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The Official Voice of Emergency Medicine

JUNE 2014

Volume 33 Number 6

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PLUS



**JUST A PATCH OR A
REAL MONITORING
SOLUTION?**
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MANAGE
PERFORMANCE
STRESS: PART 1**
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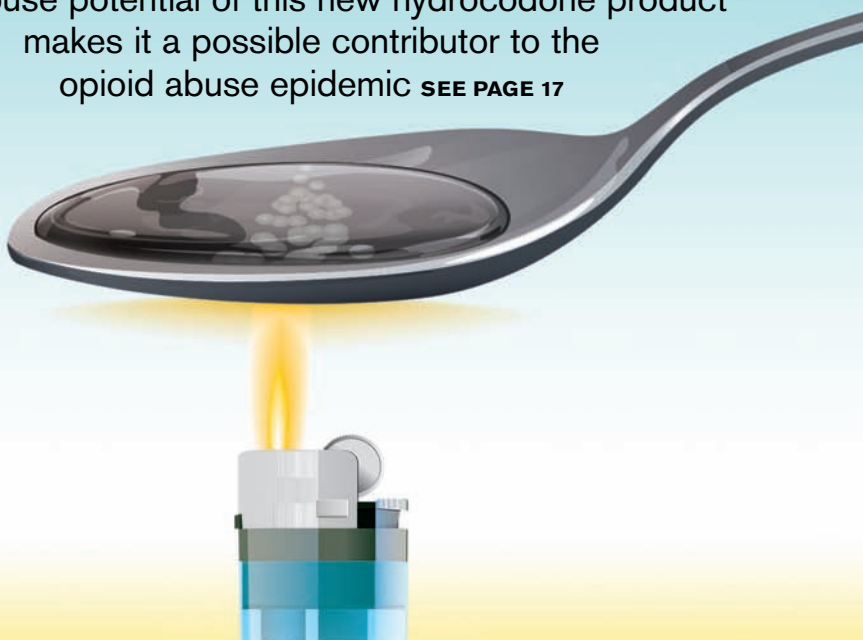
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and opinion pieces, go to:
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The Zohydro ER Affair

The conspiracy theory behind the drug approval **SEE PAGE 16**

Just Say No to Zohydro ER

The abuse potential of this new hydrocodone product
makes it a possible contributor to the
opioid abuse epidemic **SEE PAGE 17**



ILLUSTRATION/PAUL JUESTRICH; PHOTOS SHUTTERSTOCK.COM



SILVER SCREEN GOES CODE BLACK

*Documentary about life
in the emergency
department captures the
challenge and energy of
emergency medicine*

by FRANCESCA BARATTA

During his four years of residency at the University of Southern California Los Angeles County General Hospital, Ryan McGarry, MD, recorded more than 500 hours of emergency department footage. Now, one year out of residency and an assistant professor of emergency medicine at New York-Presbyterian/Weill Cornell Medical College, Dr. McGarry is about to release the 82-minute documentary those 500 hours produced: *Code Black*. The documentary is named after the highest-level code

CONTINUED on page 18

Unsung Heroes of Emergency Medicine

Even from behind the scenes,
these four professionals have
made significant contributions
to EM **SEE PAGE 8**

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EDITORIAL STAFF

MEDICAL EDITOR IN CHIEF

Kevin Klauer, DO, EJD, FACEP
kklauer@acep.org

EDITOR

Dawn Antoline-Wang
dantolin@wiley.com

ART DIRECTOR

Paul Juestrich
pjuestri@wiley.com

MANAGER, DIGITAL MEDIA
AND STRATEGY

Jason Carris
jcarris@wiley.com

ACEP STAFF

EXECUTIVE DIRECTOR

Dean Wilkerson, JD, MBA, CAE
dwilkerson@acep.org

DIRECTOR, MEMBER
COMMUNICATIONS AND
MARKETING

Nancy Calaway
ncalaway@acep.org

ASSOCIATE EXECUTIVE DIRECTOR,
MEMBERSHIP AND EDUCATION
DIVISION

Robert Heard, MBA, CAE
rheard@acep.org

COMMUNICATIONS MANAGER

Darrin Scheid
dscheid@acep.org

PUBLISHING STAFF

EXECUTIVE EDITOR/
PUBLISHER

Lisa Dionne
ldionne@wiley.com

ASSOCIATE DIRECTOR,
ADVERTISING SALES

Steve Jezzard
sjezzard@wiley.com

ADVERTISING STAFF

DISPLAY ADVERTISING

Mike Lamattina
mlamattina@wiley.com
(781) 388-8548

CLASSIFIED ADVERTISING

Kevin Dunn Cynthia Kucera
kdunn@cunnasso.com ckucera@cunnasso.com
Cunningham and Associates (201) 767-4170

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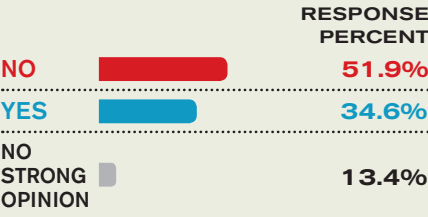
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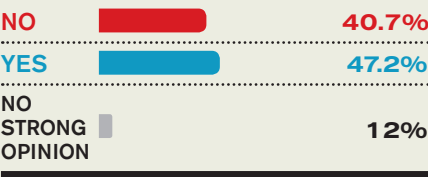
ACEP Council Speaks Out

ACEP Councillors were asked whether or not they feel certain topics should be addressed at the Council meeting in Chicago this October. Here are the results:

1. Single payer health care system



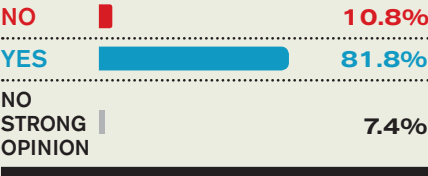
2. Alternate membership categories for physicians not board certified in EM



3. Alternate membership categories for non-physician providers in EM



4. Psychiatric patient boarding



5. Safe harbors for tort reform



6. Legalization or decriminalization of marijuana



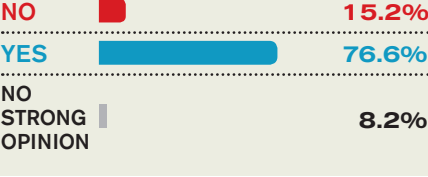
7. Providing resources for palliative care in the ED



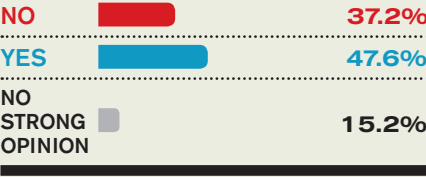
8. Readmission prevention strategies



9. ED opioid prescribing



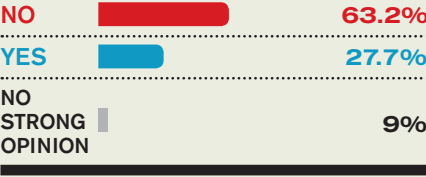
10. Paramedicine



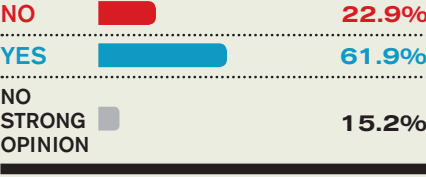
11. Patient satisfaction



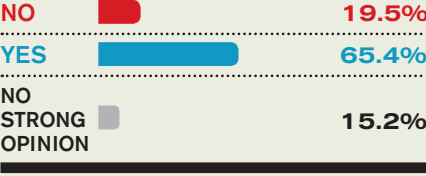
12. Gun control



13. EMTALA



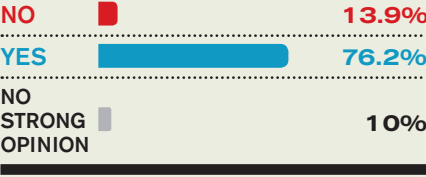
14. Medicaid professional fees



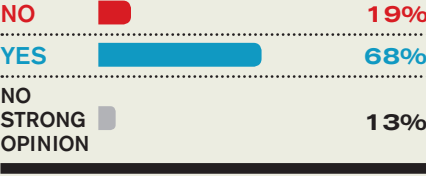
15. Career transitions for older emergency physicians



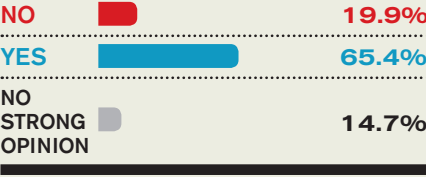
16. GME funding and position/slot allocations



17. CMS 2 midnight rule



18. CMS 3-day stay rule



19. Advanced practice provider (APP) scope of practice





UPDATES
AND ALERTS
FROM ACEP

NEWS FROM THE COLLEGE

Dr. Howard Mell Named ACEP's 2014 Spokesperson of the Year

For his work with national media outlets, including extensive interviews conducted after the 2014 Report Card on Emergency Medicine release, Howard Mell, MD, MPH, FACEP, has been named ACEP's Spokesperson of the Year. He received his award at last month's ACEP Leadership and Advocacy Conference in Washington, DC.

Dr. Mell is an emergency physician in the Cleveland, Ohio area and an outstanding member of ACEP's Spokespersons' Network. In the past year, he was quoted multiple times in news organizations such as *The Chicago Tribune*, *New York's Daily News*, *San Francisco Chronicle*, *Minneapolis' StarTribune*, *ABC News*, and several more on a variety of emergency medicine topics.

Following the publication of a series of articles on energy drinks, attorneys with the beverage industry threatened Dr. Mell with legal action if he didn't retract his quotes. Dr. Mell stood by his medical experience and did not respond, and the threats never materialized.

As a Report Card spokesperson, Dr. Mell was quoted in multiple media sources, including *The Columbus Dispatch*, *WTVN* in Ohio, and *CBS Radio* in Las Vegas. He also is very active with social media, helping to promote ACEP through Twitter and the Public Relations Committee's Tweet Team. He is also a member of the sub-group of the Public Relations Committee that evaluates *Annals of Emergency Medicine* studies for promotion to media.

Dr. Michael Miller Is 2014 Emergency Department Director of the Year

For his successful collaborative work at the University of Iowa Hospital and Clinics and 18-plus years of commitment to improving patient care, Michael Miller, MD, FACEP, was named 2014 Emergency Department Director of the Year at a May 21, 2014, ceremony in Dallas. Presented by Blue Jay Consulting and the Emergency Medicine Foundation, the award is given to an ED director who demonstrates collaborative relationships with nursing and ancillary departments to implement and improve operational and clinical standards based on evidence-based practice.

Dr. Miller captured the fifth annual award because of several initiatives he has championed, including his strategies to improve door-to-balloon times for ST segment elevation myocardial infarction (STEMI), elevated sepsis recognition with an electronic medical record-based screening strategy, improved standard ED physician-nurse communications, and standardized vasoactive drug dosing at UI Healthcare.

The 46-year-old graduate of the University of Iowa Carver College of Medicine also spearheaded Super Triage, a process to improve hospital flow and provider satisfaction of patients being admitted.

In the past six months, the emergency department's "patients left without being seen" percentage has dropped from 3 percent to 0.2, and patient satisfaction survey results have increased from the 30th percentile among similar hospitals to the 84th. The length of stay for all emergency department visitors has decreased from 3.5 hours to 3.0 in the same time frame.

Dr. Miller is the chief safety officer for the health system and one of the hospital's as-

sociate chief medical officers. He also directs the administrative curriculum for EM residents, teaching them how to function as physician administrators in their own emergency departments.

"Lasting change in a complex health care system requires building relationships and teamwork across historic silos to achieve success," Dr. Miller said. "It is important to maintain optimism in the power of creating a learning environment."

Dr. Ryan Stanton Recognized by 911 Network

The 911 Legislative Network Member of the Year Award for 2014 goes to Kentucky emergency physician Ryan Stanton, MD, FACEP. This honor is bestowed upon 911 Network members who have gone the extra mile in advocating for the specialty of emergency medicine to federal legislators and



Dr. Stanton

NOW APPROVED FOR MULTIPLE INDICATIONS

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- Reduction of the risk of stroke and systemic embolism in patients with NVA
- Treatment of DVT and PE
- Reduction in the risk of recurrence of DVT and PE

Indications and Usage

Pradaxa® (dabigatran etexilate mesylate) capsules is indicated:

- to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation;
- for the treatment of deep venous thrombosis and pulmonary embolism in patients who have been treated with a parenteral anticoagulant for 5-10 days;
- to reduce the risk of recurrence of deep venous thrombosis and pulmonary embolism in patients who have been previously treated

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

(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

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.

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

Pradaxa®
dabigatran etexilate
CAPSULES 150 mg

their staff. Dr. Stanton was the 2012 winner of the ACEP Spokesperson of the Year Award. He is active in several state and national medical societies through presentations and leadership roles. He is the Public Relations Committee chair and president of the Kentucky Chapter ACEP.

NBC Team, New Yorker Reporter Win Awards of Excellence Television Award

Barbara Morse Silva and Paul Tierney of NBC10 Rhode Island are winners of this year’s Award of Excellent in the Television category for their series, “Special Assignment: Inside the ER.” These are pieces that feature the wide range of what



Ms. Silva

emergency physicians do and the wide variety of patients they treat. It also showcases the high acuity of emergency patients. The reporters spent many hours filming and interviewing emergency physicians at an emergency department in Rhode Island.

Magazine Award

Atul Gawande of The New Yorker received this year’s Award of Excellence in the magazine category for “Why Boston Hospitals Were Ready.” His piece showcased the value of emergency medicine as it described what happened



Mr. Tierney



Mr. Gawande

following the bombings at the 2013 Boston Marathon.

Have an Idea or Suggestion? Submit a Council Resolution

The deadline to submit a resolution to the Council is July 28, 2014. Over the course of two days, the Council will consider dozens of resolutions that will shape the direction of ACEP for the coming year and beyond. Get your idea or policy considered at the Council meeting Oct. 25–26, 2014, in Chicago by following these guidelines.

- 1. Resolutions must be submitted by at least two ACEP members or by any component body represented in the Council.
- 2. Resolutions may be submitted by mail, fax, or email (preferred). Resolutions are due

at least 90 days before the Council meeting.

3. Resolutions consist of a descriptive Title, a Whereas section, and a Resolved section. The Council only considers the Resolved when it votes, and the Resolved is what the Board of Directors reviews to direct College resources.

4. There are two types of resolutions: general resolutions and bylaws resolutions. General resolutions require a majority vote for adoption, and bylaws resolutions require a two-thirds vote.

5. Councillors receive the resolutions prior to the annual meeting along with background information and cost information developed by ACEP staff. Resolutions are assigned to reference committees for discussion at the Council meeting. You, as the author of your resolution, should attend the reference committee that discusses your resolution.

CONTINUED on page 6

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 NVAF

- 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.

NVAF

- 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 NVAF 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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6. The Council considers the recommendations from the reference committees on the second day of the Council meeting. The reference committees present each resolution, providing a recommendation and summary of the debate to the Council. The Council debates each resolution and offers amendments as appropriate.
7. Any ACEP member may attend the Council meeting, but only certified Councillors are allowed to participate in the floor debate and vote. Non-councillors may address the Council at the discretion of the speaker. Such requests must be submitted in writing to the speaker before the debate.
8. When considering a resolution, the Council’s options are to adopt the resolution as written; adopt as amended by the Council; refer to the Board, the Council Steering Committee, or the Bylaws Interpretation Committee; or not adopt (defeat or reject) the resolution.
9. ACEP has more resources on the resolution process at www.acep.org/council. Review the “Guidelines for Writing Resolutions” for tips.
10. Writing and submitting Council resolutions keeps our College healthy and vital. A Council resolution is a great way for members to provide information to their colleagues and ACEP leadership. Please take advantage of this opportunity and exercise your rights as part of our emergency medicine community.
11. Stop reading, and go write your resolution. ➡

GET READY FOR MAINTENANCE OF LICENSURE

The Federation of State Medical Boards (FSMB) has adopted the new Maintenance of Licensure (MOL) system under which physicians will be required to participate in a continuous professional development program relevant to their areas of practice and measured against objective data. As a condition of license renewal under MOL, physicians will be required to provide documentation of continuous professional development programs relating to the six Accreditation Council for Graduate Medical Education core competencies: medical knowledge, patient care, interpersonal and communication skills, practice-based learning, professionalism, and systems-based practice.

While MOL is still several years away from being adopted by any state medical board, the FSMB is currently working to develop and implement various pilot projects in nine states to prepare for MOL and to determine best practices.

What are the core components of MOL? How does it relate to Maintenance of Certification and Osteopathic Continuous Certification? What do you need to do to get ready for MOL requirements?

Visit ACEPNow.com and read “Maintenance of Licensure: Three...Two...One...Ready or Not?” by Jennifer Casaletto, MD, FACEP, to learn more about MOL, and watch for more on MOL in an upcoming edition of ACEP eNow.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see package insert for full Prescribing Information.

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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.

	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.



Praise for Electronic Patient Communications

Thank you for the “Text Rx” article that appeared in the March 2014 issue of *ACEP Now* (p. 8).

I share your enthusiasm for reaching patients electronically to check on their well-being. My ED uses a system recommended by the Robert Wood Johnson Foundation to contact discharged patients by text and email. When a patient reports a “worse” condition, the details are faxed to our charge nurse and handled in a manner that

parallels the workflow for reconciling positive culture results. As well, when a patient has an aftercare issue (eg, difficulty making a follow-up appointment or questions about a newly prescribed medication) the ED case manager is automatically notified by email.

Our experience echoes your findings that an mHealth system improves outcomes and prevents unnecessary ED revisits.

—Tom Scaletta, MD
Naperville, Illinois

Revisiting CT Before LP

I was reading today (3/25/14) “Myths in Emergency Medicine: Part 2” in *ACEP Now* (March 2014, p. 17).

I wanted to ask you about myth number four: CT before LP. You state: “Consider the number-one treatment for idiopathic intracranial hypertension (pseudotumor cerebri). Not only is it safe to LP these patients without risk of herniation, it’s recommended.”

I would like to point out the error in this argument. The etiology of idiopathic intracranial HTN is different than getting a CT for

other etiologies. In this condition, LP is safe because the pressures are equal since it is communicating hydrocephalus, thus pressure in ventricles and the subarachnoid space is equal to that of the lumbar cistern, thus LP is safe.

For other causes, I would argue LP before CT is not safe. In the study you cite, 52 of 56 patients had uneventful LP in spite of abnormal CT—well, what if one of the four was a family member? I don’t care for stats always because when that small percent is me, I would be demanding a CT before the LP. Also, what happened to those four patients? I did not find the study so was not able to see.

Thank you, and great article!

—Max Rollins, MD
Atlanta, Georgia

Dr. Klauer Responds

You bring up a very reasonable point worth careful consideration. If a provider feels more comfortable obtaining a CT prior to LP, they should probably order one.

However, it is important to note that increased ICP is not truly associated with herniation following LP; brain shift is the phenomena we should be concerned about.

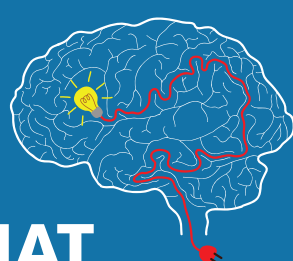
In the Hasbun study you noted, the 56 patients had abnormal findings on CT and the four did not have bad outcomes associated with LP, but the clinician decided not to perform the LP due to noted mass effect (three severe and one mild).

In addition, the authors note that all four had one or more clinical characteristics predicting this finding.

In closing, despite this age-old teaching, there is little evidence supporting the presumption that CT must be performed routinely prior to LP.

Thank you for your letter. ☺

—Kevin Klauer, DO, EJD, FACEP
Canton, Ohio



WHAT ARE YOU THINKING?

SEND EMAIL TO
ACEPNOW@ACEP.ORG;
LETTERS TO ACEP NOW,
P.O. BOX 619911, DALLAS,
TX 75261-9911; AND
FAXES TO 972-580-2816,
ATTENTION ACEP NOW.

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) ^c
Patients	N=2553	N=2554	
Major bleeding event ^a	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 ^b			
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.
^aPatients with at least one MBE.
^bBleeding site based on investigator assessment. Patients can have more than one site of bleeding.
^cConfidence 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) ^c
Patients	N=1430	N=1426	
Major bleeding event ^a	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 ^b			
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.
^aPatients with at least one MBE.
^bBleeding site based on investigator assessment. Patients can have more than one site of bleeding.
^cConfidence 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) ^c
Patients	N=684	N=659	
Major bleeding event ^a	2 (0.3)	0	
Bleeding in a critical area or organ	2 (0.3)	0	
Gastrointestinal ^b	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.
^aPatients with at least one MBE.
^bBleeding site based on investigator assessment. Patients can have more than one site of bleeding.
^cConfidence 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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► **KK:** What are top challenges in 2014 for health care? Where do we see health care going in 2014? What do you see as non-physicians and executive leaders in emergency medicine?

EG: I think the single biggest challenge we have in health care overall, and specific to emergency medicine, is this “Greatest of Three” formula (GOT) and interim final rules [see sidebar, p. 10] that we have under the Affordable Care Act (ACA) and the Centers for Medicare & Medicaid Services (CMS) regulations. What the commercial health plans are doing, in essence, is using those interim final rules to drive out-of-network (OON) reimbursement to approximately 125 percent of Medicare. Greg Hufstetler has analyzed the EmCare data and found that three of the major health plans—Aetna, Cigna, and UnitedHealthcare—have shifted more than \$600 million from the plans to the patients in 2013 using the GOT formula. It really ties to a theme that our CEO and founder Scott Law has talked about. He calls it the great fleecing of the American patient. The plans are paying Medicare plus 20 to 30 percent of the charge, which leaves a significant “balance bill” due from the patient. The balance of the provider charges less the unreasonably low reimbursement by the health plans is being transferred to the patient, and the patient’s having to pay that in states where there isn’t a restriction on balance billing, and that’s a real problem for emergency medicine and all hospital-based specialties. So if we look out over the next five to 10 years, can the emergency medicine specialty exist on a Medicaid- or Medicare-style reimbursement methodology? I don’t think it can exist in the way it does today with independent ED group practices. The recently published *Health Affairs* study showed reimbursements set to Medicare and Medicaid would produce double-digit losses for most EDs and that historically privately insured patients have subsidized all other ED payer classes.¹ With the states that do not have Medicaid expansion, there’s simply not enough reimbursement in the system to pay for the moral imperative, the Emergency Medical Treatment & Labor Act (EMTALA) imperative, and the imperative of emergency medicine to care for all comers to the ED. I think that’s the single biggest challenge we have in EM.

Unsung Heroes of Emergency Medicine

Even from behind the scenes, these four professionals have made significant contributions to EM

GH: I’d say adapting to all of the changes brought about by the ACA would be the generic answer. My number-one concern would be the prevalence of the high-deductible health plans (HDHP) being offered through the exchanges. What you really see is simply a new form of self-pay when you have \$2,000 and \$3,000 deductibles and higher, shifting patients from uninsured to the high-deductible plan. A second concern would be the morphing of the Physician Quality Reporting System into a penalty phase in the next couple of years coupled with the arrival of value-based purchasing modifier systems, which arise out of the ACA. Those two things, in combination, bring exceptional complexity, and when you see the flow chart of those two things together, it introduces almost a sense of despair and skepticism to the house of medicine. In terms of early arrivals, the GOT in 2013, this past calendar year, has resulted in major national commercial payers systematically lowering their non-par reimbursements and justifying it from the GOT regulation. Of course, two of those three rates in the GOT criteria are set by the payers and are thus in a black box unknown by providers. So payers have real-

ized, and their legal counsel has sanctioned the systematic ratcheting downward of these payments, and that poses serious challenges this year and beyond.

CE: One of the things that I think we are all still reeling from is this ICD-10 schizophrenia. We had physician groups gearing up for it and hospitals paying millions of dollars to get ready for all of the big change that didn’t happen. So do we continue to prepare for it? Do we wait until the last minute and see if we want to spend some more money keeping people’s skills sharp and then take a chance it’s going to get put on the back burner again?

Additionally, somehow the patients have become customers, and with them as customers, the hospitals are driven to assure top levels of patient satisfaction. You have your door-to-doctor time; you have your patient comments about the care they’re receiving. Many times, none of that has to do with the quality of medical care that’s being provided, and I think we’ve seen physicians who take a little bit more time with their patients and are a little bit slower than everyone else get called to the carpet for that. I see that happening more and more as we talk to more groups across the

country. Patients have been given more power, but I’m not sure they’ve been educated on how to use it, and that concerns me a lot.

I see so many changes with so many of the payers. Many of them have now set up their own internal audit departments to audit our claims and track whether our charges go up the slightest little bit or if one physician is charging higher than another. Sometimes they don’t really care about the reasons; they just want to bust your chops about it, and we have to defend ourselves. I see that more and more groups are spending more and more money on nonclinical care just to stay ahead of the audits and stay ahead of the impact of electronic medical records (EMRs) and their documentation issues. So, what I see is money tightening up and nonclinical expenses very necessarily going through the roof.

KK: Those are great follow-up comments, and I have to apologize: when you’re not going first, it leaves you a little less to say, but you’ve found some great things to add to the conversation. So, John, what do you think?

JH: There are a couple of things I always like to include in the top health care challenges in general: one being the development of health information exchanges and the second being health care going mobile or health care going retail. Shifting to the top emergency medicine issues, I really believe there are three of them, one of which is defining emergency medicine’s role and function in the care continuum. The second one is emergency medicine self-defining the value metrics by which it will be measured, and the third challenge is the specialty has to really assess and address some macro issues that I truly believe are directly impinging upon two core issues, namely EMTALA and the prudent layperson definition of an emergency. These issues are the infusion of the newly insured; the urgent care explosion; the high-deductible plans, as my three colleagues have mentioned; hospitals going into the insurance business; and what I would call the “retailization” of health care. When patients can self-direct getting their own lab tests today, the landscape has truly changed. I believe these landscape changes are going right at the heart of core issues of the specialty.

CAST OF HEROES



Caral Edelberg, CPC, CPMA, CAC, CCS-P, CHC, president of coding and compliance support company Edelberg & Associates, is an expert on emergency department, hospitalist, ambulance, and urgent care revenue cycle management, coding, and compliance. She is an honorary member of ACEP.



Ed Gaines, JD, CCP, is the chief compliance officer for Zotec Partners, one of the largest providers of physician and hospital coding, billing, and practice management services in the United States. He is an honorary member of ACEP and is a cofounder, past chair, and current board member of the Emergency Department Practice Management Association (EDPMA).



Gregory W. Hufstetler, CPA, MBA, FHFMA, is vice president of reimbursement and regulatory affairs for Reimbursement Technologies, Inc., a wholly owned subsidiary of EmCare, one of the nation’s largest contract management groups for hospital-based physician services. He is also a cofounder and current board member of EDPMA.



John G. Holstein is director of business development for Zotec Partners. His responsibilities have spanned operations, full-service client management, and, presently, new business development.

MODERATOR



Kevin M. Klauer, DO, EJD, FACEP, moderator, is director of The Center for Emergency Medical Education and chief medical officer for Emergency Medicine Physicians, Canton, Ohio; assistant clinical professor at Michigan State University College of Osteopathic Medicine; and medical editor in chief of *ACEP Now*.

KK: I think those are huge, and I appreciate the segue into the specific challenges for emergency medicine. Let's reverse the order here on the challenges specific to EM. Caral, what do you think? Any particular challenges you see that are unique to emergency medicine that haven't been mentioned already or that are more global to health care in general but something specific to emergency medicine?

CE: I think we're still the front door to much of the health care that is provided, but what happens on the other side of that door has been significantly redefined and will continue to be redefined. We have Walgreens and Walmart now providing urgent care, and patients don't quite know where they fit and where they're supposed to go. I think that's going to be a huge challenge for emergency departments. The hospitals are pushing the emergency physicians to get into some involvement with urgent care, some involvement with hospital medicine, some involvement with Walgreens and Walmart type urgent care to assure quality in their areas, to try to compete with them, and our physicians are doing a lot more than seeing patients.

GH: I think simply getting the message out about the unique payer mix and payment stream for emergency medicine is a major and vital challenge. I've developed a suite of tools or talking points for advocates within our organization and even utilized it to some degree within our trade association. I liken the emergency department group to swimmers in a very

turbulent ocean, and that's because fully 50 percent or more, often 60 to 70 percent, of the patients who arrive are either low pay, that is Medicaid, or no pay, that is uninsured. The average would be 20 percent uninsured and 30 percent Medicaid. Now, what other business has 50 to 60 percent of its customers in a status of no pay or low pay and whose revenues fund about one-third of the cost to deploy the service? None.

So what are the lifelines for this swimmer who's in very turbulent waters indeed? Well,

"I can see the ED of the future having more to do than provide ED care. ...I can see our role changing, and if we're indeed going to be responsible for that and accountable for these outcomes, we're going to need a lot more influence..." —Caral Edelberg, CPC, CPMA, CAC, CCS-P, CHC

there are two lifelines: the one is fair commercial payments—that is, from the Blues and from the other national payers, such as Aetna, Cigna, United—and the second would be a hospital subsidy. A lifeline is necessary whenever there is inadequate and unfair payment from the commercials to offset the losses from the uninsured and Medicaid, and what you see now with the "Greatest of Three" taking shape is a massive shift back to the very patient who is unable or unwill-

ing to pay. The question is: will the hospitals now be able to step up and increase their subsidies—or, in some cases, start subsidies for the first time—in order to strengthen the one remaining lifeline keeping the emergency group intact? Of course, I don't know for sure, but I am worried about the fiscal health of many of our hospital partners in an age in which disproportionate share support has been scaled back massively and value-based measures will result in steep penalties to hospitals.

seen expanded cost sharing (eg, coinsurance) for non-emergency use of the ED in what I call the "Arkansas Model" of Medicaid expansion. This premium support model has been picked up by Pennsylvania, Iowa and several other states seeking to use federal matching funds to purchase Medicaid health plan policies for the working poor. In North Carolina, Medicaid is looking at Accountable Care Organizations (ACOs) to drive significant percentages of patients out of the ED. Yet the Oregon Medicaid expansion study showed that when Medicaid expanded in Portland, ED utilization went up approximately 40 percent. It highlights the challenges we have of the moral and legal imperative of the EMTALA mandate and the issues surrounding the chronic conditions, which you know much better than all of us, in terms of that Medicaid patient base and how we deal with it. How do we arm the state chapters to be able to go and make the case that reforming Medicaid on the backs of emergency physicians is not the answer? Maybe 20 years ago, we heard, "Stand behind EMTALA and prudent layperson, and don't engage in the conversation." I don't hear that much anymore—emergency physicians want to be at the table. As Dr. Lynn Massingale of TeamHealth has said for years, "We're either at the table or on the table," and that is very hopeful for the future that the level of engagement of ED physicians has really changed for the better.

CONTINUED on page 10



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KK: Something you mentioned the readers might want to hear more about: you noted cost-sharing models that are out there. Is there anything you would like to expand upon beyond just high-deductible plans shifting burden to the patient?

EG: You know the ACO, the shared savings models, and the bundled payment experiments that were done in what was called the ACE demonstration, which is now the Bundled Payments for Care Improvement Initiative on the Medicare side. I think both of those types of programs appear from a 40,000-foot perspective as an attempt to move away from fee-for-service to something else. The question is: how do you move chronic care and patients with multiple comorbidities into a bundled payment? Maybe a bundled payment works great on hips and knees or coronary artery bypass grafting, but is it really going to affect how Dr. Klauer is going to work up the nursing home patient who is weak and dizzy, has several chronic conditions like congestive heart failure, and does not know why he doesn't feel good? How much is his ordering or diagnostic treatment protocol going to impact the total bundle payment at the end of the day? I think the good news for us is nobody's totally figured out emergency medicine

yet from an ACO or bundled payment perspective—we're in the very early innings. We're the X factor. When you listen to officials of leading hospitals who have experimented with bundled payment and ACOs talk about bundled payment arrangements or ACOs, they scratch their heads and say, "Well, but we had to carve out emergency medicine."

KK: When they can't figure us out, we have two ways to look at it. It does provide great opportunity for us to shape their understanding and create, perhaps, a larger scope for emergency medicine. But if they don't understand EM, they might also interpret this in another direction, as many have already done: that the emergency depart-

ment is an expensive place to receive care and people shouldn't go there, clearly a preposterous assumption about our specialty.

EG: But one of the biggest challenges we have, Kevin, is the old pit-doctor mentality from 20 years ago that I do not want to understand how these changes may impact my practice and my livelihood, that I'm going to work my shift, I'm going to go home, I'm going to take care of my family, I'm going to educate my kids and whatever, and I'm not going to get involved. The biggest threat is that's a doctor who thinks all of this stuff is a lot of white noise and somebody else is going to do it for him or her. We all can make a difference, and we should consider how we all stand on the shoulders of the giants of emergency medicine who carved this

specialty out of solid rock—they all stepped up time and time again, and we all need to follow their leadership and example.

KK: We're going to do it collectively and collaboratively, but we all have to be involved; at the least, we have to be informed. Do you remember that book from several years ago, *Who Moved My Cheese?* Well, they're moving our cheese. We have to evolve and move with it. If we don't change the way we think and the way we practice, this specialty will be at real risk. I have a question for each of you, based on a comment that Ed made about utilization. How many tests does it take to diagnose a hip fracture? Most emergency physicians when they ini-

[def-uh-nish-uh n]

What Is the "Greatest of Three" (GOT) Interim Final Rule (IFR)?

In Section 2719A of the Public Health Service Act, the secretaries of the Departments of Health & Human Services, Labor, and the Treasury issued regulations that require the patient's group health plan to reimburse out-of-network (OON) emergency service by paying "the greatest of three possible amounts: 1) the average amount negotiated with in-network providers for the emergency service furnished; 2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges); or 3) the amount that would be paid under Medicare for the emergency service."

The main goals of the IFR are to protect the patient who obtains OON ED services. Under the IFR, prior authorization is prohibited and balance billing is not prohibited. While the IFR states that patient protections would be defeated if the health plans pay an "unreasonably low amount to the provider," the GOT formula essentially leaves it up the plans to establish a Medicare-related method to reimburse emergency physicians for OON services, as per part two of GOT. If the patient is in a state that prohibits balance billing or the plan states that it will cover the amount of the balance bill for the patient, then the GOT rule does not apply. Several large plans use third-party entities such as DataiSight to communicate with patients, not to pay their balance bill, and to suggest (but not commit) that they will communicate with the providers regarding the balance bill. Since the passage of the ACA, ACEP and other stakeholders continue to be in dialogue with CMS regarding health plan abuses under the GOT and to advocate for clearer objective standards for fair and appropriate OON reimbursement.

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THE FIRST AND ONLY...

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



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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

tially respond will say one: a hip X-ray. How does that look to CMS and third-party payers? How many tests and how many dollars does it take to diagnose a hip fracture? Well, it's the cost of a hip X-ray, an IV, a PT, PPT, an INR, a CBC, a BMP, type and screen, a urinalysis, maybe a Foley catheter, a chest X-ray, an ECG, and anything else the admitting physician may want for medical clearance. It appears when they take care of a hip fracture payment mainly from medical clearance, the cardiologist and anesthesiologist spend no money except for their consultation. They are so efficient. But for the emergency physician, it takes a whole lot more to diagnose a hip fracture when you look at all the tests we order.

EG: What you've raised is a huge issue, I believe, because when you talk to docs about what the expectation is of those specialists, the specialists will literally not come in and treat the patient until all of what you've described has been done in advance. It's the expectation of your specialist, who is essentially demanding that you should do all this additional service. That messaging about who is driving the utilization of advanced imaging, for example, is not being made in my opinion, but it is going to be critical when it comes to bundled payments, ACO, different payment arrangements versus fee-for-service. Now, all of a sudden, maybe my client is in a gain-sharing deal and costs per patient are a factor, so she's viewed as high cost but at baseline quality. Then her

gain-sharing group's going to look at me and say, "Hey, what's your problem? You seem to be working up these patients very extensively," but that's what the specialists are expecting. Changing the specialists' expectations for those comprehensive workups could be a major practice challenge with these new payment models.

KK: Those are great comments. I'll throw in, for the readers and emergency physicians out there who may not be aware of how the value-based modifier for the physician fee schedule is rolling out, that 50 percent of value-based modifier calculation is about cost and utilization. We just don't have a very good idea yet how they're


going to calculate cost and utilization. It seems clear to me that if we're spending dollars that really should be spent by other providers, we're accepting financial responsibility for things we don't need, and that's a problem.

GH: I think fundamentally the discussion about cost is a very important one—that is, keeping cost in the ongoing discussions about value. Cost accounting is an old discipline, but it's one that's missing, if not lost, in emergency medicine. I believe it needs to be front and center. I'm not talking charges but actual cost so that we can argue the value of emergency medicine. I think that if you were to match an hour's worth of fully loaded cost to an hour's worth of

CONTINUED on page 12


ADASUVE® (loxapine) inhalation powder

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	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 escalated 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.

net revenue, the average legislator and regulator would be very surprised to see how close the margins are in the large majority of EDs.

KK: That’s a great perspective. I hadn’t thought about it that way. I really like the way you think on that, Greg. Caral, any additional thoughts on that?

CE: I see our specialty changing. I don’t want to use the word “gatekeeper” because it has such a negative connotation for so many health care professionals, but it’s a role I think we’re going to end up playing. We’re going to be directing more than just the emergency care. I can see the emergency department of the future having more to do than provide emergency department care. I can see us es-

entially responsible for driving front-end cost for health care, which is everything up to, and possibly including, the admission or everything up to the consultant coming in. I can see our role changing, and if we’re indeed going to be responsible for that and accountable for these outcomes, we’re going to need a lot more influence and a lot more power over what happens to the patients we’re responsible for.

KK: That is a great perspective, and that actually leads me to my next question. I’m going to ask you all just for one line about whether you think the scope of practice in emergency medicine will be shrinking or expanding in the next couple of years.

EG: Expanding

CE: I agree absolutely.

JH: Yes, I would see it expanding to more alliances with hospitalists, potentially radiologists and anesthesiologists.

GH: I agree entirely with John’s sentiment.

KK: Do you think these current times [health care reform] in emergency medicine are more critical than previous eras?

EG: Yes, most critical.

JH: Yes, this is another Wiegenstein moment.

GH: Yes, totally agree, most critical.

CE: I can’t say that it is, but I need to qualify that. It’s been close to 40 years that I’ve been involved in emergency medicine, and every big change that we’ve seen was a challenge for us because, at that point, we didn’t have the tools,

expertise, or organization to manage it. And from that, we grew ACEP, we grew EDPMA, we grew some amazing talent within our specialty. I see this as just another opportunity for us to learn more about what needs to happen in our specialty, another opportunity for people who want to step up and take a greater role and who have opinions and new ideas to put them into play.

KK: Could you briefly state what your role is, and how your role impacts emergency medicine?

EG: My role I really see as an advocate for emergency medicine and a facilitator. When Greg and I cofounded EDPMA with others more than 15 years ago, we looked at what

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,

we were doing to support the specialty, and obviously we couldn't be members of ACEP because we weren't physicians. We needed a trade umbrella to represent the various interested stakeholders to go to Washington and go to the state capitals, and it became the vehicle for us to be able to channel all of our energies. It was started in a crisis, the Medicare reassignment crisis, and then we had prudent layperson and Medicaid restrictive diagnosis and triage fee crises hit us right afterwards in the late '90s. We've helped emergency medicine because, as one of our colleagues said, when we come together in EDPMA, "we take off our respective company uniforms and focus on the greater good and on achieving results." It's rewarding on many levels because we have been

fortunate to be part of something larger than each of our companies or ourselves. The association also facilitated our partnership with ACEP and other EM stakeholders. It's been a fantastic working relationship, and I believe we have made a difference because we cared and we worked together. **JH:** I consider it my duty, my responsibility, to be a practice management expert and resource to emergency physicians so their practices will be financially successful. I have additionally always considered it a privilege to be an advocate for the specialty, be it in print, presentations, or payer negotiations. The bottom line is for us to absorb the business aspects of the specialty so the physicians can do what they went to medical school to do, and that is to

take care of patients. **GH:** I simply am the quarterback of an amazing team of 50-plus people in one of the nation's largest emergency medicine staffing companies, a subsidiary that does the billing and the back-office business operations with talented directors, managers, and staff. It's really my job to take the burden of all that nonclinical demand for success off of the clinicians' shoulders and to create and implement high-performing solutions in the areas of information technology, government compliance, third-party audits, third-party enrollment, coding, billing, cash collection, manage care negotiations, and fee schedule maintenance. **CE:** I feel like I have to keep reinventing myself. I own a very large technology coding and com-

pliance company. In order to do that and represent what we do to support our clients, which are hospitals, physicians, and payers and a little bit more of everything, I've never been able to step away from the sense that I have to know the details. I feel like in order to represent the priorities and potential solutions to our physicians and our clients, I really have to understand the issues, which keep changing all the time. I always feel like I have to be down in the weeds on things in order to understand them well enough to provide the right kind of consultation, the right kind of advice to our docs. 🍷

Reference

1. Wilson M, Cutler D. Emergency department profits are likely to continue as the affordable care act expands coverage. *Health Aff.* 2014;33:792-799.

presyncope or syncope. A systolic blood pressure \leq 90 mm Hg with a decrease of \geq 20 mm Hg occurred in 1.5% and 0.8% of the ADASUVE 10 mg and placebo groups, respectively. A diastolic blood pressure \leq 50 mm Hg with a decrease of \geq 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 \leq 90 mm Hg with a decrease of \geq 20 mm Hg occurred in 5.3% and 1.1% in the ADASUVE and placebo groups, respectively. A diastolic blood pressure \leq 50 mm Hg with a decrease of \geq 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



CMS Releases Physician Payment Data for the First Time Since 1979

WHILE THE MEDICARE PAYMENT DATA PROVIDE INSIGHTS INTO PAYMENT TRENDS, ANALYZING THE INFORMATION ISN'T EASY **BY KELLY APRIL TYRRELL**

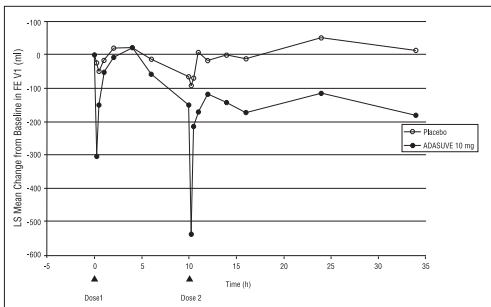
nebulizer) was administered to 23% of patients in the ADASUVE group; 8% of patients after the first dose and 21% of patients after the second dose, and to 15% of patients in the placebo group.

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

	Healthy Volunteer		Asthma		COPD	
	Placebo n (%)	ADASUVE 10 mg n (%)	Placebo n (%)	ADASUVE 10 mg n (%)	Placebo n (%)	ADASUVE 10 mg n (%)
After any Dose	N=26	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=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=17	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.poisson.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
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On April 9, 2014, the annual payments individual physicians receive from Medicare were made public by the Centers for Medicare & Medicaid Services. This data had been confidential since 1979, after the American Medical Association successfully sued the government to keep the payment amounts secret. *The Wall Street Journal* filed suit in 2011, seeking public release of the data, and after additional Freedom of Information Act requests, CMS announced it would be made public.

The data, released on the CMS website, detail the amount individual providers were reimbursed for Medicare Part B services in 2012 and are broken down by CPT code, procedure type, number of units, and average charge. But interpretation of the data is not straightforward, particularly for emergency physicians who provide an assortment of services to a variety of patients.

“Although transparency is important, this data has so many confounders, it’s hard to reach clear conclusions,” said Michael Granovsky, MD, FACEP, president of Logix-Health, a national ED billing company.

Challenges to Analysis

While the data certainly highlight outliers who may be worthy of investigation—for example, a Florida-based ophthalmologist received \$21 million from Medicare in 2012, according to the data, and he previously has been under investigation for Medicare fraud—additional details about the payments can provide important insights.

For instance, one of the highest-paid emergency physicians is credentialed in emergency medicine, yet most of his Medicare reimbursement was related to services performed at a vein clinic, the majority of which were endovenous laser procedures reimbursed at \$1,133 each. Medicare paid him more than \$1 million in 2012.

“The vein center services are not taking place in an ED and do not really have a direct relevance to ED care or costs,” said Dr. Granovsky. However, it’s there, embedded in the data along with everything else.

The CMS database includes more than 880,000 physicians with Medicare payments that rise as high as \$20 million. Of these, 37,000 are emergency physicians with Medicare reimbursements of a few hundred dollars to nearly \$2 million. Most range between a few tens of thousands to hundreds of thousands of dollars.

The wide discrepancy demonstrates that data alone do not tell the story.

“Typical ED groups receive annual Medicare reimbursement in the range of \$50,000 to \$80,000 per physician” said Dr. Granovsky,

who analyzed a subset of representative data.

Part of what throws the CMS data off are outliers like the doctor in the vein clinic, or the vascular surgeon who ranks as the highest-paid “ED” physician in the CMS dataset. Medicare paid him more than \$1.8 million in 2012. He is board certified in general surgery and vascular surgery, and the bulk of his payments came from the \$733,641 of complex femoral-popliteal artery revascularizations he performed. Few ED services contributed to his Medicare payments.

Upon the release of the CMS database, *The Wall Street Journal* and *The New York Times* quickly developed online tools to help people access the data and to provide perspective. The 9 million records included in the dataset can also be downloaded in text-delimited format from the CMS website as a .zip file that is 1.7 GB when uncompressed. It must be imported into a database or into statistical software; otherwise, the data is unwieldy, said Dr. Granovsky.

A disclaimer on the CMS website highlights that the data may not represent the full scope of a physician’s practice nor is it indicative of the quality of care provided or the health of a physician’s patient population. The data also do not provide a barometer for the necessity of the tests and procedures performed or whether they were effective.

Still, it can be difficult to reconcile the fact that seven doctors received more than \$10 million from Medicare in 2012 and 4,000 physicians were paid at least \$1 million. In addition, a quarter of doctors in the dataset were responsible for capturing more than a third of the \$77.4 billion in payments, and one in three of the top earners were ophthalmologists.

Radiation oncologists were also top earners on Medicare’s payroll. Fewer than 1,000 doctors within the specialty accounted for a total of \$1.1 billion in payments.

Applications to Emergency Medicine

Dr. Granovsky recommends all emergency physicians compare the CMS data to their own billing records; those who find themselves to be significant outliers should take a deeper dive into the data. According to *The Wall Street Journal*, regulators are scrutinizing high-paying codes, especially in places like the ED. Hospitals and health systems are also using the information to better understand how to limit and control high costs.

Payments to emergency physicians are confounded by multiple factors. Those who own urgent care centers might receive Medicare payments for hundreds of thousands of dollars, but most of it relates to medication costs and ancillary services in the urgent care center, not the traditional ED evaluation and management services most emergency physicians report.

Additionally, the CMS data do not capture some of the critical clinical factors that determine how much aggregate Medicare reimbursement emergency physicians will receive, like the volume of Medicare patients in the ED, the types of shifts the physicians work, and whether they are scheduled in the main department or fast track. It also doesn’t identify certain hospital charges that may impact billing.

“ED physicians provide services to the patients that their hospital treats based on that hospital’s individual profile and resources, such as being a trauma center and having interventional cardiology services,” said Dr.

A quarter of doctors captured more than a third of the \$77.4 billion in payments, and one in three of the top earners were ophthalmologists.

Granovsky. “If your hospital has a lot of specialty services, a large volume of Medicare patients will be seen, and they will be more complex.”

Even factors such as proximity of urgent care centers will filter out lower-acuity patients and result in a higher ratio of more complex

patients treated in the ED. Nearby nursing homes, too, can bring up the cost of providing care by simply contributing large volumes of patients.

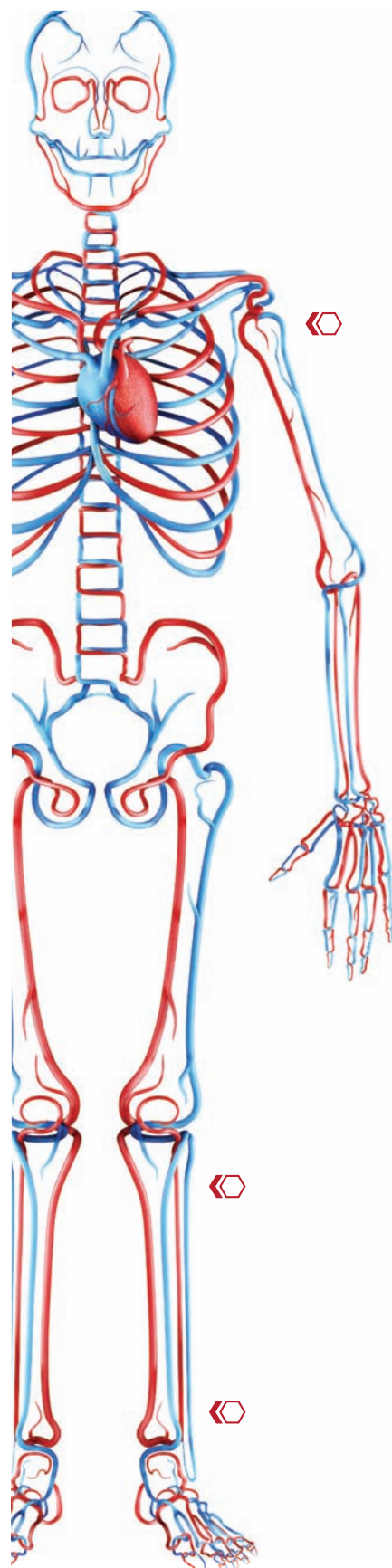
The data release comes amid ongoing debate over how to better control costs in the Medicare program and how to rein in unnec-

essary care while improving patient outcomes. Medicare spending is near \$600 billion annually, including payments to hospitals and physicians and costs for drugs. Cutting wasteful and fraudulent payments is one way to slow cost growth.

While the transparency intended by releasing the data might help some consumers choose which doctors they would like to see, when it comes to care in the ED, Dr. Granovsky is skeptical the information is useful for patients.

“I am not sure it is a valuable reference tool to help select an emergency department for care,” he said. ☺

KELLY APRIL TYRRELL is a freelance journalist based in Wilmington, Delaware.



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References: 1. Rogers JJ, Fox M, Miller LJ, Philbeck TE. Safety of intraosseous vascular access in the 21st century [WoCoVA abstract O-079]. *J Vasc Access*. 2012;13(2): 1A-40A. 2. Paxton JH, Knuth TE, Klausner HA. Proximal humerus intraosseous infusion: a preferred emergency venous access. *J Trauma*. 2009;67(3):1-7. 3. Cooper BR, Mahoney PF, Hodgetts TJ, Mellor A. Intra-osseous access (EZ-IO®) for resuscitation: UK military combat experience. *J R Army Med Corps*. 2007; 153(4):314-316. 4. Dolister M, Miller S, Borron S, et al. Intraosseous vascular access is safe, effective and costs less than central venous catheters for patients in the hospital setting [published online ahead of print January 3, 2013]. *J Vasc Access*. doi:10.5301/jva.5000130.

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THE ZOHYDRO ER AFFAIR

The conspiracy theory behind the drug approval

BY PAUL KIVELA, MD, MBA, FACEP

Whether you buy into a Food and Drug Administration conspiracy theory or not, there are many problems with the approval of Zohydro ER. Although there is certainly disagreement over the benefits and risks of the medication, almost everyone can agree that Zohydro is one the most controversial recent drug approvals by the FDA.

The opposition to the FDA's approval of Zohydro includes consumer groups, doctors, state and federal leaders, and multiple governmental organizations. FDA Commissioner Margaret Hamburg has received letters protesting the decision to approve Zohydro ER from at least 28 state attorneys general and multiple US senators. Massachusetts Gov. Deval Patrick and Vermont Gov. Peter Shumlin, issued directives to either ban or make it more difficult to prescribe and dispense the medication. Health insurers claim that opioid abuse costs more than \$70 billion a year in direct health care costs.

The potential conflicts involving Zohydro ER illustrate the involved process and complicated business operations and influence that the pharmaceutical industry might have on the approval process.

The Zohydro ER story centrally involves a company called Alkermes. This company owns a product called Vivitrol, an extended-release version of naltrexone that is given in a monthly injection to treat opioid dependence. The medication was supported by several very controversial studies and, in October 2010, was approved by the FDA to treat and prevent relapse in patients with opioid dependence who have undergone detoxification treatment. The product has had a very slow start and has failed to meet sales expectations.

In 2011, Alkermes purchased a part of another pharmaceutical company, Elan, that originally made Zohydro ER, and, with it, an exclusive marketing deal with a pharmaceutical company called Zogenix, which has the right to market the drug. Interestingly, Alkermes chose not to list Zohydro ER as one of its products and instead left the product under the Zogenix product line. Not surprisingly, many think it is a conflict of interest for Alkermes to have a product that treats opiate abuse as well as a product that has the potential to greatly increase opiate abuse.

In May 2012, a bipartisan Senate committee launched an investigation into the conflicts of interest and issued a series of subpoenas to various "consumer" groups, including the American Pain Foundation, University of Wisconsin Pain & Policy Studies Group, the American Pain Society, the Federation of State Medical Boards, and The Joint Commission. Within days, the American Pain Foundation shut down, and it was disclosed that the Federation of State Medical Boards commissioned the production of its *Responsible Opioid Prescribing—A Physician's Guide*

and other publications by the American Pain Foundation, which received 90 percent of its \$5 million in funding from pain medication manufacturers. Interestingly, the American Pain Foundation was very active in lobbying for greater pain medication use. In 2011, under investigation, Scott M. Fishman, MD, the main author of the pain guide and the past president of the American Pain Foundation, acknowledged that he had to add additional disclosures including honoraria from the pharmaceutical industry not previously disclosed.

The potential conflicts involving Zohydro ER illustrate the involved process and complicated business operations and influence that the pharmaceutical industry might have on the approval process.

In October 2013, the *Milwaukee Journal Sentinel* disclosed that the University of Rochester created two organizations: IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) and ACTION (Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks). Some alleged potential pay-to-play arrangements involving meetings between pharmaceutical industry representatives and FDA officials occurred with these organizations. Pharmaceutical industries allegedly paid between \$20,000 and \$35,000 to send one representative to a two-day meeting. Zohydro ER's original manufacturer may have participated in those meetings. Allegedly as a result of the meetings, the FDA approved a method, known as enriched enrollment, which allowed pharmaceutical companies doing pain studies to remove certain patients who did not respond well to a medication or could not tolerate it before the study began. This made it much easier

for pharmaceutical companies to prove their medications were safe and effective.

On March 10, 2014, several senators called for a special investigation into these pay-to-play allegations against several pharmaceutical companies, physicians, and FDA officials. Sen. Joe Manchin (D-WV) and Rep. Stephen Lynch (D-MA) introduced legislation to prohibit the FDA from approving similar drugs unless they are formulated to prevent abuse. Several Republican senators also demanded the FDA release safeguards to prevent abuse.

In March, Purdue Pharma announced it had developed a tamper-resistant version of its hydrocodone product for extended release. Interestingly, the company that markets Zohydro ER announced it will likely have a tamper-

proof version of Zohydro ER ready by 2016.

On April 15, 2014, a US District Court issued a preliminary injunction citing that the ban ordered by Massachusetts Gov. Patrick was unconstitutional.

The investigations are just beginning, and the controversy will undoubtedly continue. It is an unintended, and unfortunate, coincidence that Zohydro ER happens to have the word "ER" in it. ☺



DR. KIVELA is managing partner at Napa Valley Emergency Medical Group, medical director of Medic Ambulance, and part owner of Elan Medical Corporation. He is also the secretary-treasurer of the ACEP Board of Directors.



JUST SAY NO TO ZOHYDRO ER

The abuse potential of this new hydrocodone product makes it a possible contributor to the opioid misuse epidemic **BY FRANK LOVECCHIO, DO, MPH, FACEP**

Despite the United States encompassing just 5 percent of the world's population, it accounts for 84 percent of oxycodone (Oxycontin) and a whopping 99 percent of hydrocodone (Vicodin, Lortab) global consumption. Unfortunately, the prescription opiate epidemic is worsening.

New, Controversial Opioid Option

Since March 2014, patients and physicians have had a new option with a hydrocodone tablet, Zohydro ER (hydrocodone bitartrate). Hydrocodone (Zohydro ER's sole ingredient) is one of the most frequently prescribed and, unfortunately, abused opioids. One of the advantages of Zohydro ER is that the relief, or high, can last up to 12 hours per dose.¹ Zohydro ER is specifically indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Following Zohydro ER ingestion in pre-marketing studies, hydrocodone levels peak in five to six hours.

According to the package insert, the starting dose for patients who are not opioid tolerant is Zohydro ER 10 mg orally every 12 hours; this is the lowest dose. The package insert defines patients who are opioid tolerant (the target population) as those receiving, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, or an equianalgesic dose of another opioid.²

The presumed benefit of Zohydro ER—other than its strength—is that it doesn't contain acetaminophen, as do Vicodin and Percocet. It's on this basis that its maker, Zogenix, has argued that it's safer than the alternatives. Currently, there are other opiate painkillers on the market that don't contain acetaminophen. Current recommendations to minimize any risk of hepatotoxicity following chronic acetaminophen use resulted in the Food and Drug Administration recommending reducing the daily dose from 4 grams to 3 grams daily.

According to the Centers for Disease Control and Prevention, prescription opioid deaths have more than quadrupled since 1999. There were 4,030 deaths involving the drugs in 1999, compared with 16,651 in 2010. Therefore, why would the FDA approve Zohydro ER? A better question is, how they could not? If a drug meets FDA requirements, it must be approved if similar drugs have been approved. Zohydro ER could not be scapegoated simply by virtue

of being an opioid or for the "sins" of other opiates. Of the Zohydro ER approval process, Bob Rappaport, MD, director of the FDA's Division of Anesthesia, Analgesia, and Addiction Products, said, "We are obligated at the agency to operate within the regulatory framework, and that includes providing a level playing field for industry. We don't have a choice by that. It's the law."³

Zohydro ER has been heavily criticized for lacking safeguards that would diminish abuse potential. In its current form, Zohydro ER can be easily crushed, snorted, or injected. Zohydro ER is only currently available in capsule form; hence, it can easily be opened, making pure hydrocodone available. Critics of the drug's approval suggest that it should have included an "abuse-deterrent" formulation, such as additives like naloxone or niacin that

cause unwanted side effects when the drug is snorted or injected but are tolerable when taken orally as prescribed. Zohydro ER does not contain any ingredients that would safeguard against abuse. In the companies' defense, these additives seem logical but have not been a proven deterrent to abuse.

Purdue Pharma, the maker of Oxycontin, has completed testing of an abuse-resistant version of the painkiller hydrocodone. Purdue Pharma says it plans to submit its extended-release hydrocodone drug to the FDA in late 2014. It will be interesting to see if clinicians adopt this potentially safer formulation.⁴

What's a Physician to Do?

As a practicing toxicologist, I err on the side of caution with adopting newer potent opiates. For example, this drug is potentially so potent that an opiate-naïve patient could die of an overdose from just two to four pills and a toddler from one capsule. Following overdose or accidental ingestion, it is prudent for patients to undergo an extended observation period. In my opinion, such patients should be observed at least 12 hours, assuming no naloxone was used, until future data are collected.

In summary, the FDA approved Zohydro ER for the management of pain severe enough to

require daily, around-the-clock long-term opioid treatment and for which alternative treatment options are inadequate. At least initially, if you prescribe this drug, be aware of this indication. Be aware that the peak may not occur for six hours in "normal" patients in "ideal" circumstances. Be aware that Zohydro ER is metabolized via P450 interactions P450 3A4, and drugs such as macrolides orazole antifungals that inhibit this cytochrome may increase hydrocodone levels. Be aware that ethanol and other CNS depressants potentiate the effect. Be aware that clearance is altered, namely decreased in patients with hepatic and renal disease (not further identified). An FDA-approved patient medication guide, which is available with the product information and can be accessed at www.fda.gov/downloads/Drugs/DrugSafety/UCM374009.pdf, must be dispensed with this medication. Currently, it is approved as a Schedule II drug and can only be dispensed through a physician's written prescription, and no refills are allowed. There are also stringent recordkeeping, reporting, and physical security requirements for Schedule II controlled substances. Considering the risk-benefit ratio, is this too much to be aware of for one drug?

Patients and physicians want better pain relief and improved patient satisfaction. Mandates warrant "significant decreases in pain scores," further increasing the demand for a drug such as Zohydro ER. Logically, drug companies will increase supply based on demand. Regulations, lobbying, restrictions, and patient and physician education may decrease the demand for opioids. As individuals, and hopefully as a group, the simplest way for us to decrease demand for Zohydro ER and similar products is not to prescribe them. In conclusion, until further data are available—especially addressing post-marketing safety—it is best to "say no to Zohydro" in the ED. ☛

DR. LOVECCHIO is vice chair and research director at the Maricopa Medical Center in Phoenix, professor of emergency medicine, pharmacology, and medicine at the University of Arizona College of Medicine in Tucson, and co-medical director of the Banner Good Samaritan Poison & Drug Information Center.

References

1. Rauck RL, Nalamachu S, Wild JE, et al. Single-entity hydrocodone extended-release capsules in opioid-tolerant subjects with moderate-to-severe chronic low back pain: a randomized double-blind, placebo-controlled study. *Pain Med*. 2014 Feb 12. [Epub ahead of print]
2. Zohydro ER package insert. Zogenix Web site. Available at: www.zogenix.com/pdf/ZohydroER_PI_FI-NAL_102513.pdf. Accessed May 12, 2014.
3. Ramin CJ. Why did the FDA approve a new pain drug? *The New Yorker*. Dec. 3, 2013. Available at: <http://www.newyorker.com/online/blogs/currency/2013/12/zohydro-why-did-the-fda-approve-a-new-pain-drug.html>. Accessed May 12, 2014.
4. Associated Press. Abuse-resistant hydrocodone could sink sales of new drug. *New York Times*. March 12, 2014. Available at: www.nytimes.com/2014/03/13/business/abuse-resistant-hydrocodone-could-sink-sales-of-new-drug.html?src=recg&_r=0. Accessed May 12, 2014.

NEWS

Congress Questioning Ethics Behind FDA Zohydro Approval

Recent hydrocodone opioid approval raises concerns

BY JESSICA KINSELLA

The FDA's approval of the hydrocodone drug Zohydro ER has been met with criticism from health care professionals and lawmakers alike, and members of Congress, including Rosa DeLauro (D-CT), Harold Rogers (R-KY) and Stephen Lynch (D-MA), have requested an investigation into the matter from the Office of the Inspector General.

Zohydro ER, approved in October 2013, contains five to 10 times more hydrocodone than any other drug on the market and lacks safeguards to prevent immediate release through the snorting or injecting of the drug's easy-to-crush form. The FDA's Anesthetic and Analgesic Drug Products Advisor Committee displayed overwhelming opposition to Zohydro ER, with an 11-2 vote against its approval. This recommendation, combined with efforts to reclassify hydrocodone from a Schedule III drug to a Schedule II drug, has led many members of Congress to question why Zohydro ER was approved at all.

Media sources, including Milwaukee's *Journal Sentinel* and *The Washington Post*, claim that pharmaceutical companies influenced FDA officials during their participation in pay-to-play initiatives set up by professors at the University of Rochester and the University of Washington. Opioid misuse is becoming more frequent across the United States, with opioid overdoses accounting for an average of 15,000 deaths per year. In an effort to reduce opioid misuse, Massachusetts attempted to ban the sale of Zohydro ER, although a federal judge denied the request.

Congressional leaders are not the only ones taking notice of Zohydro ER's controversial approval; many emergency physicians are aware of the questions surrounding the new prescription painkiller. While the investigation into Zohydro ER's approval continues, it is up to individual emergency physicians to choose whether they prescribe the controversial drug or not.

—Jessica Kinsella is a writer based in Hoboken, New Jersey.

SILVER SCREEN GOES CODE BLACK

CONTINUED FROM PAGE 1

in LA County's institutional disaster plan, one which stands for a 30-hour wait in the emergency department and no beds upstairs. *Code Black* was the norm in the country's busiest ED at the time of the filming, so Dr. McGarry had his hands full learning the medicine, producing the documentary, and trying to maintain a personal life.

Code Black has astonished film festival attendees, winning awards at the Los Angeles Film Festival, the Aspen Filmfest, the Starz Denver Film Festival, and the Hamptons International Film Festival, along with a special recognition at the Vancouver International Film Festival. Emergency physicians and laypeople alike may experience the difficulties and triumphs of being an emergency medicine resident in one of the nation's busiest EDs, illustrating how difficult and challenging this environment really is. The film gives the real-world view from the inside, hopefully capturing the hearts and minds of those who know little about the safety net of our health care system yet are always reliant on its existence. *Code Black* will be premiering June 20th in New York City at the IFC Center. In July and August, it will be released in 40 cities throughout the United States.

Dr. McGarry, who wrote and directed *Code Black*, recently sat down with *ACEP Now's* medical editor in chief, Kevin M. Klauer, DO, EJD, FACEP, to talk about the process of making the movie and what he hopes to accomplish with the film. ☺

FRANCESCA BARATTA is a freelance writer based in New Jersey.

KK: Give us an overview of *Code Black*.

RM: *Code Black* is a feature documentary film that I directed and was released to the film festivals in 2013. The film asks the questions: If you signed up to be a doctor today, and you came in with expectations for how you wanted to practice medicine, how long would it take before the greater system and the ideas of billing, profit, regulation, documentation, and medical legal practice start to chip away at those ideals? How are you going to protect them? And, once they are threatened, how do you fight back?

KK: When did you have the epiphany that "I'm qualified to do this, and this story has to be told"?

RM: I can speak to the filmmaking qualifications first: I had none. I considered an MSA in film school, but I declined that on the notion that if I did want to pursue filmmaking someday, I'd have a lot more access to the human condition as a physician than as a film student. The documentary really formed itself when I was a rotating medical student at USC. I was with the old LA General hospital and in the middle of this special area of the ER called C-Booth. I was struck by the intensity of that space. I wanted to know, "Why does intensity matter?" And my answer is that intensity shows us priorities. We found that physicians and health care staff find nostalgia in that notion of "remember when you were just a training doc and your biggest priority was patient care." I miss that most basic of concerns. Now I'm worried about the right RVUs, statisticians, documents, and Press Ganey.

KK: Does it come out in the documentary that you were focused on care, but you lost focus because of all the regulatory red tape?

RM: That's a major theme. The three acts of the film mirror how an emergency medicine physician might mature along the way, especially in a big, busy trauma center. When physicians watch it, they grasp onto that. When laypeople watch it, I think they start to say, "I didn't realize that this is going on. Why is the system so focused on not us and not my doctor?"

KK: Who's working with you on this project?

RM: In the first days of the project, we had the support of some of the USC faculty: Drs. Ed Newton, Billy Mallon, Jan Shoenberger, and Diku Mandavia, along with the hospital administration and the LA County Board of Supervisors. Beyond that, there was the filmmaking world: Mark Jonathan Harris, who's a three-time Academy Award winner in documentary film, and Marti Noxon, who scripted for *ER*.



PHOTOS FROM CODE BLACK

Top to bottom: Danny Cheng, MD, and Jaime Eng, MD, (at left) with patient; Dave Pomeranz, MD, Ryan McGarry, MD, and Billy Mallon, MD, at bedside; Jamie Eng, MD, with patient; C-Booth at LA County Hospital.

KK: Do you think you'll make another film?

RM: [The market research] says that a part two with just Billy Mallon might sell really well! As far as *Code Black* part two, we've probably said enough on this topic in the feature.

KK: How did it affect your personal life?

RM: It was significant. I didn't expect to make a film as a resident. It was three years of no vacation, and any day off I had went toward this effort. The goal of residency is to learn how to be a proficient physician, and I had to be careful in order to assure that the film could never be more important than that. I have to thank every one of my classmates and my program director for a lot of support along the way, whether for last-minute trades or just the ability to take a 20-minute nap on a shift. Even still...residency by default should consume you, and filmmaking by default should consume you. You put them together at the same time, and there's going to be some fallout.

KK: Do you regret the decisions you've made?

RM: I regret allowing the pressure to dictate how I acted and how I thought. I certainly don't



regret making *Code Black* at the time that I did. One thing that I feel very lucky to have experienced is nonmedical people sitting through some pretty tough stuff in cases we show, and at the end of the film people give us a standing ovation. I wish I could share that with every physician, nurse, and X-ray tech who leaves a really tough shift.

KK: Is this just a venture of altruism, or is there the potential for you to have some well-deserved financial benefit?

RM: It takes in the low seven figures to produce a film of this scope. Nobody makes a buck off of documentaries. Your best-case scenario is that you break even and that you change how people think.

“At the end of the film people give us a standing ovation. I wish I could share that with every physician, nurse, and X-ray tech who leaves a really tough shift.”

—RYAN MCGARRY, MD, Director of *CODE BLACK*

KK: Roughly, what does it take to produce a documentary like this?

RM: The film is supported by SonoSite Fuji-Film. We made an agreement with them that said in exchange for private support for the production, we would make a true story about the challenges of the front lines—and the sponsor did this without any control with regards to creative oversight or required brand placement. We went through 16 cuts on *Code Black*. For a documentary, you're building an essay from a vast vocabulary of footage that exists as a library in volume. So you have an editor, an assistant editor, an archivist, a sound designer, a sound mixer, a color corrector, and, of course, all of the producers it takes to make a documentary.

KK: I think it can change perspectives a great deal about what emergency medicine is. I hope that you have a successful career as a director, and I hope we don't lose you from emergency medicine too soon because of it.

RM: I wouldn't give up my shifts for anything. I've met Academy Award winners who would love to have the ability to bridge their time in between projects with intermediate employment but don't have the opportunity to do what we do. It really gives that crowd an entirely different perspective when they're worried about a publicist or a new script and you're saying, "You know, I just helped save a life." It'd be crazy to ever give up on that investment because it's really a gift. ☺

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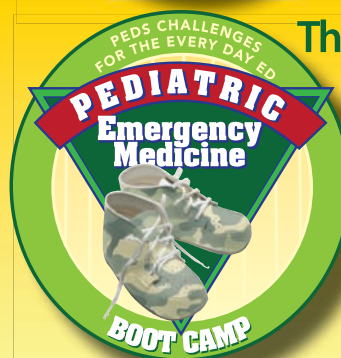
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Critical Mass

A decrease in public mental health spending is raising concerns over adequate patient care **BY JACKIE KITCHEN, MD**

The availability of inpatient psychiatric care has worsened significantly and progressively over the past four years on state and national levels. As inpatient psychiatric beds have become increasingly scarce, the number of patients seeking or requiring psychiatric assistance has also increased. These patients are spending increased time “boarding” in emergency departments, and with beds scarce and increasingly far afield, many require transfer to facilities many miles away. In the meantime, emergency physicians and other emergency department personnel must dedicate significant time and resources to not only searching for placement, but also attending to patients’ needs while ensuring the safety of both patients and departmental staff for the duration of patients’ ED stays. This leads to increased throughput times for other patients, a frightening environment for delivering care, patient safety issues, and decreased satisfaction for patients and providers.

A brief review of the literature and national statistics on mental health care confirms what most of us already know from experience: the number of inpatient psychiatric beds nationally falls woefully short of what is necessary to meet current demand. The Treatment Advocacy Center recommends that each state should have 50 public inpatient psychiatric beds for every 100,000 people in a state’s population.¹



According to the ACEP 2014 State-by-State Report Card, only three states (Mississippi, Missouri, and Arkansas) hit this target number, while 31 states had 50 percent or fewer of the target number of beds.² Unfortunately, there is little hope for improvement in these numbers as state budgets continue to cut billions of dollars from public mental health spending.

The problem of the inadequate supply of inpatient psychiatric beds affects both psychiatric patients and emergency providers. The external stimuli associated

with the busy emergency department environment have been shown to increase patient anxiety and agitation, leading to increased risk of symptom exacerbation or elopement of patients seeking treatment for mental health or substance abuse issues, which poses a danger to patients and staff.³ Elopement before screening and treatment is dangerous and leads to increased risk of self-harm and suicide.⁴

Furthermore, the need for increased security and additional ancillary staff to monitor and protect these patients, emergency

department staff, and other patients leads to increased labor costs.³ Additionally, the significant number of resources and personnel required to provide adequate care for these patients for extended periods may lead to delays in care of other ED patients. Poor clinical outcomes and increased morbidity and mortality have been directly linked to ED overcrowding and a lack of available ED beds.^{5,6}

The financial impact of boarding these patients is profound. A recent study at Wake Forest University Health Sciences Center found admitted psychiatric patients are associated with a 40 percent decrease in average physician reimbursement as compared to nonpsychiatric patients. Furthermore, the increased length of stay for each of these patients was determined to prevent the ED from caring for an additional 2.2 patients, leading to an overall financial loss to the system of approximately \$2,400 per boarded psychiatric patient.³

The effects of budget cuts to public mental health care can be felt at the ground level in many emergency departments across the nation. Per the ACEP State-by-State Report Card, Iowa ranks 16th in the nation in number of psychiatric inpatient at 28 beds per 100,000 population. Although I work at the state’s only tertiary referral hospital, we lack sufficient psychiatric beds for our needs and are frequently forced to transfer patients to other facilities. We recently conducted a review of patient records for

Emergency Departments as Mental Health Safety Nets: In Need of Creative Solutions

A shortage of psychiatric beds is leading to access issues in emergency departments across the country

With fewer places left to turn, patients in need of mental health services are increasingly flocking to emergency departments across the country.

But in EDs, mental health patients are diverting attention from medical patients, tying up emergency beds for days while awaiting inpatient or community beds. They also are at increased risk of poor outcomes due to care that is delivered in a less-appropriate setting.

Nationally, there are an average of 26.1 psychiatric beds per 100,000 people, according to ACEP’s 2014 Report Card. Meanwhile, the National Alliance on Mental Illness reports 61 million Americans experience mental illness each year, but state funding for mental health continues to drop. From 2009 to 2012, states cut \$1.6 billion in funding, a decrease of 10 percent.

Recently, the shortage of psychiatric beds contributed to an overall D+ grade on ACEP’s 2014 Report Card on Emergency Medicine, which ranked access to care more heavily than any other measure.

“We can do emergent care, stabilize individuals, but people need to get to the appropriate places to get the appropriate care,” said Jon Mark Hirshon, MD, MPH,

PhD, FACEP, associate professor in the Department of Emergency Medicine at the National Study Center for Trauma and Emergency Medical Systems in Baltimore and the Report Card Task Force chair.

For instance, late last year, Virginia State Sen. Creigh Deeds was repeatedly stabbed by his 24-year-old son, who then fatally turned a gun on himself. Deeds’ son received an emergency mental health evaluation the day before the incident, but he was released when no psychiatric bed could be found for him.

These problems don’t typically start in the ED. Instead, they are symptomatic of larger flaws within the health care system. Dr. Hirshon recently testified at a Congressional hearing meant to address the psychiatric bed shortage.

Within two hours of the start of a recent shift, ACEP President-Elect Michael Gerardi, MD, FAAP, FACEP, an emergency physician at Morristown Medical Center and Goryeb Children’s Hospital, both in Morristown, New Jersey, had already evaluated four psychiatric patients.

He expected at least one of them would board in the ED for two or three days. In addition to a shortage

of available beds and staff, he said hospitals are often reluctant to admit patients whose insurance may not pay for mental health.

This situation places EDs and hospitals at odds. EDs must treat every patient who comes through the doors. Hospitals are not bound by the same code. Dr. Gerardi is waiting to see if the Affordable Care Act changes the game.

Dr. Hirshon said some of his colleagues report that patients have boarded between two weeks and 42 days in the ED. He said it’s going to take creative solutions to solve this problem.

Nationwide, a 2008 ACEP survey showed that 99 percent of emergency physicians admit psychiatric patients each week, and nearly 80 percent report psychiatric patients are boarded in the ED.

“I think no single source is going to have all the answers,” Dr. Hirshon said. “The ED is a spot that works 24-7, 365 days a week and we’re there to help people...Our mission is to help people, but that’s problematic when they have needs that are above and beyond what we have in the ED.”

KELLY APRIL TYRRELL is a freelance journalist based in Wilmington, Delaware.

By Kelly April Tyrrell

all psychiatric patients transferred out of the University of Iowa Hospitals and Clinics (UIHC) for 2010–2013. The average length of stay for psychiatric patients requiring transfer out of our ED more than doubled in that time (from 5.6 hours in 2010 to 13.8 hours in 2013). It is not unusual for patients to wait more than 24 hours in the ED while providers attempt to locate an available psychiatric bed.

The primary problem is inadequate funding. The recent economic downturn forced states to cut approximately \$4.35 billion in public mental health spending in the period between 2009–2012, the largest reduction since deinstitutionalization in the 1960s.⁷ According to Steve Blanchard, the department administrator of UIHC Psychiatry, most hospitals run their inpatient psychiatric units at a deficit. Due to the chronic, disabling nature of mental illness, many patients seek care with coverage through government payers, which generally pay below cost. Duration of stay in an acute inpatient setting may be lengthened due to the inadequacy of outpatient community resources. In Iowa, the supply of inpatient psychiatric beds has continued to decline as inpatient facilities close due to lack of funding and retirement or exodus of Iowa psychiatrists to states with better reimbursement and more support staff. The problem of the inadequate supply of

beds is exacerbated by the poor distribution of beds; many rural areas have no access to services. UIHC recently had a patient remain on one of the acute inpatient psychiatric units for 442 days because it was nearly impossible to locate a community-based option that could accept the patient, despite contacting more than 100 facilities.

While some of these problems may be specific to Iowa, they are symptomatic of the larger national crisis of lack of adequate mental health care. In the absence of promises for increased funding for mental health from state or federal sources, alternative solutions should be pursued. For example, telepsych, or the remote psychiatric evaluation, is one alternative being piloted at UIHC. Additionally, low-cost collaboration between EDs and community outpatient alternatives has been shown to decrease emergency department boarding.⁸ This collaboration could include using mental health clinicians to train ED staff in the management and care of patients with serious mental illnesses or having a social worker in the ED who can connect patients with community services at the time of discharge. The involvement of law enforcement may help. Federal grants of up to \$250,000 over two years are available for the planning, implementation, or expansion of collaborative programs between criminal justice and

In the absence of the promises for increased funding for mental health from state or federal sources, alternative solutions should be pursued.

mental health partners, including specialized training of law enforcement officers.

As emergency care providers, whether in rural Iowa or inner-city New York, we are all impacted by the shortage of inpatient psychiatric beds. Cost, quality of care, ED throughput, and patient safety are all negatively impacted by this crisis. Solutions, such as collaborating with community mental health services, educating ED staff about the management of the boarding mental health patient, and using

telemedicine are all viable strategies that will protect a subset of ED patients who often cannot advocate for themselves. ☛


References

1. Torrey EF, Entsminger K, Geller J, et al. The shortage of public hospital beds for mentally ill persons. Arlington, Va: Treatment Advocacy Center; 2008.
2. ACEP. America's emergency care environment: A state-by-state report card 2014. Available at: www.emreportcard.org/uploadedFiles/EMReportCard2014.pdf.
3. Nicks BA, Manthey DM. The impact of psychiatric patient boarding in emergency departments. *Emerg Med Int*. 2012;2012:360306.
4. Hickey L, Hawton K, Fagg J, Weitzel H. Deliberate self-harm patients who leave the accident and emergency department without a psychiatric assessment: a neglected population at risk of suicide. *J Psychosomatic Res*. 2001;50(2):87-93.
5. Richardson DB. Increase in patient mortality at 10 days associated with emergency department overcrowding. *Med J Aust*. 2006;184(5):213-216.
6. Sprivilis PC, Da Silva JA, Jacobs IG, et al. The association between hospital overcrowding and mortality among patients admitted via Western Australian emergency departments. *Med J Aust*. 2006;184(5):208-212.
7. Glover RW, Miller J, Sadowski S. Proceedings on the state budget crisis and behavioral health treatment gap: The impact of public substance abuse and mental health treatment systems. Special Congressional Briefing; March 22, 2012.
8. Alakeson V, Pande N, Ludwig M. A plan to reduce emergency room 'boarding' of psychiatric patients. *Health Affairs*. 2010; 29(9): 1637-1642.

DR. KITCHEN is an emergency physician resident R2 at the University of Iowa Hospital and Clinics in Iowa City.

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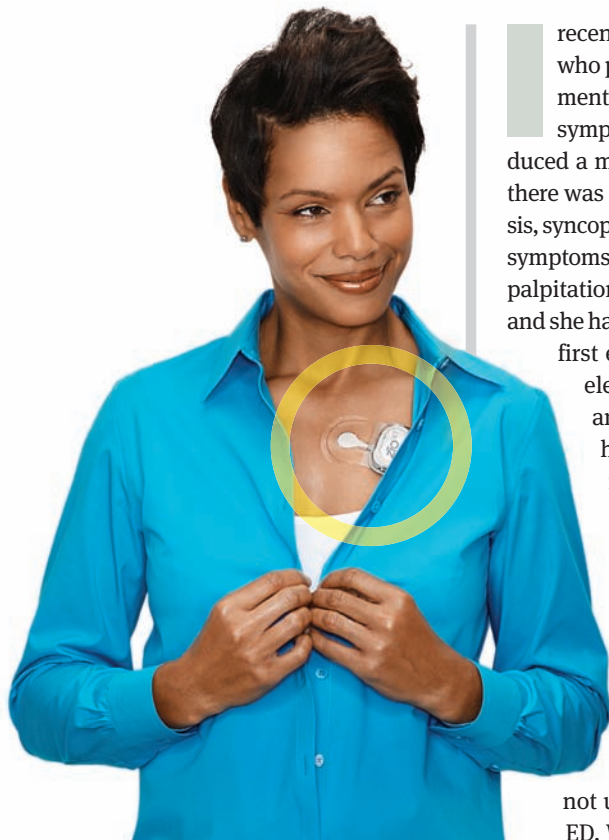
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Just a Patch or a Real Monitoring Solution?

ZIO XT Patch cardiac monitoring device may be a good option for monitoring possible dysrhythmias

BY AMAL MATTU, MD, FACEP



I recently cared for a 35-year-old woman who presented to the emergency department for evaluation of palpitations. The symptoms lasted for 10 minutes and produced a mild sense of lightheadedness, but there was no chest pain, dyspnea, diaphoresis, syncope, or other typical cardiopulmonary symptoms. The patient reported that she had palpitations a few times in the prior month, and she had presented to another ED after the first episode. At that time, she had an electrocardiogram that was normal, and she had no further workup. She had no other medical problems, took no medications, and had no primary care physician. I was unable to identify any precipitants for the palpitations: no recent changes in diet, medications, illicit drug use, or stress and no use of tobacco, stimulants, or alcohol. Her physical exam, ECG, and electrolytes were completely normal.

The patient I described is not unusual to anyone working in the ED. We often see patients like this and

A major question comes to mind as I consider the future use of this device: given the potential for widespread availability of the device, will the ZIO XT Patch become yet another overused test in very low- or no-risk populations?

debate the management. Given the absence of significant cardiopulmonary complaints, it would be difficult to justify admission, and even a 24-hour ED observation for cardiac monitoring is likely to be low-yield given the infrequency of her symptoms. My normal approach to this patient would be to recommend that she see her primary care physician or a cardiologist within a day for placement of a Holter monitor or event monitor, but given her lack of a primary care physician and the difficulty of obtaining a rapid appointment within our crowded system, I knew that I was not going to be able to help this patient find a quick diagnosis and treatment.

A Possible Solution?

A solution for scenarios like this may be on the way. The ZIO XT Patch is a single-channel continuous-recording ECG monitor, available by prescription, that can be worn up to 14 days by patients being evaluated for possible cardiac dysrhythmias. As stated in the product manual, "it is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, presyncope, syncope, fatigue, or anxiety." There are no contraindications to its use.

The ZIO XT Patch is applied against the left chest using a simple adhesive and fits under normal clothing (the device is approximately 5 inches x 2 inches with a central button that is one-half-inch raised, and it weighs 24.5 grams). It can be worn all day and night and is waterproof, although water exposure should be minimized whenever possible. The device continuously monitors the heart rhythm, but if the patient feels symptoms, a central button can be pressed to mark the recording. At the end of the 14 days, the patient removes the

device and mails it in a prepackaged box to a testing facility in Illinois or California, where the rhythm is analyzed and interpreted. Initial cost estimates are less than \$200.

Research Results

Early studies on this device have been very optimistic (although readers must always consider the usual publication bias toward positive studies with new devices). A notable recent study in the *Western Journal of Emergency Medicine* evaluated 174 patients who had presented to the ED with symptoms of possible cardiac dysrhythmias, most commonly palpitations.¹ At the time of discharge, the ZIO XT Patch was applied and worn for up to 14 days or until the patient had symptoms to trigger an event. The overall diagnostic yield for detection of a dysrhythmia was 63 percent. Almost half the patients (48 percent) were noted to have at least one significant dysrhythmia event, defined as ventricular tachycardia, paroxysmal atrial fibrillation, supraventricular tachycardia, ≥3 second pause, Mobitz II, third-degree AV block, or symptomatic bradycardia. Of note, only 10 percent of patients with significant dysrhythmias were symptomatic at the time of their dysrhythmia, suggesting that traditional event recorders, which rely on patients' recognition of symptoms, would have failed to detect these episodes. Equally important was the finding that 53 percent of symptomatic patients did not have any dysrhythmias during their triggered events, indicating a non-dysrhythmic cause of symptoms. The median time to first detection of dysrhythmia was one day (interquartile range 0.2–2.8 days), and the median time to first symptomatic event was 1.5 days (interquartile range 0.4–6.7 days), suggesting that traditional 48-hour Holter monitors would have detected a majority, but not all, of the dysrhythmias.

The ZIO XT Patch offers a promising alternative to Holter or event monitors for the outpatient evaluation of patients with possible dysrhythmias. However, a major question comes to mind as I consider the future use of this device: given the potential for widespread availability of the device, will the ZIO XT Patch become yet another overused test in very low- or no-risk populations? If this occurs, we'll undoubtedly encounter an explosion of false-positive results, which could lead to further unnecessary testing and procedures. We've already seen this occur with other diagnostic tests, including the D-dimer, cardiac stress tests, the highly sensitive troponins, and coronary CT angiograms. I look forward to reading further studies on this device and hearing the debates that will certainly follow. ☺

Reference

1. Schreiber D, Sattar A, Drigalla D, et al. Ambulatory cardiac monitoring for discharged emergency department patients with possible cardiac arrhythmias. *West J Emerg Med*. 2014;15:194-198.

DR. MATTU is professor and vice chair of the Department of Emergency Medicine and director of the Emergency Cardiology Fellowship at the University of Maryland School of Medicine in Baltimore.



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DR. LEVITAN is an adjunct professor of emergency medicine at Dartmouth's Geisel School of Medicine in Hanover, N.H., and a visiting professor of emergency medicine at the University of Maryland in Baltimore. He works clinically at a critical care access hospital in rural New Hampshire and teaches cadaveric and fiber-optic airway courses.



DR. ASKEN is a clinical, health, and performance psychologist in Pennsylvania, and serves as an instructor and consultant for several national and regional organizations. He is a fellow of the Division of Health Psychology of the American Psychological Association.

The Conspiracy of Stress: Part 1

Above 115 heartbeats per minute, fine motor control is compromised. Above 145, gross motor control is affected.

by RICHARD M. LEVITAN, MD, FACEP, AND MICHAEL ASKEN, PHD

"Too much time is dedicated to the acquisition of technique and too little to the preparation of the individual for participation."

—Bruce Lee, martial artist, actor, director

"The probability that the total system will perform correctly is the probability that the hardware/software will perform correctly, times the probability that the operating environment will not degrade the system operation, times the probability that the user will perform correctly. By defining total system this way, human performance is identified as a component of the system."

—FAA System Safety Handbook, Chapter 17: Human Factors Principles & Practices (2000)

In many instances, the "difficult airway" is a relative term—relative to the operator. Early in my career, I recall missing an intubation. I panicked and called an anesthesiologist. Picking up the same instrument, she inserted the tracheal tube without difficulty. It would have made me feel much better if she struggled with the tube, but alas, she made it look easy. For some time, I wondered what I did wrong and what she did right.

Twenty years later, I was able to successfully intubate a patient in whom anesthesia missed the tube. The patient was shot in the central box; anesthesia had placed a tube, but by direct visualization of the lungs (thoracotomy in progress), it was clear the tube was not in the trachea. I picked up the same laryngoscope, came down the tongue, suctioned the mouth, identified the epiglottis, and intubated the patient as if it were easy.

Looking back on my multidecade obsession with the techniques of airway management, I realize in hindsight how much the individual's mindset is critical to successful performance in crisis.

Proper techniques are essential:



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patient positioning, the mechanics of mouth opening, epiglottoscopy (finding the epiglottis before making any attempt to expose the larynx), understanding the subtleties of epiglottis elevation, knowing laryngeal anatomy (even when partially viewed), and the nuances of tube insertion.

The operator's mindset, however, is what allows for the proper application of techniques in the moment of crisis. It is one thing to know how something should be done but quite another to actually then pull it off in the real life-and-death, high-pressure situation. Related to the ultimate stress—fear—the Spartan commander Brasidas observed: "Fear makes men forget, and skill which cannot fight is useless."

Fear Is the Mind Killer

We each have a genetic disposition to handle stress. Looking back at my initial years in emergency medicine, I now understand that my inherent adrenaline response made it very difficult for me to perform well. I got too stressed, and the adrenaline dump that ensued made it very difficult for me.

Like everyone I know in EM, I was never given psychological performance skills to maximize my response in crisis situations. I just assumed, and was led to believe

by my teachers, that through some kind of desensitization, I would just get better. Over decades of practice I did improve, but recent interactions I have had with military personnel have now convinced me that we can train to do better by directly confronting the gorilla in the room and addressing the psychological aspects of procedural performance.

I am so convinced of this that I have added a psychologist, Michael Asken, PhD, my co-author on this article, to the faculty of my airway course in Baltimore. I now view every component of airway management with a different perspective. I think about how stress conspires to make us fail and how it must be handled at each step in the process.

"Fear is like fire. It can cook for you. It can heat your house. Or it can burn you down."

—Cus D'Amato, boxing manager, trainer

Adrenaline increases our heart rate, dilates our blood vessels, and widens our pupils; it gets us ready for the increased physical demands of a fight-or-flight situation. Excess adrenaline, however, becomes very dangerous, especially when we are required to perform complex

tasks (as opposed to just running away from a predator). In the procedural performance situation, the mismatch between the perceived demands of a task and one's perceived abilities creates "performance stress." When the mismatch is dramatic, the adrenal dump that occurs becomes detrimental. Above 115 heartbeats per minute, fine motor control is compromised. Above 145, gross motor control is affected. Time perception gets altered. Our ability to appreciate external cues (ie, listening, accurately observing the situation) becomes limited. Frozen by the stress, operators become "stuck on stupid," repeating the same response over and over (even though it's not working). The Brits jokingly refer to this as "wearing brown trousers" because in superstressful situations bowel control is compromised. Tactical operators emphasize the importance of the "battle crap" before beginning a mission. At a recent conference in Australia, I heard an EM doc refer to using bike clips with their brown trousers—now that's stressed!

While it was once believed that crisis functioning or mental toughness (the right stuff) was something that you either had or did not have, we now know this is not the case. The military, professional and Olympic athletes, and police agencies have all recognized this and created psychological training programs to maximize performance in high-stress and life-threatening situations. Emergency medicine has lagged far behind in this critical area.

In the procedural performance challenge of emergency airway management, what can we do to manage our stress appropriately? We need to have the right mindset. By adjusting our perceptions (perceived demands versus abilities), we can reduce our overall performance stress. We need to consider and design our procedural (and team) processes in ways that recognize operator stress as a risk factor for error. When actually performing the procedures, we should factor in mechanics, ergonomics, lighting, and other environmental variables so we can do our best. We will address these solutions in future columns. ☺



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

EDs, Clean Up Your Act

by SHARI WELCH, MD, FACEP

One of the most commonly observed features of the practice of emergency medicine is that workflow depends upon access to many and varying supplies. In any emergency department anywhere in the country right at this moment, myriad staff members (including physicians) can be observed scurrying around their departments, searching for and gathering the supplies necessary for treating the next patient. Most EDs tolerate a level of clutter and disorganization that most providers would not tolerate in their own homes.

Kaizen is a Japanese workplace philosophy that means “improvement” and focuses on making small continual improvements that keep a business at the top of its field. The philosophy involves everyone in the organization, managers and leaders and workers alike, and urges them to make never-ending efforts for improvement. The foundation for *Kaizen* was laid after World War II when the country was attempting to rebuild infrastructure and rethink many systems. American leaders like W. Edwards Deming and Joseph Juran came to Japan to lecture and teach, and this led to the Training Within Industry (TWI) programs, which subsequently gave way to *Kaizen* in the 1950s. The philosophy has been central to the cultures of companies like Toyota and Canon, where suggestions are regularly solicited from each employee, written down, shared, and implemented.

Kaizen has five key principles:

- 1) There is heavy reliance on **teamwork**. Everyone’s opinion is valued and considered.
- 2) Workers have a **strong personal discipline**, and morale must improve under *Kaizen*.
- 3) Workers should be **confident about offering suggestions**, even when a system is already functioning adequately.
- 4) *Kaizen* recognizes that there is **always room for improvement**.
- 5) The system uses **worker groups** (also called quality circles) that meet and work together to both solve problems and come up with innovations.

This improvement model would seem particularly appropriate in the emergency department, which has many parallels to factory-floor processes. In emergency medicine,



Left: One of Baylor Regional Medical Center at Plano’s ED carts.

Above: Organization system for airway supplies.

The foundation for *Kaizen* was laid after World War II when the country was attempting to rebuild infrastructure and rethink many systems.

our product is urgent medical care, we work in teams to provide it, and many steps are involved in the delivery of that urgent care that have no intrinsic value to the patient (customer).

Another key feature of *Kaizen* has been termed the Five S of *Kaizen*. This is a method for organizing a workplace, especially a shared workplace like an emergency department.

Seiri (Sort): Tidiness, keeping out only essential items out.

Selton (Set in order): Orderliness, eliminating extra motion.

Seiso (Shine): Cleanliness, keeping the workplace clean.

Seiketsu (Standardize): Standardizing work practices.

Shituke (Self-discipline): Sustaining and maintaining discipline and reviewing standards.

Kaizen in the ED

In a perfect example of *Kaizen* principles at work (though it was never dubbed as such), Alan Weier, MD, medical director for the emergency department at Baylor Regional Medical Center at Plano in Texas, spearheaded a project that involved the physician partners of 10 facilities within the Baylor Health Care System. The medical directors met for a strategic planning session in 2011, and one of their initiatives involved the standardization of equipment at all of their sites. They had three main areas of focus; two involved high-risk procedural equipment (airway and critical procedures), and a third focused on wound care.

The ED council, which in effect served as a *Kaizen* quality circle, worked together to standardize the equipment for three important workflows in the ED: airway, critical procedures (chest tubes, invasive vascular access, lumbar puncture) and wound care (lacerations, incision and drainage). They developed master lists of equipment for each cart and purchased the carts and supplies at a reduced rate for all 10 campuses. These carts can be moved anywhere in the department, and

this is in keeping with the new model for EDs in which any care can be rendered in any room. This standardization helped reduce clutter within the department and the need to run around the department in search of supplies for both high-acuity and high-frequency conditions within the department, standardized care. It also added discipline to the culture, and reduced costs.

The implementation phase for the change was just as important as the development of the carts. Dr. Weier and his team used staff meetings, education sessions, and checklists with photographs as part of the introduction of the carts, which took place at all sites. Continual feedback from providers ensured that the fine-tuning of the carts and their contents would be ongoing. The ED staff and physicians are so convinced that these standardized carts have improved care and increased efficiency and value that they are in the process of developing other carts for use throughout the system.

Dr. Weier and his team presented this work at the ED Innovations 2014 conference held in Las Vegas from February 19–21. It will be my pleasure to share with you more of the innovations that were showcased as posters at the conference. And apropos of the work done in Plano, I challenge you to return to your own department and “clean up your act!” ☺

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

How Much Money Do
You Need to Retire?

Retirement rules of thumb say you need 20 times your annual income to retire. Twenty times a typical emergency physician income of \$275,000 is \$5.5 million, far more than the vast majority of physicians need to enjoy a wonderful retirement.

by JAMES M. DAHLE, MD, FACEP

Question. *I am 55 years old and would like to retire. I just finished paying off my house and have \$1.5 million in my retirement accounts. Is that enough?*

Answer. Unfortunately, more information is required to find the correct answer to this question. Although there are many rules of thumb, such as you need 20 times your annual income to retire, these rules are useless for the typical American and even worse for a physician. Twenty times a typical emergency physician income of \$275,000 is \$5.5 million, far more than the vast majority of physicians need to enjoy a wonderful retirement. The best way to figure out how large your nest egg needs to be in order to retire without having to worry about ever running out of money is to first determine your expenses in retirement and then determine if you have the resources to pay those expenses.

The Good News

The best estimate of your expenses in retirement is what you are spending just before retirement along with some common-sense adjustments. The good news for physicians is that the majority of their expenses may completely disappear upon reaching financial independence and retiring. Consider Table 1, an example of a physician making \$300,000 and his pre-retirement and post-retirement expenses.

This particular physician finds that he only needs \$68,492 per year, or 23 percent of his pre-retirement income, to maintain his standard of living. However, that 23 percent is by no means a rule of thumb and is highly individualized. You may find you only need 20 percent of your pre-retirement income, or perhaps you may need as much as 50 percent. However, it is unlikely that you will need the 70 to 80 percent that some financial planners estimate once you subtract your savings, insurance costs, payroll taxes, mortgage payments, and expenses related to your children.

The Bad News

There is also some bad news associated with retirement planning. Financial professionals use a concept called the safe withdrawal rate, which is the amount of money you can withdraw from a reasonable portfolio each year, adjusted to infla-

tion, while expecting that portfolio to last throughout your retirement. Although this number varies slightly over time and no one can predict future market returns, most experts agree the number is somewhere around 4 percent. That means a portfolio of \$1 million can safely support an income of only about \$40,000 per year, adjusted upward each year for inflation. Using this number, you can quickly see that an annual income of \$120,000 will require a portfolio of \$3 million. To make matters worse, if all or most of that portfolio is in tax-deferred accounts like 401(k)s and traditional IRAs, the after-tax income will be even lower.

Other Income Sources

Other sources of income decrease the expenses your portfolio must pay for. The most common of these is Social Security. The Social Security Administration sends you a statement each year with an estimate of the income you will receive at your full retirement age. There are a few things to keep in mind when evaluating that figure. First, it assumes you will continue working until your full retirement age. If you retire early, such as at age 55, that number may be significantly lower. Social Security averages the highest 35 years of earnings in determining your payment. If you only work for 25 years, Social Security will use 10 years' worth of \$0 earnings to deter-

mine your payment.

Second, delaying Social Security payments to age 70 is one of the best ways to insure against your own longevity. But if you plan on retiring at 50 or even 60, you will need a plan to bridge the gap to Social Security at age 70 (not to mention Medicare at age 65).

Third, while many fear that Social Security will disappear completely, this seems highly unlikely given the popularity of the program. However, changes to the program are inevitable and may include raising the retirement age, lowering payments, and/or increasing the amount of Social Security tax paid. The bottom line is you should expect Social Security to provide an income of \$20,000 to \$40,000, at least in the latter half of your retirement years.

Other sources of income include pensions, the income of a spouse who continues to work after you retire, inheritances, and rental property. Each of these can be used to reduce the amount of income required from your portfolio.

Other Options

Once you have determined your expenses and matched them against other sources of income, you may find that your portfolio is not large enough to support your remaining needs. There are a couple of options to make up the difference, but both involve giving up control of assets.

The first is to use a portion of your portfolio to purchase a single premium immediate annuity (SPIA). This is an insurance contract where you

pay the insurance company a lump sum of money and, in exchange, the company pays you set amount of money each month for the rest of your life. While many annuities are complicated high-expense products designed to be sold and not bought, SPIAs are a straightforward and competitively priced way to purchase a pension. Unlike life insurance, which becomes more expensive as you get older and sicker, SPIAs become less expensive as you age and develop illnesses. The major benefit of a SPIA is that, unlike portfolio withdrawals, the income is guaranteed (although when you die, your heirs do not receive anything). A SPIA purchased on a healthy 70-year-old male currently pays about 8.3 percent per year, more than twice as much as the safe withdrawal rate of 4 percent.

Another method of increasing income is to use a reverse mortgage. While this industry has been appropriately maligned for high fees and inappropriate sales practices, a reverse mortgage allows you to convert your home equity into income while staying in your home as long as you are able.

A better option for most doctors facing a retirement shortfall is to work a few more years. A few more years of work, even part-time work, can make a huge difference in your spending level in retirement. Working longer allows for more savings, more time for prior savings to compound, and fewer years in which your portfolio must support you. Five more years of work could increase retirement income by 80 percent or more.

The nonfinancial aspects of retirement should not be ignored. Losing your identity as a practicing physician is difficult for many. Filling your time with worthwhile activities is hard for others. Your relationship with your spouse may also undergo a difficult adjustment when you work less. Emergency physicians and other shift workers are lucky in that they can often ease themselves into retirement by gradually reducing shifts, minimizing these issues compared to many specialists.

Appropriate retirement planning, done on your own or with an appropriate professional, will minimize financial worries in your later years. ☛

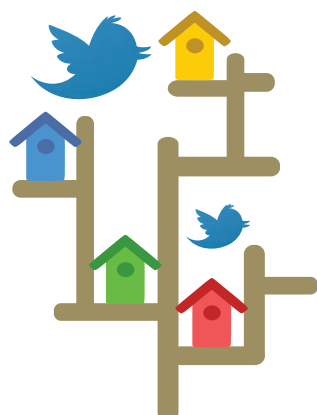
Table 1. Expenses Before and After Retirement

EXPENSE	PRE-RETIREMENT	POST-RETIREMENT
Retirement savings	\$60,000	\$0
College savings	20,000	0
Child related expenses	30,000	0
Payroll taxes	23,208	0
Mortgage	36,000	0
Life insurance	1,500	0
Disability insurance	4,800	0
Commuting/work expenses	5,000	0
Income taxes	50,000	10,000
Charity	20,000	5,000
Health savings account/health care	8,000	2,000
Other insurance	12,000	12,000
Property taxes	5,000	5,000
Food	12,000	12,000
Vacations	5,000	15,000
Other items	7,492	7,492
TOTAL	300,000	68,492



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.

Back to Basics



by JEREMY SAMUEL FAUST, MD, MS, MA

The Free Open Access Medical Education movement (#FOAMed) often focuses its attention around the hottest topics in emergency medicine. Would you use a bougie when performing a cricothyrotomy or not? What is your preferred ratio of blood products for massive blood transfusion in trauma? How do you assess response to resuscitation in septic patients? These debates rage on in the Twitterverse, and if you want in on those conversations, I heartily recommend following the Twitter feed of PHARM (Prehospital & Retrieval Medicine) podcast creator and host Minh Le Cong, MBBS (@rfdldoc). RFDS, as all Aussies but few Americans know, stands for Royal Flying Doctor Service. Dr. Le Cong seems to run a small ICU from his plane as he covers vast swaths of the Australian bush. While passing the time on long flights, he enjoys serving as a lightning rod in the #FOAMed conversation on Twitter, bringing his extensive knowledge and experience to these debates, along with his tenacity and good humor. From high-yield pearls to frequent links to new papers, his feed is certainly a busy one. So beware: following Dr. Le Cong is akin to drinking the Twitter Kool-Aid. You will learn a lot, but once you've followed him, there's no turning back.

Increasingly, emergency medicine providers are using Twitter as a tool to disseminate more traditional bread-and-butter medical knowledge, the information found in those bounded collections of pages held together with glue and thread. Ah, yes...books.

This month, there were a number of tweets that referenced “traditional” medical education that caught my eye. The first came from the feed @Master_USMLE. This account is devoted to board-review pearls found in various review books and has amassed more than 53,000 followers—many being medical students and residents. The feed mainly consists of mnemonics that you may not remember and probably don't need to. However, you might like the occasional EM-relevant entry. One recent standout: “Vertigo differential: VOMITS: Vestibulitis, Ototoxic drugs, Ménière's disease, Injury, Tumor, Spin (benign positional vertigo).” Not bad, but this tweet was



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missing something—the one cause of vertigo you simply can't afford to miss, cerebellar stroke! I applaud using VOMITS as a mnemonic for the differential diagnosis of vertigo but made this glaring omission known in my tweeted response. Mnemonics seem to work best when the acronym of the mnemonic is in some way associated with the medical problem it is used for. Vertigo tends to cause emesis, so you're more likely to remember it and use it. But the real reason to follow @Master_USMLE is that your medical students probably read it, and no one wants to be pimped by their students!

More Twitter-based PR for old-fashioned book learning came from Michael Stone, MD, emergency ultrasound fellowship director at Brigham & Women's Hospital in Boston (@bedsidesono). Last month, Dr. Stone was busy tweeting a slew of high-yield pearls from his own boss, Ron Walls, MD, author of the *Manual of Emergency Airway Management* and chair of EM at “the Brig.” Dr. Walls' checklist for the assessment of airway difficulty is second nature to many EM providers, but it's always worth repeating: “Walls - LEMON. L

**Rule of 50s to correct sugar:
% dextrose
x cc/kg=50.
Adult gets
D50 at 1cc/kg.
Kid gets D25
at 2cc/kg.
Infant gets
D10 at 5cc/kg.**

- look externally (gestalt), E - evaluate 332 [that's shorthand to say that in patients with “easier” airways, you should be able to fit three fingers between their incisors, the mandible length should be at least three-fingers wide, and the distance between the hyoid bone and the thyroid bone should be at least two-fingers wide], M - mallampati, O - obstruction/obesity, N - neck mobility.”

Pik Mukherji, MD, EM/IM attend-

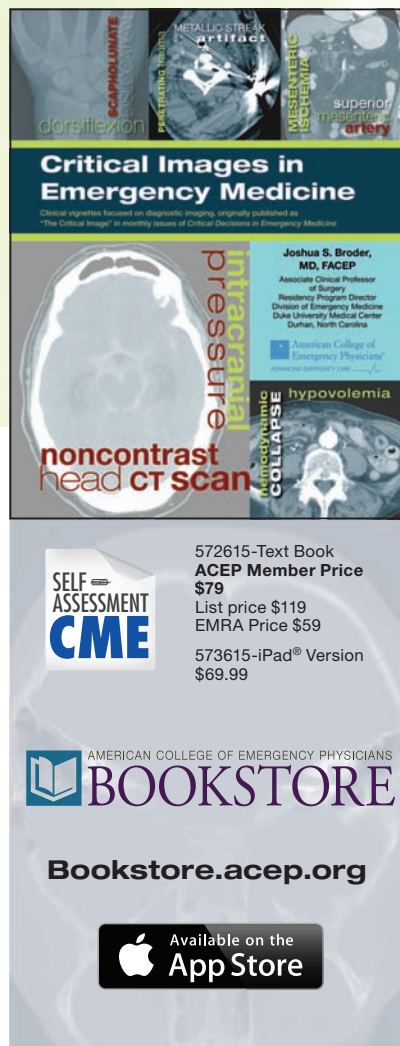
ing at Long Island Jewish Medical Center in New Hyde Park, NY (@ercowboy), seems to bask in his role as self-appointed FOAM skeptic and is known for his rhyming Twitter profile, “Devil's Advocate (by choice and intent), Offense (if given) Never Meant.” Dr. Mukherji also enjoys a reputation as a master educator. His points on Twitter are always succinct and relevant, like this excellent reminder for resuscitating hypoglycemic patients of all ages: “Rule of 50s to correct sugar: % dextrose x cc/kg=50. Adult gets D50 at 1cc/kg. Kid gets D25 at 2cc/kg. Infant gets D10 at 5cc/kg. #EMConf.”

The final entry for this month's installment of “The Feed” doesn't exactly fit the “traditional medical education” category, but it's so good that I have to include it. From University of Maryland ED pharmacist and toxicologist and frequent Academic Life in Emergency Medicine (www.academiclifeinem.com) contributor—and arguably its MVP—Bryan Hayes, PharmD (@PharmERToxGuy), comes, “The 2014 list of Oral Dosage Forms That Should Not Be Crushed. From @ismp1. <http://www.ismp.org/tools/donotcrush.pdf> #FOAMed.” This online PDF from the Institute of Safe Medication Practices, a non-profit patient safety organization, contains a list of all medications that should not be crushed. For each entry, the list includes the active ingredient, the relevant formulation (tablet versus capsule, etc.), and a brief and precise reason the medication shouldn't be crushed. Some of these are obvious and trivial (such as the advice to avoid crushing any extended-release formulation), while others are obscure yet important and downright fascinating. For example, did you know that you should never crush Cellcept (mycophenolate mofetil, an immunosuppressive agent for transplant patients) because direct exposure to the active ingredient can enhance tumor production? I sure didn't. Insights like these are what cause so many of us to keep drinking from the endless fountain of FOAM. ☺

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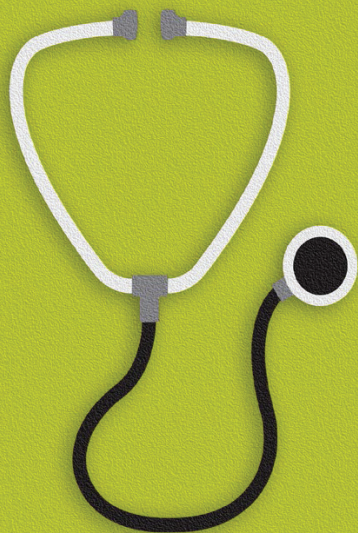
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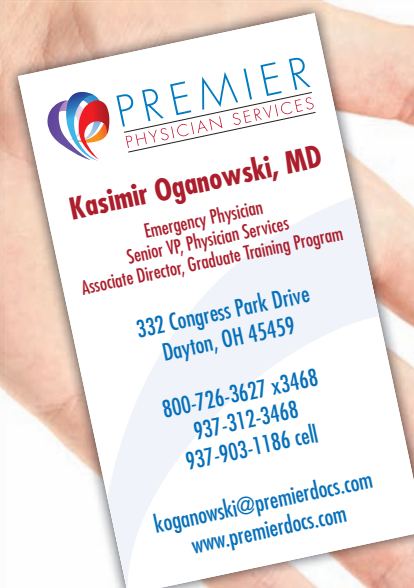


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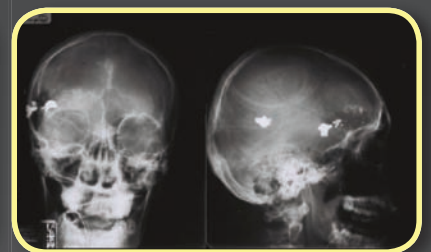
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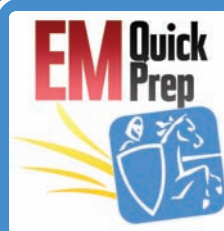
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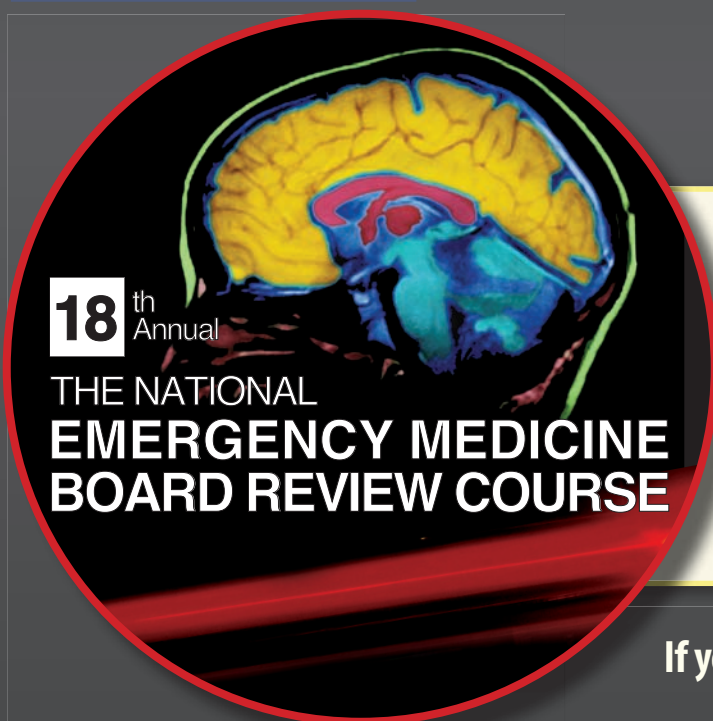
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