otolaryngology–Head and Neck Surgery, and the American Academy of Pediatrics. Acute, uncomplicated sinusitis rarely benefits from antibiotic therapy, and the population costs and harms from excessive antibiotic prescribing are undeniable.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

Don't prescribe antibiotics for otitis media in children ages 2–12 years with non-severe symptoms where the observation option is reasonable.

This is another recommendation, supported by recent American Academy of Pediatrics guidelines, aimed at reducing unnecessary antibiotic overuse.³ Otitis media is nearly uni-

versally a self-limited condition, and the observed relative curative benefit of antibiotics is counterbalanced by antibiotic-associated diarrhea and other adverse drug events.⁴

AMERICAN ACADEMY OF OPHTHALMOLOGY

Don't order antibiotics for adenoviral conjunctivitis (pink eye).

Pink eye is contagious, unsightly, and uncom-

fortable—but typically clinically apparent as a local viral process for which antibiotics are not appropriate or beneficial.

AMERICAN ACADEMY OF PEDIATRICS

CT scans are not necessary in the immediate evaluation of minor head injuries; clinical observation/Pediatric Emergency Care Applied Research Network (PECARN) criteria should be used to determine

For overt **hepatic encephalopathy (HE)** patients

OUT OF THE HOSPITAL DOESN'T MEAN OUT OF THE WOODS

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Prescribe Xifaxan 550 mg in the hospital and encourage continuous treatment in the outpatient setting. Over 90% of all patients have formulary coverage.³ Visit Xifaxan550.com for more information.

Indication:
 XIFAXAN® (rifaximin) 550 mg tablets are indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients ≥ 18 years of age.

Important Safety Information about XIFAXAN 550 mg
 XIFAXAN® (rifaximin) 550 mg tablets are contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon which may lead to overgrowth of *C. difficile*. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.

There is increased systemic exposure in patients with more severe hepatic dysfunction. The clinical trials were limited to patients with MELD scores < 25. Therefore, caution should be exercised when administering XIFAXAN to patients with severe hepatic impairment (Child-Pugh C).

Concomitant administration of drugs that are P-glycoprotein (P-gp) inhibitors with XIFAXAN can substantially increase the systemic exposure to XIFAXAN. Caution should be exercised when concomitant use of XIFAXAN and a P-gp inhibitor such as cyclosporine is needed. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to XIFAXAN.

Based on animal data, XIFAXAN may cause fetal harm. Discontinue in nursing mothers after taking into account the importance of the drug to the mother.

The most common adverse reactions occurring in ≥ 10% of patients and at a higher incidence than placebo in the clinical study were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).

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Please see Brief Summary for XIFAXAN on reverse.

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whether imaging is indicated. Neuroimaging (CT, MRI) is not necessary in a child with simple febrile seizure. CT scans are not necessary in the routine evaluation of abdominal pain.

The use of advanced imaging—particularly ionizing radiation—is of great concern to our pediatrics colleagues. Three of their five recommendations specifically address situations where excessive low-yield imaging represents costs and harms in excess of the benefits. A shared decision-making conversation given a risk-averse parent represents a challenging patient encounter, but it is our

Whether this list, or any of the Choosing Wisely recommendations, meets your expectations as representing the “low-hanging fruit” of low-yield care in your clinical setting, these efforts illuminate important cultural changes.

responsibility to protect children from the harms of medical radiation.

AMERICAN COLLEGE OF PHYSICIANS In the evaluation of simple syncope and a normal neurological examination, don’t

obtain brain-imaging studies (CT or MRI). If dizziness is the emergency physician’s least-favorite complaint, syncope cannot be far behind. Most inpatient syncope evaluations do not identify specific pathology related to syncope, and neuroimaging is of

particular low yield. If patients do not have specific high-risk features related to trauma or other neurologic abnormalities, it is preferable to defer such imaging.

AMERICAN COLLEGE OF RADIOLOGY Don’t do imaging for uncomplicated headache.

This has been the subject of several recent publications as well as a Centers for Medicare & Medicaid Services (CMS) quality measure.^{5,6} Atraumatic headache absent high-risk features by history of physical should not receive neuroimaging in the emergency department. CT, in particular, is sensitive primarily for hemorrhage but not malignancy, and it may provide false reassurance.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS–PAIN MEDICINE Avoid imaging studies (MRI, CT, or X-rays) for acute low back pain without specific indications.

This recommendation is also supported by the American College of Physicians. Emergency physicians are very familiar with the red flags associated with an increased risk of serious pathology in the setting of acute, atraumatic back pain, and otherwise routine imaging is exceedingly low yield.

AMERICAN SOCIETY OF HEMATOLOGY Don’t administer plasma or prothrombin complex concentrates for nonemergent reversal of vitamin K antagonists (eg, outside of the setting of major bleeding, intracranial hemorrhage, or anticipated emergent surgery).

Prothrombin complex concentrates, including the recent four-factor product approved in the United States, are efficacious, small-volume means to emergently reverse the coagulopathy associated with warfarin. However, these products are costly and may have increased thrombotic complications compared with fresh frozen plasma. Excepting situations where extremely rapid reversal is necessary, fresh frozen plasma should be utilized for all other conditions necessitating urgent correction.

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY Don’t perform cardiac imaging for patients who are at low risk.

This broad recommendation has many implications for emergency medicine—and conflicts in some fashion with the current standard of early provocative testing endorsed by the American Heart Association. This medico-legal risk associated with chest pain patients has led to a “zero miss” culture

CONTINUED on page 24



The following is a brief summary; see complete Prescribing Information at www.Xifaxan550.com.

INDICATIONS AND USAGE

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

Hepatic Encephalopathy

XIFAXAN 550 mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients ≥ 18 years of age.

In the trials of XIFAXAN for HE, 91% of the patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed.

XIFAXAN has not been studied in patients with MELD (Model for End-Stage Liver Disease) scores > 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction [see Warnings and Precautions (5.4), Use in Specific Populations (8.7), Clinical Pharmacology (12.3)].

CONTRAINDICATIONS

Hypersensitivity

XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis [see Adverse Reactions (6.2)].

WARNINGS AND PRECAUTIONS

Travelers’ Diarrhea Not Caused by *Escherichia coli*

XIFAXAN was not found to be effective in patients with diarrhea complicated by fever and/or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*. Discontinue XIFAXAN if diarrhea symptoms get worse or persist more than 24-48 hours and alternative antibiotic therapy should be considered.

XIFAXAN is not effective in cases of travelers’ diarrhea due to *Campylobacter jejuni*. The effectiveness of XIFAXAN in travelers’ diarrhea caused by *Shigella* spp. and *Salmonella* spp. has not been proven. XIFAXAN should not be used in patients where *Campylobacter jejuni*, *Shigella* spp., or *Salmonella* spp. may be suspected as causative pathogens.

***Clostridium difficile*-Associated Diarrhea**

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon which may lead to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

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

Development of Drug Resistant Bacteria

Prescribing XIFAXAN for travelers’ diarrhea in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Severe (Child-Pugh C) Hepatic Impairment

There is increased systemic exposure in patients with severe hepatic impairment. Animal toxicity studies did not achieve systemic exposures that were seen in patients with severe hepatic impairment. The clinical trials were limited to patients with MELD scores <25. Therefore, caution should be exercised when administering XIFAXAN to patients with severe hepatic impairment (Child-Pugh C) [see Use in Specific Populations (8.7), Nonclinical Toxicology (13.2) and Clinical Studies (14.2)].

ADVERSE REACTIONS

Clinical Studies Experience

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

Hepatic Encephalopathy

The data described below reflect exposure to XIFAXAN 550 mg in 348 patients, including 265 exposed for 6 months and 202 exposed for more than a year (mean exposure was 364 days). The safety of XIFAXAN 550 mg taken two times a day for reducing the risk of overt hepatic encephalopathy recurrence in adult patients was evaluated in a 6-month placebo-

study (n = 280). The population studied had a mean age of 56.26 (range: 21-82) years; approximately 20% of the patients were ≥ 65 years old, 61% were male, 86% were White, and 4% were Black. Ninety-one percent of patients in the trial were taking lactulose concomitantly. All adverse reactions that occurred at an incidence ≥ 5% and at a higher incidence in XIFAXAN 550 mg-treated subjects than in the placebo group in the 6-month trial are provided in Table 2. (These include adverse events that may be attributable to the underlying disease).

Table 1: Adverse Reactions Occurring in ≥ 5% of Patients Receiving XIFAXAN and at a Higher Incidence Than Placebo

	Number (%) of Patients	
	XIFAXAN Tablets 550 mg TWICE DAILY N = 140	Placebo N = 159
MedDRA Preferred Term		
Edema peripheral	21 (15%)	13 (8%)
Nausea	20 (14%)	21 (13%)
Dizziness	18 (13%)	13 (8%)
Fatigue	17 (12%)	18 (11%)
Ascites	16 (11%)	15 (9%)
Muscle spasms	13 (9%)	11 (7%)
Pruritus	13 (9%)	10 (6%)
Abdominal pain	12 (9%)	13 (8%)
Abdominal distension	11 (8%)	12 (8%)
Anemia	11 (8%)	6 (4%)
Cough	10 (7%)	11 (7%)
Depression	10 (7%)	8 (5%)
Insomnia	10 (7%)	11 (7%)
Nasopharyngitis	10 (7%)	10 (6%)
Abdominal pain upper	9 (6%)	8 (5%)
Arthralgia	9 (6%)	4 (3%)
Back pain	9 (6%)	10 (6%)
Constipation	9 (6%)	10 (6%)
Dyspnea	9 (6%)	7 (4%)
Pyrexia	9 (6%)	5 (3%)
Rash	7 (5%)	6 (4%)

The following adverse reactions, presented by body system, have also been reported in the placebo-controlled clinical trial in greater than 2% but less than 5% of patients taking XIFAXAN 550 mg taken orally two times a day for hepatic encephalopathy. The following includes adverse events occurring at a greater incidence than placebo, regardless of causal relationship to drug exposure.

Ear and Labyrinth Disorders: Vertigo

Gastrointestinal Disorders: Abdominal pain lower, abdominal tenderness, dry mouth, esophageal variceal bleed, stomach discomfort

General Disorders and Administration Site Conditions: Chest pain, generalized edema, influenza like illness, pain NOS

Infections and Infestations: Cellulitis, pneumonia, rhinitis, upper respiratory tract infection NOS

Injury, Poisoning and Procedural Complications: Contusion, fall, procedural pain

Investigations: Weight increased

Metabolic and Nutritional Disorders: Anorexia, dehydration, hyperglycemia, hyperkalemia, hypoglycemia, hyponatremia

Musculoskeletal, Connective Tissue, and Bone Disorders: Myalgia, pain in extremity

Nervous System Disorders: Amnesia, disturbance in attention, hypoesthesia, memory impairment, tremor

Psychiatric Disorders: Confusional state

Respiratory, Thoracic, and Mediastinal Disorders: Epistaxis

Vascular Disorders: Hypotension

Postmarketing Experience

The following adverse reactions have been identified during post approval use of XIFAXAN. Because these reactions are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These reactions have been chosen for inclusion due to either their seriousness, frequency of reporting or causal connection to XIFAXAN.

Infections and Infestations

Cases of *C. difficile*-associated colitis have been reported [see Warnings and Precautions (5.2)].

General

Hypersensitivity reactions, including exfoliative dermatitis, rash, angioneurotic edema (swelling of face and tongue and difficulty swallowing), urticaria, flushing, pruritus and anaphylaxis have been reported. These events occurred as early as within 15 minutes of drug administration.

DRUG INTERACTIONS

In vitro studies have shown that rifaximin did not inhibit cytochrome P450 isoenzymes 1A2, 2A6, 2B6, 2C9, 2C19, 2D6, 2E1 and CYP3A4 at concentrations ranging from 2 to 200 ng/mL [see Clinical Pharmacology (12.3)]. Rifaximin is not expected to inhibit these enzymes in clinical use.

An *in vitro* study has suggested that rifaximin induces CYP3A4 [see Clinical Pharmacology (12.3)]. However, in patients with normal liver function, rifaximin at the

CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitant CYP3A4 substrates in patients with reduced liver function who have elevated rifaximin concentrations.

An *in vitro* study suggested that rifaximin is a substrate of P-glycoprotein. It is unknown whether concomitant drugs that inhibit P-glycoprotein can increase the systemic exposure of rifaximin [see Clinical Pharmacology (12.3)].

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Rifaximin has been shown to be teratogenic in rats and rabbits at doses that caused maternal toxicity. XIFAXAN tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Administration of rifaximin to pregnant rats and rabbits at dose levels that caused reduced body weight gain resulted in eye malformations in both rat and rabbit fetuses. Additional malformations were observed in fetal rabbits that included cleft palate, lumbar scoliosis, brachygnathia, interventricular septal defect, and large atrium.

The fetal rat malformations were observed in a study of pregnant rats administered a high dose that resulted in 16 times the therapeutic dose to diarrheic patients or 1 times the therapeutic dose to patients with hepatic encephalopathy (based upon plasma AUC comparisons). Fetal rabbit malformations were observed from pregnant rabbits administered mid and high doses that resulted in 1 or 2 times the therapeutic dose to diarrheic patients, based upon plasma AUC comparisons.

Post-natal developmental effects were not observed in rat pups from pregnant/lactating female rats dosed during the period from gestation to Day 20 post-partum at the highest dose which resulted in approximately 16 times the human therapeutic dose for travelers’ diarrhea (based upon AUCs) or approximately 1 times the AUCs derived from therapeutic doses to patients with hepatic encephalopathy.

Nursing Mothers

It is not known whether rifaximin is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from XIFAXAN, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of XIFAXAN 200 mg in pediatric patients with travelers’ diarrhea less than 12 years of age have not been established. The safety and effectiveness of XIFAXAN 550 mg for HE have not been established in patients < 18 years of age.

Geriatric Use

Clinical studies with rifaximin 200 mg for travelers’ diarrhea did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger subjects. In the controlled trial with XIFAXAN 550 mg for hepatic encephalopathy, 19.4% were 65 and over, while 2.3% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

The pharmacokinetics of rifaximin in patients with impaired renal function has not been studied.

Hepatic Impairment

Following administration of XIFAXAN 550 mg twice daily to patients with a history of hepatic encephalopathy, the systemic exposure (i.e., AUC₀₋₂₄) of rifaximin was about 10-, 13-, and 20-fold higher in those patients with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment, respectively, compared to that in healthy volunteers. No dosage adjustment is recommended because rifaximin is presumably acting locally. Nonetheless, caution should be exercised when XIFAXAN is administered to patients with severe hepatic impairment [see Warnings and Precautions (5.4), Clinical Pharmacology (12.3), Nonclinical Toxicology (13.2), and Clinical Studies (14.2)].

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of aggressive, extensive, and low-yield care. It has also further spawned a boom industry in support of CT coronary angiograms in the emergency department. However, all these imaging studies have test characteristics resulting in excessive false positives in a low-risk population, and their suboptimal appropriateness should be part of shared decision making with patients and families.

SOCIETY OF HOSPITAL MEDICINE-PEDIATRIC HOSPITAL MEDICINE

Don't order chest radiographs in children with uncomplicated asthma or bronchiolitis.

Don't routinely use bronchodilators in children with bronchiolitis.

Don't use systemic corticosteroids in children under 2 years of age with an uncomplicated lower respiratory tract infection.

This set of recommendations encompasses a huge subset of pediatric visits to the emergency department, and these tests and interventions may be frequently performed in many settings. Despite the seemingly innocuous nature of these items, they are associated with rare benefits, exceeding the costs and harms.

Likewise, the evolution and additions to

these lists are likely to continue in the months and years to come. A study group led by Jeremiah D. Schuur, MD, MHS, FACEP, at Harvard Medical School in Boston used a modified Delphi consensus to create a list of care with "little value" for the institution.⁸ The process proposed more than 64 items initially, and the team surveyed physicians about 17 of these and ultimately created its own top five:

1. Do not order CT of the cervical spine after trauma for patients who do not meet the National Emergency X-ray Utilization Study (NEXUS) low-risk criteria or the Canadian C-Spine Rule.

2. Do not order CT to diagnose pulmonary embolism without first risk-stratifying for pulmonary embolism (pretest probability and D-dimer tests if low probability).

3. Do not order magnetic resonance imaging of the lumbar spine for patients with lower back pain without high-risk features.

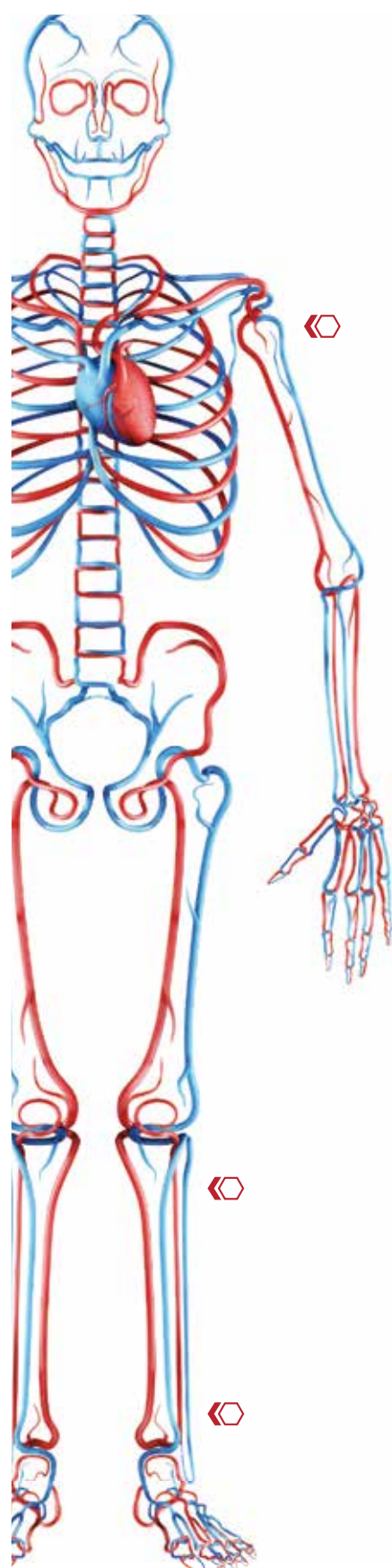
4. Do not order CT of the head for patients with mild traumatic head injury who do not meet New Orleans Criteria or Canadian CT Head Rule.

5. Do not order coagulation studies for patients without hemorrhage or suspected coagulopathy (eg, with anticoagulation therapy, clinical coagulopathy).

Whether this list, or any of the Choosing Wisely recommendations, meets your expectations as representing the "low-hanging fruit" of low-yield care in your clinical setting, these efforts illuminate important cultural changes. Beyond the specific proposals by each specialty, it is clear physicians are acutely aware of the tests and therapies that are overused despite minimal benefit. These tools provide the first steps toward more robust resource stewardship efforts that will improve the cost-effectiveness of health care delivery. 🍌

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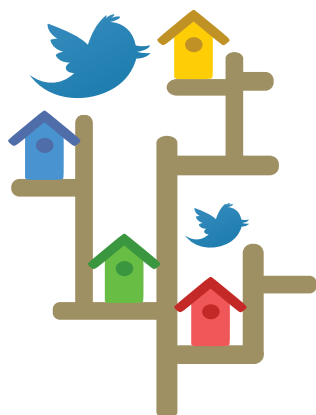
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DR. FAUST is an emergency-medicine resident at Mount Sinai Hospital in New York and Elmhurst Hospital Center in Queens. He tweets about #FOAMed and classical music @jeremyfaust.



Just the Pearls

by JEREMY SAMUEL FAUST, MD, MS, MA

If you enter #EMTOT (Emergency Medicine Tricks of the Trade) into a Twitter search you'll certainly find some clever ideas. But this hashtag isn't used as often as it could be. That doesn't mean there aren't a slew of tweets that fit the category. Here are five recent posts that should have been tagged #EMTOT, but weren't.

1 Canadian EM physician Ken Milne, MD (@thesgem), kicks things off with one of my personal favorite tricks. "... How about cranking tunes to distract peds during procedures? <http://thesgem.com/2014/06/sgem78-sunny-days-pediatric-pain-control/#FOAMed#MedEd>." The link goes to the blog post associated with Dr. Milne's latest episode of his increasingly popular podcast, The Skeptics Guide to Emergency Medicine (tagline: "Meet 'em, greet 'em, treat 'em, street 'em"). Letting kids listen to music is not just being a nice doctor—it is evidence-based! Dr. Milne and his guest Anthony Crocco, MD, division head and medical director of pediatric emergency medicine at McMaster University in Hamilton, Ontario, discuss the 2013 *JAMA Pediatrics* paper "Music to reduce

Letting kids listen to music is not just being a nice doctor—it is evidence-based! Ideas like this might save the need for yet another needle.

pain and distress in the pediatric emergency department. A randomized clinical trial." They conclude that music can help control pain in children requiring painful procedures. The data aren't as overwhelming as one might hope, but the study does support the practice. If nothing else, EM providers should have a low threshold to embrace inexpensive, safe, and patient-centered modalities whenever possible. Ideas like this might save the need for yet another needle.

2 On the other hand, sometimes another needle is necessary. But maximal pain is not. This is why small-bore "pigtail" chest tube catheters are beginning to replace conventional chest tubes for stable pneumothoraces, small hemothoraces, and pleural effusions. Mayo Clinic EM physician Daniel Cabrera, MD (@cabreraERDR), relays a short, free, and crystal-clear video (that's a #FOAMed trifecta) produced by the


department of emergency medicine at the University of Ottawa: "How to place a chest pigtail catheter, by @emergmedottawa Pig Tail <http://youtu.be/nrxuZwFpiGI>." This video is a reminder that, for some procedures, video-learning is an indispensable tool.


3 Our next trick-of-the-trade tweet comes from Australian flight and retrieval medicine guru Minh Le Cong, MBBS (@rfdsdoc). This trick is not ready for prime-time use in the ED setting, but worth sharing (disclaimer: the research came from my own institution). "Mount Si-

nai psychiatrists prove feasibility and safety of intranasal ketamine as rapid antidepressant. <http://www.mountsinai.org/about-us/newsroom/press-releases/intranasal-ketamine-confers-rapid-antidepressant-effect-in-depression>." In the future, this therapy might be an effective stopgap for psychiatric patients not requiring emergent admission or psychiatric consult, but who would benefit from short term help until connecting with their outpatient provider.

4 On a completely different note, there is always room for improvement in the way we perform CPR. No amount of training prepares providers for the adrenaline of a real code. Despite some effort, I can't seem to get my colleagues to slow down their CPR compressions to the desired rate of 104 compressions per minute. In a recent simulation study I ran, I noticed that out of 30 chest compression providers, not a sin-

CONTINUED on page 26







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gle one administered compressions too slowly. Most were too fast, some by a substantial margin. In real life, many of us have tried addressing this by playing a metronome during CPR. Unfortunately, the effect seems ephemeral and minimal. The problem stems, I believe, from people not knowing that “hard and fast” compressions can actually be too fast. But @TakeHeartAust (a nonprofit Australian organization aiming to improve CPR survival rates) has an idea. Don’t just tell your colleagues and students what to do, but also tell them why. Their short tweet sums it up elegantly: “CPR - when you push down say “BRAIN”, when you release say “HEART” [because] that’s how/when YOU are supplying them with blood!” Systole-diastole. Systole-diastole. I’ve already noticed that when a provider knows why the rate of compressions matters, they tend to better adhere the recommended rate.

5 Rounding out the list is the tweet that inspired this month’s column. Casey Parker, MBBS (@broomedocs) is a general practitioner and hospital district medical officer in Broome, Australia and the creator of the excellent broomedocs.com emergency medicine blog. Dr. Parker challenges us to be creative and resourceful by presenting a case scenario, while imposing several interesting restrictions. It is one thing to solve a case and another to do so with your hands tied behind your back. Dr. Parker asks

us to diagnose and treat a complicated patient without formal radiology or lab tests, other than point-of-care blood gas results. I refer to this type of exercise as “post-apocalypse medicine,” but Dr. Parker has a nicer name for it. “Midnight MacGyver Medicine <http://broomedocs.com/2014/06/clinical-case-103-midnight-macgyver-medicine/>...Some great responses from the smart #FOAMed faculty.” I heartily agree. Many impressive responses were posted in the blog’s comment section, coming from top EM minds all over the world, a great example of asking EM providers to think outside of the box and a yeoman display of the power of social media to generate high-level discussion and the sharing of ideas. ☺

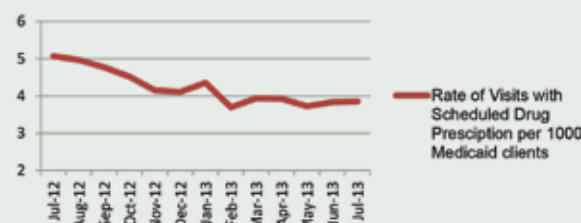
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DO YOU HAVE ANY FAVORITE TWEETS THAT ACEP NOW READERS SHOULD KNOW ABOUT VIA THE FEED?

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Rate of Visits with Scheduled Drug Prescription per 1000 Medicaid Clients



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Featured Opportunities:

Summit Medical Center (Van Buren, AR) 19K annual visits. **Medical Director.**

Lawnwood Regional (Ft. Pierce, FL) 60K annual visits, Level II Trauma.

NEW! Memorial Emergency Care-Atlantic (Jacksonville, FL) Brand new freestanding ED, affiliated with Memorial Hospital Jacksonville, opening Summer 2014.

Lake City Medical Center (Lake City, FL) 25K annual visits. **Medical Director.**

NEW! Physicians Regional-Collier (Naples, FL) 27K annual visits.

NEW! Hunter's Creek ER (Orlando, FL) Brand new freestanding ED affiliated with Osceola Regional. Estimated 18K visits in year one.

Poinciana Hospital (Orlando, FL) 35K annual visits.

Gulf Coast Med Ctr (Panama City, FL) 60K annual visits.

West Florida Hospital (Pensacola, FL) 51K annual visits.

Fawcett Memorial Hospital (Port Charlotte, FL) 25K annual visits.

Doctor's Hospital (Sarasota, FL) 23K annual visits. **Medical Director.**

FL Hospital Heartland System (Sebring, FL) 3 Hospital System. 11 - 25K annual visits.

Northside Hospital (St. Petersburg, FL) 31K annual visits. **Associate Medical Director.**

St. Petersburg General Hospital (St. Petersburg, FL) 30K annual visits. **Medical Director.**

Capital Regional (Tallahassee, FL) 65K annual visits. Affiliated Freestanding ED - **Gadsden Memorial Campus** (Quincy, FL) 15K annual visits.

University Hospital & Med Center (Tamarac, FL) 35K annual visits.

Bayfront Health (Tampa Bay, FL) 2 campus system. 26K-30K annual visits.

Bayonet Point (Tampa Bay, FL) 36K annual visits, Level II Trauma.

Brandon Regional (Tampa Bay, FL) 106K annual visits; Second campus in Plant City - 15K annual visits.

Medical Center of Trinity (Tampa Bay, FL) 50K annual visits.

NEW! Town and Country Hospital (Tampa Bay, FL). 18K annual visits. **Medical Director.**

West Palm Hospital (West Palm Beach, FL) 28K annual visits.

Cartersville Medical Center (Cartersville, GA) 48K annual visits.

Fairview Park (Dublin, GA) 36K annual visits. **Medical Director.**

Mayo Clinic at Waycross (Waycross, GA) 50K annual visits.

Hutchinson Medical Center (Hutchinson, KS) 23K annual visits. **Medical Director.**

Wesley Medical Center (Wichita, KS) 65K annual visits. **Regional Medical Director.**

Greenview Regional (Bowling Green, KY) 32K annual visits.

Murray-Calloway County Hospital (Murray, KY) 18K annual visits.

CHRISTUS St. Frances Cabrini Hospital. (Alexandria, LA). 45K annual visits

Terrebonne General (Houma, LA) 57K annual visits. **Medical Director.**

NEW! CHRISTUS St. Patrick Hospital (Lake Charles, LA) 25K annual visits. **Medical Director.**

Golden Valley Memorial Hospital (Clinton, MO) 13K annual visits.

Albemarle Hospital (Elizabeth City, NC) 47K annual visits.

McLeod Dillon/Loris/Seacoast (Dillon and Myrtle Beach area, SC) 23 - 30K annual visits.

NEW! Gateway Medical Center (Clarksville, TN) 63K annual visits.

NEW! Erlanger North Valley (Dunlap, TN) Brand new freestanding ED, affiliated with Erlanger Health, opening Summer 2014.

Southern Hills Medical Center (Nashville, TN) 41K annual visits. **Medical Director.**

TriStar ER Portland (Nashville, TN) Brand new freestanding ED, affiliated with TriStar Hendersonville.

University Medical Center (Nashville, TN) 30K annual visits.

NEW! TriStar Parkridge West (Jasper, TN) 18K annual visits. **Medical Director.**

CHRISTUS St. Elizabeth (Beaumont, TX) 50K annual visits. **Medical Director.**

Valley Regional (Brownsville, TX) 33K annual visits. **Medical Director.**

CHRISTUS Spohn Health System (Corpus Christi & surrounding areas) 6 Hospital System. 21-48 annual visits.

East Houston Regional (Houston, TX) 51K annual visits.

West Houston Regional (Houston, TX) 46K annual visits.

CHRISTUS Jasper (Jasper, TX) 23K annual visits.

CHRISTUS St. Mary (Port Arthur, TX) 27K annual visits.

Metropolitan/Northeast Methodist (San Antonio, TX) 47K/50K annual visits. Third campus - **Methodist Texsan**. 7K annual visits. **Medical Director.**

LewisGale Health System (Roanoke/Blacksburg area, VA) 13-41K annual visits. **Medical Director** (Montgomery).

Henrico Doctors' Hospital (Richmond, VA) 3 Hospital System. 14-34K annual visits. Brand new affiliated freestanding ED - **Hanover Emergency Center** Estimated 10K visits in year one.

Spotsylvania Regional (Fredericksburg, VA). 27K annual visits.



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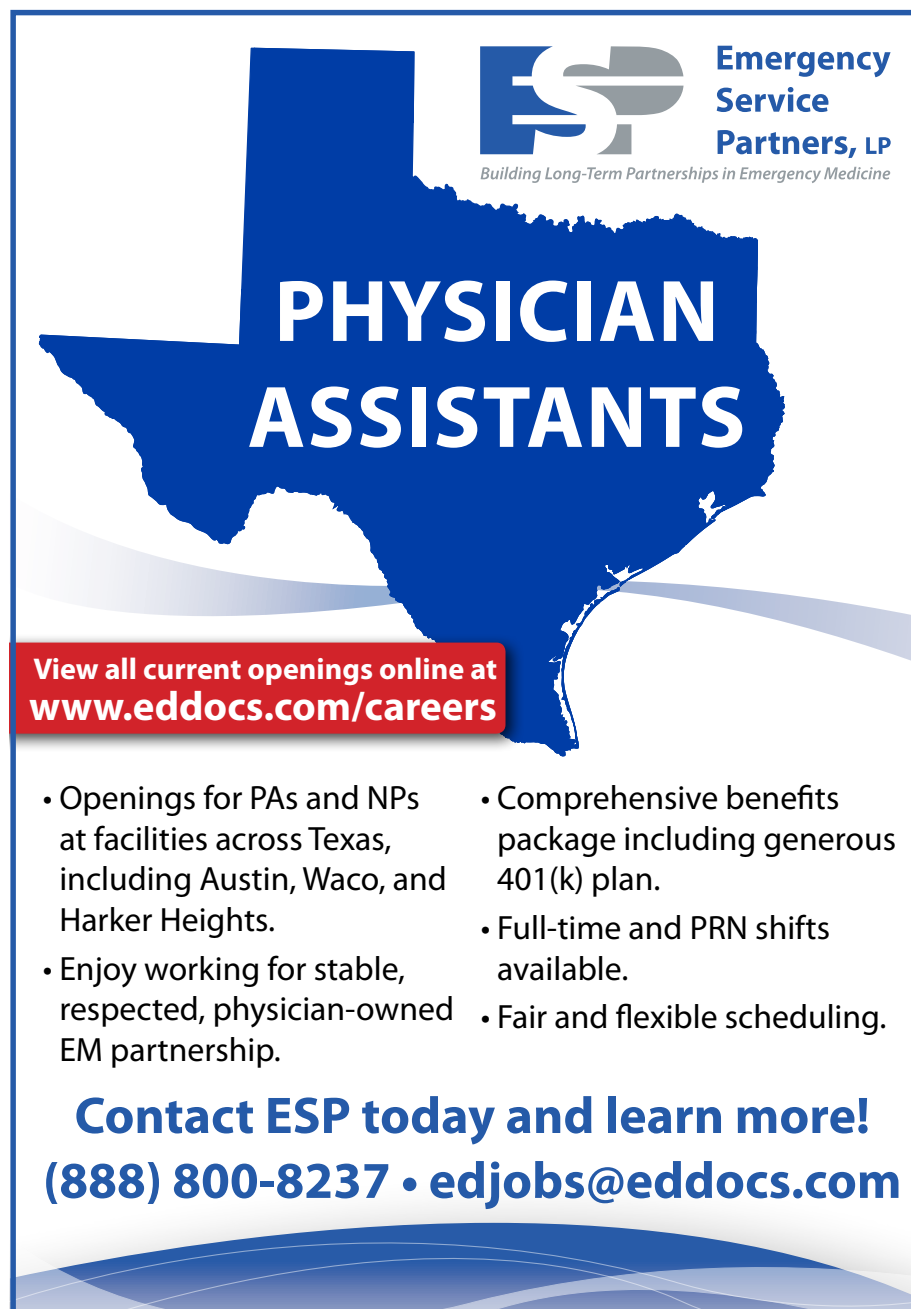
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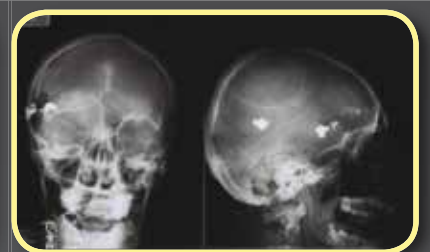
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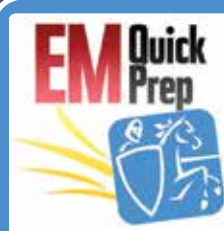
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