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# Western Journal of Emergency Medicine: Integrating Emergency Care with Population Health

### ETHICAL AND LEGAL

A Review of Lawsuits Related to Point-of-Care Emergency Ultrasound Applications L Stolz, KM O'Brien, ML Miller, ND Winters-Brown, M Blaivas, S Adhikari

### **CRITICAL CARE**

5 Posterior Reversible Encephalopathy Syndrome in the Emergency Department: Case Series and **Literature Review** 

RJ Thompson, B Sharp, J Pothof, A Hamedani

### **PATIENT SAFETY**

Anticoagulation Drug Therapy: A Review 11 K Harter, M Levine, SO Henderson

### **POPULATION HEALTH RESEARCH DESIGN**

- Feasibility of Tablet Computer Screening for Opioid Abuse in the Emergency Department 18 SG Weiner, LC Horton, TC Green, SF Butler
- 24 Discrepancy Between Clinician and Research Assistant in TIMI Score Calculation (TRIAGED CPU)

BT Taylor, M Mancini

### **EMERGENCY DEPARTMENT OPERATIONS**

- Effect of an Emergency Department Fast Track on Press-Ganey Patient Satisfaction Scores 34 CE Hwang, GS Lipman, M Kane
- 39 Waiting for Triage: Unmeasured Time in Patient Flow C Houston, LD Sanchez, C Fischer, K Volz, R Wolfe

### **HEALTH OUTCOMES**

- 43 Routine Repeat Head CT may not be Indicated in Patients on Anticoagulant/Antiplatelet Therapy **Following Mild Traumatic Brain Injury** KC McCammack, C Sadler, Y Guo, RS Ramaswamy, N Farid
- Do Emergency Department Patients Receive a Pathological Diagnosis? A Nationally-50 **Representative Sample** LS Wen, JA Espinola, JM Mosowsky, CA Camargo Jr.









Contents continued on page iii

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# Table of Contents

### continued

55 Timing of Discharge Follow-up for Acute Pulmonary Embolism: Retrospective Cohort Study DR Vinson, DW Ballard, J Huang, AS Rauchwerger, ME Reed, DG Mark

### **INJURY PREVENTION**

- 62 Descriptive Study of Prescriptions for Opioids from a Suburban Academic Emergency Department Before New York's I-STOP Act L Ung, R Dvorkin, S Sattler, D Yens
- 67 Prescription Drug Monitoring Programs: Examining Limitations and Future Approaches CA Griggs, SG Weiner, JA Feldman

### **BEHAVIORAL HEALTH**

- 71 **Predictors of Psychiatric Boarding in the Emergency Department** *RK Misek, AE DeBarba, A Brill*
- 76 Polysubstance Abuse: Alcohol, Opioids and Benzodiazepines Require Coordinated Engagement by Society, Patients, and Physicians UC Ogbu, S Lotfipour, B Chakravarthy
- 80 Screening for Sexual Orientation in Psychiatric Emergency Departments GW Currier, G Brown, PG Walsh, S Jager-Hyman, S Chaudhury, B Stanley

### **HEALTHCARE UTILIZATION**

- 85 American Academy of Pediatrics 2014 Bronchiolitis Guidelines: Bonfire of the Evidence *P Walsh, SJ Rothenberg*
- 89 Factors Associated with Decision to Hospitalize Emergency Department Patients with Skin and Soft Tissue Infection DA Talan, BA Salhi, GJ Moran, WR Mower, Y Hsieh, A Krishnadasan, RE Rothman
- 98 Trauma Center Staffing, Infrastructure, and Patient Characteristics that Influence Trauma Center Need M Faul, SM Sasser, J Lairet, N Mould-Millman, D Sugerman
- **107** Evaluation of Healthcare Use Trends of High-Risk Female Intimate Partner Violence Victims *RM Hoelle, M Elie, E Weeks, N Hardt, W Hou, H Yan, D Carden*
- 114 Low-Cost Alternative External Rotation Shoulder Brace and Review of Treatment in Acute Shoulder Dislocations K Lacy, C Cooke, P Cooke, J Schupbach, R Vaidya

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Integrating Emergency Care with Population Health

# Table of Contents *continued*

### **EDUCATION**

- 121 Objective Structured Clinical Examinations Provide Valid Clinical Skills Assessment in Emergency Medicine Education J Wallenstein, D Ander
- **127** Change to an Informal Interview Dress Code Improves Residency Applicant Perceptions *HG Hern Jr, CP Wills, B Johnson*
- 133 Educational Technology Improves ECG Interpretation of Acute Myocardial Infarction among Medical Students and Emergency Medicine Residents A Pourmand, M Tanski, S Davis, H Shokoohi, R Lucas, F Zaver
- **138 Correlation of the NBME Advanced Clinical Examination in EM and the National EM M4 exams** *K Hiller, ES Miller, L Lawson, D Wald, M Beeson, C Heitz, T Morrissey, J House, S Poznanski*
- 143 Ultrafest: A Novel Approach to Ultrasound in Medical Education Leads to Improvement in Written and Clinical Examinations K Connolly, L Beier, MI Langdorf, CL Anderson, JC Fox

### **DIAGNOSTIC ACUMEN**

- **149 13-Year-Old with Cryptic Abdominal Pain** S Spring, R Anderson, JN Carlson
- **151 Delayed Diagnosis of Gastric Outlet Obstruction from Bouveret Syndrome in a Young Woman** *Z Smith, J Totten, A Hughes, J Strote*
- **154 Complications of New Medications** *CJ Roldan, L Paniagua*
- **157 Bilateral Inferior Shoulder Dislocation** *E Cacioppo, JR Waymack*
- **158** Acute Idiopathic Compartment Syndrome of the Forearm in an Adolescent *K Smith, RW Wolford*
- 161 Achilles Tendon Rupture SP Stickles, L Friedman, M Demarest, C Raio
- **163 Tense Bullae and Urticaria in a Woman in Her Sixties** *KC Wurlitzer, CP Canders, AS Campen*
- 165 Necrotizing Fasciitis Caused by Hypermucoviscous *Klebsiella pneumoniae* in a Filipino Female in North America *D Na. B Frazee*
- **169** Herpes Zoster Ophthalmicus Extending to the Palate *T Schneberk, EJ Newton*
- 170 Persistent Pain After Lithotripsy E Jones, K DeKay

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Integrating Emergency Care with Population Health

# Table of Contents *continued*

- **172** Survival from Cervical Necrotizing Fasciitis JS Gausepohl, JG Wagner
- 175 Hemi Orolingual Angioedema after tPA Administration for Acute Ischemic Stroke B Madden, RB Chebl

### TECHNOLOGY IN EMERGENCY MEDICINE

- 178 Bedside Echocardiography for Undifferentiated Hypotension: Diagnosis of a Right Heart Thrombus JF Kenny, X Zhong, C Brown, D Das, B Royall, M Kapoor
- 181 Half-dose Alteplase for Sub-massive Pulmonary Embolism Directed by Emergency Department Point-of-care Ultrasound *R Amini, AR Panchal, D Bahner, S Adhikari*
- **184** Improving Door-to-balloon Time by Decreasing Door-to-ECG time for Walk-in STEMI Patients *CJ Coyne, N Testa, S Desai, J Lagrone, R Chang, L Zheng, H Kim*
- 190 Factors Influencing Rate of Testicular Salvage in Acute Testicular Torsion at a Tertiary Pediatric Center P Ramachandra, KL Palazzi, NM Holmes, S Marietti
- **195** Validation of a Decision Rule for Selective TSH Screening in Atrial Fibrillation SD Bellew, R Moman, CM Lohse, EP Hess, MF Bellolio

### EMERGENCY DEPARTMENT ACCESS

203 Lack of Gender Disparities in Emergency Department Triage of Acute Stroke Patients TE Madsen, EK Choo, TA Seigel, D Palms, B Silver

### DISCOURSE IN EMERGENCY MEDICINE AND POPULATION HEALTH

- 210 Comments on "Using Lean-Based Systems Engineering to Increase Capacity in the Emergency Department" *MJ Vermeulen, MJ Schull*
- 210 Reply to Comments Regarding "Using Lean-Based Systems Engineering to Increase Capacity in the Emergency Department" BA White, Y Chang, BG Grabowski, DFM Brown

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vi

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### A Review of Lawsuits Related to Point-of-Care Emergency Ultrasound Applications

Lori Stolz, MD\* Kathleen M. O'Brien, MD<sup>†</sup> Marc L. Miller, JD<sup>‡</sup> Nicole D. Winters-Brown, JD<sup>§</sup> Michael Blaivas, MD<sup>II</sup> Srikar Adhikari, MD\* \*University of Arizona, Department of Emergency Medicine, Tucson, Arizona †Massachusetts General Hospital, Division of Global Health and Human Rights, Boston, Massachusetts ‡University of Arizona, James E. Roger College of Law, Tucson, Arizona §American University, Washington College of Law, Washington DC ISt. Francis Hospital, Department of Emergency Medicine, Columbus, Georgia

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**Introduction:** New medical technology brings the potential of lawsuits related to the usage of that new technology. In recent years the use of point-of-care (POC) ultrasound has increased rapidly in the emergency department (ED). POC ultrasound creates potential legal risk to an emergency physician (EP) either using or not using this tool. The aim of this study was to quantify and characterize reported decisions in lawsuits related to EPs performing POC ultrasound.

**Methods:** We conducted a retrospective review of all United States reported state and federal cases in the Westlaw database. We assessed the full text of reported cases between January 2008 and December 2012. EPs with emergency ultrasound fellowship training reviewed the full text of each case. Cases were included if an EP was named, the patient encounter was in the emergency department, the interpretation or failure to perform an ultrasound was a central issue and the application was within the American College of Emergency Physician (ACEP) ultrasound core applications. In order to assess deferred risk, cases that involved ultrasound examinations that could have been performed by an EP but were deferred to radiology were included.

**Results:** We identified five cases. All reported decisions alleged a failure to perform an ultrasound study or a failure to perform it in a timely manner. All studies were within the scope of emergency medicine and were ACEP emergency ultrasound core applications. A majority of cases (n=4) resulted in a patient death. There were no reported cases of failure to interpret or misdiagnoses.

**Conclusion:** In a five-year period from January 2008 through December 2012, five malpractice cases involving EPs and ultrasound examinations that are ACEP core emergency ultrasound applications were documented in the Westlaw database. All cases were related to failure to perform an ultrasound study or failure to perform a study in a timely manner and none involved failure to interpret or misdiagnosis when using of POC ultrasound. [West J Emerg Med. 2015;16(1):1–4.]

### INTRODUCTION

The use of point-of-care (POC) ultrasound in the emergency department (ED) has dramatically expanded in recent years. Performing and interpreting ultrasound examinations at the patient's bedside without the aid of a radiologist or sonographer has become commonplace for emergency physicians (EP) and is now fully integrated into residency training.<sup>1,2</sup> Improved patient safety and decreased time to definitive care are drivers of this dramatic expansion in use of POC ultrasound.<sup>3-5</sup>

With any change in medical practice, the opportunity arises for lawsuits related to the usage or failure to use this

new practice, such as with the use of tissue plasminogen activator in thrombotic stroke.<sup>6</sup> Malpractice claims are a costly reality in the healthcare system, with emergency medicine (EM) considered to be one of the higher-risk specialties. The risk of a lawsuit for an EP is approximately 7.5% each year with the projected risk of claim over a typical career being between 75% and 99%.<sup>7</sup> This is an issue that affects every EP who works clinically.

With the increasing use of POC ultrasound in the ED, there is potential additional legal risk to a practicing EP. Malpractice risk to an EP may stem from failure to perform an adequate ultrasound study, failure to interpret ultrasound findings accurately, and misdiagnosis.<sup>8</sup> Some EPs may choose to forgo POC ultrasound to decrease this perceived risk or to shift potential risk onto consulting services. However, POC ultrasound has become so widely integrated into the practice of EM, the failure to integrate ultrasound into practice may lead to increased legal risk for clinicians.

A previous study on this topic by Blavais et al.<sup>9</sup> analyzed 659 available records for lawsuits related to POC ultrasound over a 20-year period from 1987-2007. They identified no cases related to performance or interpretation of POC ultrasound and one case related to alleged failure to perform POC ultrasound. The aim of this study was to continue this previous work to quantify and characterize lawsuits related to EPs performing POC ultrasound. We hypothesized that given the increased use and scope of practice of POC ultrasound in EM since the previous study, the current legal risk of *not* using POC ultrasound when it may be indicated may be significant for EPs and departments.

### **METHODS**

### **Study Design/Setting**

This is a retrospective review of the Westlaw database ("ALLCASES") for reported decisions in state and federal malpractice cases involving POC ultrasound. The Westlaw database is a repository of state and federal case law, state and federal statutes, public records and other secondary information sources. It is one of the main search engines used by legal professionals for scholarly and professional work. This study was approved by the institutional review board and the requirement for informed consent was waived.

### **Study Protocol**

We reviewed the Westlaw database "ALLCASES" for published case law in the U.S. from January 2008 through December 2012, including federal and state decisions. Boolean search terms included "ultrasound" and "sonography" with any suffix. These terms were searched within 250 words of "emergency" with any suffix and within 10 words of "physician" or "doctor." The search was designed and conducted by an academic professor of law (MM) with database assistance provided by a law student (NWB).

EPs with emergency ultrasound fellowship training reviewed records that were identified through the search

(LS, KO). Cases were included if a physician was accused of misconduct, the patient encounter was in the ED, the interpretation or failure to perform an ultrasound was discussed to any degree and the application was within the American College of Emergency Physicians (ACEP) core ultrasound applications (trauma, intrauterine pregnancy, abdominal aortic aneurysm, cardiac, biliary, urinary tract, deep vein thrombosis, soft-tissue/musculoskeletal, thoracic, ocular, procedural guidance).<sup>1</sup> Because Blaivas et al. identified one case in which an EP was named for failure to perform a study that fell within his scope of practice, methods were designed to include any ultrasound examination that could have been or was performed by a treating EP. We included cases involving ultrasound examinations performed or ordered through a radiology department that are within the scope of ACEP core emergency ultrasound applications. The inclusion criteria were broad with the intent of including cases where an EP did or could have performed a POC ultrasound.

We recorded a basic narrative of the case, the examination type involved, the department that performed the examination, and a broad category of the type of allegation (misdiagnosis, failure to interpret, failure to perform, failure to perform in a timely manner). Discrepancies were discussed between the two reviewers to reach a consensus and full consensus was reached between the two reviewers. An *a priori* plan to include a third reviewer to review discrepancies was deemed not necessary.

### RESULTS

We identified 120 records matching initial search criteria, and seven of these cases met the inclusion criteria. Two out of seven of these cases were identified by the two reviewers using the *a priori* search criteria, which upon further review were outside of the scope of the ACEP core ultrasound applications. One of these cases involved a patient with multiple bee stings, who was later found to have an ocular foreign body. Although ocular ultrasound is within the ACEP core applications, detection of intra-ocular foreign body is not. The other case involved an elderly male patient who presented with dyspnea. His final diagnosis was acute mitral valve insufficiency and the delay in obtaining an echocardiogram was discussed in the narrative as being central to his death. Identification of acute valvular insufficiency is not within the scope of POC basic cardiac ultrasound examination. The remaining cases identified are detailed in Table.

None of the cases identified were performed as POC ultrasound studies; therefore, no cases resulted from misdiagnosis with POC ultrasound or failure to interpret a POC ultrasound examination. However, all cases involved ultrasound examinations that were within the scope of EM and were ACEP emergency ultrasound core applications. All of the cases involved failure to perform a complete ultrasound study or failure to perform in a timely manner. The most common examination type was a lower extremity venous ultrasound examination (n=3). The majority of cases involved a patient's death (n=4).

### Table. Summary of cases involving emergency physicians and point-of-care ultrasound.

| Case | Case summary   | Examination type | Performing department | Allegation                                    |
|------|--|------------------|-----------------------|---|
| 1    | Middle-aged female presented with calf pain. Ultrasound study reported to be negative. Patient had fatal pulmonary embolism. (2012 WL 1100657 [Ohio App. 7 Dist])  | DVT              | Radiology             | Failure to<br>perform complete<br>examination |
| 2    | Teen-aged female presented with calf pain, palpitations<br>and pre-syncope. EKG and chest x-ray normal. Patient<br>died of massive pulmonary embolism. (2012 WL 1605709<br>(La.App. 5 Cir.), 11-1006 [La.App. 5 Cir. 5/8/12])              | DVT              | Not performed         | Failure to perform                            |
| 3    | Teen-aged boy presented after motor vehicle collision.<br>No abdominal imaging was performed. Patient was<br>discharged and died that night at home with liver laceration<br>and hemoperitoneum. (721 S.E.2d 238)                          | FAST             | Not performed         | Failure to perform                            |
| 4    | Adult female presented with abdominal pain. Right<br>upper quadrant ultrasound scheduled next day. Positive<br>for cholecystitis. Alleged delay in diagnosis prolonging<br>hospitalization and causing complications. (2009 WL<br>2473514) | RUQ              | Radiology             | Failure to perform in a timely manner         |
| 5    | Adolescent male 8 days status post knee arthroscopy presented with chest pain. Diagnosed with pleurisy and discharged. Patient subsequently died of bilateral pulmonary emboli. (2012 WL 5910796)  | DVT              | Not performed         | Failure to perform                            |

*DVT,* deep vein thrombosis; *FAST*, Focused Assessment with Sonography in Trauma; *RUQ,* right upper quadrant \*Westlaw citations in parentheses.

### DISCUSSION

The cost of malpractice litigation involving physicians is high. In addition to the actual indemnity payments, the cost of defending the 80% of lawsuits in which no payment is made is borne by all physicians and hospital systems through insurance premiums and defensive medicine practices that drive up national healthcare costs.<sup>7,10,11</sup> As the practice landscape changes with new technologies, there is potential for legal risk to clinicians for use or failure to use newly available treatment or diagnostic modalities.

This study used available data to characterize lawsuits related to the use of POC ultrasound by EPs. We designed the study to identify any potential cases where an EP performed or could have performed a POC ultrasound examination. From 2008 through 2012, there were five lawsuits documented in the Westlaw database on this topic and in none of these cases did an EP perform a POC ultrasound examination. There have been no documented cases of misinterpretation or missed diagnoses when using POC ultrasound by an EP. Of the identified cases, all cases relate to not performing a study or not obtaining a study in a timely manner. With increasing use of bedside ultrasound and mandatory ultrasound training and assessment of competency during residency training, potential for malpractice lawsuits exists for not performing POC ultrasound examinations or not performing them in a timely manner. The results from our study are limited to support this argument.

Of the reported cases, two involved ultrasound examinations that were performed by a radiology department. EPs could have performed these at the bedside as they are within the scope of ACEP core emergency ultrasound applications. These cases are of interest because of the deferral of risk.

As the use of POC ultrasound increases in EDs nationwide, steps to ensure responsible use are warranted. It is crucial to maintain a robust, ongoing ultrasound education program and quality assurance program at every institution to ensure adequate image acquisition and interpretation. Offering timely feedback and continuing education to physicians performing ultrasound examinations will improve the quality of their studies and decrease errors. The appropriate indications for POC ultrasound, as well as sound, consistent documentation should be emphasized. Particular attention should be paid to communicating the limited and focused scope of POC ultrasound to the patients, their families, and other providers.

### LIMITATIONS

Our study has several limitations, including its retrospective nature. Given the small number of identified cases, it is difficult to approximate definitively any measure of risk to EPs using POC ultrasound. Cases settled out of court, cases with unreported decisions, or cases otherwise not publicly available (i.e. private negotiations, arbitration, sealed records, etc.) were not captured in the Westlaw database, leading to a selection bias. This private information, unfortunately, cannot be captured in any publicly available database. Our findings are representative, however, of one major legal database in the United States. The time from ED visit to court verdict or public documentation of legal proceedings may have limited our success in capturing recent cases.

The output from the Westlaw database is limited, qualitative information with each case narrative providing varying levels of detail. Information regarding the ultrasound skills of the EP, access to bedside ultrasound, the level of facility support, other barriers present to performance of ultrasound, or the medical decision making process of the physician is not available in any standardized way within the reports. Therefore, we made assumptions that these EPs could have performed the given ultrasound examination at their facility. In order to adapt the qualitative information available in the cases, we attempted to minimize subjective inferences. Therefore, we cannot comment on why ultrasound was not used in each case.

### CONCLUSION

From 2008 to 2012, the Westlaw database reported no judicial decisions against an EP performing POC ultrasound. The database reports five cases related to failure to perform an ultrasound examination that was within the scope of ACEP core emergency ultrasound applications in a timely manner. Further analyses using other legal data sources and insurance claim data are desired and further work is necessary to confirm these preliminary findings.

Address for Correspondence: Lori Stolz, MD, 1609 N. Warren Ave., Room 118, PO Box 2405057, Tuscon, AZ 85724-5057. Email: Istolz@aemrc.arizona.edu.

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## **Posterior Reversible Encephalopathy Syndrome in the Emergency Department: Case Series and Literature Review**

Ryan J. Thompson, MD Brian Sharp, MD Jeffery Pothof, MD Azita Hamedani, MD, MPH University of Wisconsin, Department of Emergency Medicine, Madison, Wisconsin

Supervising Section Editor: William Whetstone, MD Submission history: Submitted October 2, 2014; Revision received December 14, 2014; Accepted December 15, 2014 Electronically published January 5, 2015 Full text available through open access at http://escholarship.org/uc/uciem\_westjem DOI: 10.5811/westjem.2014.12.24126

**Introduction**: Posterior Reversible Encephalopathy Syndrome (PRES) often has variable presentations and causes, with common radiographic features—namely posterior white matter changes on magnetic resonance (MRI). As MRI becomes a more frequently utilized imaging modality in the Emergency Department, PRES will become an entity that the Emergency Physician must be aware of and be able to diagnose.

**Case Report**: We report three cases of PRES, all of which presented to the emergency department of a single academic medical center over a short period of time, including a 53-year-old woman with only relative hypertension, a 69-year-old woman who ultimately died, and a 46-year-old woman who had a subsequent intraparenchymal hemorrhage.

**Conclusion**: PRES is likely much more common than previously thought and is a diagnosis that should be considered in a wide variety of emergency department patient presentations. [West J Emerg Med. 2015;16(1):5–10.]

### **INTRODUCTION**

Posterior Reversible Encephalopathy Syndrome (PRES) was first described in 1996 by Hinchey et al. as Reversible Posterior Leukoencephalopathy Syndrome.<sup>1</sup> PRES is characterized by a constellation of symptoms including visual changes, headache, altered mental status, and seizures and is associated with white matter edema in the posterior parietal-temporal-occipital regions, most often visualized on magnetic resonance imaging (MRI).

As the name implies, patients with PRES typically have resolution of symptoms within days of the initiation of treatment of the underlying cause, although MRI findings can take weeks to fully resolve.<sup>2</sup> There are however case reports of patients experiencing brain herniation<sup>3</sup> and death<sup>4</sup> secondary to PRES.

With the increase in advanced MRI in the Emergency Department (ED), it is likely that Emergency Physicians will be able to effectively diagnose PRES and should consider this as part of the working differential diagnosis of a variety of key chief complaints in the ED. Awareness of the range of patient presentations and outcomes will allow optimal management of such patients earlier in their presenting course. We present three patients with variable presentations who presented in a very short period of time to our emergency department with PRES.

### CASE SERIES

### Case 1

A previously healthy 53-year-old woman, with a past medical history notable only for mild esophageal dysmotility, presented to a local Urgent Care with several hours of nausea, vomiting, and diarrhea. She was treated with 4mg intravenous (IV) ondansetron and one liter (1L) normal saline (NS), and was discharged home, feeling improved. Once home, the patient had recurrent vomiting, prompting presentation to the ED of the local academic medical center. Physical examination during her ED visit was unremarkable, including heart rate (HR) 54, blood pressure (BP) 124/65, respiratory rate (RR) 16, and temperature (T) 97.7°F. Diagnostic evaluation in the ED included basic labs (complete blood count [CBC], basic metabolic panel [BMP], and urinalysis [UA]). All labs were within normal for hospital reference ranges, except for 2-5 RBC/hpf (red blood cell per high power field) and trace ketones on urinalysis. The patient received 4mg IV ondansetron, 0.625mg IV droperidol, 1L NS (normal saline) IV bolus, and was discharged home feeling improved.

Patient returned to the ED 4 days later with ongoing nausea, resulting in poor oral intake, and generalized weakness. She noted frequent falls from standing and difficulty walking because of "weakness." Initial vital signs were as follows: BP 79/53, HR 93, RR 18, and T 98.5°F. Subsequent blood pressures during her ED stay ranged from 124/63 to 148/82. Physical exam revealed a thin woman with dry mucous membranes, clear lungs, normal heart sounds, and a benign abdominal exam. Notably, neurologic exam revealed equal and intact strength in all extremities. BMP, CBC, and UA were repeated. All labs were again within hospital reference range except for potassium 3.0mmol/L (RR 3.5-4.8mmol/L), and urinalysis with 6-10 RBCs/hpf and large ketones. She was again treated with 8mg IV ondansetron, 0.625mg IV droperidol, 40mg IV pantoprazole, and 2L NS IV bolus, with resolution of her symptoms, and was discharged home with a prescription for potassium chloride tablets.

The patient returned to the same ED two days later, reporting that her nausea and vomiting had resolved and that she was now tolerating a regular diet, but had continued to have falls and over the prior hour had developed slurred speech and bilateral hand weakness. These symptoms, however, had resolved prior to ED arrival. Initial vital signs for this third ED visit were as follows: BP 102/63, HR 73, RR 18, and T 99.1°F. Patient's physical examination again revealed dry mucous membranes, normal heart and lung sounds, and benign abdominal exam. Her neurologic exam at this time was documented as intact muscle tone, normal cranial nerve exam, and intact coordination. Laboratory testing included BMP, magnesium level, phosphate level, ionized calcium level, troponin, CBC, vitamin B12 level, and urinalysis. All labs were within hospital reference range, except ionized calcium of 4.6mg/dL (RR 4.9-5.6mg/dL), Vitamin B12 level >4000pg/ml, (RR 210-911pg/ml), large ketones and 2-5 RBCs/hpf on urinalysis, and potassium 2.6mmol/L (RR 3.5-4.8mmol/L). The hypokalemia was supplemented with 20mg IV potassium chloride. Given neurologic symptoms and reported falls, patient underwent non-contrast computed tomography (CT) of her head, which demonstrated no traumatic intracranial hemorrhage or other pathology. The patient was admitted to the hospital for further evaluation of possible transient ischemic attack (TIA) and ongoing treatment of hypokalemia.

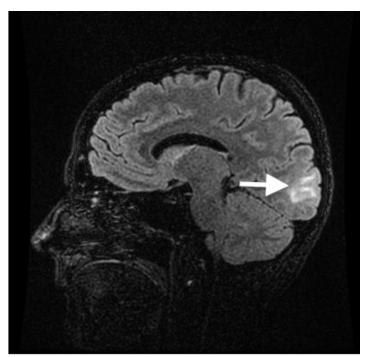
The next day, MRI/MRA (magnetic resonance angiogram)

head and neck with and without contrast showed symmetric T2 signal intensity within the occipital lobes, without evidence of infarction or enhancement, most consistent with PRES (Figure 1). Repeat neurologic exam by neurology service revealed bilateral left lower quadrantanopsia. Patient's inpatient stay included extensive evaluation for autoimmune diseases, including a celiac panel, antinuclear antibodies, erythrocyte sedimentation rate, C-reactive protein, and anti-SCL-70 antibodies. All of these laboratory tests were resulted as with normal hospital reference ranges. Patient declined a lumbar puncture for further laboratory examination of her cerebral spinal fluid.

The patient had steady improvement of her symptoms over a five-day hospital course and was discharged with outpatient physical, occupational, and speech therapies. The patient underwent outpatient MRI three months after hospital discharge, which showed complete resolution of prior PRES findings. Her visual field deficits resolved, and she has returned to work.

### Case 2

A 69-year-old woman with past medical history of endstage renal disease (ESRD) on renal dialysis, poorly controlled type-II diabetes mellitus, and hypertension, presented to a regional community ED with complaints by husband of altered mental status and rash. Specifically, husband noted that since being discharged from a community hospital one week prior, after a two-day stay for pneumonia, the patient had become increasingly fatigued and weak. During the patient's hospitalization for pneumonia, her blood pressure medications



**Figure 1.** T2 weighted magnetic resonance imaging of Patient 1, showing hyperintensity within the occipital lobe.

### Thompson et al.

(including carvedilol, clonidine, doxazosin, and lisinopril) had all been stopped due to mild hypotension. A targetoid rash had also formed on her arms, left leg, posterior shoulders, and neck. Her weakness had progressed until morning of her ED presentation, when she became acutely confused. She had called out for her husband and was complaining of pain in her bilateral shoulders and arms but was unable to further describe her discomfort.

Per report by outside hospital, patient's initial vital signs were notable for a blood pressure of 200/110, HR 72, and normal temperature. She was given 2.5mg IV enalaprilat, which improved her BP from 200/110 to 185/88. While undergoing a non-contrast head CT at the outside hospital, patient had a two to three minute long generalized tonic-clonic seizure, for which she received 2mg IV lorazepam. Head CT was interpreted as normal. Request for transfer was then made to the ED of the local academic medical center.

On arrival, the patient's vital signs included the following: BP 197/59, HR 80, RR 20, and T 99.7°F. Her physical exam revealed an ill-appearing woman with small yet reactive pupils, supple neck, normal heart and lung sounds, and benign abdominal exam. Her neurologic exam revealed a lethargic patient, only oriented to self, who could not hold up her extremities to gravity. Dermatologic exam revealed diffuse erythematous rash on bilateral upper and lower extremities and upper neck. Laboratory examination included the following: arterial blood gas, comprehensive metabolic panel (CMP), CBC, and urinalysis. All were within normal limits of hospital reference ranges except for the following: white blood cell count (WBC) 11.6 (RR 3.8-10.5 k/uL), platelets 41 (RR 160-370 k/uL), and creatinine (Cr) 5.48 (RR 0.55-1.05 mg/dL). Patient's WBC was elevated compared to baseline, her platelet count was low compared to baseline. Since she was two days short of her next dialysis, her Cr level was at baseline. The neurology service was consulted from the ED. Given concern about the rash and possible low-grade temperature, empiric broad-spectrum antibiotics were started (1g vancomycin, 3g meropenem, and 600mg acyclovir).

The patient was admitted to the inpatient medicine service with a working differential diagnosis of thrombotic thrombocytopenic purpura (TTP), encephalitis or meningitis, and hypertensive emergency. MRI of the head without contrast was obtained which showed T2 and fluid-attenuated inversion recovery (FLAIR) signal hyperintensity located in a symmetric fashion within the bilateral occipital and posterior parietal lobes, interpreted as characteristic of PRES (Figure 2).

The patient's inpatient stay focused on blood pressure management and evaluation of altered mental status. A lumbar puncture was performed which showed only one nucleated cell. Cultures of blood, spinal fluid, urine, and sputum were all negative. Dermatology was consulted regarding the patient's rash and KOH testing was suggestive of tinea corporis.

The patient continued to have a fluctuating mental status.



**Figure 2.** T2 weighted magnetic resonance imaging of Patient 2, with hyperintensity of posterior parietal and occipital lobes.

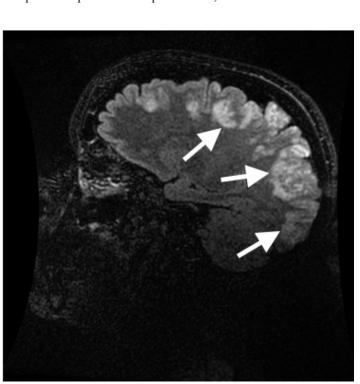
An electroencephalogram (EEG) showed a non-epileptiform pattern with generalized nonfocal slowing consistent with a global impairment. On hospital day 7, patient was made comfort care measures only by family and died shortly thereafter.

On autopsy, the brain was grossly and microscopically normal. Systemic atherosclerotic disease was noted, as well as coronary artery disease, and chronic obstructive pulmonary disease.

### Case 3

A 46 year old woman with a history of thyroid cancer (status post thyroidectomy) and adenoid cystic carcinoma (status post resection and radiation) presented to the ED of a local academic medical center complaining of 24 hours of a left-sided, throbbing headache, associated with nausea, vomiting, and diaphoresis. She stated that the headache came on rapidly over five seconds. Physical exam included BP 152/103, HR 89, RR 17, and Temp 98.6°F. Patient had a non-focal neurologic exam, including intact cranial nerves, strength, sensation, and coordination. CT and CT angiogram of her head were obtained, and showed no evidence of intracranial hemorrhage, vascular abnormality (e.g. aneurysmal dilatation or ateriovenous malformation), or any other acute abnormalities. The patient was strongly encouraged to undergo further diagnostic testing with a lumbar puncture for evaluation of a subarachnoid hemorrhage, but declined. After treatment with 1.25mg IV droperidol, 25mg IV diphenhydramine, and 0.5mg IV hydromorphone, the patient's pain was improved and she requested discharge. She left the ED at 2:15 AM.

The patient returned via ambulance 17 hours later, at 7:00 PM in the evening, after having a witnessed three-minute generalized tonic-clonic seizure at home, and another oneminute generalized tonic-clonic seizure during transport. The latter resolved with 5mg intranasal midazolam. She arrived to the ED alert, oriented to self and location, but not time. She complained of a severe generalized headache. Initial vital signs were as follows: BP 183/113, HR 143, and RR 13. Finger stick glucose was 195mg/dl (ranger 70-99mg/ dL). Laboratory testing included CMP, magnesium level, phosphate level, CBC, thyroid stimulating hormone, alcohol, urine drug screen, and urinalysis which were all normal except for positive opiates and benzodiazepines on urine drug screen (thought most likely secondary to medications given to patient during her ED stay earlier that day), WBC count 12.8, phosphate 1.9mg/dL[RR 2.5-4.5mg/dL] and potassium 3.1mg/dL. Head CT was repeated and showed Illdefined areas of low-attenuation in the cortical and subcortical regions of the bilateral posterior parietal and occipital lobes. The patient's neurologic exam was remarkable only for a new left inferior homonymous quadrantanopsia. She was loaded with 1.5g levetiracetam and admitted to the neurology service. MRI/MRA of the head and neck with and without contrast subsequently demonstrated abnormal increased T2 and T2 FLAIR signal intensity throughout the cortical and subcortical gray matter of the bilateral frontal, parietal, occipital and posterior temporal lobes, with scattered areas of



**Figure 3.** Initial T2 weighted magnetic resonance imaging of Patient 3 on second emergency department visit, showing increased T2 intensity throughout the cortical and subcortical gray matter of the bilateral frontal, parietal, occipital and posterior temporal lobes.

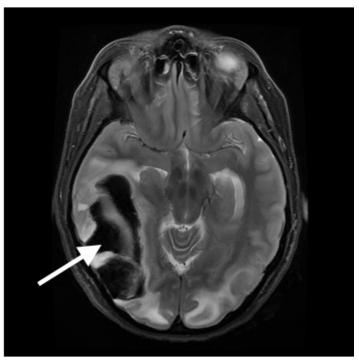
restricted diffusion within the posterior cortex of the bilateral parietal regions, concerning for PRES (Figure 3). The patient underwent lumbar puncture, with normal cerebrospinal fluid studies.

Once admitted, her chest x-ray showed patchy opacities bilaterally, and her oxygen saturation on repeat measures slowly dropped to 80%. As such, patient was intubated on her first hospital day for presumed aspiration pneumonia. She was treated with ampicillin and sulbactam, and her hypoxemia steadily resolved. She received daily enoxaparin injections for thrombosis prophylaxis. On hospital day four, the patient was noted to have a sudden decline in mental status and repeat MRI showed a massive right-sided temporoccipital intraparenchymal hemorrhage (Figure 4). The patient was taken for decompressive craniectomy and drainage.

Her mental status slowly improved and she was transferred to the rehabilitation service on hospital day 21. Her subsequent course was complicated by a surgical wound infection, requiring surgical washout. She was discharged home with ongoing physical, occupational, and speech therapies 41 days after her initial presentation. Two months after discharge, the patient has some mild to moderate persistent short-term memory loss and persistent left visual field deficit, but is otherwise neurologically intact.

### Discussion

These three cases demonstrate the extremely variable presentation and clinical course of patients found to have PRES on neuroimaging. The medical literature in general,



**Figure 4.** T2 weighted magnetic resonance imaging of Patient 3 on hospital day 4 with massive right-sided temporo-occipital intraparenchymal hemorrhage.

and emergency medicine (EM) literature in particular, is very limited with respect to prevalence, epidemiology, etiology, and management of PRES. In the few published reviews of patients diagnosed with PRES, however, the most common clinical manifestations were seizure (74%-91.7% of patients), followed by encephalopathy (28%-92%), headaches (26%-83.3%) and visual disturbances (20%-62.5%).<sup>5-7</sup> Hypertension was the most common associated co-morbid condition (53%-91.7%), followed by kidney disease (20.8%-45%), autoimmune disease (45%), malignancy (32%), organ transplant (24%), cytotoxic medications (19%), renal artery stenosis (12.5%), sepsis (7%), pre/eclampsia (6%), Takayasu's arteritis (4.2%), Sheehan syndrome (4.2%) and multi-organ dysfunction (1%) for the patients included in these reports.<sup>5-7</sup> PRES has now also been well described in the pediatric population.8 Given the wide and variable range of patient presentations, PRES is a difficult diagnosis to make in the ED.

Several pathophysiologic mechanisms have been thought to lead to the development of PRES. The current theory is that endothelial dysfunction leads to edema of the surrounding tissues.<sup>1</sup> The posterior cerebrum is thought to be especially sensitive to such injuries because of poor sympathetic innervation of the vasculature.<sup>9</sup> This could explain why PRES can present as a complication of a wide array of disease processes which all can lead to endothelial dysfunction.

Two studies in the literature report their experience in treating patients with PRES. Prompt lowering of blood pressure, treatment of associated seizures and removal of the causative agent are recommended in the management of PRES.<sup>10,11</sup> A mean arterial blood pressure reduction to 105-125mmHg is suggested with no more than 25% of this reduction occurring in the first hour. First line agents to achieve this effect are calcium channel blockers (e.g. nicardipine) or beta-blockers (e.g. labetalol). Second line agents to consider are sodium nitroprussiate and hydralazine. Nitroglycerin should be specifically avoided secondary to reports of worsening cerebral edema likely mediated by enhancing cerebral vasodilation.<sup>10,11</sup>

Management of seizures has been recommended to follow that of other epileptic seizures. This includes benzodiazepines, such as lorazepam or diazepam, as first line agents. Second line agents include fosphenytoin or phenobarbital. In pregnant patients one can consider magnesium sulfate. Refractory seizures can be managed with propofol or pentobarbital. There are reports of patients treated with valproic acid for seizures.<sup>10,11</sup>

A few key points should be highlighted with respect to the above three cases. The patient in Case 1 had only mild hypertension (140s/80s), although this was significantly higher than the patient's baseline blood pressures, which were systolic blood pressures in the 80s-90s range. Her history of esophageal dysmotility is also suggestive of a possible autoimmune process, such as scleroderma. However, her subsequent rheumatologic workup was negative. Of note, the patient subsequently submitted multiple complaints to regulatory bodies. A thorough review and discussion of the case during EM monthly Morbidity and Morality Conference case conference revealed only 12 out of 23 attending emergency physicians had ever heard of PRES, and only five had cared for a PRES patient in the past.

The patient in Case 2 presented with marked hypertension, altered mental status, and seizures as is typical of PRES presentations. It is atypical, however, for PRES to proceed to death. Autopsy did not reveal any alternate cause of death. The patient in Case 3 had a subsequent intraparenchymal hemorrhage. The exact etiology of the bleed in this case is not clear, although it may have been secondary to prolonged hypertension. PRES itself has been associated with intracranial hemorrhage, as well. One retrospective series of 263 patients with PRES found an intracranial hemorrhage prevalence of 19.4%, of which 90% were intraparenchymal hemorrhages.<sup>12</sup> The majority of these (63%) were small punctate bleeds, with only 8.7% resulting in extensive hemorrhages, as seen in case 3. All intraparenchymal bleeds were located within or near the area of initial PRES-related parenchymal edema.

These cases highlight the difficulty in diagnosing PRES in the emergency department. Patient 1 and Patient 3 both had multiple ED visits prior to being admitted and diagnosed with PRES. Any patient who presents with altered mental status, headache, or seizure may benefit from consideration of PRES in the differential diagnosis. Such a consideration should prompt earlier MRI and neurology consultations. This is especially important because earlier diagnosis will lead to a more proactive search for, and treatment of, underlying causes. Of note, there are ongoing research studies looking into possible laboratory markers of PRES, including lactate dehygrogenase.<sup>13</sup> While such markers, at present, will not be specific, a sensitive laboratory study can also assist evaluation and management of such patients.

### CONCLUSION

PRES can present to the ED in a variety of ways, and is associated with a wide variety of underlying pathology, as illustrated by these three cases. With the increasing awareness of this diagnosis by emergency physicians and increasing use of MRI in the ED, a PRES diagnosis may be made more frequently in the ED in the future. Ideally, earlier identification of PRES will result in more expedited evaluation and treatment, and better short and long-term outcomes for ED patients.

Address for Correspondence: Ryan J. Thompson, MD, University Bay Office Building, 800 University Bay Drive, Suite 310, Madison, WI 53792. Email: RThompson@medicine.wisc.edu.

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### **Anticoagulation Drug Therapy: A Review**

Katherine Harter, MD Michael Levine, MD Sean O. Henderson, MD University of Southern California, LA+USC Medical Center, Department of Emergency Medicine, Los Angeles, California

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Historically, most patients who required parenteral anticoagulation received heparin, whereas those patients requiring oral anticoagulation received warfarin. Due to the narrow therapeutic index and need for frequent laboratory monitoring associated with warfarin, there has been a desire to develop newer, more effective anticoagulants. Consequently, in recent years many novel anticoagulants have been developed.

The emergency physician may institute anticoagulation therapy in the short term (e.g. heparin) for a patient being admitted, or may start a novel anticoagulation for a patient being discharged. Similarly, a patient on a novel anticoagulant may present to the emergency department due to a hemorrhagic complication. Consequently, the emergency physician should be familiar with the newer and older anticoagulants. This review emphasizes the indication, mechanism of action, adverse effects, and potential reversal strategies for various anticoagulants that the emergency physician will likely encounter. [West J Emerg Med. 2015;16(1):11–17.]

### INTRODUCTION

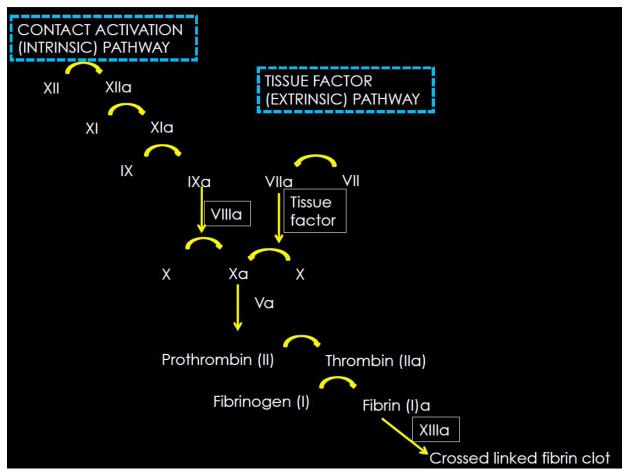
During routine homeostatic conditions, the human body maintains a constant balance between thrombus formation and destruction. This equilibrium is maintained by a complex interaction between platelets and the vascular endothelium, the coagulation cascade, and the fibrinolytic system. The coagulation cascade (Figure 1) involves an interaction between the contact activation pathway (previously called the intrinsic system), and the tissue factor pathway (previously the extrinsic system). These two seemingly independent pathways lead to the conversion of factor X to Xa, which is the start of the common pathway. This common pathway converts prothrombin to thrombin, which subsequently catalyzes the formation of fibrin and ultimately leads to the stabilization of aggregated platelets to form a stable clot.<sup>1,2</sup>

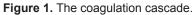
Historically, vitamin K antagonists, such as warfarin, were the only anticoagulants widely available for human use. It has been estimated that more than 65,000 patients are treated in U.S. emergency departments (ED) annually for warfarin-related hemorrhage.<sup>3</sup> Because of this high rate of bleeding, along with the drug's narrow therapeutic index and the need for frequent monitoring, there has been a desire to create safer anticoagulants without such strict drug monitoring. Consequently, there have been several novel anticoagulants (NACs) developed, including direct thrombin inhibitors (e.g. dabigatran), and factor Xa inhibitors (e.g. rivaroxaban, apixaban), designed to target different points of the coagulation cascade (Figure 2).<sup>4,5</sup>

As NACs become more pervasive in the clinical setting, used for both therapeutic and prophylactic purposes, it will become essential for the emergency physician to become aware of the indications to start specific drugs, as well as unique complications and recommended reversal methods for such agents. An intimate knowledge of these drugs will be required for the ideal management. Unfortunately, while the clinical efficacy of NACs has been established, much less is known about the risks of adverse reactions as well as the ability to reverse these agents.<sup>6</sup> Figure 3 below summarizes the most widely-used anticoagulants; they will be discussed in this article. This article provides a review of the literature as it focuses on both the risks associated with anticoagulants, as well as reversal agents of the most commonly used NACs to help guide management in the emergency setting.

### Vitamin K antagonists

Vitamin K antagonists (VKAs) such as warfarin function by blocking the vitamin K-epoxide reductase, thereby preventing





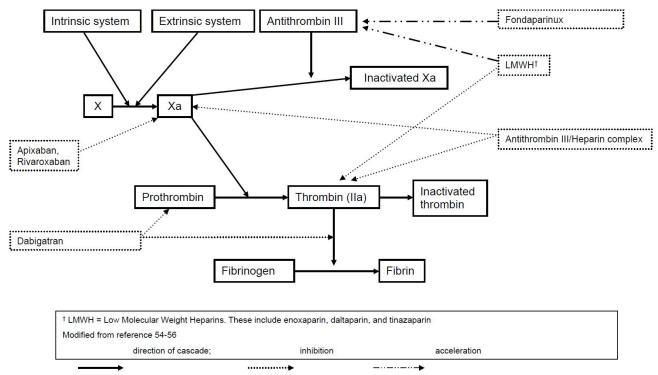


Figure 2. Site of action of drugs. Modified, with permission, Gresham C, Levine M, Ruha AM.<sup>17</sup>

|                 | Dose Reduction in    | Laboratory                            | Adverse           | <b>Potential Reversal Agents</b>                           |
|-----------------|----------------------|---------------------------------------|-------------------|--|
|                 | <b>Renal Failure</b> | Monitoring                            | Events            |  |
| Vitamin K Anta  | gonist               |                                       |                   |  |
| Warfarin        | None                 | PT, INR                               | Hemorrhage        | Vitamin K: PO vs IV  |
|                 |                      |                                       | <b>Purple Toe</b> | FFP  |
|                 |                      |                                       | Skin Necrosis     | PCC: 3 vs 4 factor   |
|                 |                      |                                       | Teratogen         | rVIIa  |
| Heparins        | 1                    |                                       |                   |  |
| Unfractionated  | None                 | aPTT                                  | Hemorrhage        | Protamine Sulfate: 1mg per 100U                            |
| Heparin         | 8                    |                                       | HIT               | of UFH given over previous 4 hrs                           |
| Enoxaparin      | Yes                  | Anti-factor Xa                        | Hemorrhage<br>HIT | Protamine Sulfate: 1mg per 1mg<br>of enoxaparin            |
| Daltaparin      | Yes                  | Anti-factor Xa                        | Hemorrhage<br>HIT | Protamine Sulfate: 1mg per 100U<br>of factor Xa inhibition |
| Tinzaparin      | Yes                  | Anti-factor Xa                        | Hemorrhage<br>HIT | Protamine Sulfate: 1mg per 100U<br>of factor Xa inhibition |
| Factor Xa Inhib | itor                 |                                       |                   |  |
| Fondaparinux    | Yes                  | Anti-factor Xa                        | Hemorrhage        | Possibly four-complex PCC                                  |
| Rivaroxiban     | Yes                  | Anti-factor Xa                        | Hemorrhage        | Possibly four-complex PCC                                  |
| Apixaban        | Unknown              | Anti-factor Xa                        | Hemorrhage        | Possibly four-complex PCC                                  |
| Direct Thrombin | n Inhibitor          |                                       |                   |  |
| Dabigatran      | Yes                  | Thrombin time<br>Ecarin Clotting Time | Hemorrhage        | Possibly four-complex PCC                                  |
| Bivalirudin     | Yes                  | Thrombin time<br>Ecarin clotting time | Hemorrhage        | Possibly four-complex PCC                                  |
| Argatroban      | None                 | Thrombin time<br>Ecarin clotting time | Hemorrhage        | Possibly four-complex PCC                                  |
| Fibrinolytics   |                      | Š.                                    |                   |  |
| Alteplase       | None                 | PT, aPTT, fibrinogen                  | Hemorrhage        | Aminocaproic acid<br>Tranexamic acid                       |
| Reteplase       | None                 | PT, aPTT, fibrinogen                  | Hemorrhage        | Aminocaproic acid<br>Tranexamic acid                       |
| Tenecteplase    | None                 | PT, aPTT, fibrinogen                  | Hemorrhage        | Aminocaproic acid<br>Tranexamic acid                       |
| Urokinase       | None                 | PT, aPTT, fibrinogen                  | Hemorrhage        | Aminocaproic acid<br>Tranexamic acid                       |

Figure 3. Comparison table for anticoagulants.9,19,25,38

*PT*, pro-thrombin time; *INR*, international normalized ratio; *HIT*, heparin-induced thrombocytopenia; *PO*, oral administration; *IV*, intravenous; *FFP*, fresh frozen plasma; *aPTT*, activated partial thromboplastin time; *UFH*, unfractionated heparin; *PCC*, prothrombin complex concentrates

formation of the active form of the vitamin K-dependent clotting factors.<sup>7</sup> The VKAs have an initial pro-thrombotic effect, by initially blocking proteins C and S, followed by a delayed antithrombotic effect, through the inhibition of coagulation factors II, VII, IX, and X.<sup>7</sup>

### Warfarin

Federal Drug Administration indications for use include long-term anticoagulation following a thrombotic event or prevention of thrombotic events in patients at high risk, including post-operative states, atrial fibrillation, and those with artificial valves.<sup>8</sup> Because of the initial pro-coagulant effect, if rapid anticoagulation is required, warfarin is paired with a rapid-acting parenteral anticoagulant, which can be discontinued after therapeutic levels are achieved and stable over the course of 24 hours.

Warfarin is taken orally, at doses typically ranging from 5-10mg daily, tailored based on the international normalized ratio (INR), the universal monitoring index based on prothrombin time (PT). Warfarin is primarily metabolized through the P450 system.<sup>9</sup> Induction or inhibition of the isoenzymes involved with warfarin's metabolism can potentially increase the INR significantly.<sup>7</sup> Furthermore, alterations in oral vitamin K consumption can create significant fluctuations in the INR.<sup>10</sup>

### Side Effects and Reversal Agents

Hemorrhage is the most significant adverse effect associated with warfarin and is directly related to the level of INR; the risk of hemorrhage is increased if the INR is greater than five.7 Risk factors for warfarinrelated hemorrhage include advanced age, serious comorbid conditions including cancer, chronic kidney disease (CKD), liver dysfunction, arterial hypertension, prior stroke, alcohol abuse, and the concomitant use of antiplatelet or other drugs.<sup>7</sup> In the event of hemorrhage, the anticoagulant effects of warfarin can be reversed with the administration of vitamin K (phytonadione), fresh frozen plasma (FFP) or prothrombin complex concentrates (PCCs).<sup>12,13</sup> In addition, recombinant factor VIIa (rfVIIa) has been suggested as a possible reversal agent. While the use of rfVIIa has been demonstrated to provide a rapid reduction in the INR, its use is not associated with improved clinical outcomes.14,15

### Heparins

Antithrombin III (AT3) is a peptide that inhibits several of the activated clotting factors. Drugs that augment the function of AT3 serve as anticoagulants. Unfractionated heparin (UFH) binds to and increases the activity of antithrombin III by inducing a conformational change to Factor Xa, which ultimately leads to inhibition at Xa and IIa in a 1:1 ratio.<sup>16</sup> Unfractionated heparin also has some inhibition on factors IXa, XIa, XIIa.<sup>17</sup> Low molecular weight heparins (LMWH), which also bind AT3, are smaller and have a higher proportional impact on Xa, versus IIa, in a 3:1 or 2:1 ratio.<sup>16,17</sup> As a result of this inhibition, both the UFH and LMWH ultimately inhibit thrombin activation.

### Unfractionated Heparin (UFH)

UFH is indicated for numerous conditions including the treatment and prophylaxis of venous thromboembolisms (VTE), thrombus prophylaxis in atrial fibrillation, and treatment of disseminated intravascular coagulation.<sup>18</sup> Unlike warfarin, UFH is administered parenterally, both subcutaneous for its prophylaxis use and as a continuous intravenous infusion when used therapeutically. UFH has much faster onset of action as compared to warfarin; when used intravenously, therapeutic efficacy occurs almost immediately, while therapeutic efficacy is reached within 20-60 minutes when administered subcutaneously.<sup>9</sup> UFH has a shorter halflife than warfarin, and does not require dosage adjustment in renal failure.<sup>9</sup>

Side Effects and Reversal Agents Hemorrhage is a main adverse event in those receiving UFH. The incidence of major bleeding varies based on the indication of its use, dosage and route of administration. However, on average, UFH is associated with a 2.0% incidence of major bleeding when used therapeutically for VTE.<sup>19</sup> While major bleeding can be potentially fatal, UFH can be reversed with the administration of protamine sulfate. Typically, protamine is dosed based on the amount of UFH administered, not based on laboratory abnormalities. A dose of 1mg will reverse 100 units of UFH.

Another significant and well-documented adverse outcome of UFH use is the development of heparin-induced thrombocytopenia (HIT). A detailed discussion of HIT, however, is beyond the scope of this review. Nonetheless, treatment options for HIT include discontinuation of UFH, and the subsequent use of a different class of NAC, either a direct thrombin inhibitor (e.g. argatroban) or a factor Xa inhibitor (e.g. fondaparinux).

### Low Molecular Weight Heparin (LMWH)

The LMWH are parenterally-administered drugs, and include dalteparin, enoxaparin, and tinzaparin. Compared with UFH, the LMWH have the advantage of a more predictable dose-response curve.<sup>17</sup> Consequently, the LMWHs are administered at a fixed dose, based on total body weight, and do not require tight regulation and monitoring as is indicated with warfarin and UFH.<sup>17</sup> These drugs have near 100% bioavailability and reach peak levels 2-4 hours after subcutaneous administration.<sup>9,17</sup> They have a half-life of 3-4 hours and are eliminated primarily (80%) via renal clearance, thus necessitating dose reduction considerations in patients with renal insufficiency.9 Additionally, since dosing is based on total body weight, rather than ideal body weight, dosing complications arise in obese patients.<sup>17</sup> While therapeutic monitoring is not routinely indicated, in cases of renal insufficiency, obesity, or when iatrogenic overdose is a concern, antifactor Xa levels can be used to monitor LMWH.9,17 Ideally, the antifactor Xa level should be obtained four hours after the administration of the LMWH.

### Side Effects and Reversal Agents

Acute bleed is the major risk associated with LMWH. When used prophylactically the incidence of major bleeding associated with the LMWH is approximately 1.5-1.7%.<sup>19,20</sup> The incidence of major bleeding associated with therapeutic dosage of the LMWH is slightly higher at approximately 2%, with even higher incidences observed when used to treat acute coronary syndrome (ACS).<sup>19</sup> In the event of a major bleed, protamine sulfate can be used as a partial reversal agent and can reverse at most 60% of the anticoagulation effect of LMWH.<sup>19</sup> Initial doses of 1mg per 100 units of antifactor Xa should be administered within eight hours of LMWH administration. A second dose of 0.5mg per 100 units antifactor Xa can be repeated.<sup>17</sup> For significant bleeding associated with LMWH, cryoprecipitate and fresh frozen plasma is also recommended.<sup>17,19</sup>

### **Factor Xa inhibitors**

Factor Xa inhibitors are used for prophylaxis and treatment of VTE, as well as for prophylaxis of embolic disease in non-valvular atrial fibrillation, and as an alternative anticoagulant in the setting of HIT. These drugs inhibit factor Xa, the first step in the common pathway, either directly or indirectly. The inhibition occurs in a dosedependent manner.<sup>21</sup> Apixaban and rivaroxiban, directly bind to the active site of factor Xa, thereby inhibiting both free and clot-associated factor Xa. These drugs also inhibit prothrombinase activity.<sup>5</sup> Indirect Xa inhibitors, such as fondaparinux, bind to AT3, resulting in a conformational change, thereby inhibiting factor Xa without having any effect on IIa.17 Fondaparinux is primarily eliminated unchanged in the urine. Thus, its use in patients with renal insufficiency is contraindicated as its use in this patient population may increase the risk of hemorrhage.

There are no specific laboratory parameters available to monitor the anticoagulant impact of factor Xa inhibitors. A dose-dependent prolongation of aPTT and PT may be seen 1-4 hours after administration of direct Xa inhibitors such as rivaroxiban, matching the peak plasma level; however, this increase is short lived and in general PT, aPTT and bleeding time should not be affected at therapeutic levels of these drugs.9 Supratherapeutic concentrations of Xa inhibitors, however, have been associated with a dosedependent increase in PT.9 This increase in PT does not directly correlate with the increase in PT secondary to VKAs, and there is not a consistent conversion between the PT and the INR with these drugs.<sup>22</sup> Antifactor Xa levels were originally designed and calibrated for LMWH; however, they can also be used to monitor or confirm overdose of factor Xa inhibitors.<sup>9</sup> This test must be specifically calibrated for Factor Xa inhibitors, as the results of the antifactor Xa level is assay specific.17,23

### Side Effects and Reversal Agents

Adverse events related to Xa inhibitors include hemorrhage, as is the case with all anticoagulants. Thrombocytopenia has also been reported following the use of Xa inhibitors; however, the mechanism is unclear.<sup>17</sup> While no specific reversal agent exists, both rVIIa and PCC have been proposed.<sup>9,19</sup> The Thrombosis and Hemostasis Society of North America suggests that four-factor PCC may be the best option currently available.<sup>24</sup> The German Society of Neurology recommends PCC for reversal of factor Xa inhibitorinduced coagulopathy. However, at present, there is insufficient data to clearly support any reversal agent or to develop a standard of care.<sup>25</sup>

### Direct thrombin inhibitors (DTIs)

As their name implies, the direct thrombin inhibitors (DTIs) inhibit the intrinsic activity of the thrombin. Unlike heparin, which also inhibits thrombin, the DTIs do not require a factor, and can inhibit thrombin directly.<sup>7,26</sup> Most direct thrombin inhibitors are administered parenterally, including argatroban, bivalirudin; however, dabigatran is orally administered. These drugs are used for prophylaxis and treatment of VTE and ACS, and for prophylaxis of thrombus formation in non-valvular atrial fibrillation. They are also used as anticoagulation alternatives in the setting of HIT. Dabigatran, the only orally available DTI, is approved for treatment of VTE in patients treated with concomitant parenteral anticoagulation for at least five days, and for the treatment of thrombus secondary to non-valvular atrial fibrillation.

Laboratory evaluation of the DTIs includes measurement of a thrombin time (TT) or ecarin clotting time (ECT).<sup>29</sup> However, these tests are not widely available, thereby limiting their applicability, particularly in the emergency setting. The Hemoclot test is a diluted thrombin time assay designed specifically as an assay for the DTIs; however, like the TT and ECT, this test is not routinely available.<sup>30,31</sup> In the clinical setting, activated partial thromboplastin time (aPTT) can be used as a surrogate to monitor the effect of the DTIs; aPTT increases following a non-linear dose response curve and plateaus at higher concentrations of DTIs. Thus, a normal aPTT excludes the presence of significant amounts of a DTI, but the degree of elevation of the aPTT does not necessarily correlate with the degree of DTI-induced coagulopathy.<sup>29</sup>

### Side Effects and Reversal Agents

The primary toxicity of patients on DTIs is hemorrhage, including gastrointestinal bleeding and intracranial hemorrhage. The rate of bleeding is dose dependent, and is more common in those over 75 years of age.<sup>27,28</sup> Like many other NACs, no specific antidotes exist. The American College of Cardiology Foundation and the American Heart Association recommend transfusion of packed red blood cells and FFP, in addition to surgical intervention, if feasible, to control bleeding.<sup>32</sup> However, given that FFP contains factor II, which is inhibited from activation by DTIs, the use of FFP is unlikely to be beneficial.<sup>25</sup> For patients with impaired renal function who have life-threatening bleeding following dabigatran-induced coagulopathy, hemodialysis has been recommended by some experts.<sup>29</sup> Others have suggested that in the event of significant bleeding, the use of a four-complex PCC may be the most effective option; however, there is limited evidence-based data.25

### Fibrinolytics

The antithrombotic effect of fibrinolytics, which include tissue plasminogen activator (tPA) and urokinase, is achieved by inducing the conversion of inactive plasminogen into the active enzyme plasmin, which degrades the fibrin matrix responsible for stabilizing a thrombus.33 Recombinant forms of tPA and urokinase have been manufactured as fibrinolytics. Alteplase, an unmodified form of human tPA, along with reteplase and tenecteplase, a modified form of human tPA, are the most commonly used drugs in this class.<sup>34</sup> Common uses of these drugs include the treatment of acute cerebrovascular accidents (CVA), myocardial infarction, pulmonary emboli, as well as to dissolve thrombi in indwelling catheters. Following administration of fibrinolytics, an increase in the PT/INR and aPTT can be observed, along with a corresponding decrease in the fibrinogen; however, there are no specific laboratory indices to precisely measure the anticoagulant effect of fibrinolytics.

### Side Effects and Reversal Agents

The incidence of hemorrhage varies depending on the indication for the fibrinolytic. When used for acute CVA, tPA is associated with symptomatic intracranial hemorrhage at a rate of approximately 6%.<sup>35,36</sup> However, when tPA is given to those with healthy brains, the rate of such hemorrhage is much lower.<sup>37</sup>

In the event of acute hemorrhage the administration of blood products, including FFP, PCC, and platelets, have been found to have poor efficacy, and other agents, including tranexamic acid (TXA) and epsilonaminocaproic acid (EACA), have been considered.<sup>38</sup> TXA and EACA are both structurally similar to the amino acid lysine and inhibit fibrinolysis by competitively inhibiting plasminogen activation.<sup>38</sup>

### CONCLUSION

Acute hemorrhage is the most feared adverse event associated with all anticoagulants. While it is relatively uncommon that patients present with a life-threatening hemorrhage while on systemic anticoaguation, prompt recognition and management is vital. As the NAC become more frequently used in clinical settings, it will be imperative that the emergency physician has a thorough understanding of these agents, and is knowledgeable about potential reversal strategies, when available. *Conflicts of Interest:* By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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Address for Correspondence: Michael Levine, MD, Department of Emergency Medicine, Section of Medical Toxicology, 1200 North State Street, Room 1011, Los Angeles, CA 90033. Email: mdlevine@usc.edu.

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### Feasibility of Tablet Computer Screening for Opioid Abuse in the Emergency Department

Scott G. Weiner, MD, MPH\* Laura C. Horton, BA<sup>†</sup> Traci C. Green, PhD, MSc<sup>‡§</sup> Stephen F. Butler, PhD<sup>§</sup> \*Brigham and Women's Hospital, Department of Emergency Medicine, Boston, Massachusetts
<sup>†</sup>Tufts University School of Medicine, Boston, Massachusetts
<sup>‡</sup>Rhode Island Hospital, Department of Emergency Medicine, Providence, Rhode Island
<sup>§</sup>Inflexxion, Inc. Newton, Massachusetts

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**Introduction**: Tablet computer-based screening may have the potential for detecting patients at risk for opioid abuse in the emergency department (ED). Study objectives were a) to determine if the revised Screener and Opioid Assessment for Patients with Pain (SOAPP®-R), a 24-question previously paper-based screening tool for opioid abuse potential, could be administered on a tablet computer to an ED patient population; b) to demonstrate that >90% of patients can complete the electronic screener without assistance in <5 minutes and; c) to determine patient ease of use with screening on a tablet computer.

**Methods**: This was a cross-sectional convenience sample study of patients seen in an urban academic ED. SOAPP®-R was programmed on a tablet computer by study investigators. Inclusion criteria were patients ages ≥18 years who were being considered for discharge with a prescription for an opioid analgesic. Exclusion criteria included inability to understand English or physical disability preventing use of the tablet.

**Results**: 93 patients were approached for inclusion and 82 (88%) provided consent. Fifty-two percent (n=43) of subjects were male; 46% (n=38) of subjects were between 18-35 years, and 54% (n=44) were >35 years. One hundred percent of subjects completed the screener. Median time to completion was 148 (interquartile range 117.5-184.3) seconds, and 95% (n=78) completed in <5 minutes. 93% (n=76) rated ease of completion as very easy.

**Conclusions**: It is feasible to administer a screening tool to a cohort of ED patients on a tablet computer. The screener administration time is minimal and patient ease of use with this modality is high. [West J Emerg Med. 2015;16(1):18–23.]

### **INTRODUCTION**

Screening tools to detect undiagnosed mental health and substance use problems have been developed to enable earlier detection of disorders, and thus, earlier care.<sup>1</sup> Multiple tools have been developed for this purpose, including the Patient Health Questionnaire (PHQ-9) for depression, Alcohol Use Disorders Identification Test (AUDIT) and the Drug Abuse Screening Test (DAST).<sup>2-4</sup> These tools are an important first

step in the process of SBIRT (screening, brief intervention and referral to treatment).<sup>5</sup> Using such screening tools in the emergency department (ED) can be powerful, particularly at the time of exacerbation of disease.<sup>6,7</sup>

The process of screening patients may be time consuming, costly and can require staff resources that do not exist.<sup>8</sup> Computerized screening may be a solution to this dilemma.<sup>9</sup> Computerized screening requires minimal staff time, scores are calculated without error and, with the recent increased number of available products and expanded use of tablet computers in society over the past several years, patients are becoming comfortable interacting with technology. Given these factors and the evolution of tablet computers that are now lighter, less expensive and with a longer battery life,<sup>10</sup> screening ED patients with tablet computers may be an attractive option.

In this study, we used an electronic tablet version of a screener for opioid prescription abuse potential. Opioid prescription abuse in the United States has increased exponentially over the past decade.<sup>11</sup> Deaths from drug overdose have surpassed deaths from motor vehicle accidents, and the problem has been described as an epidemic,<sup>12,13</sup> elevating screening for opioid abuse potential to great importance.

The screening tool we chose for our ED population is the Revised Screener and Opioid Assessment for Patients with Pain (SOAPP®-R).<sup>14</sup> This proprietary screening measure, developed and validated by Inflexxion, Inc. as part of a NIDA-funded Small Business Innovative Research (SBIR) grant, was developed and validated in pain clinic patients and is also commonly used in primary care practices. The Centers for Disease Control and Prevention have concluded: "Health-care providers should only use opioid pain relievers in carefully screened and monitored patients when nonopioid pain reliever treatments are insufficient to manage pain."<sup>11</sup> Despite the fact that up to 42% of ED visits are for painful conditions<sup>15</sup> and that emergency physicians commonly prescribe opioids, screening tools like this are not commonly used in the ED setting.

Our study has the following objectives: a) To determine if this screening tool could be administered on a tablet computer in an ED patient population; b) To demonstrate that >90% of patients can complete the screener without assistance in <5 minutes and; c) To determine patient perception of ease of use with screening on a tablet computer.

### MATERIAL AND METHODS Study Location

This was a cross-sectional, prospective, convenience sample study of patients seen at a single urban academic Level I trauma center with approximately 42,000 annual visits. The protocol was approved as exempt by our hospital's institutional review board. Patient consent was determined by the patient indicating willingness to continue on the welcome screen of the tablet computer program.

### **Programming the Tablet Screener**

SOAPP®-R was administered on a generic seven-inch tablet running the Android operating system (PC709 Android 4.0 Tablet, dimensions 7x5x0.25 inches). Permission to use the SOAPP®-R instrument in electronic format for this study was granted by its copyright holder (Inflexxion, Inc., Newton, MA). The tablet was programmed using the "App Inventor" programming language.<sup>16</sup> In addition to the screening tool, basic demographic questions and a final question asking satisfaction/ease of use with the tablet screener were included.

### Patients

Included individuals were patients ages  $\geq 18$  years who were being considered for discharge with an opioid analgesic by the attending emergency physician. Exclusion criteria were the following: inability to understand English, physical disability preventing use of the tablet, the patient was not being prescribed an opioid for the treatment of acute or chronic pain (e.g. codeine given for cough suppression or buprenorphine or methadone for maintenance of a drug treatment program), dementia or other mental impairment, or the patient was a prisoner.

### Intervention

Patients were identified by physicians informing the research assistant that they were being discharged with an opioid analgesic, or when the research assistant saw on the electronic charting system (Medhost EDIS, Medhost, Inc., Plano TX) that the patient was being discharged with such a prescription. This trained researcher approached the patient, briefly described the study, and handed them the tablet with the survey program open. Consent was acknowledged on the tablet, and a welcome screen informed patients that their responses would not be shared with their treating clinicians, and thus, not affect medications prescribed to them. Although the researcher was present at all times, patients were required to complete the screener without assistance. The researcher was also unaware of the patients' screening results, which were stored only on the tablet for later analysis and not reported at the time of screening. The internet functionality of the tablet was disabled to prevent possible breach of data, and the tablet was stored in a locked safe at the clinical site when not in use. Data were exported to a computer in a locked office on a weekly basis during the study.

The SOAPP®-R is a 24-question screening tool that has a question stem followed by one of five responses, each with an associated number of points: never (0 points), seldom (1 point), sometimes (2 points), often (3 points), and very often (4 points). Therefore, the range of total points possible is 0-96. A positive score on the screener, which has been identified as predicting aberrant medication-related behavior within six months after initial testing, is 18 points or higher. This score was determined to have a sensitivity of 81% for detecting high-risk patients.<sup>14</sup> The tool was originally designed to be administered on paper and completed in less than 10 minutes (600 seconds). A screen shot of the tablet version is found in the Figure.

### **Outcome Measures**

The three outcome measures were a) to determine if the SOAPP®-R could be administered on a tablet computer to an ED patient population, determined by survey completion rate; b) to demonstrate that the vast majority of patients can complete



Figure. Sample screenshot of the electronic screening tool.

the electronic screener without assistance in <5 minutes (an arbitrary cutoff we thought would be most reasonable for patients and clinicians) and; c) to determine patient ease of use with screening on a tablet computer determined by a survey question built in to the tablet application asking patients to describe their experience as one of five choices: very easy, somewhat easy, neutral, somewhat difficult, or very difficult.

# THEORY/CALCULATION Power Calculation

Our sample size was based on calculations for a companion study comparing SOAPP-R scores with prescription drug monitoring data. We estimated that 30% (+/- 10%) of patients who completed SOAPP®-R would score as "at-risk" (score  $\geq$ 18). The necessary sample size to obtain that margin of error with a 95% CI was determined to be 81 patients. This estimate was based on a prior study at our site showing that 33.1% of patients had evidence of aberrant drug-related behavior ( $\geq$ 4 opioid prescriptions and  $\geq$ 4 providers in a 12-month period) on the state prescription drug monitoring program database.<sup>17</sup> We purport that this number of patients is also sufficient for gathering adequate pilot data for this study.

### **Statistical Analysis**

We exported data from the tablet to a desktop computer and imported the data into statistical analysis software. There was no manual transfer of data required, so risk of data loss was negligible. Descriptive statistics were generated. We calculated mean, standard deviation, median, and minimum and maximum values for all continuous variables. Frequencies and percentages were calculated for all categorical variables. We analyzed all data with JMP v8.0 (SAS Institute, Inc., Cary, NC).

### RESULTS

### Patients

Between May and August 2013, 93 patients were approached for inclusion, and 82 (88%) provided consent. Patient characteristics are demonstrated in Table.

### **Outcome Measures**

One hundred percent of subjects were able to complete the tablet screener without assistance. Every patient completed the screener, answering all of the questions. Distribution of time to completion was not parametric. The median time to completion of the 24 questions on the SOAPP®-R was 148.0 seconds (interquartile range=117.5-185.3). Seventy-eight of 82 patients (95.1%) were able to complete the screener in <300 seconds (5 minutes). The mean SOAPP®-R score was 16.0 (95% CI 13.2-18.8). Approximately one third (32.9%, n=27) of patients had a SOAPP®-R score  $\geq$ 18, indicating that they were "at risk" for aberrant behavior.

Patients rated ease of completion as 93% (n=76) very easy, 1% (n=1) somewhat easy, 5% (n=4) neutral, 1% (n=1) somewhat difficult. Overall, the tablet had no malfunctions and operated normally throughout the study.

### DISCUSSION

This study demonstrated that a screening tool for opioid abuse potential can be administered electronically to an ED

| Table. Characteristics of included patients in tablet computer- |
|---|
| based screening for possible risk for opioid abuse.             |

| Characteristics          | n (%)      |
|--------------------------|------------|
| Age (years)              |            |
| 18-25                    | 19 (23.2%) |
| 26-35                    | 16 (19.5%) |
| 36-45                    | 19 (23.2%) |
| 46-55                    | 23 (28.0%) |
| 56-older                 | 5 (6.1%)   |
| Race                     |            |
| White                    | 51 (62.2%) |
| Black                    | 21 (25.6%) |
| Asian                    | 2 (2.4%)   |
| Other/declined to answer | 8 (9.8%)   |
| Ethnicity                |            |
| Latino                   | 10 (12.2%) |
| Not Latino               | 72 (87.8%) |

patient population. Our research joins multiple prior studies in various clinical settings demonstrating the applicability and feasibility of electronic screening. Early studies of computerized screening in healthcare settings were performed before the introduction of tablet computers, and focused mainly on the fidelity between paper and electronic versions of the screener. For example, Olajos-Clow et al. studied patients completing the Mini Asthma Quality of Life questionnaire.<sup>18</sup> Patients were randomized to either a paper or a computerized version. The researchers found that there was good agreement between the two methods and that the electronic version was preferred by most participants. Similar findings were present in other crossover comparison studies of electronic versus original paper versions.<sup>19-22</sup>

Other studies have looked at technology-based screening specifically in the ED patient population. Cotter et al. surveyed adolescents and young adults about their energy drink and caffeinated beverage use, administered on a tablet computer.<sup>23</sup> Ewing et al. administered the computerized alcohol screening and intervention (CASI) system to screen over 1,000 traumatized patients for alcohol use with the aforementioned AUDIT tool in electronic format.<sup>24</sup> And although not for screening purposes, an interactive computerized history-taking program has been successfully used to augment history information at triage without delaying patient care.<sup>25</sup>

In a large study, Ranney et al. interviewed 664 ED patients about their use of technology.<sup>26</sup> The study found that baseline use of computers and mobile phones was high (>90%) in their patient population, although the methodology oversampled adolescents/young adults, and mean patient age was 31 years. Patients were concerned about their confidentiality in regards to the internet and social media, but were interested in technology-based behavioral health interventions.

All of these studies confirm that patients can interact with the technology. That said, one of our concerns at the onset of this research was truthfulness of patients. It would be easy to simply select the same answer for each question or not answer honestly. One of the earliest studies to evaluate this problem was Lucas et al. in 1977.<sup>27</sup> Using a primitive computer system, it was determined that patients being screened for alcohol consumption reported significantly greater amounts of alcohol use to the computer than they reported to psychiatrists asking the same question. Our results, demonstrating that 32.9% of patients had a score of 18 points or higher ("at-risk") on the SOAPP®-R screener, suggest they were most likely being truthful and is remarkably consistent with our prior research indicating that 33.1% of patients with back pain, headache or dental pain exhibited aberrant medication use behavior.<sup>17</sup> It must be emphasized that patients were told that the results were not going to be shared with their treating clinician. If they had been, results may have varied. Future dedicated research on the accuracy of the screener must be done before any

conclusions can be made about this aspect of the screening tool. Furthermore, it is not known what steps emergency clinicians would take after they learn about a positive screening result for one of their patients.

There are also studies describing the downsides of such technology. For example, while initial reports of diagnostic computer kiosks were positive, Ackerman and colleagues described the failure of kiosks in their EDs and concluded that there are context-related factors involved in implementation of information technology projects into complex medical settings.<sup>28</sup> The study serves as a warning that what is feasible in one hospital may not work in others.

There are important factors to consider with selfprogramming of a tablet screener, such as a possible copyright infringement if permission to use commercial screener is not obtained, issues of collection and protection of protected health information (especially when dealing with sensitive issues such as substance abuse histories and other highly confidential patient data), and eventual integration into an electronic medical record. The developers of the SOAPP®-R at Inflexxion do offer a commercially available tablet version (the Pain Assessment Interview Network—Clinical Advisory System – "PainCAS").

This study supports three concepts. The first is that, with graphics-based programming languages like App Inventor, it is now possible for clinicians with minimal prior programming experience to create programs that can be used in the clinical setting, rendering development and implementation costs minimal. The second is that patients are able to interact with the technology of tablet computers in the ED setting, find them easy to use and appear to respond truthfully to the questions asked on a screener. The third concept is that, because it is electronic, there is little chance of data loss and exact times to completion of the survey can be recorded. Our app recorded the exact time taken from the first question of SOAPP®-R appearing on the screen to answering the last question, allowing for a precise measurement of time that did not rely on a researcher.

### LIMITATIONS

As this was a convenience sample, selection bias may have been present. The study was conducted when research staff was available to enroll so only a small percentage of potentially eligible subjects was enrolled. We only included patients who were fluent in English and might have therefore excluded at-risk minority populations. Furthermore, because this is a single center study in an urban environment, the results may not be externally applicable to other patient populations. Specifically, we do not know if our patient population has more experience using tablet computers than others. Only 6.1% of our patients were aged 56 or older, so it is not possible to comment on the use of the tablet computer in the elderly population. Although about one-third of patients had an "at-risk" SOAPP®-R score, it is possible that patients were not truthful with the results. Alternatively, because patients knew that the results would not be reported to their treating clinician, they may have been honest when they would not have been if they feared that their answers would prevent them from receiving an opioid pain reliever.

Configuration of the tablet response buttons (vertical layout) is different than the paper version (horizontal layout) and may have predisposed patients towards simply the top answers (i.e. never or seldom), which could result in our study underestimating the true prevalence of "at-risk" SOAPP®-R scores. We did not compare paper and computerized versions of the screener, which may have indicated advantages of one modality over the other.

### CONCLUSION

Our study demonstrates that it is feasible to program a tablet-based screening tool for opioid abuse potential and administer it in a time-efficient fashion to a cohort of ED patients. Patients rated the screening tool as easy to use. All enrolled patients were able to complete the tool without assistance, and required no additional staff resources for screening. The efficient completion time and patient-reported ease of completion support the conclusion that tablet computers may be used to screen ED patients.

Address for Correspondence: Scott G. Weiner, MD, MPH, 75 Francis Street, Neville House, Boston, MA 02115. Email: sgweiner@partners.org.

*Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. Dr. Stephen Butler of Inflexxion, Inc., who is a co-creator of SOAPP-R, and Dr. Traci Green, who works for this company, provided input on study design and helped edit the manuscript prior to submission. However, they did not contribute to the running of the study or data analysis. Dr. Scott Weiner, the principal investigator of the study, purchased the tablet and programmed the survey. The company did not provide funding for the study, tablet or programming.

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### Discrepancy Between Clinician and Research Assistant in TIMI Score Calculation (TRIAGED CPU)

Brian T. Taylor, DO Michelino Mancini, DO Lakeland HealthCare, Department of Emergency Medicine, St. Joseph MI, Department of Emergency Medicine, Saint Joseph, Michigan

Supervising Section Editor: Amal Mattu, MD

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**Introduction:** Several studies have attempted to demonstrate that the Thrombolysis in Myocardial Infarction (TIMI) risk score has the ability to risk stratify emergency department (ED) patients with potential acute coronary syndromes (ACS). Most of the studies we reviewed relied on trained research investigators to determine TIMI risk scores rather than ED providers functioning in their normal work capacity. We assessed whether TIMI risk scores obtained by ED providers in the setting of a busy ED differed from those obtained by trained research investigators.

**Methods**: This was an ED-based prospective observational cohort study comparing TIMI scores obtained by 49 ED providers admitting patients to an ED chest pain unit (CPU) to scores generated by a team of trained research investigators. We examined provider type, patient gender, and TIMI elements for their effects on TIMI risk score discrepancy.

**Results:** Of the 501 adult patients enrolled in the study, 29.3% of TIMI risk scores determined by ED providers and trained research investigators were generated using identical TIMI risk score variables. In our low-risk population the majority of TIMI risk score differences were small; however, 12% of TIMI risk scores differed by two or more points.

**Conclusion:** TIMI risk scores determined by ED providers in the setting of a busy ED frequently differ from scores generated by trained research investigators who complete them while not under the same pressure of an ED provider. [West J Emerg Med. 2015;16(1):24–33.]

### **INTRODUCTION**

Chest pain is the second most common complaint of patients presenting to emergency departments (ED) in the United States, accounting for approximately seven million visits annually.<sup>1</sup> Early determination of whether a patient's chest pain origin is cardiac versus noncardiac is imperative. Patients diagnosed early with acute coronary diseases (ACS) may benefit from early interventions.<sup>2-6</sup> A missed diagnosis of ACS may result in wrongful discharge, myocardial infarction and sudden death. Despite the use of electrocardiography (ECG) results, biomarker assays, patient history and clinical acumen, 0.4-5% of patients with acute myocardial infarction are inadvertently discharged from the ED.<sup>7-14</sup>

In an effort to improve outcomes in patients with acute

coronary syndromes, researchers have developed numerous risk stratification tools.<sup>15-57</sup> Of all the risk stratification systems developed, the thrombolysis in myocardial infarction (TIMI) risk score is the most studied, supported and used.<sup>3,7,58,59</sup>

A patient's TIMI risk score is determined by assigning a value of one point for each of seven equally weighted prognostic variables with the total score determining a patient's risk of adverse cardiac outcome (death, MI, severe recurrent ischemia requiring revascularization) within 14 days of presentation.

The TIMI risk score was originally derived from a retrospective analysis of a relatively high-risk population of patients with known unstable angina/non-ST elevation myocardial infarction.<sup>15</sup> In this patient population the TIMI

risk score was associated with 4.7% to 40.9% (or greater) risk of adverse cardiac outcome.<sup>15</sup> Following the development of the TIMI risk score tool, several studies were performed validating the tool's ability to stratify risk among patients with cardiac disease.<sup>16,60-62</sup>

Though not originally designed for ED use, several additional studies have attempted to demonstrate the TIMI risk score's ability to stratify risk among real-world ED populations.<sup>7,17-21,63-68</sup> As a result of these studies, the TIMI risk score tool has made its way into the protocols of EDs and hospitals around the world, often determining whether a patient is admitted to a hospital, observation unit or discharged home.<sup>64</sup>

### Importance

For many reasons, complete and accurate TIMI risk scores can be difficult to obtain when patients present with chest pain to a busy ED. Several studies have demonstrated how interruptions, distractions, and workload affect an ED provider's ability to maintain thought flow and increase the likelihood of errors occurring.<sup>69-72</sup> Pines et al.<sup>73</sup> suggest that patients presenting to the ED during times of increased ED crowding are at greater risk for adverse cardiovascular outcomes. Inaccurate TIMI risk scores may result in inaccurate risk stratification, as well as ineffectual or inappropriate management of patients with nonspecific chest pain.

Most studies validating the utility of the TIMI risk score among ED populations used trained research investigators or a combination of trained researchers and ED providers to generate TIMI risk scores.7,17,18,20,23,63 Trained research investigators do not work under the same time constraints and in the same distracted environment as a working ED provider. Trained research investigators have the benefit of spending more time interviewing patients, reviewing medical records, scrutinizing ECG patterns, and reviewing their own scores for errors and clarification.7,17 Unfortunately, the ED provider does not usually have a trained research investigator at his or her disposal to determine accurate TIMI risk scores. Our review of the literature found very few prospective studies using ED providers exclusively as assessors for the TIMI risk score. In the select studies where ED providers assessed TIMI risk scores, their scores were not compared against those of trained study investigators for accuracy or validity.<sup>64,65</sup>

Current guidelines from the American College of Cardiology, American Heart Association, and National Institute for Health and Clinical Excellence strongly encourage the use of early risk stratification tools such as the TIMI risk score when patients present to healthcare providers with chest pain.<sup>2-4,74</sup> In addition, Gallegher et al.<sup>75</sup> suggest the possibility of medicolegal pitfalls by providers not using risk-stratifying tools when assessing patients for evidence of ACS. As a result, the TIMI risk score tool is increasingly being used by ED providers as a basis for therapeutic decision-making despite a lack of supporting studies using ED provider-obtained data.

### **Outcomes of Interest**

The primary goal of our study was to determine if TIMI risk scores obtained by ED providers in the setting of a busy ED differ substantially from those obtained by trained research investigators who complete them while not under the same pressure of a working ED provider. In addition, we evaluated whether ED provider type or patient gender had any effect on TIMI risk score discrepancy, which aspects of the TIMI risk score most frequently differ between assessors, and whether lower TIMI risk scores (i.e., 0-3) or higher TIMI risk scores (i.e., >3) more frequently match research investigator scores.

### **METHODS**

### **Study Design**

This was a prospective observational cohort study comparing TIMI scores obtained by ED providers admitting patients to the chest pain unit (CPU) at an academic-based community hospital to scores generated by trained research investigators. The local institutional review board approved the study without need for written informed consent.

### **Study Setting and Population**

Lakeland Regional Medical Center is an academicbased community hospital with an annual ED census of approximately 50,000 patients. The hospital's six-bed CPU opened in 2010 and is situated adjacent to the ED. The CPU is open 24 hours a day, seven days a week and on holidays, with research investigators available 24 hours a day to enroll patients. The CPU is under the direct supervision of ED providers. All ED providers admitting patients to the CPU from October 27, 2012 until July 28, 2013 were included in the study. Participating ED providers included 18 attending physicians, 21 resident physicians and 10 midlevel providers (physician's assistants and nurse practitioners). No ED providers were excluded from the study. Patient inclusion criteria included all comers presenting to the ED with non-traumatic chest pain suggestive of ACS who were admitted to our hospital's CPU, irrespective of age. At our institution, ED providers independently determine who is to be placed in the CPU. Patient exclusion criteria for study enrollment mirrored CPU exclusion criteria as set by the hospital's Chest Pain Center Door-to-Balloon Committee. Accordingly, patients with chest pain were excluded from admission to the CPU when any of the following were present:

- ST-elevation acute myocardial infarction (STEMI)
- Positive cardiac biomarkers suggestive of myocardial injury
- ECG changes

- Unrelenting chest pain
- Coronary revascularization in the last 60 days
- Abnormal vital signs
- New dysrhythmia (any run of ventricular dysrhythmia is not a candidate for the CPU)
- Aortic dissection
- Pneumothorax
- Pneumonia
- Esophageal rupture
- Pulmonary embolism
- Pericardial tamponade
- Congestive heart failure
- Uncontrolled diabetes
- Electrolyte abnormalities that could not be cared for with PO electrolyte replacement
- Psychiatric instability
- Inability to perform activities of daily living
- Pleural effusions
- Renal failure requiring dialysis during their time in the CPU
- Any diagnosis meeting admission criteria

### **Study Protocol**

Research investigators consisted of registered CPU nurses who have completed formal ACS didactic sessions and learning modules. Prior to data collection, these research investigators received additional training on how to obtain TIMI risk scores. Their standardized training involved handouts, Microsoft Office PowerPoint presentations, and one-on-one training with clarification to increase the likelihood of unambiguous collection of data. Research investigators were instructed to use all resources available to them, including a patient's hospital record, accessible outside records, labs, prior cardiac catheterization reports, cardiology notes, and patientreported responses. Research investigators routinely evaluated the patient and assessed TIMI risk score variables within 24 hours of a patient's presentation to the ED (Figure 1). In situations where patients were unaware or unable to answer questions concerning pertinent medical history (for example, an adopted patient unaware of his or her family history), patients were not given any points for those variables.

Our goal for the research investigator was not to obtain 100% infallible TIMI scores, but rather to generate scores as close as possible to scores assigned by research investigators performing similar TIMI risk-score validation studies.

Separately, ED providers assigned TIMI risk scores to all patients admitted to the CPU at the time of CPU admission per hospital protocol. No additional TIMI training or education was provided to ED providers prior to data collection. Research investigators and ED Providers were blinded to one other's TIMI risk scores throughout the study.

- 1. Age ≥ 65
- Presence of known coronary artery stenosis ≥50%\*
   Prior cardiac catheterization with known disease
- Prior MI, CABG, angioplasty, or stent
- 3. Aspirin use in the preceding 7 days
- 4. At least 2 episodes of severe chest pain within last 24 hrs
- 5. ST changes ≥0.5mm on admission ECG
- 6. Initial serum cardiac biomarker elevation (Troponin I above normal range)
- 7. At least 3 of the following risk factors for CAD:
  - High blood pressure (≥140/90 or on antihypertensive medicine)
  - Diabetes, prediabetes, or hyperglycemia
  - Family history of premature CAD or MI (CAD in male 1st-degree relative, or father <55, or female 1st-degree relative or mother <65)
  - Elevated LDL (≥100), reduced HDL (≤40 for men, <50 for women), elevated triglycerides (≥150)
  - Smoking in the past 5 years\*\*

**Figure 1.** TIMI variables assessed by research investigators. *TIMI*, thrombolysis in myocardial infarction; *MI*, myocardial infarction; *CABG*, coronary artery bypass graft; *ECG*, electrocardiogram; *CAD*, coronary artery disease; *LDL*, low density lipoprotein; *HDL*, high density lipoprotein \*Similar to Pollack et al.,<sup>65</sup> this parameter was expanded in our study because actual cardiac catheterization reports were not always available in the emergency department. \*5 years was chosen as a cut-off because risk associated with smoking has been found to diminish after 5 years.<sup>76-78</sup>

### Data Analysis

Upon completion, we entered the pertinent data into an electronic database. We used SPSS software to make comparisons of TIMI risk scores obtained by research investigators and ED providers. Where significance testing was reported, we analyzed variables using the Pearson chisquare test.

### RESULTS

The patient population consisted of 543 patients who presented to the ED with symptoms suspicious for cardiac chest pain and were admitted to the CPU. Research investigators provided all variables used to form the TIMI risk score for 543 patients. ED providers provided the necessary variables for 501 patients. Because some ED providers did not record TIMI scores for every patient, we only had complete data for 501 patients. Of these 501 patients, 277 were female and 224 were male. The median age of the patient study population was 57 (ages 18 to 94).

Though the frequency distributions for research investigators and ED providers were similar, the two scores often did not match for a given patient (Table 1). In fact, of the 501 patients in the study with complete data, ED provider and researcher TIMI risk scores matched for only 213 patients (42.5%). Of the 213 patients with the same TIMI scores, only 147 scores (29.3%) were determined using identical TIMI variables. For example, one patient was given a TIMI score of one by both the research investigator and ED provider. On further analysis, however, the research investigator gave a point for aspirin use over the preceding seven days, while the ED provider gave a point for having three or more risk factors for CAD.

Further breakdown of TIMI scores revealed that scores differed by one point for 228 patients (45.5%), two points for 52 patients (10.4%), and three points for eight patients (1.6%). No scores varied by more than three points (Table 2).

Table 3 shows the incidence of TIMI variables as reported by research investigator and ED provider. The frequencies of several variables were similar, such as "Age  $\geq 65$ ", "Aspirin use", "ECG changes", and "Elevated Troponin." Research investigators reported a greater incidence of "Known CAD" and "Angina," while ED providers reported a greater prevalence of "CAD Risk Factors."

Our analysis showed that salient disagreements in TIMI variables existed between ED providers and research investigators. For example, ED providers reported the incidence "Angina" in only 59 of 207 patients (28.5%) determined by research investigators to have had "Angina". Additionally, ED providers reported "Angina" as being present in 67 patients not reported by research investigators. Table 4 shows how often ED providers and research investigators agreed on reported variables.

We performed additional analysis based on ED provider type assessing the TIMI score (attending physician, resident physician or midlevel provider). Attending physicians determined the scores for 183 patients, resident physicians scored 225 patients, and midlevel providers scored 93 patients. Overall TIMI risk score determinations were similar across all provider types. TIMI scores matched 43.2% of researcher scores for attending physicians, 42.7% for resident physicians, and 40.9% for midlevel providers. When discrepancies occurred, attending physicians and midlevel providers reported slightly lower TIMI scores, while resident physicians reported slightly higher TIMI scores (Figure 2).

Further analysis showed that gender had little effect on TIMI score differences. ED provider scores agreed with research investigator scores for 112/277 female patients (40.4%) and for 103/224 male patients (46.0%).

Because the CPU at our institution is used to screen a population of patients at low-risk for ACS, far more low TIMI scores (TIMI 0-3) were generated. Based on the scores obtained by research investigators, 407 patients presenting to the CPU had TIMI scores 0-3, while only 94 had TIMI scores >3. There was no difference in the frequency of ED provider scores matching researcher scores on the basis of the number of variables involved (Table 5).

### DISCUSSION

This study demonstrated that a majority of TIMI scores as determined by ED providers in the setting of a busy ED differ from scores generated by trained research investigators who complete them while not under the same pressure of an ED provider. In our study only 29.3% of TIMI scores were calculated using identical TIMI risk score variables. The majority of TIMI risk score differences were either negligible (same TIMI risk score obtained despite differing TIMI variables used) or diverged by no more than one point in our low-risk patient population; however, 12% of patient scores differed by two or more points.

Our study examined a specific cohort of low-risk patients presenting to the ED with chest pain. CPU patients do not make up the entirety of patients presenting to the ED complaining of chest pain. Many times high-risk patients with ACS are admitted directly to the hospital or cath lab, and patients with noncardiac etiologies of chest pain (such as trauma or rash) are discharged home. Even though CPU populations make up a narrow range of the entire TIMI scale our data demonstrated a significant degree of variation between ED provider and trained research investigator scores. One might expect a greater degree of variation when using the whole spectrum of TIMI-derived risk scores.

We have shown that ED provider type has little effect on the likelihood of TIMI risk scores matching TIMI scores obtained by trained research investigators. Neither the

| TIMI score     | Researcher (n) | ED provider (n) | ED provider score matches researcher score |
|----------------|----------------|-----------------|--|
| 0              | 96             | 99              | 54 (56.3%)                                 |
| 1              | 130            | 121             | 48 (36.9%)                                 |
| 2              | 92             | 109             | 34 (37.0%)                                 |
| 3              | 89             | 88              | 33 (37.1%)                                 |
| 4              | 71             | 70              | 38 (53.5%)                                 |
| 5              | 22             | 12              | 5 (22.7%)                                  |
| 6              | 1              | 2               | 1 (100%)                                   |
| 7              | 0              | 0               | 0 (100%)                                   |
| Total patients | 501            | 501             | 213 (42.5%)                                |

Table 1. Research investigator and ED provider TIMI scores.

TIMI, thrombolysis in myocardial infarction; ED, emergency department

**Table 2.** Discrepancy between emergency department provider and researcher TIMI scores.

| Range of TIMI<br>discrepancy | n   | % of Total scores |
|------------------------------|-----|-------------------|
| -4                           | 0   | 0                 |
| -3                           | 4   | 0.8               |
| -2                           | 27  | 5.4               |
| -1                           | 125 | 25.0              |
| 0*                           | 213 | 42.5              |
| +1                           | 103 | 20.6              |
| +2                           | 25  | 5.0               |
| +3                           | 4   | 0.8               |
| +4                           | 0   | 0                 |
| Total                        | 501 | 100               |

*TIMI,* thrombolysis in myocardial infarction \*Matching

Table 3. Incidence of TIMI variables.

| Table 5. Incidence of | Researcher<br>n (%) | ED provider<br>n (%) |
|-----------------------|---------------------|----------------------|
| Age ≥65               | 166 (33.1%)         | 167 (33.3%)          |
| Known CAD             | 149 (29.7%)         | 118 (23.6%)          |
| ASA use               | 239 (47.7%)         | 254 (50.7%)          |
| Angina                | 207 (41.3%)         | 126 (25.1%)          |
| ECG changes           | 9 (1.8%)            | 7 (1.4%)             |
| Elevated trop         | 21 (4.2%)           | 10 (2.0%)            |
| CAD risk factors      | 190 (37.9%)         | 274 (54.7%)          |

*TIMI,* thrombolysis in myocardial infarction; *ED*, emergency department; *CAD*, coronary artery disease; *ASA*, aspirin; *ECG*, electrocardiogram; *Trop*, troponin I cardiac biomarker

| Table 4. TIMI variable agreement (ED provider variable matched |
|--|
| research investigator variable for the same patient).          |

|                  | Positive n<br>(ED/R) | Negative n<br>(ED/R) |  |
|------------------|----------------------|----------------------|--|
| Age ≥65          | 166/166 (100%)       | 334/335 (99.7%)      |  |
| Known CAD        | 104/149 (69.8%)      | 338/352 (96.0%)      |  |
| ASA use          | 181/239 (75.7%)      | 189/262 (72.1%)      |  |
| Angina           | 59/207 (28.5%)       | 227/294 (77.2%)      |  |
| ECG changes      | 2/9 (22.2%)          | 487/492 (99.0%)      |  |
| Elevated trop    | 7/21 (33.3%)         | 477/480 (99.4%)      |  |
| CAD risk factors | 173/190 (91.1%)      | 210/311 (67.5%)      |  |

*TIMI*, thrombolysis in myocardial infarction ED, emergency department provider; R, research investigator; CAD, coronary artery disease; ASA, aspirin; ECG, electrocardiogram; Trop, troponin I cardiac biomarker

patient gender nor the quantity of positive variables had a significant effect on TIMI risk score differences.

Patient age was the variable most agreed upon by TIMI risk score assessors with only one instance of an ED provider

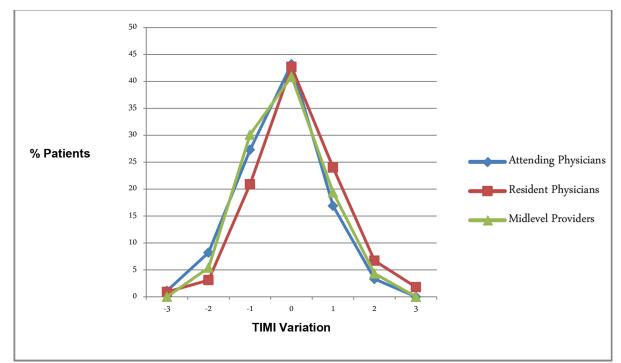
incorrectly giving a point to a 57-year-old for being  $\geq 65$ years old. TIMI variables requiring more active investigation showed greater variation. Researchers reported greater incidence of known CAD, possibly due to having more time available to review patient records and interview the patient. ED providers were apt to report a greater incidence of  $\geq 3$ CAD risk factors. Confirmation bias (or myside bias) is one potential reason for this. For example, in ascertaining the presence of multiple CAD risk factors (a time- consuming task), an ED provider might assume that when one or two risk factors are present, such as smoking and hypertension, other risk factors are likely present as well. Unfortunately, the TIMI risk score recorded in the electronic medical record by our ED providers simply shows when  $\geq$ 3 CAD risk factors are present and does not further categorize which CAD risk factors were recognized by the ED provider.

Research investigators reported a few more instances of ECG and biomarker changes than were reported by ED providers. However, ECG changes and biomarker elevations were seldom present in our study, likely reflecting the low-risk nature of our CPU study population.

Both ED providers and research investigators reported similar numbers of aspirin users among our population; however, only 75.7% of these patients matched. Seventythree patients recognized by ED providers as having taken aspirin went unrecognized by our research investigators. Likewise, research investigators reported an additional 58 patients whom ED providers said had not taken aspirin. Similar to aspirin, there was a discrepancy in the reporting of angina episodes. Researchers, who had the benefit of spending more time with patients, reported far more occurrences of angina than ED providers (207 to 126 occurrences). ED providers only recognized 59 of the 207 patients (28.5%) designated as having had angina by research investigators. Interestingly, ED providers reported angina as being present in 67 patients who research investigators did not feel met criteria for angina.

There are many barriers to obtaining accurate histories from patients.<sup>79-81</sup> Patients who present to the ED in chest pain often do so under great duress, likely compounding the already difficult job of extracting accurate history. Studies have shown that patients in stressful situations have impairments in cognition, memory and verbal recall.<sup>82-83</sup> Many clinicians recognize the phenomenon of the contradictory account, where the second person to interview a patient obtains an entirely different story. Perhaps in recognition of this, Hess et al.<sup>17</sup> excluded patients with unreliable history from his prospective study on TIMI-score validity in the ED. The variability of patient-reported responses in the ED suggests a need for risk stratification tools which place greater weight on objective variables that can be assessed independently of interviews with the patient.

Many ED providers support the idea of using a clinical



**Figure 2.** Range of TIMI score discrepancy from research investigator by ED provider type. *TIMI*, thrombolysis in myocardial infarction; *ED*, emergency department

| Table 5. | TIMI r | risk score | divergence | by | range. |
|----------|--------|------------|------------|----|--------|
|----------|--------|------------|------------|----|--------|

| TIMI risk score range | Researcher (n) | ED provider matches<br>researcher TIMI score | Matching TIMI score with<br>identical variables |
|-----------------------|----------------|--|---|
| 0 to 3                | 407            | 169 (41.5%)                                  | 116 (28.5%)                                     |
| 4 to 6                | 94             | 44 (46.8%)                                   | 31 (33.0%)                                      |
| Total                 | 501            | 213 (42.5%)                                  | 147 (29.3%)                                     |

TIMI, thrombolysis in myocardial infarction; ED, emergency department

prediction rule for the identification of ACS among patients with chest discomfort in hopes of offering early discharge to low-risk patients.<sup>84</sup> A few recent studies have suggested that a rapid TIMI risk score protocol can be employed to safely discharge low- risk ED patients with chest discomfort home from the ED.<sup>22,23,84</sup> Though the TIMI risk score device has the potential to stratify risk among ED populations, our study suggests that it may depend on how and by whom the TIMI risk score data is obtained. In a study examining the use of a risk stratification tool commonly used in stroke management, Perry et al.85 demonstrated that ABCD2 scores calculated by ED physicians at bedside in the manner in which the score was intended to be used differed from scores calculated by trained research investigators, being lower for one-third of patients. It is important that any study suggesting validity and broad applicability of a risk-stratification tool for regular use in the ED, be examined closely to determine if the working data were obtained by ED providers while working in their normal environment. We commend validation studies such as Chase et al.64 and Pollack et al.65

for using ED providers to determine risk scores and call for more similar studies. We also question the applicability of studies that rely on data largely obtained by trained research investigators in place of ED providers.

Additional areas for future research may include investigating challenges particular to the application of riskstratification tools in an ED environment, such as effects of ED crowding, ED provider staffing, and time restraints and distractions placed upon the ED provider. Studies examining the accuracy of patient-reported history in an ED environment may be useful in determining which elements of patient-recalled data can be reliably used in an ED-based risk-stratification tool. Furthermore additional studies comparing Attending level ED provider-obtained data to that of other ED attendings may be helpful in the evaluation of ED scoring accuracy.

## LIMITATIONS

Some researchers have suggested that ECG and biomarker indices should carry greater weight in riskstratification scores.<sup>17,40</sup> Modified TIMI risk scoring tools have been developed that assign more points to ECG and biomarker variables.<sup>17,40</sup> Because so few ECG and biomarker changes were present in our study it is difficult to make generalizations on the ED provider's ability to recognize and assign a proper TIMI risk score for those variables. Though not significant, the few ECG and biomarker changes recognized in our study were slightly underreported by ED providers, which may reflect a degree of selection bias or simply differences in interpretation. It is possible that ED providers under-report some aspects of the TIMI risk score (such as angina, ECG and biomarker changes) since they have already deemed a patient low risk and not likely suffering from true ACS by virtue of placing the patient in the CPU. In addition, ED providers may be less likely than research investigators to report a Troponin I level at the very edge of the cutoff as "positive," especially in a patient with known chronic renal insufficiency, for example.

We asked our research investigators to obtain scores within 24 hours of patient presentation. This was done to improve the likelihood of obtaining complete data for the majority of patients. We recognize that research investigators in other studies may have had additional time to perform their investigations.

Research investigator TIMI risk score ECG interpretation was performed by our trained research investigators and not physicians well-versed in ECG interpretation. Additionally, CPU nurses have variable levels of clinical experience, which could have variable effects on TIMI scores, such as interpreting anginal chest pain. Had we included a second trained research investigator to determine a third TIMI score it is possible that differing scores may have resulted, thereby demonstrating further inter-assessor variability. Moreover, midlevel providers and resident physicians also have variable levels of training which could effect TIMI score variance.

Most data were acquired using information readily available to the research investigator in the CPU setting, which is similar to what is available to the ED provider. Data could sometimes be obtained via fax or telephone during regular business hours. Midway through the project some cardiologists released online access to their outpatient clinical electronic medical records, providing additional means of data acquisition.

Patient demographics may have also contributed to some study variation. Though predominantly English-speaking, our geographic area does contain some non-English speaking individuals, which could have impeded an assessor's ability to obtain a reliable history.

### CONCLUSION

Our study demonstrates discordance between TIMI scores generated by trained research investigators and busy ED providers. Our study questions the reliability, validity, and applicability of previous TIMI risk score validation studies where scores were ascertained predominantly by trained research investigators.

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Address for Correspondence: Brian T. Taylor, DO, Lakeland HealthCare, Department of Emergency Medicine, 1234 Napier Avenue, Saint Joseph, MI 49085. Email: btaylor@ lakelandregional.org.

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## Effect of an Emergency Department Fast Track on Press-Ganey Patient Satisfaction Scores

| Calvin E. Hwang, MD*             | *Stanford University School of Medicine, Stanford/Kaiser Emergency Medicine                     |
|----------------------------------|---|
| Grant S. Lipman, MD <sup>†</sup> | Residency, Stanford, California   |
| Marlena Kane, MS <sup>‡</sup>    | <sup>†</sup> Stanford University School of Medicine, Division of Emergency Medicine, Department |
|                                  | of Surgery, Stanford, California  |
|                                  | <sup>‡</sup> Stanford Hospital and Clinics, Department of Patient Care Services, Stanford,      |

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**Introduction**: Mandated patient surveys have become an integral part of Medicare remuneration, putting hundreds of millions of dollars in funding at risk. The Centers for Medicare & Medicaid Services (CMS) recently announced a patient experience survey for the emergency department (ED). Development of an ED Fast Track, where lower acuity patients are rapidly seen, has been shown to improve many of the metrics that CMS examines. This is the first study examining if ED Fast Track implementation affects Press-Ganey scores of patient satisfaction.

**Methods:** We analyzed returned Press-Ganey questionnaires from all ESI 4 and 5 patients seen 11AM - 11PM, August-December 2011 (pre-fast track), and during the identical hours of fast track, August-December 2012. Raw ordinal scores were converted to continuous scores for paired student t-test analysis. We calculated an odds ratio with 100% satisfaction considered a positive response.

**Results:** An academic ED with 52,000 annual visits had 140 pre-fast track and 85 fast track respondents. Implementation of a fast track significantly increased patient satisfaction with the following: wait times (68% satisfaction to 88%, OR 4.13, 95% CI [2.32-7.33]), doctor courtesy (90% to 95%, OR 1.97, 95% CI [1.04-3.73]), nurse courtesy (87% to 95%, OR 2.75, 95% CI [1.46-5.15]), pain control (79% to 87%, OR 2.13, 95% CI [1.16-3.92]), likelihood to recommend (81% to 90%, OR 2.62, 95% CI [1.42-4.83]), staff caring (82% to 91%, OR 2.82, 95% CI [1.54-5.19]), and staying informed about delays (66% to 83%, OR 3.00, 95% CI [1.65-5.44]).

**Conclusion:** Implementation of an ED Fast Track more than doubled the odds of significant improvements in Press-Ganey patient satisfaction metrics and may play an important role in improving ED performance on CMS benchmarks. [West J Emerg Med. 2015;16(1):34–38.]

### **INTRODUCTION**

In October 2012, the Centers for Medicare & Medicaid Services (CMS) announced a new hospital-payment system called value-based purchasing (VBP). This initiative tied 964 million dollars of federal hospital reimbursement in its first year of implementation to a combination of clinical process of care and patient experience of care domains,<sup>1</sup> with the former comprising 70% and the latter 30% of the overall score.<sup>2</sup> The patient experience of care domain in VBP is based on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and encompasses eight aspects of the consumer experience in the healthcare system: communication with nurses, communication with doctors, responsiveness of hospital staff, pain management, cleanliness and quietness of hospital environment, communication about medicines, discharge information, and overall rating of hospital.<sup>2</sup> Press-Ganey surveys of patient satisfaction are currently employed by almost 50% of the hospitals in America, with many questions in areas directly targeted by the HCAPS survey.<sup>3</sup> There is increasing hospital awareness of customer satisfaction with implementation of VBP, and some states have linked physician salaries to patient satisfaction.<sup>4</sup> Moreover, there appears to be a trend amongst emergency physician groups linking compensation and incentive payments to patient satisfaction scores, though no published data on this currently exists in the literature today.

Emergency department (ED) fast track is a designated area where lower acuity ED patients are rapidly seen. ED Fast Tracks have become more prevalent in recent years, with nearly 80% of EDs in the United States currently incorporating some type of fast track area.<sup>5</sup> ED Fast Track has been shown to improve several metrics associated with both provider and patient satisfaction.<sup>6,7</sup> This is the first study examining if implementation of an ED Fast Track affects Press-Ganey scores of patient satisfaction.

## **METHODS**

## **Study Design and Setting**

This was a serial before and after cross-sectional study of Press-Ganey questionnaires completed by low acuity and ED Fast Track patients seen in an academic ED with approximately 50,000 visits annually from August-December 2011 and August-December 2012. The study was deemed exempt by the Stanford University School of Medicine institutional review board.

### Methods, Measurements and Outcomes

Press-Ganey questionnaires were sent to 100% of discharged ED patients with a 4-day lag from the visit date. We analyzed returned surveys were analyzed from all low acuity patients (defined as Emergency Severity Index 4 and 5, e.g. stable patient requiring only one or fewer resources) seen 11AM-11PM, August-December 2011 (pre-Fast Track) and during the identical hours of ED Fast Track August-December 2012. The medical record numbers on the Press-Ganey file were linked to an ED Arrival Flat File to ensure that multiple patient visits were matched with the correct survey. A review was performed to ensure the dates of service matched. We selected for analysis survey data for seven areas corresponding to the patient experience of care: wait times, nurse courtesy, doctor courtesy, being kept informed about delays, staff caring, pain control, and likelihood to recommend.

### Intervention

A new ED Fast Track was created in July 2012, operating from 11AM-11PM daily for low acuity patients and staffed with its own attending physician, nurse, and ED technician. This required the addition of 2.4 full time equivalents (FTEs) to the ED attending staff. No mid-level providers or residents were used. The patient care area consisted of three chairs in one large room that was newly allocated to the ED from another department at the start of the study period. Radiographs and intravenous medications could be administered in fast track, while any computed tomography or more advanced imaging would be done in radiology. All fast track staff were part of the larger ED pool and were randomly assigned to the fast track area. Prior to implementation of the ED Fast Track, no Fast Track type area existed and all patients presenting to the ED were seen in the main department. Patients presenting to the ED during these times with low acuity chief complaints were identified on arrival and immediately routed to the ED Fast Track area.

## Analysis

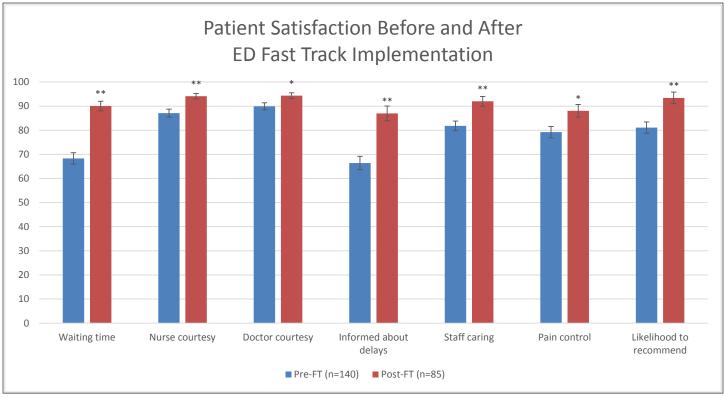
We then converted raw ordinal Press-Ganey scores for the appropriate ESI 4 and 5 patient visits to continuous scores used to calculate the mean result for each question. The preintervention group consisted only of returned surveys from patients with ESI 4 and 5 presenting to the ED during the same time of day as the post-intervention group in order to include the same acuity and type of patient. We subsequently used these data to calculate student t-test scores pre- and post-intervention. The raw ordinal scores were also used to calculate an odds ratio, with only a 100% satisfaction response (represented by a 5 out of 5 response on the Press-Ganey Likert scale) for a particular question considered a positive result. P-values < 0.05 were considered significant. We performed all statistical analyses using MedCalc for Windows (version 12.7.8, Ostend, Belgium).

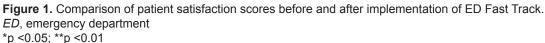
## RESULTS

We analyzed 140 respondents in the pre-ED Fast Track group and 85 in the ED Fast Track group, with an overall 14.8% response rate. Patients in the pre-ED Fast Track and ED Fast Track cohort represented approximately 9% of the overall ED volume during each time period. There were significant improvements in patient satisfaction after the implementation of an ED Fast Track area in each of the seven categories selected for analysis (Figures 1 and 2). Patient satisfaction with wait times increased from 68% to 88% (OR 4.13, 95% CI [2.32-7.33], p<0.0001), doctor courtesy 90% to 95% (OR 1.97, 95% CI [1.04-3.73], p=0.05), nurse courtesy 87% to 95% (OR 2.75, 95% CI [1.46-5.15], p<0.01), staying informed about delays 66% to 83% (OR 3.00, 95% CI [1.65-5.44], p<0.0001), staff caring 82% to 91% (OR 2.82, 95% CI [1.54-5.19], p<0.01), pain control 79% to 87% (OR 2.13, 95%) CI [1.16-3.92], p=0.018), and likelihood to recommend 81% to 90% (OR 2.62, 95% CI [1.42-4.83], p<0.01).

## DISCUSSION

This is the first study to the authors' knowledge that demonstrated a statistically significant improvement in patient satisfaction with the implementation of an ED Fast Track. While prior studies examined improvements in time metrics,<sup>6</sup> these are indirectly linked to satisfaction.<sup>7</sup> Our study relied





on a cross sectional survey of patient

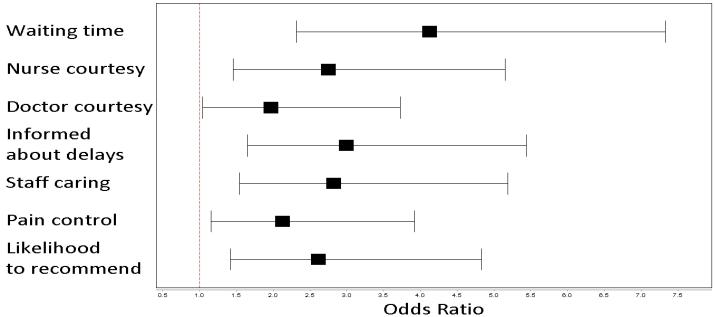
on a cross sectional survey of patients' perspectives with a response rate of approximately 15%, similar to national average of returns for surveys of this type.<sup>8</sup> The determinants of VBP will be based on surveys that will have response rates similar to our study.

In 2008, the first national, standardized, publicly reported patient experience of care survey for the inpatient hospital experience was implemented (Hospital Consumer Assessment of Healthcare Providers and Systems - HCAHPS).<sup>2</sup> Until this survey, there was no national standard for collecting and publicly reporting information about the patient experience that supported comparisons between hospitals. Beginning in October 2012, hospitals that performed poorly on these measures had to forfeit a percentage of their Medicare payments through the new Hospital Value-Based Purchasing Program. However, this survey does not address a patient's ED experience. The Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) have recently announced that a patient experience-of-care survey for the ED is next in line (ED CAHPS), given that the ED is often considered the "front door" to the hospital and is an essential component to patients' overall hospital experience. This tool will survey patients and caregivers of patients who have received care in an ED to evaluate items such as "waiting time to see physician" and "communication with providers." In addition, in January

2012 CMS began monitoring median time between ED arrival and when the patient leaves the ED to an inpatient room and ED median time from ED admit decision to when the patient leaves the ED to an inpatient room. Following past CMS practices, these metrics will likely be factored into hospital reimbursement in the near future.

As healthcare providers face more pressure to manage costs and do more with less, patient satisfaction surveys like Press-Ganey can be an invaluable tool to improve the patient experience, as well as overall operational performance. Collecting patient satisfaction data helps to provide an understanding of potential opportunities for improvement and may prevent organizations from implementing solutions that are not connected to the root cause of the problem. Moreover, understanding and acting on patient concerns will support hospitals in getting ready for the new ED CAHPS quality measures that will be put in place to measure how satisfied patients are with their visit to the ED.

Development of an ED Fast Track has enabled the studied ED to improve the value of care delivered to patients, despite the operational challenges of a growing census and space constraints that are being faced by EDs throughout the nation, ultimately resulting in quicker service, increased capacity, and improved patient satisfaction. A number of patient-centered metrics outside the control of the ED, including a 4% increase in overall volume and a 37% increase in hours spent boarding,



## Patient Satisfaction After ED Fast Track

Figure 2. Odds ratio comparison of 100% patient satisfaction responses (5 out of 5 on Press-Ganey Likert scale) after implementation of ED fast track.

ED, emergency department

worsened in the post-ED Fast Track implementation period. Despite these forces that would normally lead to worse patient satisfaction, not only was implementation of ED Fast Track associated with an improvement in Press-Ganey patient satisfaction scores amongst this cohort of patients, but other patient care metrics for the entire department such as median length of stay and door-to-MD time each also improved by 9%. One hypothesis for this improvement is that the ED Fast Track allows for rapid turnover of low acuity patients, optimizing flow and resources in the rest of the department.

This is timely considering the mandated patient surveys portion of CMS remuneration will soon place hundreds of millions of dollars in federal funding at risk if EDs do not meet performance and quality standards. It remains to be seen how incorporation of an ED Fast Track impacts the care and flow of patients through the other parts of the ED.

## LIMITATIONS

We analyzed a particular subset of low acuity ED patients in this study. Only patients seen and discharged from the ED Fast Track were analyzed in 2012 population. However, the pre-fast track cohort was gathered from their triage index, and it was unknown if they had been under-triaged or would have been fast track appropriate, possibly leading to underestimation of acuity and resulting over-estimation of the intervention's significance. There was also a noticeable difference in the size of the pre- and post-intervention group, potentially biasing the results. As there is no available database allowing for comparison of individual hospital performances, it is not known if these improvements were part of a generalized trend towards improvement nationwide or indeed unique to this institution. It is also unknown if resource utilization was different in the ED Fast Track, which could have impacted patient satisfaction. However, given that all patients were triaged prior to MD evaluation based on a pre-defined ESI criteria incorporating number of resources anticipated to be used, it is likely that the same types of patients were present in both the pre and post-intervention groups and resource utilization would not be significantly different.

While we could not determine if our observed improvements in patient satisfaction were in part due to decreased lengths of stay, shorter wait times, dedicated resource utilization, or other unknown variables, implementation of an ED Fast Track program was clearly associated with increased patient satisfaction. Nevertheless, further studies need to be done on the cost of ED Fast Track. In this study, a hospital space was reallocated to the ED to serve as the ED Fast Track, and additional staff and physician time had to be allocated. Additional funds from VBP as a result of increased satisfaction and efficiency from the ED Fast Track may outweigh these costs. This is also a potential confounder to the data as the addition of ED space and staffing alone could also have improved these Press-Ganey metrics.

## CONCLUSION

The implementation of an ED Fast Track program was associated with statistically significant improvements in seven dimensions of Press-Ganey patient satisfaction metrics. With the initiation of value-based purchasing and subsequent linkage of hospital reimbursement with the patient care experience, implementation of ED Fast Track programs may play an important role in improving ED performance on CMS benchmarks of quality with lower acuity patients.

Address for Correspondence: Calvin Hwang, MD, Stanford Sports Medicine Center, 341 Galvez Street, Lower Level, Stanford, CA 94305. Email: calvinhwang@stanford.edu.

*Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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## Waiting for Triage: Unmeasured Time in Patient Flow

Christopher Houston, MD Leon D. Sanchez, MD, MPH Christopher Fischer, MD Kathryn Volz, MD Richard Wolfe, MD Beth Israel Deaconess Medical Center, Department of Emergency Medicine, Boston, Massachusetts

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**Introduction**: The Centers for Medicare and Medicaid Services (CMS) requires reporting of multiple time-sensitive metrics. Most facilities use triage time as the time of arrival. Little is known about how long patients wait prior to triage. As reimbursement to the hospital may be tied to these metrics, it is essential to accurately record the time of arrival. Our objective was to quantify the time spent waiting to be triaged for patients arriving to the emergency department (ED).

**Methods**: We conducted this study in an urban, academic, tertiary care center with approximately 54,000 annual ED visits. All patients arriving to the ED from November 1, 2012, to October 1, 2013, were enrolled. If patients didn't go directly to a bed or triage, an observer greeted patients as they entered the ED and recorded the time of arrival. The triage time was recorded as normal. We calculated the difference between the arrival time and triage time.

**Results**: There were 50,576 patient visits during the study period. Of these, 7,795 (15.4%) patients did not go directly to a bed or triage. For patients who waited for triage, median time from arrival to triage was 11 minutes (IQR 5-19, range 1-105). When stratified by the number of new patients who arrived in the ED in the previous hour, the percentage of greeted patients who waited more than 10 minutes for triage was: 0-5 new patients – 12.4%; 6-10 new patients – 48.8%; 11-15 new patients – 64.4%; 16+ new patients – 68%.

**Conclusion**: Patients often waited more than 10 minutes to be triaged. As the number of patients registered in the previous hour increased, the percentage of patients who waited more than 10 minutes for triage increased significantly. During times of peak volume, 8.5% of all patients arriving to the ED waited more than 10 minutes for triage. This wait is not accounted for in the normal reporting of ED throughput times and metrics. [West J Emerg Med. 2015;16(1):39–42.]

### **INTRODUCTION**

The Centers for Medicare and Medicaid Services (CMS) requires that hospitals report time-based metrics to evaluate emergency department (ED) performance. These include time from arrival to the ED to evaluation by a healthcare provider, to discharge or admission, and to various therapeutic interventions. It is expected that, in the near future, some of these metrics will determine Medicare reimbursement rates. The way times are recorded will thus need to be standardized to ensure compliance, as well as to provide a valid comparison between hospitals. Most facilities use the time of initial triage and registration as the time of arrival. Triage commonly includes obtaining a chief complaint, vital signs, a brief history, and at times a review of recent ED visits and hospitalizations. This detailed triage provides important information but it takes time to perform. If multiple patients arrive simultaneously, there may be a delay in registering patients and recording the time to triage because of queuing. This unrecorded wait time prior to triage may cause significant underestimation of timebased metrics. The objective of this study was to quantify the time spent waiting to be triaged for all patients arriving to the ED. It is our hypothesis that during times of peak volume, patients may spend a significant amount of time waiting to be triaged, time that is not captured, thus affecting throughput metrics. As reimbursement to the hospital may be tied to these metrics, it is essential to accurately record the time of arrival.

## **METHODS**

We conducted this study in an urban, academic, tertiary care center with approximately 54,000 annual ED visits. A determination was made that this project does not meet the federal definition of human subject research. All patients arriving to the ED from November 1, 2012, to October 1, 2013, were enrolled in the study in one of several ways. Emergency medical services (EMS) radio calls go directly to a bed where a physician and nursing staff meet them. Other EMS traffic as well as walk-in patients arrive to the ED and typically go directly to triage. In both of these instances, the triage time is the same as the arrival time. If all of the triage stations are occupied with patients, an observer greeted patients and ambulances as they entered the ED. The observer recorded the time of arrival and chief complaint. This information was listed on the tracking dashboard as "pre-triage." An observer is present 24 hours a day, seven days a week. The triage time was recorded as normal. We calculated the difference between the arrival time and triage time. The two months preceding data collection was used as a trial period so all staff could become accustomed to this recording process and patients would not be missed.

### RESULTS

Of the 50,576 visits that occurred during the study period, 7,795 patients, 15.4% of all ED visits, waited to be triaged. There were patients who had to wait to be triaged at all hours of the day, but the longest wait times occurred between the hours of 10:00 and 20:00, which is when most EDs have the highest volume (Figure 1). For patients who waited to be triaged, wait times ranged from 1 to 105 minutes. The median time from arrival to triage was 11 minutes (IQR 5-19, range 0-105). 4,286 (8.5%) patients arriving to the ED waited 10 or more minutes to be triaged. Of those who waited for triage, 55% waited 10 or more minutes. When stratified by the number of new patients who arrived in the ED in the previous hour, the percentage of greeted patients who waited more than 10 minutes for triage was: 0-5 new patients - 12.4%; 6-10 new patients - 48.8%; 11-15 new patients - 64.6%; 16+ new patients – 68% (Figure 2).

### DISCUSSION

Little is known about how long patients wait prior to triage. There are multiple studies looking into the triage system, how it affects throughput, and ways to increase efficiency, but no studies specifically address this issue.<sup>1-3</sup> A study by Weber et al.<sup>4</sup> did record actual arrival times to the ED in order to look at whether or not mandatory triage identifies high-acuity patients within recommended time frames. They did not report times for patients of all acuity.

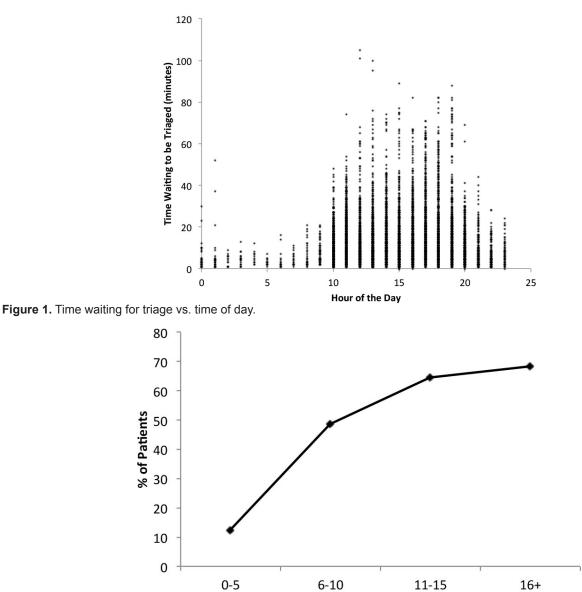
The door-to-doctor time is an important quality metric that has received increased scrutiny. With increased volume in EDs across the country, the goal of decreasing wait times has been difficult to accomplish. According to a 2009 paper by Horwitz,<sup>5</sup> the time patients wait to see a doctor steadily increased from 1997 to 2006.

According to our data, patients often waited more than 10 minutes from the time of arrival to the ED until they were triaged. As the number of patients registered in the previous hour increased, the percentage of patients who waited more than 10 minutes for triage increased significantly as expected based on queuing theory. 8.5% of all patients arriving to the ED waited more than 10 minutes for triage. This wait is not accounted for in the normal reporting of ED throughput metrics, and may have an effect on quality of care. Our data implies that door-to-doctor times are longer than the standard method of reporting would indicate.

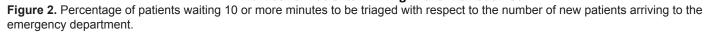
The Agency for Healthcare Research and Quality (AHRQ) has several pending quality measures that will be significantly affected by unaccounted time waiting for triage. The door to time of diagnostic evaluation by a qualified medical professional (door-to-doctor time) is a particularly important measure to patients as shown in previous studies.<sup>6,7</sup> Numerous EDs already advertise real-time wait times on their websites. The methodology for the times advertised is normally not explained. Currently, there is no goal door-todoctor time, but as more data is collected, there will surely be in the near future. The AHRQ mandates that these times be reported and published on the Medicare.gov website. As of November 2013, the mean national wait time is 28 minutes. The mean for Massachusetts is 38 minutes. The range is 8-35 minutes for the four tertiary care academic centers in the Boston area. When including community sites in the Boston area, the range is 8-50 minutes.8 One solution to the problem of having extended door-to-doctor times is to have a physician in triage. This has been studied at multiple sites but may not be feasible at all institutions.<sup>9,10</sup>

### LIMITATIONS

The major limitation of this study is that it was conducted at a single institution. Differences in the triage protocol, and the ratio of triage staff to patient volume will affect queuing times and may vary considerably from one institution to another. This study looked only at the time spent waiting for triage. Another question, which was not in the scope of this pilot study, is to determine if the patients who wait for triage have an increase in adverse events or bad outcomes. This will be addressed in future studies.







### CONCLUSION

In our study, we found that a significant number of patients are waiting 10 or more minutes for triage, which is approximately 30% of the mean national door-to-doctor time. We suspect that this phenomenon is not limited to our ED and suggest that this be studied in other locations. In our ED, we have begun tracking all patients as soon as they arrive to the ED and are listed as "pretriage." Recording arrival time accurately will be essential in ensuring that time-based metrics can be used to compare between institutions and that Medicare billing is compliant.

Address for Correspondence: Christopher Houston, MD, Beth Israel Deaconess Medical Center -2nd Floor, 1 Deaconess Road, Boston, MA 02115. Email: cwhousto@bidmc.harvard.edu. *Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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## Routine Repeat Head CT may not be Indicated in Patients on Anticoagulant/Antiplatelet Therapy Following Mild Traumatic Brain Injury

Kevin C. McCammack, MD\* Charlotte Sadler, MD<sup>†</sup> Yueyang Guo, BS<sup>\*‡</sup> Raja S. Ramaswamy, MD\* Nikdokht Farid, MD\* \*University of California, San Diego, Department of Radiology, San Diego, California <sup>†</sup>University of California, San Diego, Department of Emergency Medicine, San Diego, California

<sup>‡</sup>University of California, San Diego, School of Medicine, San Diego, California

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**Introduction:** Evaluation recommendations for patients on anticoagulant and antiplatelet (ACAP) therapy that present after mild traumatic brain injury (TBI) are controversial. At our institution, an initial noncontrast head computed tomography (HCT) is performed, with a subsequent HCT performed six hours later to exclude delayed intracranial hemorrhage (ICH). This study was performed to evaluate the yield and advisability of this approach.

**Methods:** We performed a retrospective review of subjects undergoing evaluation for ICH after mild TBI in patients on ACAP therapy between January of 2012 and April of 2013. We assessed for the frequency of ICH on both the initial noncontrast HCT and on the routine six-hour follow-up HCT. Additionally, chart review was performed to evaluate the clinical implications of ICH, when present, and to interrogate whether pertinent clinical and laboratory data may predict the presence of ICH prior to imaging. We used multivariate generalized linear models to assess whether presenting Glasgow Coma Score (GCS), loss of consciousness (LOC), neurological or physical examination findings, international normalized ratio, prothrombin time, partial thromboplastin time, platelet count, or specific ACAP regimen predicted ICH.

**Results:** 144 patients satisfied inclusion criteria. Ten patients demonstrated initial HCT positive for ICH, with only one demonstrating delayed ICH on the six-hour follow-up HCT. This patient was discharged without any intervention required or functional impairment. Presenting GCS deviation (p<0.001), LOC (p=0.04), neurological examination findings (p<0.001), clopidogrel (p=0.003), aspirin (p=0.03) or combination regimen (p=0.004) use were more commonly seen in patients with ICH.

**Conclusion:** Routine six-hour follow-up HCT is likely not indicated in patients on ACAP therapy, as our study suggests clinically significant delayed ICH does not occur. Additionally, presenting GCS deviation, LOC, neurological examination findings, clopidogrel, aspirin or combination regimen use may predict ICH, and, in the absence of these findings, HCT may potentially be forgone altogether. [West J Emerg Med. 2015;16(1):43-49.]

### **INTRODUCTION**

Anticoagulation or antiplatelet (ACAP) therapy is frequently employed to treat or prevent vascular thromboembolic disease and associated complications.<sup>1,2</sup> As a result, it is a relatively common occurrence for patients on ACAP regimens to present to emergency departments (ED) and trauma centers after traumatic brain injury (TBI), and recommendations for the appropriate evaluation of these patients are valuable. The imaging study of choice to evaluate for the presence of intracranial hemorrhage (ICH) is a noncontrast head computed tomography (HCT), which is able to detect the presence of acute intracranial hemorrhage with a rate of greater than 90%.<sup>3-5</sup> However, review of the existing literature regarding its appropriate use in patients on ACAP therapy, particularly in cases of mild TBI, yields conflicting results with some authors concluding that imaging may not always be indicated,<sup>6,7</sup> others contending that at least an initial HCT is prudent in patients on ACAP due to increased risk of injury without reliable pretest risk factors,<sup>8-10</sup> and still others advocating serial imaging after an initial negative HCT to evaluate for delayed ICH.<sup>11</sup>

At our institution, patients on ACAP agents who present to the ED after mild TBI are routinely evaluated with an initial non-contrast HCT and a six-hour follow-up HCT if the first is negative to exclude delayed ICH prior to discharge. While this method is certainly reasonable given the lack of consensus data regarding this subject, the advisability of this or similar approaches has been called into question.<sup>12,13</sup> In an era of stringent healthcare resource utilization measures and radiation safety concerns, expensive algorithms that rely heavily on imaging must be thoroughly evaluated. We sought to examine the current protocol at our institution for the evaluation of patients on ACAP agents presenting to the ED after mild TBI, including the overall yield of the routine sixhour follow-up HCT to exclude delayed ICH. We also aimed to assess whether or not clinical and laboratory data may be able to predict the presence or absence of ICH.

### **METHODS**

We performed a retrospective review of patients on ACAP therapy who sustained TBI and presented to our institution for subsequent evaluation from January 2012 through April 2013. Institutional review board exemption status was obtained, with informed patient consent waived. We queried our Radiology Information System for patient history information as provided by ordering clinicians when ordering a noncontrast HCT January 2012 through April 2013, with those patients noted to be on ACAP regimens selected for imaging and clinical review. Patients were then included in the study if they had suffered mild closed TBI, defined as having an initial Glasgow Coma Scale score (GCS) of 13-15, had completed both an initial noncontrast HCT as well as an interval followup HCT, and were on an ACAP agent or agents prior to the trauma. We included patients in the study even if they were on a single agent warfarin or dabigatran regimen with an initial international normalized ratio (INR) measurement in the normal range, commonly defined as less than 1.3, as the current practice in place at our institution makes no such distinction. Of note, all patients in this study who met the criteria for the six-hour follow-up HCT (i.e. presenting to the ED after mild TBI and on ACAP agents) underwent follow-up imaging, with no exceptions to this rule.

Patients were imaged on either a 64-detector row General Electric (GE) scanner with 0.625 mm detector width or a 320-detector row Toshiba scanner with 0.5 mm detector width. Imaging was performed from the skull base through the vertex, with multiple axial slice thickness reconstructions available in both bone and soft tissue algorithms. Coronal and sagittal reformats were universally available for interpretation. Patients were imaged at initial presentation and approximately six hours later, with some unavoidable variation in timing of the follow-up HCT due to demands of patient transport and scheduling.

A second-year radiology resident (KM) reviewed the final reports of all HCTs, with positive studies defined as having reported the presence of ICH, specifically epidural hematoma, subdural hematoma, subarachnoid hemorrhage, intraventricular hemorrhage, or parenchymal hemorrhage/contusion. Time interval between the two scans was also recorded. A boardcertified neuroradiologist (NF) with over five years of experience reassessed equivocal cases when necessary.

The hospital electronic medical records system (EPIC) was examined with data logged in duplicate and independently by a second-year radiology resident (KM) and a fourthyear medical student (YG), recording the following using a standardized data abstraction form: age, sex, mechanism of injury, initial GCS, presence or absence of associated loss of consciousness (LOC), pertinent neurological and physical examination findings, specific ACAP regimen and treatment indication at the time of injury, INR, prothrombin time (PT), partial thromboplastin time (PTT), platelet count, any possible neurosurgical intervention, hospital encounter outcome, and any possible follow-up information available up to 30 days after the trauma. A senior emergency medicine resident (CS) blinded to the study hypotheses assessed the abstracted clinical data for accuracy, with any inadvertent discrepancies rectified by additional chart review.

Using multivariate generalized linear models, co-varying for the effects of age and sex throughout, we evaluated the relationship between intracranial hemorrhage as detected on either the initial or six-hour follow-up noncontrast HCT examination and the following: presenting GCS, presence or absence of associated loss of consciousness (LOC), presence or absence of neurological and pertinent physical examination findings, specific ACAP regimen (multivariate analysis assessing each agent effect individually), INR, PT, PTT, and platelet count. Statistical significance was assigned to p-values less than 0.05.

## RESULTS

One hundred forty-four patients (77 female, 67 male) satisfied the study inclusion criteria for the interrogated period of January 2012 through April 2013. The mean patient age was 74 years (median 77 years, range 25-96 years). ACAP medications in use at the time of TBI included warfarin, aspirin (ASA), clopidogrel, dipyridamole, dabigatran, or a combination of these agents (Table 1). Indications for ACAP therapy included atrial fibrillation, deep venous thrombosis/pulmonary thromboembolic disease, cardiac valve replacement, ischemic coronary artery disease/ coronary artery stent, cerebral infarction or prior transient ischemic attack, New York Heart Association class III or greater congestive heart failure, hypercoagulable state, or a combination of these factors.

Ten patients had an original presentation HCT positive for the presence of ICH (6.9%) while 134 were initially negative. Of the 134 patients with an initially negative HCT, only one was positive on the follow-up HCT (Figure 1), yielding a 0.7% incidence of delayed ICH. Of note, all 11 cases of ICH were deemed to most likely represent traumatic ICH given the constellation of radiographic findings and the absence of clinical findings to suggest hypertensive hemorrhagic infarcts. The single patient with delayed ICH had two follow-up HCT examinations over the next two days, which demonstrated stability followed by a slight decrease in size and conspicuity of the ICH, after which the patient was discharged at his baseline functional status with an outpatient follow-up appointment. No neurosurgical intervention was required and the patient had no readmission or post-traumatic sequelae greater than 30 days after the event.

Of the 10 patients with ICH on their initial HCT, six demonstrated stability of findings, three demonstrated interval worsening (Figure 2), and one actually improved on their subsequent examination. Two of the three patients who worsened between scans expired during the hospitalization secondary to their injuries. The third patient with interval worsening between scans was placed in a skilled nursing facility after discharge, with a significant, likely permanent,

**Table 1.** Demographic information of patient population in a study of patients on anticoagulant and antiplatelet therapy after mild traumatic brain injury.\*

|                                 | # of patients |
|---------------------------------|---------------|
| Mechanism of injury             |               |
| Mechanical fall                 | 107           |
| Syncope                         | 17            |
| Intoxicated/found down          | 8             |
| Motor vehicle accident          | 6             |
| Assault                         | 4             |
| Seizure activity                | 2             |
| Agents in use at time of trauma |               |
| Warfarin                        | 134           |
| Aspirin                         | 22            |
| Clopidogrel                     | 13            |
| Dabigatran                      | 2             |
| Dipyridamole                    | 1             |
| Combination regimen             | 25            |
|                                 |               |

\*Age (mean in years [range]) of patient population was 74 (25-96).

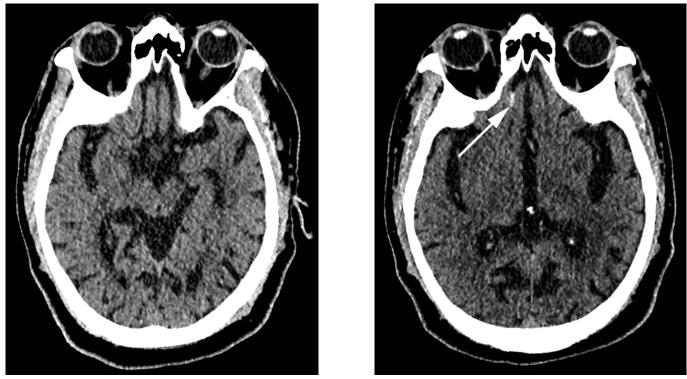
impairment from baseline. Two of the six patients with stable ICH on subsequent follow-up HCT were discharged to skilled rehabilitation facilities with mild persistent deficits, but were expected to return to their baseline. The remainder of patients with ICH on their initial HCT examinations were discharged home at their functional baseline without readmission or evidence of trauma-related symptoms greater than 30 days after the event.

Review of the electronic medical records of the 133 patients with initial and follow-up HCT both negative for ICH revealed no evidence of readmission or trauma-related symptoms for any patient at least 30 days after the event. As such, there is no available evidence that delayed ICH was missed in any of these patients.

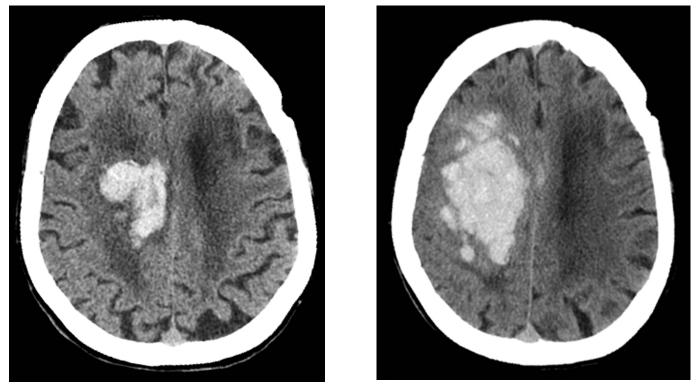
We compared clinical and laboratory data available before imaging for patients with and without ICH on either the initial or follow-up HCT (Table 2). There was no significant difference between these groups in terms of age, sex, presence of physical examination findings reflecting trauma to the head, coagulation profile, or platelet count. Additionally, warfarin, dipyridamole, and dabigatran use did not significantly differ between the two groups. Those with ICH did demonstrate lower mean GCS at presentation than those without (14.3 versus 14.9, p<0.001) and LOC was more often seen in patients with ICH than those without (54.5% versus 26.5%, p<0.05). Pertinent neurological examination findings were present in 72.7% of patients with ICH compared to only 9.8% of patients without (p<0.001). ASA inclusion in therapeutic regimens was more common in patients with ICH (36.4% versus 13.6%, p<0.05) as was clopidogrel (36.4% versus 6.8%, p<0.01). Combination regimens were also more common in those with ICH (36.3% versus 15.9%, p < 0.01). Please note, at our institution the ED and trauma departments are separate units which both treat this patient population, though these patients are treated identically. For the sake of brevity, we will refer to both of these units in this paper as the ED.

## DISCUSSION

Falls are the leading cause of trauma-related mortality for patients 65 years of age or older in the United States, with just under 8,000 deaths resulting from TBI in 2005.14 A 1% annual risk of spontaneous ICH is often quoted as resulting from anticoagulation therapy even without any antecedent trauma<sup>15</sup>, reasonably leading one to believe that TBI patients on ACAP agents must be treated with a high degree of clinical suspicion. It is critical to identify those patients on ACAP therapy with ICH early, as prompt coagulopathy reversal measures have been shown to reduce hemorrhagic progression and death.<sup>16</sup> Studies evaluating the effects of ACAP agents on the development of ICH and resulting management recommendations are conflicting, with some suggesting specific criteria even for initial imaging and the most cautious advocating routine serial imaging to exclude delayed ICH in all patients on ACAP agents prior to discharge.<sup>6-9,11</sup> Still other



**Figure 1.** Noncontrast head computed tomography performed (top left) at initial presentation and (top right) six hours following injury demonstrates interval development of a small amount of subarachnoid hemorrhage in the right olfactory sulcus (arrow). This patient was on single-agent clopidogrel therapy and demonstrated no deviation from his functional baseline upon discharge.



**Figure 2.** Noncontrast head computed tomography performed (top left) at initial presentation and (top right) six hours following injury demonstrates interval progression of the intraparenchymal and intraventricular hemorrhage centered predominately in the region of the right centrum semiovale, as well as corona radiata and body of the right lateral ventricle. This patient was on a coumadin and aspirin combination therapy with a presentation Glasgow Coma Scale of 13 and uneven pupillary response on neurological examination. This patient expired during the hospitalization.

**Table 2.** Clinical and laboratory data compared between those patients with negative initial and follow-up head computed tomography and those positive for intracranial hemorrhage on either the initial or follow-up examination.

|                   | Negative | Positive | Р      | Odds ratio | 95% CI      |
|-------------------|----------|----------|--------|------------|-------------|
| Age               | 73.8     | 79.9     | 0.19   |            |             |
| Sex               |          |          | 0.91   |            |             |
| Male (%)          | 47.0     | 45.5     |        | 0.95       | 0.28-3.28   |
| Female (%)        | 53.0     | 54.5     |        | 1.42       | 0.41-4.87   |
| GCS*              | 14.9     | 14.3     | <0.001 |            |             |
| OC (%)*           | 26.5     | 54.5     | 0.04   | 9.44       | 2.57-34.73  |
| leuro exam (%)*   | 9.8      | 72.7     | <0.001 | 24.62      | 5.80-104.42 |
| Physical exam (%) | 58.3     | 54.5     | 0.64   | 0.87       | 0.25-3.00   |
| Varfarin (%)      | 93.9     | 90.9     | 0.61   | 0.64       | 0.07-5.64   |
| Clopidogrel (%)*  | 6.8      | 36.4     | 0.003  | 11.17      | 2.33-53.59  |
| Aspirin (%)*      | 13.6     | 36.4     | 0.03   | 4.74       | 1.16-19.36  |
| Dipyridamole (%)  | 0.8      | 0        | 0.68   |            |             |
| Dabigatran (%)    | 1.5      | 0        | 0.65   |            |             |
| Combination(%)*   | 15.9     | 36.3     | 0.004  | 4.11       | 1.59-10.82  |
| NR                | 2.4      | 2.8      | 0.51   |            |             |
| т                 | 29.3     | 31.7     | 0.75   |            |             |
| тт                | 39.5     | 37.9     | 0.55   |            |             |
| Platelet Count    | 200.7    | 218.9    | 0.35   |            |             |

GCS, Glasgow Coma Scale score; LOC, loss of consciousness; INR, international normalized ratio; PT, prothrombin time; PTT, partial thromboplastin time

\*Denotes statistical significance.

evidence suggests imaging of all elderly patients with mild TBI, even when there is no history of ACAP therapy.<sup>17</sup>

Our findings demonstrate that the use of a routine sixhour follow-up HCT in patients on ACAP treatment after mild TBI is of extremely low yield, with delayed ICH occurring in only one of 134 patients (0.7% incidence) in our study population. Furthermore, the one case of delayed ICH required no intervention and resulted in no sustained deviation from the patient's baseline. This is in agreement with similarly structured retrospective studies that demonstrate a comparable incidence and a lack of clinical significance in those occurrences of delayed ICH.<sup>12,13</sup> Tauber et al demonstrate a slightly higher incidence of delayed ICH and observed clinically significant consequences in half of those cases.<sup>11</sup> It is interesting to note that their study included only patients on ASA therapy, which, in our study, proved to be an independent statistically significant risk factor for ICH when included in the therapeutic regimen, as did clopidogrel, while anticoagulant agents alone did not. It is possible that antiplatelet agents serve as a greater risk factor for ICH than anticoagulant medications, and that this accounts for or at least contributes to the discrepancy between our studies.

A prospective study by Nishijima et al. in fact addressed this question and compared the risk of immediate and delayed ICH in patients on warfarin versus those on clopidogrel, demonstrating an increased risk of immediate

ICH in those patients on clopidogrel (12.0%) compared to those on warfarin (5.1%).<sup>18</sup> This study largely agrees with our data, suggesting an increased risk of ICH in patients on antiplatelet agents over anticoagulant therapy, and their overall ICH rate of 7.0% is similar. Their rate of delayed ICH (0.4%) was also similar to ours; however, it was seen only in patients on warfarin. This may reflect the overall preponderance of patients on warfarin rather than clopidogrel within their study population, rather than indicating an increased risk of delayed ICH in patients on anticoagulant therapy versus antiplatelet agents. Regardless, the rate of delayed ICH is too low in both of our studies to draw a firm conclusion as to whether anticoagulant versus antiplatelet agents portend a larger comparative risk for delayed ICH. Overall, our data lends credence to this prior study, but also expands upon it by more comprehensively analyzing additional clinical factors that may predict the presence of ICH on HCT.

Combining the single patient who developed delayed ICH and the 10 patients with initially positive HCT examinations, the total incidence of ICH in our patient population was 7.6%. Gittleman et al. demonstrate a very similar rate of 7.8%, and they also show a statistically significant association between the absence of GCS abnormalities and neurological examination findings and negative initial HCT.<sup>7</sup> Our findings support those conclusions. As demonstrated in Table 2, we observed statistically significant associations between decreased mean GCS at presentation, as well as neurological examination findings and the presence of ICH. Additionally, we demonstrate a statistically significant association between sustained LOC and the presence of ICH. As previously mentioned, the antiplatelet agents (ASA and clopidogrel) were statistically significant risk factors for the presence of ICH when included in therapeutic regimens, as were combination treatment strategies in general. Single agent warfarin, dabigatran, and dipyridamole regimens were not associated with statistically increased risk of ICH in this study. No patient with a normal GCS and neurological examination, without LOC at the time of the traumatic event, and on single anticoagulant agent therapy demonstrated ICH at any point during this study.

This study questions the advisability of routine six-hour follow-up HCT after an initial negative HCT for the exclusion of ICH in patients on ACAP agents prior to discharge, suggesting that clinically significant delayed ICH does not occur in these patients. Previous studies suggest that clinical findings herald the progression of ICH when present, and that routine follow-up HCT is not necessary, even in patients with known ICH.<sup>19,20</sup> Additionally, while routine serial imaging even in patients with proven ICH is shown not to influence clinical outcomes, it needlessly increases hospital length of stay.<sup>21</sup> In an era where cost containment and radiation safety are particularly emphasized, and acute care facility throughput is critical, it may therefore be most prudent to abandon such an approach, instead observing these patients clinically and performing additional imaging only if clinical examination changes dictate such prior to discharge.

### LIMITATIONS

Our study is limited primarily by the relatively low sample numbers and retrospective design. While we were able to achieve significance with our statistical analyses, a greater positive ICH sample size may provide additional information, particularly if there are any factors at play that may predict the evolution of ICH, when present, between serial scans. This can be better assessed using a prospective design in the future. Additionally, we were limited in our ability to obtain clinical information, besides what had been recorded in the electronic records, due to the retrospective design. While we have no evidence of any missed cases of delayed ICH, it may be possible that some patients did develop eventual symptoms after discharge and presented to a different institution for evaluation and treatment. A prospective design would allow for the establishment of a specific follow-up protocol to more thoroughly assess for this possibility.

### CONCLUSION

Despite limitations, our study provides an important data point in the ongoing debate regarding the appropriate management of patients on ACAP therapy who sustain mild TBI. Based on these results, for patients with normal presentation GCS and neurological examinations, no associated LOC, on single anticoagulant therapy and no antiplatelet agent, we may be able to forego initial imaging altogether. Furthermore, a six-hour follow-up HCT is of extremely low yield in general and is likely not indicated, as our data suggests that clinically significant delayed ICH does not occur.

Address for Correspondence: Kevin Charles McCammack, MD, University of California, San Diego, Department of Radiology 200 W. Arbor Drive, #8756, San Diego, CA 92103. Email: kmccammack@ucsd.edu.

*Conflicts of Interest:* By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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# Do Emergency Department Patients Receive a Pathological Diagnosis? A Nationally-Representative Sample

Leana S. Wen, MD, MSc\* Janice A. Espinola, MPH<sup>†</sup> Joshua M. Mosowsky, MD<sup>‡</sup> Carlos A. Camargo, Jr., MD, MPH, PhD<sup>†</sup> \*George Washington University, Department of Emergency Medicine, Washington, District of Columbia

<sup>†</sup>Massachusetts General Hospital, Department of Emergency Medicine, Boston, Massachusetts

<sup>‡</sup>Brigham and Women's Hospital, Department of Emergency Medicine, Boston, Massachusetts

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**Introduction:** Understanding the cause of patients' symptoms often requires identifying a pathological diagnosis. A single-center study found that many patients discharged from the emergency department (ED) do not receive a pathological diagnosis. We analyzed 17 years of data from the National Hospital Ambulatory Medical Care Survey (NHAMCS) to identify the proportion of patients who received a pathological diagnosis at ED discharge. We hypothesized that many patients do not receive a pathological diagnosis, and that the proportion of pathological diagnoses increased between 1993 and 2009.

**Methods:** Using the NHAMCS data from 1993-2009, we analyzed visits of patients age  $\geq$ 18 years, discharged from the ED, who had presented with the three most common chief complaints: chest pain, abdominal pain, and headache. Discharge diagnoses were coded as symptomatic versus pathological based on a pre-defined coding system. We compared weighted annual proportions of pathological discharge diagnoses with 95% CIs and used logistic regression to test for trend.

**Results:** Among 299,919 sampled visits, 44,742 met inclusion criteria, allowing us to estimate that there were 164 million adult ED visits presenting with the three chief complaints and then discharged home. Among these visits, the proportions with pathological discharge diagnosis were 55%, 71%, and 70% for chest pain, abdominal pain, and headache, respectively. The total proportion of those with a pathological discharge diagnosis decreased between 1993 and 2009, from 72% (95% CI, 69-75%) to 63% (95% CI, 59-66%). In the multivariable logistic regression model, those more likely to receive pathological diagnoses were females, African-American as compared to Caucasian, and self-pay patients. Those more likely to receive a symptomatic diagnosis were patients aged 30-79 years, with visits to EDs in the South or West regions, and seen by a physician in the ED.

**Conclusion:** In this analysis of a nationally-representative database of ED visits, many patients were discharged from the ED without a pathological diagnosis that explained the likely cause of their symptoms. Despite advances in diagnostic testing, the proportion of pathological discharge diagnoses decreased. Future studies should investigate reasons for not providing a pathological diagnosis and how this may affect clinical outcomes. [West J Emerg Med. 2015;16(1):50–54.]

## INTRODUCTION

Research into patient preferences suggests that patients value a precise diagnosis from their doctors.<sup>1</sup> Understanding the diagnosis is seen to be the first step of healing, allowing for discussions of prognosis and treatment. However, anecdotal reports suggest that many patients are discharged from the emergency department (ED) without a diagnosis that explains the likely nature and cause of their symptoms. That is, these patients are discharged with the same diagnosis as their chief complaint (e.g., "chest discomfort"), rather than a specific pathological diagnosis (e.g., "gastritis").

To our knowledge, only one study has examined the proportion of ED patients who receive symptomatic versus pathological discharge diagnoses.<sup>2</sup> This pilot study was a chart review over a one-month period at a single, urban teaching hospital. As hypothesized, the authors found that most patients were discharged from the ED without a pathological diagnosis that explained the likely cause of their symptoms.

In this study, we used a national database with annually reported data from 1993-2009 to examine the proportion of ED patients who are discharged with symptomatic versus pathological discharge diagnoses. Based on the results of the single-center pilot study, we hypothesized that many patients do not receive a pathological diagnosis. Given advances in diagnostic testing, we further hypothesized that the proportion of pathological diagnoses increased between 1993 and 2009.

## METHODS

## **Study Design**

We conducted a cross-sectional analysis of the ED component of the 1993-2009 National Hospital Ambulatory Medical Care Survey (NHAMCS) database. NHAMCS was designed by the U.S. National Center for Health Statistics of the Centers for Disease Control and Prevention and is a national probability survey conducted for hospital outpatient and ED visits.<sup>3</sup> The local institutional review board approved this study.

## **Study Setting and Population**

The NHAMCS is a four-stage probability sample survey gathering data from non-institutional general and short-stay hospitals in the U.S., excluding federal, military and Veteran Administration hospitals. NHAMCS is conducted annually and covers geographic primary sampling units, hospitals within primary sampling units, EDs within hospitals, and patients within EDs. The non-response rate for most items was <5%, and error rates were <2% for items requiring medical coding. National estimates were obtained through use of a multistage estimation procedure and patient visit weights.

Our study population included all ED visits by patients age  $\geq 18$  years in the 1993-2009 NHAMCS database who presented with the three most common chief complaints (as coded in NHAMCS as "reason for visit"), and who were subsequently discharged from the ED. Those three most

common chief complaints were chest pain, abdominal pain, and headache. Separately, two emergency physicians coded all International Classification of Diseases-9 discharge diagnoses corresponding to these chief complaints as symptomatic or pathological diagnoses. There was 100% inter-rater agreement in the coding. Visits were categorized as a symptomatic discharge diagnosis if the discharge diagnoses (up to three per visit) contained only symptomatic and no pathological diagnosis code (e.g., "abdominal pain" alone, without specific diagnoses such as "biliary colic"). All others that contained either solely pathological diagnosis code or both symptomatic and pathological diagnoses were categorized as pathological (e.g., "biliary colic" alone, or "abdominal pain" and "biliary colic").

## Data Analysis

We performed all analyses using Stata 11.0 (StataCorp, College Station, TX). To account for the complex 4-stage sampling frame, we performed all analyses using the survey design variables and appropriate survey commands in Stata.

We compared weighted annual proportions of pathological discharge diagnoses with 95% CIs. Annual trends in the proportion of pathological discharge diagnoses were analyzed using weighted logistic regression. Additionally, we created a multivariable logistic regression model predicting discharge with a symptomatic diagnosis, with results reported in odds ratios (OR) and 95% CIs. A two-tailed p-value <0.05 was considered statistically significant.

## RESULTS

Among the 299,919 sampled visits, 44,742 visits met inclusion criteria. From these data, we estimated that there were 164 million (95% CI, 151-178 million) adult ED visits who presented with the three most common chief complaints and who were later discharged to home. Among these ED visits, the proportions with pathological discharge diagnosis were 55% for chest pain, 71% for abdominal pain, and 70% for headache (Table 1). Between 1993 and 2009, the proportion of pathological discharge diagnoses significantly decreased among those presenting with any of these three chief complaints ( $p \le 0.02$  for all; Figure).

In the multivariable logistic regression model (Table 2), those presenting with any of the chief complaints of chest pain, abdominal pain, and headache who were more likely to receive pathological diagnoses were females, African-American as compared to Caucasian, Hispanics, and selfpay patients. Patients aged 30-79 years, with visits to EDs in the South or West regions, and those seen by a physician in the ED were more likely to receive a symptomatic discharge diagnosis.

## DISCUSSION

In this major subset of a nationally-representative database of ED visits from the U.S., many patients were

|                         |                   | % (95% CI)                                  |  |  |  |
|-------------------------|-------------------|---|--|--|--|
| Chief complaint         | No. of visits (n) | Pathological discharge diagnosis, 1993-2009 | Pathological discharge diagnosis, 1993 | Pathological discharge diagnosis, 2009 |  |
| Chest pain              | 7,666             | 55% (54-57%)                                | 63% (58-69%)                           | 52% (48-57%)                           |  |
| Abdominal pain          | 14,766            | 71% (70-72%)                                | 79% (75-82%)                           | 66% (62-70%)                           |  |
| Headache                | 7,180             | 70% (69-72%)                                | 74% (70-78%)                           | 70% (65-75%)                           |  |
| Any of the 3 complaints | 29,612            | 66% (65-67%)                                | 72% (69-75%)                           | 63% (59-66%)                           |  |

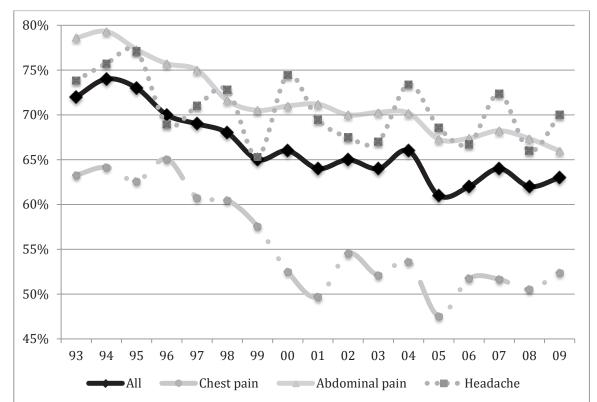


 Table 1. Proportion of pathological discharge diagnosis for the three most common chief complaints among U.S. emergency department visits, 1993-2009.

Figure. Proportion of emergency department patients discharged with pathological discharge diagnosis for three most common chief complaints, 1993-2009.

discharged from the ED without a pathological diagnosis that explained the likely cause of their presenting symptoms. These results are similar to those obtained from a pilot study at a single teaching hospital in Boston.<sup>2</sup> Reasons for physicians choosing a symptomatic rather than pathological discharge diagnosis are varied, and include individual style (e.g. not wanting to commit to a specific diagnosis), concern of malpractice (e.g. thinking that a symptomatic diagnosis is more defensible), and billing (e.g. assuming that a higher level of billing can be justified for those with an undifferentiated diagnosis). Some physicians would further argue that obtaining a definitive, pathological diagnosis is often not possible in the ED setting and that our goal in the ED should be to "rule out" life-threatening diseases and not to make pathological diagnoses. With growing recognition of the goal of patient-centeredness,

this must be weighed against the desire by many patients to receive a pathological diagnosis.<sup>4</sup>

The results raise several interesting questions. For example, contrary to our second hypothesis, despite advances in diagnostic testing and technology, the proportion of pathological discharge diagnoses decreased. Either the ready availability and accuracy in diagnostic testing have contributed to more unwillingness to commit to a pathological diagnosis, or practice patterns are shifting due to the other reasons listed above. In addition, we find it curious that women, ages 30-79, African-American and Hispanic patients are more likely to be provided with a pathological diagnosis, and that patients seen by physicians are more likely to be given a symptomatic diagnosis. We encourage further research in this neglected research topic to elucidate the reasons behind these variations.

| Characteristics  | Odds ratio (95% CI)   | p-value |
|--|-----------------------|---------|
| Age  |                       | •       |
| 18-29  | 1.00 (Refe            | rence)  |
| 30-39  | 0.85 (0.80-0.91)      | <0.001  |
| 40-49  | 0.77 (0.72-0.83)      | <0.001  |
| 50-59  | 0.77 (0.71-0.84)      | <0.001  |
| 60-69  | 0.84 (0.75-0.93)      | 0.001   |
| 70-79  | 0.85 (0.75-0.97)      | 0.02    |
| 80+  | 0.95 (0.82-1.10)      | 0.47    |
| Sex  |                       |         |
| Male   | 1.00 (Refe            | rence)  |
| Female   | 1.11 (1.05-1.17)      | <0.001  |
| Race   |                       |         |
| White  | 1.00 (Refe            | rence)  |
| Black  | 0.86 (0.80-0.93)      | <0.001  |
| Other  | 0.90 (0.79-1.02)      | 0.11    |
| Ethnicity  |                       |         |
| Non-Hispanic   | 1.00 (Refe            | rence)  |
| Hispanic   | 0.85 (0.78-0.94)      | 0.001   |
| Unknown  | 0.98 (0.91-1.06)      | 0.64    |
| Insurance  |                       |         |
| Private  | 1.00 (Refe            | rence)  |
| Public   | 1.02 (0.96-1.09)      | 0.44    |
| Other  | 1.26 (1.11-1.43)      | <0.001  |
| Self-pay   | 1.20 (1.11-1.29)      | <0.001  |
| Unknown  | 1.00 (0.99-1.15)      | 0.96    |
| Region   |                       |         |
| Northwest  | 1.00 (Refe            | rence)  |
| Midwest  | 0.88 (0.79-0.99)      | 0.03    |
| South  | 0.87 (0.79-0.95)      | 0.004   |
| West   | 0.84 (0.76-0.93)      | 0.001   |
| Urban  |                       |         |
| MSA  | 1.00 (Refe            | rence)  |
| Non-MSA  | 1.13 (1.01-1.26)      | 0.03    |
| Hospital ownership   |                       |         |
| Voluntary non-profit   | 1.00 (Ref             | ,       |
| Government, non-federal  | 1.15 (1.03-1.28)      | 0.010   |
| Proprietary  | 1.15 (1.05-1.26)      | 0.003   |
| Season of visit  |                       |         |
| Winter (December-February)   | 1.00 (Refe            |         |
| Spring (March-May)   | 0.97 (0.90-1.06)      | 0.52    |
| Summer (June-August)   | 0.94 (0.86-1.02)      | 0.12    |
| Fall (September-November)  | 0.89 (0.82-0.97)      | 0.01    |
| $\frac{\text{Seen by physician}}{MSA, \text{Metropolitan statistical area}}$ | 0.78 (0.65-0.94)<br>a | 0.01    |

This study also raises the overarching question of whether provision of a pathological diagnosis helps not just patient satisfaction but also clinical outcomes. Anecdotal reports suggest that patients are better able to understand their prognosis and treatment options if provided with a specific pathophysiologic diagnosis, and some studies have correlated unscheduled returns to the ED with medical error and with lack of patient understanding their diagnosis and prognosis.<sup>5-7</sup> Discharge communication may be particularly important for ED patients who are discharged home and may not have ready access to follow up.<sup>8</sup> Future studies can focus on the perceived importance to patients of being given a pathological diagnosis at ED discharge, as well the impact of receiving a pathological diagnosis on objective health outcomes.

## LIMITATIONS

Like all survey research, there is the possibility of error in data collection and coding, and in using a secondary data source. NHAMCS data use an ED-based sample and is not population based; thus, caution should be used regarding generalizing the results to the overall population. There are also limitations of coding symptomatic and pathological diagnoses. However, criteria for coding charts were clearly defined in advance. The strong consistency of the two reviewers' independent coding (>99% agreement) also argues against this bias. In addition, we studied only three presenting complaints. The three we studied are the most common chief complaints in the ED. While it is possible that the many excluded chief complaints will have clear pathological diagnoses (e.g., "fracture"), at the same time, excluded complaints may also be more prone to symptomatic classifications (e.g., "weakness"). Finally, this study only examined discharge diagnoses. It is possible that verbal or written discharge instructions provided information on specific diagnoses, though results from a prior study involving chart review suggest that the proportion of diagnoses provided at discharge was low,<sup>2</sup> and studies have commented on the inadequacy of the discharge communication process.8

## CONCLUSION

According to our analysis of a nationally-representative database of ED visits, many patients with the three most common chief complaints of chest pain, abdominal pain, and headache are discharged from the ED without a pathological diagnosis that explains the likely cause of their presenting symptoms. Despite advances in diagnostic testing and technology, the proportion of pathological discharge diagnoses decreased between 1993 and 2009. We encourage further research to identify the reasons why ED clinicians often do not provide a pathological diagnosis, and to examine whether provision of a pathological diagnosis affects patient satisfaction and clinical outcomes. Address for Correspondence: Leana S. Wen, MD, MSc, George Washington University, Department of Emergency Medicine, 2120 L St NW Suite 450, Washington DC 20032. Email: wen.leana@gmail. com.

*Conflicts of Interest:* By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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## Timing of Discharge Follow-up for Acute Pulmonary Embolism: Retrospective Cohort Study

David R. Vinson, MD\*<sup>†‡</sup> Dustin W. Ballard, MB, MBE<sup>\*‡§</sup> Jie Huang, PhD<sup>‡</sup> Adina S. Rauchwerger, MPH<sup>‡</sup> Mary E. Reed, DrPH<sup>‡</sup> Dustin G. Mark, MD<sup>\*¶</sup> For The Kaiser Permanente CREST Network \*The Permanente Medical Group, Oakland, California <sup>†</sup>Kaiser Permanente Roseville Medical Center, Roseville, California <sup>‡</sup>Kaiser Permanente Division of Research, Oakland, California <sup>§</sup>Kaiser Permanente San Rafael Medical Center, San Rafael, California <sup>¶</sup>Kaiser Permanente Oakland Medical Center, Oakland, California

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**Introduction:** Historically, emergency department (ED) patients with pulmonary embolism (PE) have been admitted for several days of inpatient care. Growing evidence suggests that selected ED patients with PE can be safely discharged home after a short length of stay. However, the optimal timing of follow up is unknown. We hypothesized that higher-risk patients with short length of stay (<24 hours from ED registration) would more commonly receive expedited follow up (≤3 days).

**Methods:** This retrospective cohort study included adults treated for acute PE in six community EDs. We ascertained the PE Severity Index risk class (for 30-day mortality), facility length of stay, the first follow-up clinician encounter, unscheduled return ED visits ≤3 days, 5-day PE-related readmissions, and 30-day all-cause mortality. Stratifying by risk class, we used multivariable analysis to examine age- and sex-adjusted associations between length of stay and expedited follow up.

**Results:** The mean age of our 175 patients was  $63.2 (\pm 16.8)$  years. Overall, 93.1% (n=163) of our cohort received follow up within one week of discharge. Fifty-six patients (32.0%) were sent home within 24 hours and 100 (57.1%) received expedited follow up, often by telephone (67/100). The short and longer length-of-stay groups were comparable in age and sex, but differed in rates of low-risk status (63% vs 37%; p<0.01) and expedited follow up (70% vs 51%; p=0.03). After adjustment, we found that short length of stay was independently associated with expedited follow up in higher-risk patients (adjusted odds ratio [aOR] 3.5; 95% CI [1.0-11.8]; p=0.04), but not in low-risk patients (aOR 2.2; 95% CI [0.8-5.7]; p=0.11). Adverse outcomes were uncommon (<2%) and were not significantly different between the two length-of-stay groups.

**Conclusion:** Higher-risk patients with acute PE and short length of stay more commonly received expedited follow up in our community setting than other groups of patients. These practice patterns are associated with low rates of 30-day adverse events. [West J Emerg Med. 2015;16(1):55–61.]

### **INTRODUCTION**

Historically, emergency department (ED) patients with acute pulmonary embolism (PE) in the United States have been admitted for at least several days of inpatient care.<sup>1,2</sup> In

addition to the initiation of treatment, a multi-day inpatient stay allows for the prompt detection of disease extension and treatment complications. It also provides opportunities for important patient education prior to discharge. Growing evidence suggests that carefully selected lowrisk patients with PE can be safely discharged home either directly from the ED or after a short hospital stay (<24 hours).<sup>3-5</sup> Truncating the typical inpatient stay limits the time available for patient observation and education. Timely postdischarge follow up, however, may serve to mitigate this loss by providing opportunities for urgent patient re-evaluation and education reinforcement. In fact, outpatient management of patients with acute PE is inadvisable without both "welldeveloped patient education" and "adequate support and follow-up mechanisms for the discharged patient,"<sup>6,7</sup> key elements of a safe transition of care.<sup>8-10</sup> However, the optimal nature and timing of follow up after expedited discharge for these patients has not been established.

Prospective studies of the outpatient management of PE vary widely in their timing and frequency of scheduled follow up. The reports range, on the one hand, from daily phone contact for seven consecutive days following discharge<sup>11</sup> to no pre-arranged contact with a clinician until an outpatient appointment one week after discharge.<sup>12</sup> Retrospective descriptive studies of outpatient management programs for ED patients with PE also vary considerably in their follow-up strategies.<sup>13,14</sup> Follow-up practice patterns from 'real life' community settings have not been reported.

We hypothesized that higher-risk outpatients with acute PE being discharged home after a short hospital length of stay (<24 hours from ED registration) would more commonly receive expedited follow up ( $\leq$ 3 days) than their lower-risk or longer-stay counterparts. We undertook this study to describe the practice patterns of PE management in community hospitals and to evaluate the influence of length of stay, risk class, and site-of-discharge on the timing of post-discharge outpatient follow up and short-term outcomes.

### **METHODS**

### **Study Design and Setting**

This retrospective cohort study included adult ED patients who were diagnosed with acute PE between January 1, 2013 and May 31, 2013 in six community EDs within Kaiser Permanente (KP) Northern California, a large integrated healthcare delivery system that provides comprehensive care for more than 3.4 million members. KP health plan members represent approximately 25-30% of the population in areas served and are similar to the general population with respect to race/ethnicity, socioeconomic status, and education.<sup>15,16</sup> The study was approved by the KP Northern California Health Services Institutional Review Board.

The EDs had an annual census in 2013 from 26,000 to 85,000 and were staffed by residency-trained, board-certified emergency physicians. The medical centers had inpatient bed capacities ranging from 50 to 325. Inpatient care is provided by board-certified internists, all of whom are hospitalists. Three medical centers were satellite sites for residency training programs and had residents rotate to various degrees

through their emergency and hospitalist departments.

During 2013, all facilities had 24/7 access to on-site computed tomography pulmonary angiography with aroundthe-clock interpretation by board-certified radiologists. Formal compression ultrasonography and ventilation perfusion imaging were not available during late night hours. Two facilities had a designated clinical decision area, functioning akin to a short-stay (<24 hours) observation unit, managed by hospitalists. Initial site-of-care decisions and total length of stay were in the hands of the treating physicians; no clinical care pathways for PE were in effect.

All facilities provided pre-discharge patient education regarding the disease and its treatment and had pharmacy available around-the-clock for discharge medications and supplemental patient education. Treating physicians commonly employed the standard KP Northern California discharge orderset for thromboembolism, which recommends warfarin with concomitant bridging therapy using enoxaparin. Alternative oral anticoagulants approved for the treatment of PE were not often prescribed, as the formulary restricts their use to patients who have failed or are unable to adhere to warfarin. Outpatient warfarin dosing was managed by each facility's pharmacy-led anticoagulation service. The percent time in therapeutic international normalized ratio range at these facilities in 2013 was a respectable 72% to 74% (the higher the percentage, the higher the quality of care and the better the clinical outcomes).<sup>17-19</sup>

Throughout the study period no follow-up policy was in effect at any of the medical centers for patients with acute PE who were discharged home. The timing and nature (telephone vs clinic) of the follow-up appointment with the patient's primary care provider was arranged at the discretion of the discharging clinician, who either directly provided the follow-up appointment or recommended the patient arrange it themselves within a certain time frame. These patient-driven access appointments were secured either via a 24/7 telephone appointment call center, an email directly to the patient's primary provider, or by electronically booked appointment times available through the patient portal of kp.org.<sup>20-22</sup>

## **Selection of Participants**

Non-gravid ED patients aged 18 years or older were included if they had an acute PE that was objectively confirmed by radiographic imaging, performed either in the ED or within the 12 hours prior to ED arrival, and no recent diagnosis of acute venous thromboembolism in the prior 30 days. Objective diagnostic confirmation was based on the final interpretation by a board-certified radiologist (or nuclear medicine physician, as indicated). We also included patients with a compression ultrasound positive for deep vein thrombosis in conjunction with respiratory complaints consistent with acute PE, as other outpatient PE research studies have done.<sup>11,23,24</sup>

Patients with the following conditions were excluded

## **Data Collection**

Investigators used a standard computerized data collection tool that combined extracted administrative data with manual chart review of the comprehensive integrated electronic health record.<sup>25</sup> Patient-level clinical data was electronically accessible within hierarchical databases as described previously.<sup>26</sup> We assessed risk for all-cause 30-day mortality using the PE Severity Index, the most well-studied validated risk stratification tool available.<sup>11,27</sup> We chose this prognostic tool because it is recommended by international society guidelines as a safe and effective means of identifying patients eligible for outpatient management.<sup>28,29</sup> We calculated the ED PE Severity Index score using the worst, and not the first, ED vital signs. We also included qualifying pre-arrival vitals from the clinic or emergency medical services that were documented in the physician notes. Patients with scores <85 points were classified as low risk (<5%) for 30-day mortality and those with scores above 85 as higher risk (>5%), based on published data.11,27

An outpatient appointment qualified as a clinician follow up if the provider (physician or nurse practitioner) who evaluated the patient was a generalist or a specialist in pulmonary medicine or hematology/oncology. Timing was measured in days since discharge and included both in-person and telephone visits. We excluded Internet-based secure messages between patients and their providers.<sup>20,22,30</sup>

## **Outcome Measures**

Our primary outcome measure was an expedited postdischarge follow up  $\leq 3$  days of discharge. A three-day endpoint defined expedited follow up since it represents the conservative end of the range in the outpatient PE literature<sup>3</sup> and is commonly used in research on telephone follow up, both after hospitalization and ED care.<sup>31,32</sup>

Unscheduled return ED visits ≤3 days included ED visits for any reason that were not initially arranged at the index visit. Five-day readmissions were counted as PE-related if any of the following were noted: complaints of dyspnea, chest pain, syncope, leg pain, or bleeding; findings of pleural effusion, elevated liver enzymes, new anemia or hemorrhage, new or worsening deep vein thrombosis or PE; or one of the following interventions: respiratory support (non-rebreather mask, noninvasive ventilation, endotracheal intubation, or mechanical ventilation), parenteral vasopressors, inferior vena cava filter placement or removal, or cardiopulmonary resuscitation.

Multiple processes were instituted to enhance the accuracy and reliability of the data abstraction process. All abstractors received training on the content and coding of each data element, data handling and data transmission procedures, as well as protocols to respond to questions or problems during the study. The principal investigator (DRV) monitored day-today data collection activities and answered coding questions. All complications were reviewed by two investigators for confirmation. Ambiguities in classification or diagnosis were arbitrated by a third investigator. Additionally, 15% of cases were randomly selected for independent review by a second investigator to assess for inter-rater reliability, reported as percent agreement, on the following variables: PE Severity Index score, risk class, site of discharge, expedited follow up, nature of the follow up, 3-day, 5-day, and 30-day outcomes.

## **Statistical Analysis**

Continuous variables are presented as means with standard deviation and categorical data are presented as the percentage of frequency of occurrence, with 95% CIs. We performed bivariate analysis to compare patients with expedited follow up ( $\leq 3$  days) and those with non-expedited follow up (>3 days). P-values are shown for t-test or chisquared test. A two-tailed p-value of less than 0.05 indicated statistical significance. In analyses stratified by PE Severity Index risk status, adjusted odds ratios (aORs) were calculated using multivariate logistic regression to determine whether length of stay <24 hours was associated with expedited follow-up after adjusting for age and sex. Tested covariates included age, sex, discharge from the ED or clinical decision area, and length of stay <24 hours from ED registration. Pairwise correlation for covariates was tested with a threshold r-value of less than 0.7 for inclusion in the model. The variance inflation factor was also determined for all variables in the regression model with an upper threshold of 10 for inclusion. We performed analyses using STATA v13.1 (StataCorp LP, College Station, Texas).

## RESULTS

We identified 203 cases of PE, 28 of which were excluded because of hospital discharge to a skilled nursing facility (n=15), non-member status (n=8), and inpatient death (n=5). The mean age of the remaining 175 patients was  $63.2 (\pm 16.8)$ years, and 87 (49.7%) were female. Overall, 56 patients (32.0%) were discharged within 24 hours.

The short and longer length-of-stay groups were comparable in age, sex, and rate of timely engagement with anticoagulation services, but differed significantly in their PE Severity Index risk classification and their site of discharge (Table 1). Overall, 93.1% (n=163) of our cohort received follow up within one week of discharge. One hundred patients (57.1%) received expedited follow up ( $\leq$ 3 days), most often by telephone (67/100).

We report the timing of initial post-discharge follow up stratified by risk class and length of stay in Table 2. This bivariate analysis suggests that higher-risk PE patients with short length of stay more commonly experienced expedited Table 1. Patient characteristics, management, and outcomes of patients with acute pulmonary embolism stratified by facility length of stay.

|  | Visit length of stay (n=175)    |                                   |         |
|--|---------------------------------|-----------------------------------|---------|
|  | Short-stay<br>(<24 hrs)<br>n=56 | Longer-stay<br>(≥24 hrs)<br>n=119 | p-value |
| Patient characteristics                                  | n (%)                           | n (%)                             |         |
| Age years*   | 60.4 (18.4)                     | 64.3 (16.1)                       | 0.16    |
| Sex female   | 24 (42.8)                       | 63 (52.9)                         | 0.28    |
| Pulmonary Embolism Severity Index: low risk <sup>†</sup> | 35 (62.5)                       | 44 (37.0)                         | <0.01   |
| Management   |                                 |                                   |         |
| Site of discharge  |                                 |                                   |         |
| Emergency department (ED) or clinical decision area      | 43 (76.8)                       | 2 (1.7)                           | <0.001  |
| Inpatient unit   | 13 (23.2)                       | 117 (98.3)                        |         |
| Expedited follow up with clinician (≤3d)                 | 39 (69.6)                       | 61 (51.3)                         | 0.03    |
| By telephone   | 25                              | 42                                | 0.78    |
| In clinic  | 14                              | 19                                |         |
| Follow up with clinician ≤7d                             | 53 (94.6)                       | 110 (92.4)                        | 0.83    |
| Anticoagulation services                                 |                                 |                                   |         |
| Discharged on warfarin                                   | 53 (94.6)                       | 107 (89.9)                        | 0.45    |
| Anticoagulation telephone contact ≤3d                    | 50 (94.3)                       | 99 (92.5)                         | 0.92    |
| Adverse outcomes   |                                 |                                   |         |
| Unscheduled ED visit ≤3d                                 | 1 (1.8)                         | 1 (0.8)                           | 0.58    |
| Thromboembolism-related readmission to hospital ≤5d      | 1 (1.8)                         | 1 (0.8)                           | 0.58    |
| Post-discharge all-cause mortality <30d                  | 0                               | 2 (1.7)                           | 0.83    |
| Sum of adverse events                                    | 2 (3.6)                         | 4 (3.4)                           |         |

\*Mean (SD).

<sup>†</sup>Low risk: Pulmonary Embolism Severity Index Class I or II (points <85); higher risk: Class III through V (points >85).

**Table 2.** Timing of initial post-discharge follow up stratified by risk class and length of stay for emergency department patients with acute pulmonary embolism (unadjusted).

|                         | Timing of initial post-discharge outpatient follow up |                  |                  |         |
|-------------------------|---|------------------|------------------|---------|
|                         | Cases   | ≤3 days<br>n (%) | >3 days<br>n (%) | p-value |
| Low-risk*               |   |                  |                  | p value |
| Short-stay <sup>†</sup> | 34  | 22 (65)          | 12 (35)          | 0.00    |
| Longer-stay             | 44  | 22 (50)          | 22 (50)          | 0.29    |
| Higher-risk             |   |                  |                  |         |
| Short-stay              | 21  | 17 (81)          | 4 (19)           | 0.04    |
| Longer-stay             | 74  | 39 (53)          | 35 (47)          | 0.04    |

\*Low risk: Pulmonary Embolism Severity Index Class I or II (points <85); higher risk: Class III through V (points >85). \*Short-stay: Time from emergency department registration to departure from the facility <24 hours; longer-stay: ≥24 hours.

follow up compared with higher-risk patients with longer length of stay or low-risk patients with either short or longer length of stay.

Given the interaction between length of stay and risk class, we stratified the cohort by PE Severity Index class (higher risk vs. low risk) for the multivariate analysis. The association we found in bivariate analysis held up after controlling for age and sex. We found that short length of stay was independently associated with expedited follow up in the higher-risk patients (aOR of 3.5 [95% CI [1.0-11.8]; p=0.04]), but not the low-risk patients (aOR of 2.2, 95% CI [0.8-5.7]; p=0.11). Site of discharge (ED or clinical decision area) was collinear with short length of stay (r=0.8) and accordingly was not included in the regression models.

Of the 43 patients sent home from the ED or clinical decision area after a short stay, 23 were discharged from the ED and 20 from the clinical decision area. The rates of expedited follow up between these two sites-of-discharge groups were not statistically significant: ED (21/23) and clinical decision area (15/20).

Unscheduled return ED visits  $\leq 3$  days were uncommon (1.1%; 95% CI [0.1%-4.3%]), as were PE-related readmissions to the hospital  $\leq 5$  days (1.1%; 95% CI [0.1%-4.3%]), neither of which were significantly different between the short-stay and the longer-stay groups (Table 1). Rates of post-discharge all-cause 30-day mortality were also low (1.1%; 95% CI [0.1%-4.3%]) and not significantly different between the two groups.

The two patients who died were both Class V on the PE Severity Index, and hence at higher risk for 30-day allcause mortality.<sup>27</sup> One patient was a 52-year-old woman with advanced metastatic breast cancer who at hospital discharge was enrolled in hospice care. She died at home 12 days later. The other was an 87-year-old man with significant comorbidities whose index hospital course was complicated by a major lower gastrointestinal hemorrhage on day seven, requiring a transfusion of two units of red blood cells. He had an out-of-hospital asystolic arrest on day 30.

The inter-rater reliability results for the following eight variables ranged between 96% to 100% agreement: PE Severity Index score, risk class, site of discharge, expedited follow up, nature of follow up, 3-day, 5-day, and 30-day outcomes.

## DISCUSSION

This retrospective cohort study found that higher-risk patients with acute PE sent home within 24 hours of ED registration more commonly received expedited follow up within three days than low-risk patients and those of any risk category with longer lengths of stay. Given the relative novelty in the U.S. of home management of ED patients with acute PE, we suspected that physicians might feel the need to be more vigilant when sending higher risk patients home who had received only a short period of medical observation. Our results support this hypothesis.

The optimal timing of follow-up appointments for patients with acute PE who are discharged home is unknown, though this transition of care can be critical to patient safety, especially in the elderly.<sup>8-10</sup> How a patient's risk classification, site of discharge, or their comorbidities and psychosocial factors should influence the timing of follow up is also unknown. The timing of post-discharge follow up reported for this population varies. Prospective studies of outpatient PE management ensure telephone follow up as soon as the next day<sup>11</sup> or wait for a week before seeing the patient in the clinic.<sup>11</sup> Other prospective studies fall between these extremes.<sup>3</sup> One established outpatient treatment protocol for ED patients with acute PE in Canada has their discharged patients seen in the thrombosis clinic in 24-48 hours.<sup>13</sup> No published outpatient PE policy defers the initial follow up beyond the first week.

The nature of the initial post-discharge follow up also varies: some see their patients in person and others contact them by phone.<sup>3,13</sup> If an element of the physical examination is crucial to the follow-up assessment, which is uncommon with PE, then an in-person clinic visit is preferred. Otherwise, a telephone conversation may be just as effective, despite the loss of face-to-face communication.<sup>31,32</sup> A phone encounter offers greater patient convenience by reducing their outlay of time, travel, and costs. Telephone follow up has been demonstrated to improve patient satisfaction, as well, though its impact on clinical outcomes remains inconclusive.<sup>33,34</sup> Video visits may offer a promising alternative, maintaining the convenience of a telephone visit with the advantages of virtual face-to-face communication.<sup>21,35</sup>

Follow-up appointments, either in person or over the telephone, allow for continuing patient education, encouragement of treatment compliance, management of symptoms, and the answering of questions. It is difficult to unravel the contribution made by timely follow up to the favorable outcomes associated with outpatient management of select patients with acute PE. Studies of home management all include careful post-discharge follow up one or more times within the first week as well as frequent telephone contact with anticoagulation services.<sup>3-5,13</sup> We do not know if such low rates of adverse outcomes could have been achieved apart from timely patient reassessment during that first week after discharge. This is an important area for future investigation.

## LIMITATIONS

This study is subject to the limitations inherent in its retrospective design. Some of those shortcomings, however, are mitigated by our comprehensive electronic health record, our excellent capture of outcomes among KP health plan members, who seek care almost exclusively within the health plan, and the study's high inter-rater reliability. Our limited sample size means the rates of adverse outcomes we measured are estimates with wide confidence intervals. The majority of our patients were discharged on warfarin and therefore also received close and careful monitoring by the pharmacy-led anticoagulation service. It is uncertain how clinic-based follow-up arrangements will change (or should change) for patients taking newer oral anticoagulants that don't require efficacy monitoring.<sup>36</sup>

Our results may not be readily generalizable, as they reflect the practices of physicians who work within an integrated healthcare delivery system, where prompt outpatient follow up can be reliably arranged<sup>37</sup> and our anticoagulation services carefully manage their patients. This tightly coordinated continuity of care may allow for shorter length of stay in the ED and inpatient units than in healthcare systems lacking reliable outpatient monitoring and follow up. Lastly, outpatient PE management is not altogether new in our healthcare system, having been practiced to a small degree for over a decade.<sup>38,39</sup> Though more commonly employed in Europe and Canada, outpatient PE management has been uncommon in the U.S. A recent large PE registry from 22 EDs in the U.S. found that only 21 of 1,880 (1.1%) patients were discharged home from the ED without hospitalization.<sup>2</sup>

### CONCLUSION

In sum, we found that outpatients with acute PE nearly always received post-discharge follow up within the first week and over half received expedited follow up within three days. Higher-risk patients who were sent home within 24 hours of ED registration were more likely to receive expedited follow up. For all patients, the rate of adverse outcomes at both five days and 30 days was very low, though our study was not adequately powered to ensure the safety of this management approach. Short length of stay combined with expedited post-discharge follow up, however, appears to be a safe practice for selected patients in this integrated healthcare system. The effects of expedited follow up on patient satisfaction and clinical outcomes warrant further investigation.

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Address for Correspondence: David R. Vinson, MD, Kaiser Permanente Roseville Medical Center, Department of Emergency Medicine, 1600 Eureka Road, Roseville, CA 95661. Email: drvinson@ucdavis.edu.

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## Descriptive Study of Prescriptions for Opioids from a Suburban Academic Emergency Department Before New York's I-STOP Act

Lyncean Ung, DO\* Ronald Dvorkin, MD<sup>†</sup> Steven Sattler, DO\* David Yens, PhD<sup>‡</sup>§ \*Good Samaritan Hospital Medical Center, Department of Emergency Medicine, West Islip, New York

<sup>†</sup>Premier Care Physicians, Department of Emergency Medicine, Bellmore, New York <sup>‡</sup>New York Colleges of Osteopathic Medicine Educational Consortium, New York, New York

§Touro College of Osteopathic Medicine, Middletown, New York

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**Introduction:** Controlled prescription opioid use is perceived as a national problem attributed to all specialties. Our objective was to provide a descriptive analysis of prescriptions written for controlled opioids from a database of emergency department (ED) visits prior to the enactment of the I-STOP law, which requires New York prescribers to consult the Prescription Monitoring Program (PMP) prior to prescribing Schedule II, III, and IV controlled substances for prescriptions of greater than five days duration.

**Methods:** We conducted a retrospective medical record review of patients 21 years of age and older, who presented to the ED between July 1, 2011 – June 30, 2012 and were given a prescription for a controlled opioid. Our primary purpose was to characterize each prescription as to the type of controlled substance, the quantity dispensed, and the duration of the prescription. We also looked at outliers, those patients who received prescriptions for longer than five days.

**Results:** A total of 9,502 prescriptions were written for opioids out of a total 63,143 prescriptions for 69,500 adult patients. Twenty-six (0.27%) of the prescriptions for controlled opioids were written for greater than five days. Most prescriptions were for five days or less (99.7%, 95% CI [99.6 to 99.8%]).

**Conclusion:** The vast majority of opioid prescriptions in our ED prior to the I-STOP legislature were limited to a five-day or less supply. These new regulations were meant to reduce the ED's contribution to the rise of opioid related morbidity. This study suggests that the emergency physicians' usual prescribing practices were negligibly limited by the new restrictive regulations. The ED may not be primarily contributing to the increase in opioid-related overdoses and death. The effect of the I-STOP regulation on future prescribing patterns in the ED remains to be determined. [West J Emerg Med. 2015;16(1):62–66.]

### **INTRODUCTION**

Pain is one of the most common chief complaints treated in the emergency department (ED), and for many years there has been a strong emphasis on addressing adequate pain control.<sup>1</sup> Despite the increased importance placed on providing appropriate analgesia, emergency physicians (EP) continue to provide inadequate pain management.<sup>2</sup> This practice may be related to the clinician's awareness of the significant problems with drug dependence in the United States. There is an increase in the abuse of prescription drugs, specifically oxycodone and hydrocodone, and it far exceeds the increases in abuse of illicit substances, including marijuana, cocaine, and heroin.<sup>2</sup>

Even with attempts to reduce narcotic abuse and addiction, people continue to exhibit violent behaviors to obtain narcotics. Violent acts led the New York State Legislature to introduce a bill that enhanced the effectiveness of New York's existing Prescription Monitoring Program (PMP) with the intention of reducing drug diversion.<sup>3</sup> "The Internet System for Tracking Over-Prescribing (I-STOP) Act" established an online, real-time controlled substance reporting system that mandates physicians and pharmacists to search for and report certain data at the time a schedule II, III, IV, or V controlled substance prescription is issued and at the time such substance is dispensed."<sup>4</sup> It took effect in August of 2013. In New York, EPs are waived from the mandatory consultation of the PMP for prescriptions written for five days or less.

There is an association between the maximum prescribed daily dose by any physician and opioid overdose-related deaths, with higher opioid doses related to an increased risk of an opioid overdose death.<sup>5-13</sup>Although multiple studies track the number of prescriptions written by EPs over a period of time, our literature search found no articles that examine the quantity of opioids prescribed to each individual patient during one visit. The duration of pain medications were not included in these particular studies.

We designed this descriptive study to assess the prescription patterns of EPs for opioids prior to the enactment of the New York I-STOP act in a single academic community ED on Long Island. Our expectation is that EPs had been prescribing no more than five days of controlled opioids even before the creation of the new legislation.

### METHODS

This was a retrospective chart review to analyze the prescriptions for controlled opioids prior to the enactment of the I-STOP law. The study was conducted at a suburban academic community hospital ED with an annual census of approximately 95,000 patients. All patients older than 21 years are seen in an adult ED area (69,500).

The database search included all patients 21 and older who received a prescription for a controlled opioid at discharge between the dates of July 1, 2011 and June 30, 2012. We characterized each prescription as to the type of controlled opioid, the quantity dispensed, and the length of time for the prescription. Medical records with insufficient or inconsistent time stamps and/or other entries and patients who left prior to formal discharge were excluded. The data extracted included the following: hospital account number, age, sex, ethnicity, diagnosis, arrival date, time, and prescriptions written.

We abstracted the data from the electronic medical record (Allscripts ED<sup>TM</sup> - formerly Healthmatics A4<sup>TM</sup>) for patients discharged from the ED with one or more prescriptions. This computerized patient charting and

order entry system enables the collection of standardized information for each patient and integrates that information into a relational database and also has the advantage of generating prescriptions that were included in the medical record. The database was queried by SQL Cognos Impromptu<sup>™</sup> (Cognos), which allows the administrator to create reports using criteria filters. Using the inclusion criteria, a report was created with Cognos that queried all patients seen in the ED who fit the criteria for study enrollment. This report was further analyzed by Microsoft Excel 2007. This method has been used and described in other studies.<sup>14-16</sup>

The prescriptions analyzed were those written for opioids including hydrocodone, morphine, hydromorphone, and fentanyl (patches) as seen in Table 1. Tramadol was not analyzed, as it only has been considered a controlled substance in New York since August 27, 2012. We also excluded a cough syrup containing hydrocodone with homatropine in low dose (Hycodan<sup>®</sup>) because it was never prescribed in amounts of more than 120mL, which was equivalent to the total hydrocodone of 24 pills (a quantity usually of no more than five days as traditionally prescribed), and we could find little evidence for this significantly contributing to the epidemic of prescription drug abuse overdoses or deaths.

We calculated the number of days prescribed by using the number of doses prescribed, shortest recommended dosing frequency and converting this to the number of days the prescription would last (Figure 1). All patient charts that had a prescription of more than five days were manually reviewed.

### RESULTS

A total of 63,143 prescriptions were written between July 1, 2011 and June 30, 2012. The demographics are listed in Table 2. Of those prescriptions, 9,502 prescriptions were written for opioids. We excluded 71 prescriptions from the study because they were duplicates of the original prescription or lacking information on the prescription to calculate the number of days. Of the 9,502 prescriptions written that were included in our study, 99.7% already complied with the new regulations (95% CI [99.6 to 99.8%]). Twenty-six prescriptions (0.27%) were written for greater than five days as seen in Figure 2. Some were a result of larger intervals between each dose than typically recommended. For example,

#### Table 1. Percentage of opioid prescriptions written.

| % (No.) of prescriptions |
|--------------------------|
| 84.08% (8040)            |
| 14.47% (1324)            |
| 0.02% (2)                |
| 1.24% (119)              |
| 0.18% (17)               |
|                          |

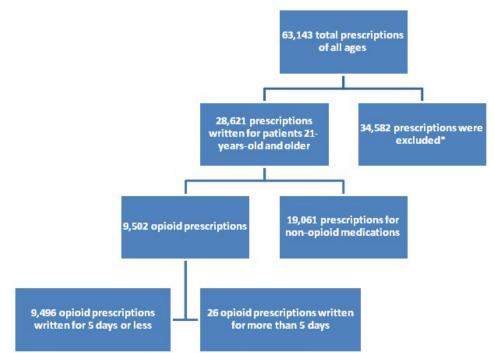
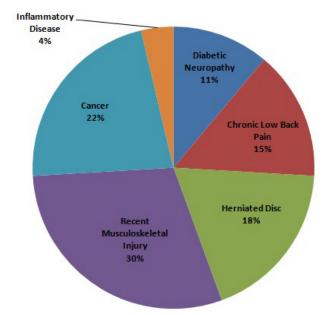


Figure 1. Analysis of prescriptions written in the emergency department.

\*The prescriptions that were excluded as listed in the methods section include those written for patients who are less than 21 or have a malignancy and chronic inflammatory disease. Patients who also received Hycodan<sup>®</sup> were also excluded.

**Table 2.** Demographics of patients receiving opioid versus nonopioid prescriptions.

|                  | Opioid      | All prescription |
|------------------|-------------|------------------|
| Ν                | 9,502       | 28,621           |
| Mean age, y (SD) | 44.9 (15.2) | 44 (16.4)        |
| Male (%)         | 42.8%       | 43.2%            |
| White (%)        | 61.2%       | 61.5%            |



**Figure 2**. Diagnosis of patients receiving opioid prescriptions for greater than 5 days (n=26).

fentanyl usually is packaged in a box of five patches and each patch is used for three days at a time. The prescriptions written for greater than five days were categorized by diagnosis. A breakdown of the 26 outlying prescriptions and related diagnoses are provided in Figure 2 with their corresponding diagnoses. All written opioid prescriptions were further divided by the number of days they were written for, which is seen in Figure 3.

Our study found that prescriptions for opioids were usually for no more than five days in length and would have almost always complied with the new state regulations.

## DISCUSSION

I-STOP made New York the first state in the nation to mandate that physicians consult a database of a patient's prescription history before prescribing a schedule II, III, or IV controlled substance.<sup>17</sup> Studies analyzing the impact of PMPs have been unanimous in regards to decreasing drug dependence and diversion by inhibiting growth in prescription sales for pain relievers. This act may further enhance the PMP's goal; however, it can be hindering in an emergency setting. There is ongoing concern about EPs undertreating pain and the majority of emergency patients suffering from acute injury.

In the ED, pain management continues to be a significant complaint requiring practitioner attention as seen from the data of this study where approximately onesixth of all prescriptions written were for opioid analgesics. As seen in numerous studies conducted previously, oxycodone continues to be the most commonly prescribed

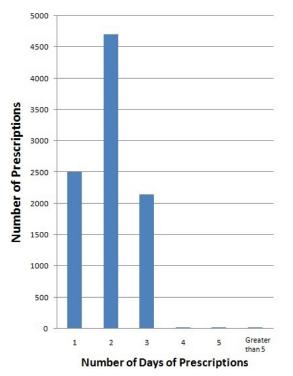


Figure 3. Breadkdown of opioid prescriptions into the number of days they were written for.

opioid (84%).<sup>15,18-20</sup> We were able to illustrate that in a large suburban, community ED, most physicians were prescribing five days or less worth of prescriptions for opioids, with the majority being for three days or less. This pattern could be affected by the presence of an electronic medical record (EMR) that has prebuilt prescriptions for a set number of pills. Even though prescriptions could be typed up individually with varying dosing and number of pills, it might be more efficient for a physician to select a prebuilt prescription.

Of the opioids considered in this study, short-acting oxycodone is still the most commonly prescribed opioid as well as the most commonly prescribed for greater than five days. The small number of patients who received more than five days' worth of opioids had pain from acute musculoskeletal injuries, chronic low back pain, herniated disc, and diabetic neuropathy.

Giving ED physicians the privilege of providing opioid pain relievers without referring to the PMP permits them to function effectively in their environment. Our study shows that the EP already displays independent responsibility in opioid prescribing patterns. The PMP in theory may add little to reduce the amount of drug overdoses in the ED setting.

Prior to enactment of this legislation, EPs had not been giving prescriptions of opioids that were excessive and therefore not likely to be contributing to the rise of opioid overdoses and deaths in the community. Further regulations requiring the additional step of consulting a database before prescribing controlled opioids may have the potential to inhibit opioid prescriptions for acute pain and promulgate oligoanalgesia.

### LIMITATIONS

Our study has several limitations. It was a retrospective study and has all the limitation therein. It was completed at a single suburban academic community hospital ED and therefore might not represent other communities or institutions. It cannot determine if the patient is "doctorshopping" and visiting other EDs, doctors' offices, or even the same ED but on subsequent days or weeks. We focused on the duration of opioid prescriptions written rather than the maximum concentration of the opioid all together or total per day. There is increased risk of overdose in patients receiving medically prescribed opioids at higher doses.<sup>5-13</sup>

Patients can still "doctor-shop," and if an EP does not have a clinical suspicion for substance abuse, the small amounts of opioids given can supply an addiction from multiple sources. Furthermore, a patient's inability to obtain a sufficient quantity of prescription opioids may lead them to solicit street drugs that have unregulated compositions adding to potentially worse adverse outcomes.

The study did not provide any data on the type of pain or response to initial treatment. It was not designed to determine whether pain was adequately treated. The results could be influenced by variations in individual provider practice, and the study did not control for the effect of clustering by individual providers. Providers in this department see patients on a next patient basis and do not choose the next patient to be seen, thus minimizing this type of selection bias.

Whether the implementation of this regulation will change the prescribing practices of physicians is not known and would be an interesting question to pursue.

#### CONCLUSION

The duration of opioids prescribed from one ED visit in this suburban, community Long Island ED prior to the I-STOP legislature was largely limited to five days or less. This suggests that EPs had been largely abiding with the spirit of the new bill prior to its drafting. Although the PMP might assist with abuse and dependency of opioids in this community, it remains unknown whether this will impact optimal prescribing practices for pain.

Address for Correspondence: Lyncean Ung, DO, Good Samaritan Hospital Medical Center, 1000 Montauk Hwy, West Islip, NY 11795. Email: lyncean.ung@gmail.com.

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# Prescription Drug Monitoring Programs: Examining Limitations and Future Approaches

| Christopher A. Griggs MD, MPH*       | *Carolinas Medical Center, Department of Emergency Medicine, Charlotte, North                      |
|--------------------------------------|--|
| Scott G. Weiner MD, MPH <sup>†</sup> | Carolina <sup>†</sup> Brigham and Women's Hospital, Department of Emergency Medicine, Boston,      |
| James A. Feldman, MD <sup>‡</sup>    | Massachusetts  |
|                                      | <sup>‡</sup> Boston University School of Medicine, Boston Medical Center, Boston,<br>Massachusetts |

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Prescription drug abuse is a leading cause of accidental death in the United States. Prescription drug monitoring programs (PDMPs) are a popular initiative among policy makers and a key tool to combat the prescription drug epidemic. This editorial discusses the limitations of PDMPs, future approaches needed to improve the effectiveness of PDMPs, and other approaches essential to curbing the rise of drug abuse and overdose. [West J Emerg Med. 2015;16(1):67–70.]

#### **INTRODUCTION**

Prescription drug abuse is a leading cause of accidental death in the United States. Local, state, and federal agencies have implemented several policies to address this epidemic, including drug take-back programs, prescriber education, pain clinic laws, and prescription drug monitoring programs (PDMP). PDMPs are a popular initiative among policy makers, as they easily provide clinicians with scheduled medication histories, helping identify patients that may be diverting medications or abusing them. As of October 2014, 22 states have passed laws mandating that providers use the PDMP in certain circumstances. However, enthusiasm for PDMPs as a key tool to combat the prescription drug epidemic may cause proponents and policy makers to overlook their potential limitations. This enthusiasm may also prevent the development of more comprehensive and evidence-based strategies to address this public health crisis and the conclusion that additional steps are needed to combat the opioid epidemic.

Evidence to support the effectiveness of PDMPs comes largely from observational studies or surveys of providers.<sup>1</sup> Recent data from Florida show a decline in prescription drug overdose deaths and doctor shopping after the implementation of their PDMP and pain clinic law.<sup>2,3</sup> Virginia also reported a fall in the number of "doctor shoppers" after implementation.<sup>4</sup> Additionally, national data from the Centers for Disease Control (CDC) show that overdose deaths due to opioid analgesics decreased by 5% from 2011 to 2012, the first decrease in a decade.<sup>5</sup> It is not clear if PDMPs were responsible for this decline or if other interventions, such as laws limiting dispensing of medications from pain clinics and overall prescriber awareness of the risks of opioids, led to this decline. Contrary to this evidence, previous studies examining PDMP effects on opioid prescribing show mixed effects before 2008, with some states having reduction in prescribing and overdose deaths and others showing an increase.<sup>6-8</sup> While PDMPs are likely contributing to the overall decline in drug diversion and prescription opioid overdoses, the true effect of PDMPs is to be determined and there are several substantial limitations that should be addressed.

#### PDMP Data - Devil in the Details

PDMPs identify "doctor shopping" through unsolicited reports sent from government agencies to clinicians, surveillance of aberrant prescribing behavior to identify irresponsible prescribing and by clinician review of patient reports before prescribing. PDMP databases generate data from pharmacies directly reporting to the state when a prescription is filled. States have varying delays in how long it takes for the data to appears in the database, for example in Massachusetts, there is up to a three-week delay. For data to be accurate, the name and date of birth must be reported correctly by the patient, written correctly on the prescription, entered correctly by the pharmacy, and again entered correctly by the clinician searching for the report. Any error may generate an incorrect report. Currently only 22 states require a patient to show identification before dispensing a controlled substance, allowing "doctors shoppers" and "pill mills" to easily deceive the system.<sup>9</sup> Improved identification at both the point of prescribing and dispensing should be explored as a means to improve the effectiveness of PDMPs.

The PDMP relies on Drug Enforcement Administration (DEA) numbers to identify prescribers. In the case of residents and moonlighting clinicians, many hospitals use hospital-based DEA numbers and the database reports the hospital name instead of the specific prescriber. If a patient sees multiple providers at the same clinic, the database is unable to indicate whether the providers are working together. Such a profile may lead a clinician to inappropriately conclude a patient is "doctor shopping," when the patient is, in fact, following up correctly. The confusion created by DEA numbers could be remedied if further information was provided on the PDMP database that indicated a prescriber's specialty and association with a specific clinic or group. Additionally, hospital-based DEA numbers should be registered with the state PDMPs to give prescriber specific information.

To date, there is no agreed upon threshold to define questionable behavior, and each government agency or clinician is left to decide what criteria should cause them concern. The lack of objective criteria creates a challenge for clinicians who are balancing their duty to treat pain, to meet patient expectations, and to prevent misuse and diversion in their communities. The Massachusetts Department of Public Health recommends discussing concerning PDMP profiles with patients and to use the PDMP in the context of a complete patient evaluation, including review of outside medical records, and discussions with other providers.<sup>10</sup> There is, however, no guidance on how to interpret the report in this context.

Recent studies have shown increases in mortality in patients with greater than four providers, greater than four pharmacies and using greater than 100 morphine milligram equivalents per day.<sup>11</sup> However, using any absolute value results in identifying patients as "doctor shoppers" or at risk for overdose who, in fact, are not. Many patients have multiple prescribers because of poor primary care access, visits to emergency departments (ED) for acute exacerbations of pain, and conditions requiring visits to multiple specialists. Having to interpret the PDMP in this context allows bias and other factors outside of objective data to determine who is labeled as at risk or not.

#### **PDMP and Sources of Opioids**

PDMP effectiveness is dependent on the amount of misuse and diversion that results from clinician

prescribing. Studies examining the PDMP profiles of those who died from prescription drug overdoses report the percentage of deaths related to "doctor shopping" range from 21% to 32%.<sup>12</sup> Among those using opioids for nonmedical purposes, a national survey identified that 20% of individuals received opioids from more than one prescriber, while the remaining received opioids from their friends, family, drug dealers, or strangers.<sup>13</sup> It is unknown how much of diverted medications result from "doctor shopping." Diversion may alternatively result from patients with one prescriber, theft, or falsified prescriptions. PDMPs are therefore unable to identify many important sources of diversion and interventions are needed to target the other causes of diversion.

#### PDMP effects on prescribing

Clinical studies depict mixed effects of PDMP reports on prescribing. Baehren et al.<sup>14</sup> found PDMP use changed emergency physicians' prescription plans in 41% of cases and resulted in less prescribing. Another study by Weiner et al.<sup>15</sup> found PDMP data influenced prescribing behavior in only 9.5% of cases and resulted in more prescribing. Baehren et al.<sup>14</sup> enrolled 18 providers but four providers were responsible for 63% of the patient encounters, compared to the Weiner et al.<sup>15</sup> study that enrolled 38 providers and limited the participation of any one provider to 10%. The true effect of PDMPs on prescribing is likely closer to the results in the Weiner et al. study due to the bias inherent in the Baehren et al. study; however, further investigation is needed.

#### Where do we go from here?

PDMPs are a valuable tool in concept, but their effectiveness must still be proven. Patients determined to deceive the system may do so by crossing state borders in states without effective data sharing or reporting false personal information when registering with hospitals and clinics. It also remains unclear if patients chronically treated with opioids will be adversely affected by PDMPs. In particular, pain patients with fragmented care and a poor primary care network are more likely to have a suspicious PDMP profile and may be undertreated.

The promise of PDMPs is to improve data sharing among providers in order to avert diversion and prescribing to those at risk of abuse and overdose. However, this data sharing is limited to a few data points. PDMPs could provide means of communication between providers within the Internet portal that is compliant with privacy laws and allows better communication on opioid prescribing. This would also allow emergency providers to notify other prescribers of patients who have either overdosed, are at risk for overdose, or have a pain contract.

If PDMPs are to be successful, further improvements are needed to improve accuracy, accessibility and

interpretability of the data. Easy access with little effort on the part of the clinician is essential to increased usage. Even with legal mandates, enforcement will be challenging and clinicians are already overloaded with work, making PDMP review for all patients a challenge in many clinical settings. Further funding to integrate PDMP data into medical records is essential. Effective use of the PDMP will require studies determining how the PDMP should be used alongside the complete clinical encounter and to identify what values in a PDMP report should trigger intervention from the clinician.

While PDMPs are one tool in the fight against the opioid epidemic, they are not the panacea and a more comprehensive approach is needed. Our profession must come to consensus on the indications for opioid pain medications and their appropriate use in managing acute and chronic pain. Training clinicians in chronic pain management and responsible opioid prescribing may do more to reduce opioid prescribing than access to PDMPs. Improved patient education for those receiving opioids is also needed so our patients fully understand the risks and benefits of opioid therapy.

The aforementioned CDC data show a decrease in opioid analgesic overdose in 2012, but also show a 35% increase in heroin deaths over the same year and a continued rise in drug overdose deaths overall.<sup>4</sup> If current interventions are able to decrease abuse and overdose from prescription opioids, the overdose epidemic may rage on from opioids provided through the black market. It is not enough to simply refuse to prescribe opioids to those with a concerning PDMP profile, but physicians must have candid conversations with their patients, particularly in the ED. Adequate funding is needed for drug abuse treatment programs, which will allow ED referrals to be more effective. Additionally, overdose education and naloxone distribution has shown promise in reducing opioid overdose death.<sup>16</sup> The ED is a particularly critical location where naloxone distribution could be effective and further research on ED distribution of naloxone is warranted.

We are at a critical point in the opioid epidemic, and the path forward requires addressing opioid addiction and abuse via multiple methods. PDMPs have shown promise but have limitations and we must work to improve their effectiveness. ED providers are essential to identifying and participating in these improvements and expanding the discussion on how to effectively prevent overdose and abuse of opioids.

Address for Correspondence: Christopher Griggs, MD, MPH, Department of Emergency Medicine, Suite 304-K, Medical Education Building, Carolinas Medical Center, 1000 Blythe Blvd, Charlotte, NC 28232. Email: Christopher.Griggs@ carolinashealthcare.org. *Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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# Predictors of Psychiatric Boarding in the Emergency Department

Ryan K. Misek, DO Ashley E. DeBarba, DO April Brill, DO Midwestern University, Chicago College of Osteopathic Medicine, Department of Emergency Medicine, Downers Grove, Illinois

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**Introduction**: The emergency psychiatric care is system is overburdened in the United States. Patients experiencing psychiatric emergencies often require resources not available at the initial treating facility and frequently require transfer to an appropriate psychiatric facility. Boarding of psychiatric patients, defined as a length of stay greater than four hours after medical clearance, is ubiquitous throughout emergency departments (EDs) nationwide. Boarding is recognized as a major cause of ambulance diversions and ED crowding and has a significant adverse impact on healthcare providers, patient satisfaction, and hospital costs. We sought to identify differences between patients who boarded versus patients who did not board, to identify factors amenable to change and identify interventions that could lead to a decrease in overall psychiatric patient length of stay and improve patient care.

**Methods**: This study is a retrospective multicenter cohort study of all patients assessed to require inpatient psychiatric hospitalization at two community EDs in Illinois from July 1, 2010 through June 30, 2012. We identified 671 patients and collected insurance status, sex, age, time of arrival, time of disposition and time of transfer.

**Results:** There was a statistically significant difference in the insurance status between the cohort of patients boarding in the ED compared to non-boarders prior to inpatient psychiatric admission. Our study identified 95.4% of uninsured patients who were boarded in the ED, compared to 71.8% of Medicare/Medicaid patients and 78.3% of patients with private insurance ( $\chi^2$ =50.6, df=2, p<0.001). We found the length of stay to be longer for patients transferred to publicly funded psychiatric facilities compared to those transferred to private facilities, with a mean time spent in the ED of 1,661 minutes and 705 minutes, respectively (p<0.001). Patients with Medicare/Medicaid were nearly twice as likely to return to the ED for psychiatric emergencies than self-pay and privately insured patients, requiring repeat inpatient psychiatric admission (estimate=0.649, p=0.035, OR=1.914).

**Conclusion**: This study found that unfunded patients boarded significantly longer than Medicare/ Medicaid and privately insured patients. Patients with private insurance boarded longer than those with Medicare/Medicaid. Patients transferred to publicly funded facilities had significantly longer ED length of stay than patients transferred to private facilities. [West J Emerg Med. 2015;16(1):71–75.]

# INTRODUCTION

Emergency department (ED) "crowding" is an international problem that has received much attention as it is associated with increased morbidity and mortality.<sup>3</sup> A major contributing factor in ED crowding is patient boarding. A 2008 American College of Emergency Physicians survey found that nearly 80% of EDs reported boarding psychiatric patients who were not admitted to their facility.<sup>1</sup> Psychiatric patients have been "deinstitutionalized" over recent decades with their care shifting from the inpatient to outpatient setting. In 1970, state and county psychiatric inpatient beds numbered approximately 400,000 and in 2006 numbered at just 50,000.4,5 Concurrently, patients with substance abuse or mental health problems have surged from 5.4% of all ED visits in 2000 to 12.5% of the 95 million ED visits in 2007.6 The decrease in inpatient psychiatric beds combined with the increase in mental health-related ED visits have amplified the number of patients boarding in the ED.<sup>1</sup>

Recently, Chang et al.<sup>7</sup> explored characteristics of patients who boarded over 24 hours at five Massachusetts' hospitals and found that homelessness, inter-hospital transfer, public insurance and use of restraints or sitters placed the patient at a higher risk for boarding in the ED.<sup>7</sup> Only 2.6% of Massachusetts residents were uninsured in the state's integrated healthcare system at the time of the study. A similar study by Weiss et al.<sup>8</sup> found that a medical need for hospitalization, restraint use and use of diagnostic imaging as factors associated with prolonged boarding.<sup>8</sup> Additional research identified high variability in boarding times between hospitals and postulated that this was due to differences in psychiatric services offered and inpatient bed availability.9 In pediatric patients requiring inpatient psychiatric admission, one study found patients who boarded were more likely to have presented over the weekend, during school vacation or with suicidal ideations.<sup>10</sup> A prospective cohort study in which psychiatric clinicians were surveyed found that staff and bed availability, need for clinical stability, obtaining additional information and patients' financial issues as the rate limiting step for discharge of psychiatric patients.9 While several studies have evaluated the characteristics of psychiatric boarders in Massachusetts, few have studied this cohort of psychiatric boarders in a state without an integrated healthcare system in place.<sup>11,12</sup> Our hypothesis was that patients without insurance are at highest risk for boarding in the ED. Through the identification of predictive factors that lead to ED boarding we hope to bring attention to the need for increased psychiatric services for this group as well as improve ED efficiency and allocation of resources.

# METHODS

The authors conducted a retrospective multicenter cohort study of adult patients presenting to two suburban teaching hospital EDs in Illinois from July 1, 2010 through June 30, 2012 assessed to require inpatient psychiatric hospitalization. Exclusion criteria consisted of patients under 18 years of age, patients over 65 years of age, patients who required stabilization of a medical condition prior to transfer, patients who were pregnant, and patients who were discharged from the ED prior to transfer to a psychiatric facility. The main outcome was placement into a psychiatric facility or boarding in the ED. All patients were evaluated in the ED and deemed to require inpatient psychiatric treatment by the attending emergency physician. Institutional review board approval was granted by the host hospital system and the host educational institution.

The patients determined to require inpatient psychiatric hospitalization were transferred to one of approximately 36 regional psychiatric facilities, as neither study hospital had an in-house psychiatric unit at the time of the study. All decisions regarding patient disposition were approved by an attending physician. Placement at psychiatric facilities was facilitated through a regional psychiatric coordination service that assists with patient placement to appropriate facilities after disposition decision is made by the ED attending physician.

The hospital's medical record department generated a list of patients meeting inclusion criteria into an Excel spreadsheet. Using patient encounter numbers, data were collected from each chart in the hospital's general medical record system and entered into the spreadsheet by student research assistants. One of the researchers (RM) then coded these data. De-identified coded data were sent to the host institution statistician for analysis. We analyzed data using statistical package for the social sciences/predictive analytics software statistics.

The main outcome measure was placement into a psychiatric facility or boarding, defined as remaining in the ED for four hours or longer following disposition decision. Patients who boarded were followed to see if they re-presented to one of the two participating EDs within a year of initial presentation for a complaint requiring psychiatric evaluation. Study participants were evaluated for the following: time from presentation to the ED to decision to admit; time from admission decision to transfer to a psychiatric facility; time of ED presentation to transfer to a psychiatric facility; and date of first re-presentation, or "bounce back," to the ED within 12 months following initial ED psychiatric visit. We collected additional demographic and treatment data to compare the boarding to the non-boarding cohort to examine factors that may contribute to the "bounce back." These factors included race, sex, age and insurance coverage (private, Medicare/ Medicaid or self-pay).

We conducted chi-square analyses to compare insurance status between cohorts of ED boarders and nonboarders. An analysis of variance test was used to analyze differences in time to disposition and time from disposition to transfer between the different insurance status groups. Secondary outcomes investigated insurance status and the likelihood of "bounce back." To investigate this, we used generalized linear models specifying a binomial distribution and logit link function to test the importance of the predictor variables. Models 1 and 2 only contained a single predictor variable, insurance status and boarder status, respectively. Model 3 contained the two predictor variables of interest, as well as three variables sex, race/ethnicity, and age - as covariates.

### RESULTS

Overall, 910 patients met inclusion criteria of which 671 qualified for the study after exclusion criteria. Of these, 81.4% of the 671 patients were identified in the ED boarder cohort. Uninsured patients were boarded in the ED 95.4% before psychiatric inpatient admission ( $\chi^2$ =50.6, df=2, p<0.001) compared to 71.8% of Medicare/Medicaid patients ( $\chi^2$ =50.6, df=2, p<0.001) and 78.3% of patients with private insurance ( $\chi^2$ =50.6, df=2, p<0.001) (Table 1). Mean ED length of stay was 705 minutes for patients transferred to private psychiatric facilities compared to 1661 minutes when transferred to public psychiatric facilities (p<0.001).

No significant differences were found in time from ED arrival to decision to admit for patients regardless of insurance status. Time from ED arrival to decision to admit for privately insured, Medicare/Medicaid, and uninsured patients had a mean time of 241 minutes, 216 minutes, 226 minutes, respectively, before transfer to a private psychiatric facility. Time from ED arrival to decision to admit for privately insured, Medicare/Medicaid, and uninsured patients had a mean time of 279 minutes, 228 minutes, and 360 minutes, respectively, before transfer to a public psychiatric facility.

Secondary outcomes investigated the correlation of insurance status and boarding in the ED on the likelihood of "bounce back," defined as the return to the ED at any point during the study period requiring inpatient psychiatric admission. For Model 1, we found a significant effect of insurance status on "bounce back" (estimate=0.649, p=0.035). Specifically, patients with Medicare/Medicaid were nearly two times as likely to be associated with bounce back (OR=1.914). In contrast, being a boarder was not significantly associated with "bounce back" (p=0.405, OR=0.809). Using the multivariate generalized linear model produced similar results to our chi-square analysis. Only insurance status was significantly related to "bounce back" with Medicaid/ Medicare coverage significantly related to "bounce back" (estimate=0.652, p=0.037, OR=1.919). Being a boarder, sex, race/ethnicity, nor age were related to "bounce back."

#### DISCUSSION

ED crowding is a multifactorial problem faced by hospitals nationwide. The boarding of patients is

recognized as a major cause of ambulance diversions and ED crowding, and has a significant impact on healthcare providers, patient satisfaction, and hospital costs.<sup>2,13</sup> Psychiatric boarding is becoming an increasingly more prevalent practice disrupting patient care as well as ED throughput and is only expected to increase with the continued closures of state-run psychiatric facilities. Our findings show that indeed patients without insurance are at highest risk for boarding in the ED. Medicare/Medicaid patients, in our study, were most likely to require repeat inpatient psychiatric admission. This could be because Medicare/Medicaid patients are better connected to the healthcare system than the uninsured; further research is needed to investigate this correlation. We have also identified at risk cohorts of psychiatric patients, uninsured and Medicare/Medicaid, for whom we can improve care and ED throughput.

There were no significant differences found between insurance status and the length of time it took from initial ED presentation to disposition by the emergency physician. This suggests that the emergency physician delivers care that identifies psychiatric patients requiring inpatient hospitalization in a consistent manner regardless of insurance status. This implies that the time for disposition by the emergency physician is not a confounding factor for increased boarding time of psychiatric patients in the ED and that the main variable affecting boarder versus non-boarder status is the insurance coverage of the patient.

Interestingly, our study found that privately insured patients were boarded more often than publicly insured patients (78.3% vs 71.8%, p<0.001). This could be due to differences in the approval process that is required prior to psychiatric facility placement of these patients. Privately insured patients often require authorization from their insurance company prior to being admitted at a psychiatric facility, whereas Medicare/Medicaid patients do not require pre-authorization. A small convenience sample of cases found an average wait time of 38 minutes for authorization, although 10% of these privately insured patients waited an hour or longer for approval.<sup>14</sup>

Research on psychiatric care in the ED is limited. Several prior studies analyzed characteristics of psychiatric patients in Massachusetts, where there were more psychiatric services compared to other parts of the country.<sup>7-9,14</sup> Our study evaluated another region of the country, one in which psychiatric care is lacking after repeated cuts to inpatient and outpatient psychiatric services, and provides insight into challenges faced by community emergency providers.

One challenge faced by providers of psychiatric care in the U.S. has been the shrinking number of psychiatric beds available to inpatients, which has decreased by 14% nationally from 2005 to 2010. In 2005, there were 50,509 state psychiatric beds available, and by 2010, 43,318. Nationwide,

#### Table 1. Insurance effect on psychiatric boarding in the emergency department.

|                   |                           | Boa   | arder |            |
|-------------------|---------------------------|-------|-------|------------|
|                   |                           | Yes   | No    | -<br>Total |
| nsurance status   |                           |       |       |            |
| Private           | Count                     | 94    | 26    | 120        |
|                   | % within insurance status | 78.3% | 21.7% | 100%       |
|                   | % within boarder          | 17.2% | 20.8% | 17.9%      |
|                   | % of total                | 14.0% | 3.9%  | 17.9%      |
| Medicare/medicaid | Count                     | 224   | 88    | 312        |
|                   | % within insurance status | 71.8% | 28.2% | 100%       |
|                   | % within boarder          | 41.0% | 70.4% | 46.5%      |
|                   | % of total                | 33.4% | 13.1% | 46.5%      |
| Self-pay          | Count                     | 228   | 11    | 239        |
|                   | % within insurance status | 95.4% | 4.6%  | 100%       |
|                   | % within boarder          | 41.8% | 8.8%  | 35.6%      |
|                   | % of total                | 34.0% | 1.6%  | 35.6%      |
| Total             | Count                     | 546   | 125   | 671        |
|                   | % within insurance status | 81.4% | 18.6% | 100%       |
|                   | % within boarder          | 100%  | 100%  | 100%       |
|                   | % of total                | 81.4% | 18.6% | 100%       |

closures reduced the number of beds available in the combined 50 states to 28% of the number considered necessary for minimally adequate inpatient psychiatric services.<sup>15</sup>

Secondary outcomes identified a population of psychiatric patients who were likely to return to the ED during the study period and require inpatient psychiatric admission. Medicare/Medicaid patients were nearly twice (OR=1.919) as likely to return to the ED during the 24-month study period requiring psychiatric admission. Ironically, these patients spent the least time boarding in the EDs compared to privately funded patients. The variables of age, sex, boarder status, race/ethnicity, were not found to be significantly related to "bounce back." This suggests that Medicare/Medicaid patients may be a population at risk for psychiatric decompensation. Whether this is due to lack of outpatient options or other factors should be further investigated.

#### LIMITATIONS

Limitations of this study, as with any retrospective cohort study, are an increased risk for errors due to confounding and selection bias. We attempted to limit selection bias as data were collected by research assistants blinded to the primary and secondary outcomes. Furthermore, data were analyzed by an outside statistician who was also blinded to the outcome measures. While it is difficult to establish a cause-and-effect relationship from retrospective cohort studies, our research identifies several areas for future prospective studies to include the relationship of insurance status to boarder status and frequency of return to the ED. Another limitation is that the study was limited to patients from two community EDs in Illinois, and results may not be applicable to other regions or hospital systems. Results on "bounce back" may also be skewed as data were not available on patients who may have presented to a hospital outside of our catchment area.

#### CONCLUSION

Our study found patients without insurance boarded significantly longer than Medicare/Medicaid and privately insured patients. In addition, patients with private insurance boarded longer than those with Medicare/Medicaid. Secondary analysis identified significantly longer ED length of stay for patients transferred to publicly funded facilities compared to those transferred to private facilities.

Our research adds another perspective regarding characteristics of psychiatric boarders and which psychiatric patients decompensate following antecedent psychiatric admission. The boarding of psychiatric patients has been identified as a problem that affects EDs of all types across the U.S. and is familiar to most emergency physicians. Further research is needed to delineate which psychiatric patients board and "bounce back" so that future interventions can be made on their behalf to enhance their care, reduce their time spent boarding and prevent psychiatric decompensation. Significant benefits for the patient, hospital, and ED staff may be realized by improving the placement and management for patients requiring inpatient psychiatric treatment. Address for Correspondence: Ryan K. Misek, DO, Midwestern University, 555 31st Street, Downers Grove, IL 60515. Email: ryan.misek@gmail.com.

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# Polysubstance Abuse: Alcohol, Opioids and Benzodiazepines Require Coordinated Engagement by Society, Patients, and Physicians

Uzor C. Ogbu, MD, PhD Shahram Lotfipour, MD, MPH Bharath Chakravarthy, MD, MPH University of California, Irvine, Department of Emergency Medicine, Orange, California

Supervising Section Editor: Mark I. Langdorf, MD, MHPE Submission history: Submitted November 19, 2014; Accepted November 25, 2014 Electronically published December 15, 2014 Full text available through open access at http://escholarship.org/uc/uciem\_westjem DOI: 10.5811/westjem.2014.11.24720

The Centers for Disease Control and Prevention (CDC) has published significant data trends related to substance abuse involving opioid pain relievers (OPR), benzodiazepines and alcohol in the United States. The CDC describes opioid misuse and abuse as an epidemic, with the use of OPR surpassing that of illicit drugs. Alcohol has also been a persistent problem and is associated with a number of emergency department visits and deaths independent of other substances. The use of these drugs in combination creates an additive effect with increased central nervous system suppression and a heightened risk of an overdose. We present a summary of the findings from the Morbidity and Mortality Weekly Report (MMWR) with commentary on strategies to combat prescription drug and alcohol abuse. [West J Emerg Med. 2015;16(1):76–79.]

# **CDC MMWR FINDINGS**

In the October 10, 2014, issue of Morbidity and Mortality Weekly Report (MMWR), the Centers for Disease Control and Prevention (CDC) published data and trends related to emergency department (ED) visits and deaths associated with the combined use of alcohol, opioid pain relievers (OPR), and benzodiazepines.<sup>1</sup> The MMWR article examined the overall trends, and age- and gender-specific trends in combined drug and alcohol use. They concluded that alcohol plays a significant role in ED visits and deaths associated with OPR and benzodiazepine misuse and abuse.

The CDC report used 2010 data from the Substance Abuse and Mental Health Services Administration's Drug Abuse Warning Network (DAWN). DAWN monitors hospital ED visits (DAWN ED) and drug-related deaths (DAWN ME). The network collects data on illegal drugs, prescription and over-the-counter medications that contribute to an ED visit or death, and alcohol use associated with the event. A stratified random sample of DAWN ED data from 237 hospitals was used with hospital specific post-stratification weights applied. DAWN ME data were obtained from the 13 states (Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Mexico, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Virginia, and West Virginia) that provide data to DAWN.

In 2010, DAWN estimates indicate that of the 438,718 ED visits in the United States associated with OPR abuse, 18.5% (81,365) involved alcohol. Alcohol involvement was higher for ED visits related to benzodiazepine use with alcohol involvement noted in 27.2% (111,165) of the 408,021 ED visits. OPR-related ED visits involving alcohol were highest among persons aged 30 - 44 years (20.6%) and 45 - 54 years (20.0%). Benzodiazepine-related ED visits involving alcohol were highest among person aged 45 - 54 years (31.1%). ED visits with the combined use of alcohol, and OPR (81,365 visits) or benzodiazepines (111,165 visits) were more common among men (22.9%, 95% CI [18.7%–27.7%]) for OPR and 30.6%, 95% CI [26.7%–34.8%]) for benzodiazepines] than women 13.5%, 95% CI [11.1%–16.4%]) for OPR and 24.1%, 95% CI [19.6%–29.2%]) for benzodiazepines].

In 2010 of the 3,833 OPR-related deaths and 1,512 benzodiazepine-related deaths recorded in DAWN, 22.1% (860) and 26.1% (393) of deaths respectively involved alcohol. OPR-related deaths involving alcohol were highest among those aged 40–49 years (25.2%) and 50–59 years (25.3%). Benzodiazepine-related deaths were highest among those 60 years and older (27.7%). The report highlights a few limitations of the study and the DAWN data, which include the completeness of the data, potential misclassification, and sampling limitations. Drug identification, amount of alcohol consumed, and subsequent inclusion in DAWN may be incomplete. The death data are limited to 13 states with varying triggers for coroner review, which is required for inclusion in DAWN ME. There is also variation in toxicology testing practices, which affects detection of drugs and inclusion in the DAWN ME database. In addition, DAWN data does not distinguish between medical and non-medical use.

# COMMENTARY

An estimated 181.7 million opioid prescriptions were written in 2012, representing a 33% increase from 2001.<sup>2</sup> Sales of opioid medication in 2010 are estimated to be of sufficient volume to supply every adult American with 5mg of hydrocodone every six hours for 45 days.<sup>3</sup> Benzodiazepines have long been among the most prescribed psychoactive agents.<sup>4</sup> The combination of both drugs has become a cause for growing concern with a recent study indicating that among chronic pain patients a significant proportion tested positive for benzodiazepine metabolites in their urine.<sup>4</sup> The lifetime prevalence of alcohol abuse is 17.8%, with a large overlap with the abuse of other substances.<sup>5</sup> The combined use of OPR, benzodiazepine, and alcohol potentiates the effect sought by the user but also exposes them to significant additional risk of adverse events, even when the individual agents are used as prescribed.<sup>6,7</sup> The ED is the frontline for the treatment of these adverse events despite ED physicians prescribing fewer pills and less potent opioid formulations than office-based physicians.8

The commercial availability of alcohol requires that efforts to combat alcohol abuse focus on the individual. Public service announcements advocate drinking responsibly, legal statutes prescribe a maximum allowed blood-alcohol concentration, and screening and brief interventions identify individuals at risk and attempt to get them into treatment. OPR and benzodiazepines are controlled substances that require a prescription to obtain. Efforts to combat abuse of these substances have largely focused on limiting their availability, identification of those at risk, and referral for treatment. Prescription drug monitoring programs (PDMP) were established to combat doctor shopping and identify potentially dangerous interactions such as concurrent prescriptions for an OPR and benzodiazepines. However, technical issues such as lack of interstate interoperability -and the limited penetration among prescribing physicians have limited the effectiveness of state-based PDMP.9 OPR prescribing guidelines have become a new tool in some states such as New York and Washington where there are limits on the number of pills a physician is allowed to prescribe.<sup>10,11</sup> However, anecdotal evidence suggests that these efforts, while effective, result in a change in abuse behavior.<sup>12,13</sup> Drug-seeking patients cross

state lines to obtain drugs, switch to illicit drugs, or find nonphysician sources for opioids. A recent report indicates that heroin use and heroin-related adverse events have increased in states such as California, Florida, Kentucky, Massachusetts, New York, Ohio, Oregon, and Washington alongside a decline in the availability of OPR.<sup>14</sup>

At the center of this polysubstance misuse and abuse problem is an individual. Individuals involved in adverse events associated with OPR, benzodiazepine, and alcohol can be placed along a spectrum. On one end are short-term users with acute pain who were prescribed these drugs and attempt to use them as intended but are unaware of the full scope of potential adverse events. At the other extreme are those who are aware of the risks and willfully neglect these risks in the throes of their dependence or addiction. Among other groups between these extremes are non-patients, such as children and other family members, who improperly obtain these substances to experiment with them. Abuse prevention efforts need to be addressed on multiple levels that include the society, patients, and physicians. While a number of organizations have conducted community-based interventions aimed at raising awareness of prescription drug abuse, these initiatives are often interpreted as being targeted at 'abusers' and concerned parents. The physician-encounter that leads to an OPR prescription for acute pain represents an important teachable moment when patients and their families can be educated about their medications, side effects and potential interactions. However, lack of time limits a physician's ability to capitalize on these moments, especially in the ED. For example, studies of discharge instructions indicate that few patients (<20%) are aware of what to do with unused medication.<sup>15,16</sup> Sharing of leftover opioid pills is common among patients who often retain them for later use.<sup>17,18</sup> This contributes to estimated diversion rates as high as 29% in young adults and college students.<sup>19</sup>

Prescribed OPR pills may flow through a number of consumption pathways from appropriate use to misuse and diversion. Adequate patient education about their medications represents an additional opportunity to disrupt the pipeline of early-stage non-medical use of opioids, complementing policies aimed solely at physicians. Among short-term users, the risk of dependency and addiction is small with appropriate use. However, in a recent analysis of the source of opoids among those reporting non-medical use in the past year, 70% reported obtaining drugs (free, stolen, or bought) from friends or family members, approximately 20% from a physician and 10% from other illicit sources.<sup>20</sup> Among those reporting use lasting only 1–29 days the portion identifying a friend or family member as a source was approximately 75%.

The expansion of access to health insurance increases the number of at-risk individuals by increasing access to prescription medications. However, it also represents an opportunity to educate more patients and families. A White House policy document pinpoints education, tracking and monitoring, proper medication disposal, and enforcement as key approaches to combating the opioid epidemic.<sup>21</sup> However, education interventions have focused on physicians and pharmacists. Few interventions aim to change the attitudes and behavior of patients towards opioids.<sup>22,23</sup> This information gap is exacerbated by direct marketing campaigns that highlight the potential benefits of opioids.<sup>24</sup> Patients assume that medications prescribed by their doctor are safe and pose little risk. Detailed discussion of the potential for addiction, the need for safe storage and disposal, and an indepth exploration of alternative treatments is often neglected, particularly for non-chronic pain patients. A recent study attributes medication-related adverse events to host factors and environmental factors such as patient health literacy, awareness of how to use medications, awareness of side effects, and multiple prescribers and limited communication among prescribing physicians.25 The communication failure may be due to the manner in which the information is presented. Warning labels, medication sheets, and prescribing information are presented on packaging, pill bottles, or with discharge instructions. These text-dense sources are not read, ignored, or not fully comprehended by patients.<sup>26-28</sup> Future research should develop effective tools for communicating medication information to a wide audience of patients acknowledging differences in health literacy and levels of engagement. Alternative forms of communication such as short multimedia videos, text messages or social media should be explored. Such efforts will add an additional front to the battle against substance abuse and reduce the number of unintentional injuries, deaths, and ED visits associated with prescription drug abuse.

Address for Correspondence: Bharath Chakravarthy, MD, MPH, Department of Emergency Medicine, 101 The City Drive South, Rte 128-01. Email: bchakrav@uci.edu.

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# Screening for Sexual Orientation in Psychiatric Emergency Departments

Glenn W. Currier, MD, MPH<sup>\*†</sup> Gregory Brown, PhD<sup>‡</sup> Patrick G. Walsh, MPH<sup>\*</sup> Shari Jager-Hyman, PhD<sup>‡</sup> Sadia Chaudhury, PhD<sup>§</sup> Barbara Stanley, PhD<sup>§</sup> \* University of Rochester Medical Center, Department of Emergency Medicine, Rochester, New York \* University of Pennsylvania School of Medicine, Department of Psychiatry, Philadelphia, Pennsylvania <sup>§</sup> Columbia University School of Medicine, Department of Psychiatry, New York, New York

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**Introduction:** Our goal was to explore whether emergency department (ED) patients would disclose their sexual orientation in a research evaluation and to examine demographic and clinical characteristics of patients by self-identified sexual orientation.

**Methods:** Participants (n=177) presented for psychiatric treatment at three urban EDs in New York City, Rochester, NY, and Philadelphia, PA. Participants were interviewed in the context of a larger study of a standardized suicide risk assessment. We assessed participants' willingness to answer questions regarding sexual orientation along three dimensions: a self-description of sexual orientation, a self-description of sexual attraction, and the gender of any prior sexual partners.

**Results:** No participants (0/177) refused to respond to the categorical question about sexual orientation, 168/177 (94.9%) agreed to provide information about prior sexual partners, and 100/109 (91.7%) provided information about current sexual attraction toward either gender. Of all 177 participants, 154 (87.0%) self-identified as heterosexual, 11 (6.2%) as bisexual, 10 (5.6%) as gay or lesbian, and 2 (1.1%) indicated they were not sure. As compared with heterosexual patients, lesbian, gay and bisexual (LGB) patients were significantly younger and more likely to be non-white, but did not differ significantly in terms of education, income, employment, or religious affiliation or participation. Further, LGB participants did not differ from self-identified heterosexual participants for lifetime suicide attempt rate or lifetime history of any mood, substance-related, psychotic spectrum, or other Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) Axis I disorder. Of self-identified heterosexual participants 5.6% (5/89) reported sexual attraction as other than 'only opposite sex,' and 10.3% (15/142) of sexually active 'heterosexual' participants reported previous same-gender sexual partners.

**Conclusion:** Assessing patients' sexual orientation in the ED by a three-question approach appeared feasible in the ED and acceptable to ED patients. However, since many patients have sexual experiences not suggested by simple labels, self-report of sexual identity alone may not inform clinicians of health risks inherent in same or opposite gender sexual contact. [West J Emerg Med. 2015;16(1):80–84.]

# INTRODUCTION Background

According to a nationally representative 2012 Gallup survey, approximately 3.5% of U.S. adults aged 18 or over self-identify as lesbian, gay, bisexual, or transgender.<sup>1</sup> Disparities in health outcomes and health behaviors exist between lesbian, gay, and bisexual (LGB) populations and heterosexual populations, including poorer mental health and less overall access to care and preventive services.<sup>2</sup> LGB adults have thus been reported to seek treatment in emergency departments (EDs) at rates that are higher than the overall population.<sup>3,4</sup> Increased ED use by LGB patients may be promoted by a variety of factors, including delayed routine healthcare due to reluctance to disclose sexual information to primary care providers.<sup>5-7</sup> Further, mood, anxiety and substance-use disorders may be more prevalent in some LGB cohorts, both male and female.8,9 LGB patients may present to EDs seeking immediate onsite access to specialty mental health treatment, as well as expedited access to communitybased mental health and chemical dependency treatment after ED discharge.10

Sexual orientation can be examined within three separate but related constructs: 1) self-defined sexual orientation; 2) sexual fantasy or desire; and 3) sexual behavior. This three-part definition is consistent with published recommendations,<sup>11-13</sup> and was recently used in a populationbased survey of substance abuse in U.S. adults aged 18 and over.<sup>14</sup> Prior work employing this three-part approach suggests that risk of mood and anxiety disorders may be higher among people who affirmatively self-identify as LGB, but not in those who simply acknowledge experiencing same-sex attraction or behaviors without self-defining as LGB.<sup>15</sup>

The Institute of Medicine (IOM) issued a report on LGBT health in 2011, highlighting the gaps in health research on this population.<sup>16</sup> This report, entitled "The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding," recommended addressing several priority research areas, including first adding measures to screen patients for sexual identity in a variety of clinical settings, including the ED. However, data on sexual identity are not routinely collected in most ED settings. Reasons are varied and may include time constraints, unawareness of the heightened risk of medical and psychiatric morbidity associated with identifying as LGB, or with provider discomfort asking these particular questions.<sup>17</sup> The latter barrier seems less likely in psychiatric EDs, since comprehensive biopsychosocial assessment usually involves detailed questions about a variety of other highly personal matters.

# Objective

As a component of a larger study exploring suicide risk in ED patients, we explored whether a subset of those patients would readily disclose their sexual orientation, gender attraction and prior sexual experiences in the context of research evaluation. Sexual orientation was measured along three dimensions: a self-description of sexual orientation (How would you describe your sexual orientation?: heterosexual, gay/lesbian, bisexual, not sure), a self-description of sexual attraction (Who are you attracted to sexually?: only opposite sex, mostly opposite sex, equal, mostly same sex, only same sex), and the gender of any prior sexual partners (Who have you had sex with?: only opposite sex, only same sex, both, never had sex). We tracked willingness of ED patients to answer these three questions in the context of a full suicide risk assessment. We also examined demographic and clinical characteristics of patients who selfidentified as heterosexual versus those who did not. Finally, we examined whether self-identification as heterosexual or otherwise was a valid proxy for actual past sexual experiences in this sample.

# METHODS

In a study examining standardized suicide risk assessment,<sup>18</sup> we enrolled participants (n=177) who presented for psychiatric treatment at three large urban emergency departments in New York City (n=68), Rochester, NY (n=55), and Philadelphia, PA (n=54). Each of these facilities had a specialty psychiatric emergency service as a component of the general ED. All subjects provided written informed consent for participation and were interviewed by trained research staff. Primary Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) Axis I diagnoses were collapsed into groupings of mood, psychosis, substancerelated disorders, or other types of disorders. We used t-tests to compare groups for continuous variables and chi-square tests to compare categorical variables.

# RESULTS

Of 177 participants, none (0%) refused to respond to the categorical question about sexual orientation and 168/177 (94.9%) also agreed to provide information about prior sexual partners. One hundred subjects (100/109; 91.7%) provided information about current sexual attraction toward either gender (attraction was not asked of Columbia subjects). Of all 177 participants, 154 (87.0%) self-identified as heterosexual, 11 (6.2%) as bisexual, 10 (5.6%) as gay or lesbian, and 2 (1.1%) indicated they were not sure. Most subjects were female (57.4%), with a mean age of 36.1 years (SD 12.4). Over half (51.1%) were white, whereas 23.6% were African-American, 19.8% were Hispanic, and 5.5% self-identified as members of another race. To conserve sample size, all subjects who did not self-identify as heterosexual were combined for further analyses. As shown in Table 1, while more LGB patients had presented to the ED for reasons of suicide attempt or self-injury (73.9%) then heterosexual patients (63.6%), this difference did not reach statistical significance. As compared with

#### Table 1. Demographic characteristics of participants in study of self-defined sexual orientation.

|  | Self-defined sexual orientation |  | Test <sup>b</sup> |         |
|--|---------------------------------|--|-------------------|---------|
| Demographic characteristics <sup>a</sup>   | Heterosexual<br>n=154 (%)       | Other than<br>heterosexual<br>n=23 (%) | Statistic         | p-value |
| Study group                                |                                 |  |                   |         |
| Attempter or self-injurer                  | 98 (63.6)                       | 17 (73.9)                              |                   | 0.335   |
| Non-attempter/non-self-injurer             | 56 (36.4)                       | 6 (26.1)                               | 0.929             |         |
| Gender                                     |                                 |  |                   |         |
| Male                                       | 70 (45.5)                       | 6 (26.1)                               | 0.004             | 0.000   |
| Female                                     | 84 (54.5)                       | 17 (73.9)                              | 3.064             | 0.080   |
| Age: years, mean (SD)                      | 36.5 (12.1)                     | 30.7 (12.9)                            | 2.154             | 0.033   |
| Race                                       |                                 |  |                   |         |
| White                                      | 81 (52.6)                       | 7 (30.4)                               |                   | 0.047   |
| Non-white                                  | 73 (47.4)                       | 16 (69.6)                              | 3.932             |         |
| Religious affiliation                      |                                 |  |                   |         |
| Catholic/Protestant/Jewish                 | 91 (60.3)                       | 11 (47.8)                              |                   | 0.259   |
| Other                                      | 60 (39.7)                       | 12 (52.2)                              | 1.273             |         |
| Frequence of religious services attendance |                                 |  |                   |         |
| Once or more per month                     | 55 (36.2)                       | 4 (17.4)                               | 0.457             | 0.076   |
| Less than once per month                   | 97 (63.8)                       | 19 (82.6)                              | 3.157             |         |
| Employed or student <sup>c</sup> - Yes     | 50 (33.1)                       | 8 (34.8)                               | 0.025             | 0.874   |
| Household income                           |                                 |  |                   |         |
| Less than 20K                              | 83 (61.9)                       | 13 (68.4)                              |                   | 0.585   |
| 20K and greater                            | 51 (38.1)                       | 6 (31.6)                               | 0.299             |         |
| Highest education                          |                                 |  |                   |         |
| Less than high school graduate             | 43 (27.9)                       | 3 (13.0)                               | 0.000             | 0.129   |
| High school grad and higher                | 111 (72.1)                      | 20 (87.0)                              | 2.303             |         |
| Number of children: mean (SD)              | 1.23 (1.54)                     | 0.74 (1.51)                            | 1.442             | 0.151   |
| Parent (at least 1 child) - Yes            | 86 (55.8)                       | 6 (26.1)                               | 7.099             | 0.008   |

<sup>a</sup> Totals do not always equal 237 due to missing data.

<sup>b</sup> Test comparing 'straight' and 'other than straight' groups. Continuous variables tests are t-tests, categorical variables tests are Chisquares.

° 'Yes' includes full-time or part-time, 'no' includes unemployed, retired, homemaker, disabled, other.

heterosexual patients, LGB patients were significantly younger and more likely to be non-white, but did not differ significantly in terms of education, income, employment, or religious affiliation or participation. Females appeared more likely to identify as non-heterosexual, although this did not reach statistical significance. Over half (55.8%) of heterosexual patients were parents while approximately one quarter (26.1%) of LGB patients were parents, a statistically significant difference.

Table 2 displays clinical characteristics of the two groups. LGB participants did not differ from their heterosexual counterparts in terms of lifetime suicide attempt rate or lifetime history of any mood, substance-related, psychotic spectrum, or other DSM-IV Axis I disorder. Current Global Assessment of Function score averages were in the 30s range for both groups, indicating significant impairment due to a mental disorder. Likewise while 10% more LGB subjects met diagnostic criteria for borderline personality disorder when compared with the heterosexual group, these differences were not statistically significant.

Data on self-described sexual attraction and previous sexual partners revealed that 5.6% (5/89) of participants that self-categorized their sexual orientation as 'heterosexual' reported sexual attraction as other than 'only opposite sex,' and 10.3% (15/142) of sexually active 'heterosexual' participants reported previous same-gender sexual partners. Conversely, all 11 participants who defined their sexuality as other than heterosexual reported sexual attraction as other than

Table 2. Clinical characteristics for heterosexual and other than heterosexual groups.\*

| Continuous variables [mean (SD)]    | Heterosexual (n=154) | Other (n=23)  |
|-------------------------------------|----------------------|---------------|
| Number of lifetime suicide attempts | 2.03 (2.59)          | 1.96 (2.10)   |
| Global assessment of function (GAF) | 35.39 (9.98)         | 31.83 (10.51) |
| Categorical variables [n (%)]       |                      |               |
| Mood disorder                       |                      |               |
| Yes                                 | 124 (84.9)           | 20 (95.2)     |
| No                                  | 22 (15.1)            | 1 (4.8)       |
| Substance disorder                  |                      |               |
| Yes                                 | 67 (45.9)            | 9 (42.9)      |
| No                                  | 79 (54.1)            | 12 (57.1)     |
| Anxiety disorder                    |                      |               |
| Yes                                 | 15 (10.3)            | 2 (9.5)       |
| No                                  | 131 (89.7)           | 19 (90.5)     |
| Psychotic disorder                  |                      |               |
| Yes                                 | 12 (8.2)             | 0 (0)         |
| No                                  | 134 (91.8)           | 21 (100)      |
| Other axis-I disorder               |                      |               |
| Yes                                 | 5 (3.4)              | 1 (4.8)       |
| No                                  | 141 (96.6)           | 20 (95.2)     |
| BPD (meets dx criteria)**           |                      |               |
| Yes                                 | 32 (34.0)            | 7 (43.8)      |
| No                                  | 62 (66.0)            | 9 (56.3)      |

BPD, borderline personality disorder

\*Totals do not always equal 177 due to missing data.

\*\*Borderline Personality Disorder (BPD) information not obtained for Rochester sample.

'only opposite sex,' and a majority (63.6%, 14/22) of sexually active non-heterosexual participants nonetheless reported prior opposite-gender sexual partners.

# DISCUSSION

No ED subjects refused to provide a self-definition of sexual orientation. Almost all (94.9%) were also willing to provide information about the gender of prior sexual partners in the context of a health examination. A majority (91.7%) also agreed to answer a question about current sexual attraction toward either or both genders. This supports the practicality of a three-question screening strategy in the ED environment, where privacy is a major concern.

LGB people were represented in this sample of ED subjects at rates similar or higher than their reported proportions in the overall U.S. populace. The LGB subjects identified were younger, perhaps reflecting a generational shift in willingness to disclose non-heterosexual orientations. LGB subjects were also more likely to be racially diverse, but did not vary from heterosexuals in terms of the other socioeconomic or clinical indices examined.

Finally, there was incomplete concordance between self-defined sexual orientation and actual sexual experience,

with about one in 10 self-attributed heterosexuals disclosing previous same-sex encounters, and six in 10 self-attributed non-heterosexuals describing previous opposite-sex encounters. If one of the main purposes of posing these questions is to ascertain health risks, then simply asking the patient to define their sexual identity will likely be misleading in some instances.

#### LIMITATIONS

This study has important limitations, including a small sample size. We did not ask about the timing, duration, extent, potential medical or psychological consequences or personal meaning of the sexual activities identified. We also did not ask specifically about transgendered people. We did not explore reasons for subject reluctance to answer any of the questions about sexual identity. Questions were asked by research staff and not by ED clinicians. Questions were also asked in psychiatric EDs and not medical EDs, so findings may not generalize.

# CONCLUSION

Assessing patients' sexual orientation in the ED by a three-question approach appeared feasible in the ED and

acceptable to ED patients. However, since many patients have sexual experiences not suggested by simple labels, self-report of sexual identity alone may not inform clinicians of health risks inherent in same or opposite gender sexual contact.

Address for Correspondence: Glenn W. Currier, MD, MPH, URMC Department of Psychiatry, 300 Crittenden Blvd, Rochester, NY 14642. Email: Glenn\_Currier@urmc.rochester.edu.

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# American Academy of Pediatrics 2014 Bronchiolitis Guidelines: Bonfire of the Evidence

Paul Walsh, MD, MSc\*<sup>†</sup> Stephen J. Rothenberg, PhD<sup>‡</sup> \*University of California, Davis, Department of Emergency Medicine, Davis, California \*Sutter Medical Centers of Sacramento, Pediatric Emergency Medicine, Sacramento, California

<sup>‡</sup>Instituto Nacional de Salud Pública, Centro de Investigación en Salud Poblacional, Cuernavaca, Morelos, Mexico

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#### A BONFIRE OF THE EVIDENCE

The American Academy of Pediatrics (AAP) 2014 Bronchiolitis guidelines (the guidelines) were recently published in the official journal of the AAP, Pediatrics.<sup>1</sup> The committee that wrote the guidelines anticipates that these will form the basis of bronchiolitis treatment throughout the house of medicine, not just in pediatricians' offices. Emergency physicians may well encounter pressure to follow these guidelines from their pediatric colleagues who, not unreasonably, rely on guidelines from their professional organization.

However, two key recommendations in these guidelines could substantially change pediatric emergency medicine practice. These recommendations are (1) to not use even a trial of bronchodilators and (2) to regard oxygen saturations of 90% rather than 92%-94% as the degree of hypoxia at which oxygen should be administered.<sup>1</sup> Neither of these recommendations is sufficiently justified by the evidence and both are potentially harmful. We deal first with the new guideline to not use bronchodilators.

The committee bases its recommendation to not attempt even a trial of bronchodilators on the following:

(1) The committee's interpretation of a meta-analysis that reported a decrease in hospital admissions when epinephrine rather than placebo was given in the emergency department (ED).<sup>1</sup>

(2) A meta-analysis contained in a Cochrane review, which did not show decreased hospital admissions from the ED when albuterol rather than placebo was given.<sup>2</sup>

(3) Albuterol non-responders cannot be distinguished from responders, and clinicians' ability to observe a clinically relevant response to bronchodilators is limited.<sup>1</sup>

(4) Albuterol's risks and expense outweigh its benefits.<sup>1</sup>

We deal with each of these in turn. Bronchiolitis

causes lower airway obstruction through a combination of bronchiolar obstruction with inflammatory cells, cellular debris, increased mucus secretion, and varying degrees of bronchospasm. This combination has prompted treatment with nebulized epinephrine, which can decrease mucosal edema and has bronchodilator properties, and albuterol, which is best known for its bronchodilator properties (Footnote[a]).<sup>3-5</sup>

A meta-analysis found a decrease in hospital admissions from the ED risk ratio 0.67 (95% CI [0.50-0.89]) favoring epinephrine over placebo.<sup>6</sup> This analysis was heavily influenced by Plint et al.,which recruited 800 patients divided into four groups comparing combinations of epinephrine, saline, dexamethasone, and placebo and found early benefits but little difference at one week between nebulized epinephrine and normal saline.<sup>7</sup> Both this meta-analysis and Plint et al. were published by the same group, and as reported the meta-analysis would have justified further funding for additional studies.<sup>6</sup>

However, this meta-analysis excluded another large randomized controlled trial (RCT) comparing albuterol and epinephrine.<sup>6</sup> Walsh et al. randomized 703 patients in two groups comparing nebulized albuterol and epinephrine.<sup>83</sup> This study found a relative increase in ED discharge of 18% when albuterol rather than epinephrine was used (aRR 1.18 for successful ED discharge without admission at three days follow up).<sup>8</sup> This is equivalent to a risk ratio of 0.86 (95% CI [0.76-0.98]) for decreased admission. Since an adequately powered large RCT had already demonstrated decreased admissions from the ED when albuterol rather than epinephrine is used, neither the meta-analysis nor another RCT were needed. Contrary to the committee's assertions, the data show progressively decreasing admissions from the ED when nebulized normal saline, epinephrine, or albuterol are used in treatment.

The second rationale relied on by the committee to recommend against the use of albuterol is a meta-analysis

contained in a Cochrane review performed by Gadomski et al. This meta-analysis reported an OR 0.77, (95% CI [0.44-1.33]) for hospital admission from the ED.<sup>2</sup> This null result was interpreted by the guideline authors as 'clearly negative.'<sup>1,9</sup> Such an interpretation is unfortunate: the statistical power of this analysis to detect a relative decrease of 20% in admission was 18% (n=404 with the reported sample characteristics,  $\alpha$ =0.05). A null result in an inadequately powered study is no basis for concluding a drug has no effect.

The committee attached particular weight to placebocontrolled studies, which it regards as 'the highest form of evidence,' and therefore excluded studies that compared bronchodilators from their deliberations. However, when placebo is not the standard of care then placebo is not necessarily the best or even correct comparator.<sup>10</sup> To demonstrate this effect we have recreated the meta-analysis relied on by the committee, this time including the largest excluded study which did show a benefit to using albuterol in the ED. (We conservatively assumed epinephrine to be no more effective than placebo, and used relative risk rather than odds ratios because hospital admission is not rare and risk is easier to interpret.) The result (Figure) shows that albuterol treatment of bronchiolitis in the ED leads to decreased admissions and how little underpowered studies contribute to our knowledge.

We disagree with both components of the committee's third rationale for not using bronchodilators. First, the assertion that albuterol non-responders cannot be distinguished from responders is inaccurate. A therapeutic trial distinguishes them handily. Second, the committee's assertion that clinicians are unable to adequately observe clinically relevant responses to bronchodilators ignores the reality that emergency physicians are highly experienced in the management of bronchospasm and the use of bronchodilators. The recommendation that albuterol be withheld from everyone with bronchiolitis because it may prevent admission in only a minority,<sup>1,9</sup> denies clinicians the common sense practice of the therapeutic trial. If the child responds to albuterol it can be continued; if not, it can be discontinued.

We also disagree with the committee's fourth rationale for recommending against the use of bronchodilators, namely their assessment of the dangers and expense of albuterol.<sup>1</sup> Albuterol in reasonable doses has a long record of safety in infants and children; we even allow primary school children to carry and self-administer it. And premixed albuterol ampoules retail for 36 cents/dose at a large multipurpose national retailer. The 18% relative reduction in hospital admissions from the ED that can be obtained using albuterol is surely also an important part of any cost-benefit calculation.<sup>8</sup>

Other studies, including a Cochrane review metaanalysis cited by the committee as evidence against using albuterol, in fact demonstrate that albuterol in the ED significantly improves clinical scores.<sup>2</sup> Clinical scores reflect respiratory distress, which certainly seems worth relieving. Not all cases of this short-term relief of respiratory distress will translate into decreased hospital admissions. But some will. This evidence has been ignored in formulating the current guidelines.<sup>1</sup>

The second recommendation which emergency physicians might best ignore is that clinicians may withhold supplemental oxygen if the oxygen saturation is  $\geq$ 90% rather than the 92% used elsewhere. The committee writing the guidelines base this recommendation on 'low level evidence and reasoning from first principles.'<sup>1</sup> The committee's rationale is that:

(1) Oxygen saturations of 90% are not materially different from oxygen saturations of 92%.

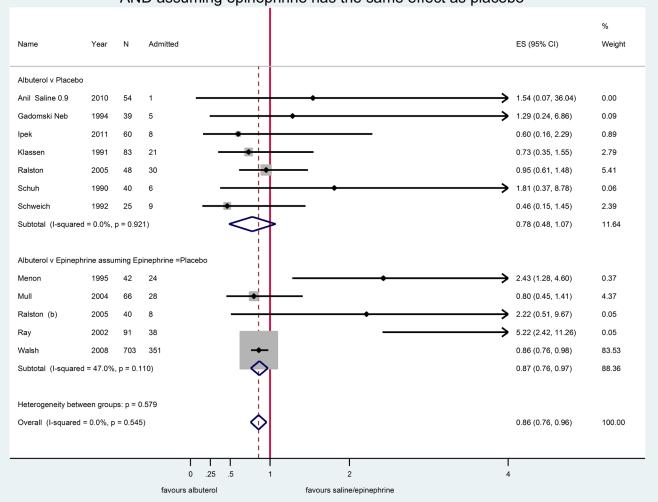
(2) The Collaborative Home Infant Monitoring Evaluation (CHIME) study found that oxygen desaturations commonly occur in the sleep of normal infants without ill effect.<sup>11</sup>

This recommendation appears to discount the fact that the normal range of oxygen saturation for this age group at sea level is 97%-100%.<sup>12</sup> It also ignores evidence that a pulse oximeter reading of 90% tends to overestimate the actual oxygen saturation in children (mean bias 4.2% between 86% and 90% and 1.8% between 91%-95%).<sup>13</sup>

There is uncertainty as to what level and duration of hypoxia is harmful in infants in general and bronchiolitis in particular. Increasing altitude increases the odds of being at risk for neurodevelopmental problems (100-meter increase in altitude: OR= 1.02; 95% CI [1.001–1.037] after adjustment for other factors).<sup>14</sup> A detailed systematic review of the literature on hypoxia in children found causal evidence for adverse effects of chronic and intermittent (as can occur in snoring/ sleep disorders) hypoxia in children. These adverse effects included decreased intelligence quotient (IQ), neurocognitive functioning, and increases in behavioral disorders and attention deficit hyperactivity disorder symptoms when oxygen saturation even intermittently ranges from 90%-94%. These associations are insufficient to prove causality, but these same adverse effects were also found for hypoxia related to asthma and respiratory instability in infants.<sup>15</sup>

The CHIME study found transient oxygen desaturation during sleep is not uncommon in infants and appears to have little adverse effect.<sup>7</sup> However these transient oxygen desaturations were short: ≤6 seconds duration. When hypoxia occurs in bronchiolitis it can be expected to be present for hours or days, not seconds. The CHIME study is simply not pertinent.

Knowing that even relatively mild hypoxia (90%-94%) may have long-term sequelae in infants, and knowing that the duration of hypoxia of acute bronchiolitis is likely to be to be prolonged, it is difficult to justify withholding oxygen. Sensible oxygen administration that avoids hyperoxia is not risky. Whether one should choose an oxygen saturation treatment threshold of 92% or 94% in previously healthy



# Effect of adding excluded study to a meta-anlysis AND assuming epinephrine has the same effect as placebo

**Figure.** The purpose of this Forest plot is to show the effect of excluding a single large randomized controlled trial and how little information is actually contained in smaller ones. The top analysis reproduces the meta-analysis of Gadomski et al. The boxes reflect study weight which is a function of study size and the number of events (admissions). In both comparisons studies showing a benefit to albuterol have narrower confidence intervals reflecting the greater precision of these studies. *ES*; effect size as relative risk of discharge

<sup>a</sup> Steroids do not generally decrease hospital admission from the emergency department, although steroids may have a role in recurrent episodes if there is a family history of asthma. Factors other than simple bronchodilation may also play a role in albuterol's effect. <sup>b</sup> Includes two (albuterol and 0.9% normal saline and epinephrine and 0.9% normal saline) of the five arms of the original study without penalizing any arm.

<sup>c</sup> Includes two of the three arms of the study, again without penalizing the epinephrine/placebo arm.

infants is worthy of discussion; 90% is probably too low. Studies of neurocognitive function in at least some infants with treated and untreated hypoxia from bronchiolitis have not been carried out nor are they likely to be. Waiting for such studies as the committee appears to be doing strikes us as unwise. However, we can anticipate that in infants, many of whom will be less than four months old and may still have fetal hemoglobin, the low Pa02 associated with an Sa02 of 90% will fall yet further after discharge. These recommendations within the guidelines seem to be premised on an underlying belief that because bronchiolitis is a short-lived generally non-fatal disease, treatment cannot offer long-term benefit, and that most treatment should therefore be avoided. Emergency physicians' *raison d'être* however is to treat acute conditions; relieving acute respiratory distress and hypoxia using interventions as simple as albuterol and oxygen is not only good emergency medicine practice; it is in fact supported by the available evidence. Address for Correspondence: Paul Walsh, MD, MSc, UC Davis Medical Center, Department of Emergency Medicine, 4150 V Street #PSSB 2100, Sacramento, CA. Email: pfwalsh@ucdavis.edu.

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# **Factors Associated with Decision to Hospitalize Emergency Department Patients with Skin and Soft Tissue Infection**

David A. Talan, MD\* Bisan A. Salhi, MD<sup>†</sup> Gregory J. Moran, MD\* William R. Mower, MD<sup>‡</sup> Yu-Hsiang Hsieh, MD<sup>§</sup> Anusha Krishnadasan, MD\* Richard E. Rothman, MD<sup>§</sup>  \*Olive View-UCLA Medical Center, Department of Emergency Medicine, Sylmar, California
 <sup>†</sup>Emory University, Department of Emergency Medicine, Atlanta, Georgia
 <sup>‡</sup>Ronald Reagan Medical Center, University of California at Los Angeles, Department of Emergency Medicine, Los Angeles, California
 <sup>§</sup>Johns Hopkins Medical Center, Department of Emergency Medicine, Baltimore, Maryland

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**Introduction:** Emergency department (ED) hospitalizations for skin and soft tissue infection (SSTI) have increased, while concern for costs has grown and outpatient parenteral antibiotic options have expanded. To identify opportunities to reduce admissions, we explored factors that influence the decision to hospitalize an ED patient with a SSTI.

**Methods:** We conducted a prospective study of adults presenting to 12 U.S. EDs with a SSTI in which physicians were surveyed as to reason(s) for admission, and clinical characteristics were correlated with disposition. We employed chi-square binary recursive partitioning to assess independent predictors of admission. Serious adverse events were recorded.

**Results:** Among 619 patients, median age was 38.7 years. The median duration of symptoms was 4.0 days, 96 (15.5%) had a history of fever, and 46 (7.5%) had failed treatment. Median maximal length of erythema was 4.0cm (IQR, 2.0-7.0). Upon presentation, 39 (6.3%) had temperature >38°C, 81 (13.1%) tachycardia, 35 (5.7%), tachypnea, and 5 (0.8%) hypotension; at the time of the ED disposition decision, these findings were present in 9 (1.5%), 11 (1.8%), 7 (1.1%), and 3 (0.5%) patients, respectively. Ninety-four patients (15.2%) were admitted, 3 (0.5%) to the intensive care unit (ICU). Common reasons for admission were need for intravenous antibiotics in 80 (85.1%; the only reason in 41.5%), surgery in 23 (24.5%), and underlying disease in 11 (11.7%). Hospitalization was significantly associated with the following factors in decreasing order of importance: history of fever (present in 43.6% of those admitted, and 10.5% discharged; maximal length of erythema >10cm (43.6%, 11.3%); history of failed treatment (16.1%, 6.0%); any co-morbidity (61.7%, 27.2%); and age >65 years (5.4%, 1.3%). Two patients required amputation and none had ICU transfer or died.

**Conclusion:** ED SSTI patients with fever, larger lesions, and co-morbidities tend to be hospitalized, almost all to non-critical areas and rarely do they suffer serious complications. The most common reason for admission is administration of intravenous antibiotics, which is frequently the only reason for hospitalization. With the increasing outpatient intravenous antibiotic therapy options, these results suggest that many hospitalized patients with SSTI could be managed safely and effectively as outpatients. [West J Emerg Med. 2015;16(1):89–97.]

# INTRODUCTION

Between 1993 and 2005, annual U.S. emergency department (ED) visits for skin and soft tissue infections (SSTI) increased from 1.2 to 3.4 million,<sup>1</sup> coinciding with the emergence of community-associated methicillinresistant *Staphylococcus aureus* (MRSA).<sup>2</sup> Hospitalizations for SSTI increased 29% between 2000 and 2004, whereas hospitalizations for community-acquired pneumonia (CAP) remained unchanged or decreased.<sup>3,4</sup> Unlike CAP, guidelines for ED disposition for patients with SSTI based on validated risk stratification models do not exist.

Hospitalization is necessary for care of complicated wounds and severe sepsis, and for monitoring for acute deterioration. However, unnecessary hospitalization is expensive and associated with adverse events.<sup>5,6</sup> Recently, the availability of outpatient parenteral antibiotic treatment strategies have expanded, which may allow alternatives to hospital admission in some cases. These strategies include use of peripherally inserted central catheters (PICC),<sup>7</sup> maintenance of standard peripheral catheters with next day follow up,<sup>8</sup> and administration of single-dose and weekly administered parenteral antimicrobials recently approved by the U.S. Food and Drug Administration (FDA).<sup>9,10</sup> To identify opportunities to reduce avoidable hospitalizations for SSTI, the reasons for physician disposition decisions first need to be understood.

The primary goal of the study was to identify factors that influence the physician decision to hospitalize a patient with a SSTI. Therefore, we conducted a prospective study of adults presenting to 12 U.S. EDs in which their treating physicians were surveyed regarding reason(s) for admission, and patient clinical characteristics were correlated with hospitalization. As a secondary goal, we determined the frequency of serious sequelae.

# **METHODS**

# Study design and setting

We conducted a prospective study of adult patients presenting to the ED with a SSTI at 12 U.S. sites comprising *EMERGE*ncy ID NET in August of 2008.<sup>11,12</sup>

# **Selection of Participants**

We included patients who were  $\geq 18$  years of age, had a SSTI with symptoms present <1 week, and had purulent material available for culture. Consecutive patients were attempted to be enrolled, and an audit was conducted to compare characteristics of missed and enrolled eligible patients.<sup>12</sup> Each site's local institutional review committee approved the study. Informed consent was obtained in writing at six sites and verbally at six sites. The present study was conducted along with an analysis of SSTI bacteriology among the same study population, which was the reason that culturable material was required; the bacteriological analysis has been published.<sup>12</sup>

#### **Methods and Measurements**

At the time of ED care, treating physicians completed a structured form and collected the following data (Table 1): demographics; infection duration, location, type, and mechanism; co-morbidities; symptoms; prior treatment failure for the same infection; infection-related inability to perform activities of daily living; vital sign abnormalities at triage and at the time of disposition decision; laboratory tests; presence of severe edema, lymphangitis, or extreme tenderness; maximal length and width of erythema and, if an abscess was present, estimated abscess dimension and maximal abscess depth; imaging studies; and disposition. ED providers selected the reason(s) for hospital admission from a structured list (Table 2). Abscess dimension was assessed by measurement from the apparent border on skin examination, and depth by inspection following incision and drainage. Area of erythema was estimated by the product of maximal length and width. Subjective patient and provider ratings were used to grade symptom and finding severity. We categorized a laboratory result as abnormal if it was outside the hospital's normal range.

# Outcomes

Follow-up information collected included in-hospital duration, death, intensive care unit (ICU) admission, amputation, and/or operating room debridement/drainage.

# Analysis

We divided the enrolled cohort into admitted and discharged patients. We calculated frequencies, percentages, and relative risk for categorical outcomes, and median and interquartile ranges for continuous outcomes. Thresholds for erythema length and area were chosen based on guideline standards.<sup>13,14</sup> We used Statpages 2-way Contingency Table Analysis to calculate relative risk and 95% confidence intervals for categorical variables.<sup>15</sup> We employed chi-square binary recursive partitioning to assess for independent predictors of admission.<sup>16</sup>

# RESULTS

# Characteristics of study subjects

Of 619 enrolled patients, 94 (15.2%) were hospitalized; 80 (12.9%) admitted to a ward, 3 (0.5%) to the ICU, and 11 (1.8%) to an observation unit. The number of patients and admission rates varied by site from 13 to 104 and 3% to 63%, respectively. Patients' characteristics are summarized in Table 1. Median age was 38.7 years (interquartile range [IQR], 28.0-47.6) and 57.5% were male. A comorbidity was present in 201 (32.5%) patients, with diabetes 75 (12.1%) being most common; 46 (7.5%) had prior treatment failure.

Upon presentation, 39 (6.3%) had temperature  $\geq$ 38°C, 81 (13.1%) tachycardia, 35 (5.7%) tachypnea, and 5 (0.8%) hypotension; at the time of the ED disposition decision, these findings were present in 9 (1.5%), 11 (1.8%), 7 (1.1%), and 3 (0.5%) patients, respectively.

| Table 1. Demographic and clinical characteristics of 619 U. S. emergency department patients with a skin and soft tissue infection, by |
|--|
| admission or discharge.  |

| Characteristics                         | All patients<br>(n=619*) | Admitted<br>(n=94) | Discharged<br>(n=525) | Relative risk<br>[95% CI]       |
|---|--------------------------|--------------------|-----------------------|---------------------------------|
| Age (years; median [IQR])               | 38.7 [28.0, 47.6]        | 44.0 [36.2, 52.0]  | 37.2 [26.7, 47.0]     | N/A                             |
| <u>≥</u> 65 years - n/total (%)         | 12/66 (2.0)              | 5/93 (5.4)         | 7/523 (1.3)           | 2.86 [1.11 – 5.08]†             |
| Gender - n (%)                          |                          |                    |                       |                                 |
| Male                                    | 356 (57.5)               | 59 (62.8)          | 297 (56.6)            | 1.25 [0.83 – 1.88]              |
| Female                                  | 263 (42.5)               | 35 (37.2)          | 228 (43.4)            | 0.80 [0.53 – 1.20]              |
| Race - n (%)                            |                          |                    |                       |                                 |
| White                                   | 283 (45.7)               | 58 (61.7)          | 225 (42.9)            | 1.91 [1.28 – 2.88] <sup>1</sup> |
| Black                                   | 319 (51.5)               | 35 (37.2)          | 283 (53.9)            | 0.56 [0.37 – 0.84]†             |
| Other                                   | 17 (2.7)                 | 1 (1.1)            | 16 (3.0)              | 0.38 [0.06 – 2.57]              |
| Ethnicity - n (%)                       |                          |                    |                       |                                 |
| Hispanic                                | 138 (22.3)               | 17 (18.1)          | 121 (23.0)            | 0.77 [0.45 – 1.27]              |
| Co-morbidity - n (%)                    |                          |                    |                       |                                 |
| Any                                     | 201 (32.5)               | 58 (61.7)          | 143 (27.2)            | 3.35 [2.25 – 5.00] <sup>-</sup> |
| Prior MRSA infection                    | 56 (9.0)                 | 14 (14.9)          | 42 (8.0)              | 1.76 [1.00 – 2.89] <sup>-</sup> |
| Diabetes                                | 75 (12.1)                | 23 (24.5)          | 52 (9.9)              | 2.35 [1.50 – 3.53]              |
| Peripheral vascular disease             | 6 (1.0)                  | 3 (3.2)            | 3 (0.6)               | 3.37 [0.92 – 5.90               |
| Eczema or other chronic skin condition  | 9 (1.5)                  | 4 (4.3)            | 5 (1.0)               | 3.01 [1.02 – 5.41]              |
| Chronic ulcer in area of infection      | 1 (0.2)                  | 1 (1.1)            | 0 (0.0)               | 6.65 [0.36 – 6.65               |
| Chronic edema                           | 6 (1.0)                  | 4 (4.3)            | 2 (0.4)               | 4.54 [1.61 – 6.52]              |
| Chronic renal failure                   | 4 (0.6)                  | 0 (0.0)            | 4 (0.8)               | 0.0 [0.0 – 4.04                 |
| Chronic liver failure                   | 4 (0.6)                  | 1 (1.1)            | 3 (0.6)               | 1.51 [0.08 – 4.80               |
| COPD                                    | 8 (1.3)                  | 3 (3.2)            | 5 (1.0)               | 2.52 [0.68 – 5.13               |
| CHF                                     | 3 (0.5)                  | 1 (1.1)            | 2 (0.4)               | 2.21 [0.44 – 11.1]              |
| Pregnancy                               | 3 (0.5)                  | 0 (0.0)            | 3 (0.6)               | 0.0 [0.0 – 4.61                 |
| HIV                                     | 31 (5.0)                 | 9 (9.6)            | 22 (4.2)              | 2.01 [1.00 – 3.51]              |
| Cancer                                  | 6 (1.0)                  | 1 (1.1)            | 5 (1.0)               | 1.10 [0.06 – 4.30               |
| Bedridden/paralysis                     | 1 (0.2)                  | 0 (0.0)            | 1 (0.2)               | 0.0 [0.0 - 6.28]                |
| nfection type - n (%)                   |                          |                    |                       |                                 |
| Abscess                                 | 527 (85.1)               | 63 (67.0)          | 464 (88.4)            | 0.35 [0.25 – 0.51]              |
| Infected wound                          | 55 (8.9)                 | 14 (14.9)          | 41 (7.8)              | 1.79 [1.09 – 2.95]              |
| Cellulitis                              | 37 (6.0)                 | 17 (18.1)          | 20 (3.8)              | 3.47 [2.31 – 5.22]              |
| nfection mechanism - n (%)              |                          |                    |                       |                                 |
| Recent wound or other break in the skin | 114 (18.4)               | 20 (21.3)          | 94 (17.9)             | 1.20 [0.73 – 1.90               |
| Chronic wound                           | 3 (0.5)                  | 3 (3.2)            | 0 (0.0)               | 6.77 [2.06 – 6.77]              |
| IVDU                                    | 25 (4.0)                 | 13 (13.8)          | 12 (2.3)              | 3.81 [2.23 – 5.54]              |
| Insect/spider bite                      | 106 (17.1)               | 9 (9.6)            | 97 (18.5)             | 0.51 [0.25 – 1.00]              |

COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; HIV, human immunodeficiency virus; IVDU, intravenous drug users; ED, emergency department; SBP, systolic blood pressure; WBC, white blood cell count; CPK, creatine phosphokinase; CT, computed tomography; MRI, magnetic resonance imaging; MRSA, methicillin-resistant S. aureus; MSSA, methicillin-sensitive S. aureus \*Subjects with unknown or missing values for characteristics were excluded from calculations. Denominators are provided for the number of subjects with complete data.

<sup>†</sup>Statistically significant associations.

<sup>‡</sup>For abnormal tests, the number and percent abnormal of those with test performed is shown.

Table 1 (continued). Demographic and clinical characteristics of 619 U. S. emergency department patients with a skin and soft tissue infection, by admission or discharge.

| Characteristics                                   | All patients<br>(n=619*) | Admitted<br>(n=94) | Discharged<br>(n=525) | Relative risk<br>[95% CI]       |
|---|--------------------------|--------------------|-----------------------|---------------------------------|
| Animal/human bite                                 | 3 (0.5)                  | 1 (1.1)            | 2 (0.4)               | 2.28 [0.12 – 5.89]              |
| Burn infection                                    | 1 (0.2)                  | 1 (1.1)            | 0 (0.0)               | 6.65 [0.36 – 6.65]              |
| Infection of surgical wound                       | 16 (2.6)                 | 8 (8.5)            | 8 (1.5)               | 3.51 [1.73 – 5.44]†             |
| No apparent precipitating event                   | 304 (49.1)               | 30 (31.9)          | 274 (52.2)            | 0.49 [0.32 – 0.74]†             |
| Other   | 47 (7.6)                 | 9 (9.6)            | 38 (7.2)              | 1.29 [0.63 – 2.38]              |
| Infection location - n (%)                        |                          |                    |                       |                                 |
| Head/neck   | 57 (9.2)                 | 8 (8.5)            | 49 (9.3)              | 0.92 [0.42 – 1.80]              |
| Torso   | 101 (16.3)               | 12 (12.8)          | 89 (17.0)             | 0.75 [0.40 – 1.34]              |
| Groin/perineum/buttock                            | 132 (21.3)               | 12 (12.8)          | 120 (22.9)            | 0.54 [0.29 – 0.97]†             |
| Upper extremity                                   | 174 (28.1)               | 27 (28.7)          | 147 (28.0)            | 1.03 [0.66 – 1.58]              |
| Lower extremity                                   | 172 (27.8)               | 37 (39.4)          | 135 (25.7)            | 1.69 [1.13 – 2.49]†             |
| Failed prior treatment for same infection - n (%) | 46/611 (7.5)             | 15/93 (16.1)       | 31/518 (6.0)          | 2.36 [1.38 – 3.72]†             |
| Total symptom duration (days; median [IQR])       | 4.0 [3.0, 6.0]           | 4.0 [3.0, 6.0]     | 4.0 [3.0, 6.0]        | N/A                             |
| Symptoms - n (%)                                  |                          |                    |                       |                                 |
| Fever   | 96 (15.5)                | 41 (43.6)          | 55 (10.5)             | 4.21 [2.92 – 5.96]†             |
| Chills/sweats/rigors                              | 99 (16.0)                | 31 (33.0)          | 68 (13.0)             | 2.59 [1.72 – 3.78] <sup>†</sup> |
| Severe nausea/vomiting                            | 28 (4.5)                 | 10 (10.6)          | 18 (3.4)              | 2.51 [1.31 – 4.14] <sup>†</sup> |
| Extreme pain                                      | 264 (42.6)               | 53 (56.4)          | 211 (40.2)            | 1.74 [1.17 – 2.59]†             |
| Lymphangitis                                      | 31/535 (5.8)             | 15/84 (17.9)       | 16/451 (3.5)          | 3.53 [2.12 – 5.21] <sup>†</sup> |
| Marked local edema                                | 275/576 (47.7)           | 68/91 (70.1)       | 207/485 (42.7)        | 3.24 [2.05 – 5.22]†             |
| Extreme tenderness                                | 381/594 (64.1)           | 73/91 (75.3)       | 308/503 (61.2)        | 2.27 [1.37 – 3.86]†             |
| ED Vital Sign Abnormalities - n (%)               |                          |                    |                       |                                 |
| Temperature ≥38°C                                 | 39 (6.3)                 | 20 (21.3)          | 19 (3.6)              | 4.02 [2.60 – 5.66]†             |
| Hypotension (SBP <90mmHg)                         | 5 (0.8)                  | 2 (2.1)            | 3 (0.6)               | 2.67 [0.48 – 5.66]              |
| Tachycardia (>100/minute)                         | 81 (13.1)                | 29 (30.9)          | 52 (9.9)              | 2.96 [1.97 – 4.30]†             |
| Tachypnea ( <u>≥</u> 20/minute)                   | 35 (5.7)                 | 12 (12.8)          | 23 (4.4)              | 2.44 [1.35 – 3.94]†             |
| Disposition vital sign abnormalities - n (%)      |                          |                    |                       |                                 |
| Temperature ≥38°C                                 | 9 (1.5)                  | 5 (5.3)            | 4 (0.8)               | 3.81 [1.52 – 5.97]†             |
| Hypotension (SBP <90mmHg)                         | 3 (0.5)                  | 2 (2.1)            | 1 (0.2)               | 4.46 [1.96 – 10.1] <sup>†</sup> |
| Tachycardia (>100/minute)                         | 11 (1.8)                 | 4 (4.3)            | 7 (1.3)               | 2.46 [0.82 – 4.78]              |
| Tachypnea ( <u>&gt;</u> 20/minute)                | 7 (1.1)                  | 2 (2.1)            | 5 (1.0)               | 1.90 [0.34 – 4.77]              |
| Size of wound-erythema (cm)                       |                          |                    |                       |                                 |
| Maximal length - median [IQR] n=589               | 4.0 [2.0, 7.0]           | 8.0 [4.0, 10.0]    | 4.0 [2.0, 6.0]        | N/A                             |
| Maximal width - median [IQR] n=588                | 3.0 [2.0, 5.0]           | 6.0 [4.0, 10.0]    | 3.0 [2.0, 5.0]        | N/A                             |
| Max dimension <u>≥</u> 5cm - n (%)                | 262/589 (44.5)           | 72/94 (76.6)       | 190/495 (38.4)        | 4.09 [2.57 – 6.62] <sup>†</sup> |
| Max dimension ≥10cm - n (%)                       | 97/589 (16.5)            | 41/94 (43.6)       | 56/495 (11.3)         | 3.92 [2.72 – 5.56] <sup>†</sup> |
| Area ≥19.7cm² - n (%)                             | 203/588 (34.5)           | 64/94 (68.1)       | 139/494 (28.1)        | 4.05 [2.68 – 6.18]†             |
| Area ≥78.5cm² - n (%)                             | 64/589 (10.9)            | 30/94 (31.9)       | 34/495 (6.9)          | 3.85 [2.62 – 5.39]†             |

COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; HIV, human immunodeficiency virus; IVDU, intravenous drug users; ED, emergency department; SBP, systolic blood pressure; WBC, white blood cell count; CPK, creatine phosphokinase; CT, computed tomography; MRI, magnetic resonance imaging; MRSA, methicillin-resistant S. aureus; MSSA, methicillin-sensitive S. aureus \*Subjects with unknown or missing values for characteristics were excluded from calculations. Denominators are provided for the number of subjects with complete data.

<sup>†</sup>Statistically significant associations.

<sup>‡</sup>For abnormal tests, the number and percent abnormal of those with test performed is shown.

Table 1 (continued). Demographic and clinical characteristics of 619 U. S. emergency department patients with a skin and soft tissue infection, by admission or discharge.

| Characteristics                         | All patients<br>(n=619*) | Admitted<br>(n=94) | Discharged (n=525) | Relative risk<br>[95% CI]       |
|---|--------------------------|--------------------|--------------------|---------------------------------|
| Size of abscess (cm)                    |                          |                    |                    |                                 |
| Maximal length - median [IQR] n=534     | 2.0 [1.0, 3.5]           | 4.0 [2.0, 10.0]    | 2.0 [1.0, 4.0]     | N/A                             |
| Maximal width - median [IQR] n=571      | 2.0 [1.0, 3.0]           | 3.0 [2.0, 8.0]     | 2.0 [1.0, 3.0]     | N/A                             |
| Abscess depth - n (%)                   |                          |                    |                    |                                 |
| Limited to skin                         | 551/579 (95.2)           | 68/83 (81.9)       | 483/496 (97.4)     | 0.23 [0.16 – 0.38]†             |
| Involves deep fascia/muscle             | 26/579 (4.5)             | 15/83 (18.1)       | 11/496 (2.2)       | 4.69 [2.87 – 6.59] <sup>†</sup> |
| Involves bone/joint                     | 2/579 (0.3)              | 0/83 (0.0)         | 2/496 (0.4)        | 0.00 [0.00 – 5.68]              |
| Laboratory tests - n (%) <sup>‡</sup>   |                          |                    |                    |                                 |
| WBC <sup>‡</sup> – performed            | 130 (21.0)               | 86 (91.5)          | 44 (8.4)           | 40.4 [20.4 - 87.1]†             |
| WBC – abnormal                          | 72/130 (55.4)            | 51/86 (59.3)       | 21/44 (47.7)       | 1.17 [0.90 – 1.55]              |
| Creatinine – performed                  | 122 (19.7)               | 78 (83.0)          | 44 (8.4)           | 19.9 [12.2 – 33.4] <sup>†</sup> |
| Creatinine – abnormal                   | 15 (12.3)                | 13/78 (16.7)       | 2/44 (4.5)         | 1.43 [0.93 – 1.65]              |
| $HCO_3 - performed$                     | 91 (14.7)                | 55 (58.5)          | 36 (6.9)           | 8.18 [5.79 – 11.4]†             |
| HCO <sub>3</sub> – abnormal             | 8 (8.8)                  | 7/55 (12.7)        | 1/36 (2.8)         | 1.51 [0.78 – 1.75]              |
| Lactate – performed                     | 16 (2.6)                 | 11 (11.7)          | 5 (1.0)            | 5.00 [2.91 – 6.62] <sup>†</sup> |
| Lactate – abnormal                      | 0 (0)                    | 0 (0)              | 0 (0)              | N/A                             |
| Glucose – performed                     | 177 (28.6)               | 79 (84.0)          | 98 (18.7)          | 13.2 [7.74 – 23.2]†             |
| Glucose – abnormal                      | 70 (39.5)                | 35/79 (44.3)       | 35/98 (35.7)       | 1.22 [0.85 – 1.71]              |
| CPK <sup>‡</sup> – performed            | 13 (2.1)                 | 10 (10.6)          | 3 (0.6)            | 5.55 [3.21 – 6.95]†             |
| CPK – abnormal                          | 4 (30.8)                 | 3/10 (30.0)        | 1/3 (33.3)         | 0.96 [0.38 – 1.47]              |
| Imaging performed - n (%)               |                          |                    |                    |                                 |
| Ultrasound                              | 32 (5.2)                 | 8 (8.5)            | 24 (4.6)           | 1.71 [0.80 – 3.13]              |
| X-ray                                   | 67 (10.8)                | 38 (40.4)          | 29 (5.5)           | 5.59 [3.95 – 7.58]†             |
| СТ                                      | 22 (3.6)                 | 11 (11.7)          | 11 (2.1)           | 3.60 [2.00 – 5.38]†             |
| MRI                                     | 4 (0.6)                  | 3 (3.2)            | 1 (0.2)            | 5.07 [1.46 – 6.74]†             |
| Any                                     | 115 (18.6)               | 53 (56.4)          | 62 (11.8)          | 5.67 [3.93 – 8.12] <sup>†</sup> |
| Imaging results - n (%)                 |                          |                    |                    |                                 |
| Abscess                                 | 45 (7.3)                 | 15 (16.0)          | 30 (5.7)           | 2.42 [1.42 – 3.80]†             |
| Gas/air in tissues                      | 3 (0.5)                  | 2 (2.1)            | 1 (0.2)            | 4.46 [0.83 – 6.65]              |
| Osteomyelitis                           | 8 (1.3)                  | 7 (7.4)            | 1 (0.2)            | 6.15 [3.19 – 7.05] <sup>†</sup> |
| Other abnormality                       | 22 (3.6)                 | 14 (14.9)          | 8 (1.5)            | 4.75 [2.92 – 6.41]†             |
| Debridement procedure in the ED - n (%) | 538/615 (87.5)           | 66 (70.2)          | 472/521 (90.6)     | 0.34 [0.23 – 0.51]†             |
| Culture results - n (%)                 |                          |                    |                    |                                 |
| Any bacterial growth                    | 580 (93.7)               | 88 (93.6)          | 492 (93.7)         | 0.99 [0.47 – 2.43]              |
| MRSA <sup>‡</sup>                       | 366 (59.2)               | 45 (47.9)          | 321 (61.1)         | 0.64 [0.43 – 0.94]†             |
| MSSA <sup>‡</sup>                       | 94 (15.2)                | 16 (17.0)          | 78 (14.9)          | 1.15 [0.66 – 1.89]              |
| β-hemolytic streptococci                | 36 (5.8)                 | 9 (9.6)            | 27 (5.1)           | 1.72 [0.84 – 3.06]              |
| Viridans streptococci                   | 23 (3.7)                 | 7 (7.4)            | 16 (3.0)           | 2.09 [0.94 – 3.80]              |

COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; HIV, human immunodeficiency virus; IVDU, intravenous drug users; ED, emergency department; SBP, systolic blood pressure; WBC, white blood cell count; CPK, creatine phosphokinase; CT, computed tomography; MRI, magnetic resonance imaging; MRSA, methicillin-resistant S. aureus; MSSA, methicillin-sensitive S. aureus \*Subjects with unknown or missing values for characteristics were excluded from calculations. Denominators are provided for the number of subjects with complete data.

<sup>†</sup>Statistically significant associations.

<sup>‡</sup>For abnormal tests, the number and percent abnormal of those with test performed is shown.

Table 2. Physician reasons for admission among 94 emergency department patients hospitalized with a skin and soft tissue infection.

| Reason for admission                    | Frequency (%)* |
|---|----------------|
| Needs intravenous antibiotics           | 80 (85.1)      |
| Needs surgical intervention             | 23 (24.5)      |
| Needs complex wound care                | 9 (9.6)        |
| Unable to tolerate oral medications     | 0 (0.0)        |
| Needs pain control                      | 5 (5.3)        |
| Significant underlying disease          | 11 (11.7)      |
| Homeless                                | 2 (2.1)        |
| Unreliable for taking medications       | 4 (4.3)        |
| Possible necrotizing fasciitis          | 2 (2.1)        |
| Possible deep vein thrombosis           | 1 (1.1)        |
| Possible osteomyelitis/septic arthritis | 5 (5.3)        |
| Possible endocarditis                   | 2 (2.1)        |
| Possible sepsis/bacteremia              | 4 (4.3)        |
| *More than one reason could be given.   |                |

More than one reason could be given.

Most infections were on the extremities. Median length of erythema was 4.0cm (IQR, 2.0-7.0). Of 579 patients (93.5%) with an abscess, 28 (4.8%) were thought to involve fascia, muscle, bone, or joint.

Laboratory tests were performed in approximately onethird of patients, including blood glucose in 177 (28.6%), white blood cell count (WBC) in 130 (21.0%), creatinine in 122 (19.7%), bicarbonate in 91 (14.7%), lactate in 16 (2.6%), and creatine phosphokinase (CPK) in 13 (2.1%). Abnormal glucose results were present in 70 (11.3%; 5 [0.81%] had glucose >500mg/dl), WBC in 72 (11.6%, 20 [3.2%] had a WBC count  $>15,000/\text{mm}^3$ ), creatinine in 15 (2.4%), bicarbonate (low) in 8 (1.3%), lactate in none, and CPK in 4 (0.65%). Imaging was performed in approximately 20% of patients; 8 (1.3%) had evidence of osteomyelitis and 3 (0.5%)had soft tissue air/gas.

# **Main results**

Univariate associations with hospital admission are listed in Table 1. Based on binary recursive partitioning, hospitalization was significantly associated with the following independent factors in decreasing order of importance: history of fever (present in 43.6% of those admitted, and 10.5% discharged); maximal length of ervthema >10 cm (43.6%, 11.3%); history of failed treatment (16.1%, 6.0%); any comorbidity (61.7%, 27.2%); and age  $\geq$ 65 years (5.4%, 1.3%). At least one of these characteristics was present in 89 of the 94 admitted patients, while all were absent in 291 of 525 discharged patients.

Reasons cited by the treating physician to admit their patient to the hospital are summarized in Table 2. Need for intravenous antibiotics was the most common reason for admission, cited for 80 (85.1%) patients, and was the only

reason for admission in 39 (41.5%). The next most common reasons were need for surgical intervention in 23 (24.5%), significant underlying disease in 11 (11.7%), and complex wound care in 9(9.6%).

Median hospital duration was four days (IQR, 2-6). Among admitted cases, debridement/drainage in the operating room, amputation, subsequent ICU admission, and/or death occurred in 20 (21.3%), 2 (2.1%), 0 (0%), and 0 (0%), respectively. One patient who underwent amputation was admitted to the floor with diabetes and a foot ulcer infection with a 30 x 15cm area of cellulitis, and initial radiograph demonstrating soft tissue gas. The second patient requiring amputation was also a diabetic who was admitted to the ICU with a large cellulitis area, 20 x 12cm, soft tissue gas on radiograph, and a WBC count of 34,000/mm<sup>3</sup>.

# DISCUSSION

ED visits and hospitalizations for SSTI have greatly increased over the last decade.<sup>1,3</sup> One study estimated that there were approximately three million ED visits for SSTI and 500,000 associated hospitalizations annually based on data from 2008 through 2010.15 The estimated mean cost of an SSTI hospitalization in the U.S. is \$8,023 with a 4.9 day length of stay, and hospitalization is also associated with various risks.<sup>5,6</sup> In this study, we sought to identify factors that may affect the decision to hospitalize an ED patient with a SSTI. We also determined the rate of major procedures and serious complications that may justify hospitalization. Among 619 patients, 15.2% were admitted, and only 0.5% were admitted to the ICU. Even among admitted patients, vital sign abnormalities at the time of ED discharge were rare. For the first time that we are aware, we surveyed treating physicians at the time of their care decisions as to their reasons for hospitalizing a patient with a SSTI. We found that the most common reason for hospital admission by far was perceived need for intravenous antibiotics, cited for 85.1% of patients. Administration of intravenous antibiotics was the sole reason for hospitalization for 41.5% of patients. A patient's inability to take oral medication was rarely cited as a reason for admission. Anticipated need for major surgery or wound management was indicated for about one-quarter. While EPs tended to hospitalize patients who had fever, larger lesions, failed treatment, co-morbidities and advanced age, of 94 admitted patients, none had subsequent ICU transfer or died, and only two had amputations, both of whom had soft tissue gas on their initial radiographs. In light of expanded options for outpatient parenteral antibiotic administration, it appears that a substantial proportion of ED patients hospitalized for SSTI could instead be safely and effectively managed as outpatients.

Unlike CAP, robust outcome data that would inform admission decisions have never been reported for patients with SSTI. This is not surprising since, as we observed, serious adverse events are rare in this infection compared to CAP, with CAP hospitalization rates over 50% and inpatient mortality estimated at 8-14%.<sup>4,18-21</sup> In contrast, and consistent with our observations, an analysis of over eight million adults presenting with SSTI using U.S. Healthcare Cost and Utilization Project Nationwide Emergency Department Sample (HCUP NEDS) data from 2008 to 2010 found a hospitalization rate of 17% and an inpatient mortality rate of only 0.5%.<sup>17</sup>

To the best of our knowledge, this is also the first ED-based study of a large group of patients with SSTI in which a broad range of patient characteristics was collected prospectively and examined for their association with patient disposition. We found factors independently associated with hospitalization were history of fever, maximal wound dimension  $\geq 10$ cm, history of failed treatment, presence of any co-morbidity, and age  $\geq 65$  years. One retrospective ED investigation by Sabbaj et al.<sup>20</sup> described 846 patients and also found that fever was associated with hospitalization.

Hospital admission is neither required to administer parenteral antibiotics nor to achieve good patient outcomes, even among patients with fever, large areas of cellulitis, and co-morbidities. Newly FDA-approved parenteral lipoglycopetides, dalbavancin and oritavancin, have exceptionally long half-lives that allow either a single dose or two doses, one week apart, which could be initiated in the ED prior to discharge.9,10 Two randomized, doubleblind, double-dummy, trials comparing dalbavancin, two injections one week apart to intravenous vancomycin, at least three days followed by oral linezolid, found similar response rates among 1,315 SSTI patients, the majority of whom were hospitalized.<sup>10</sup> Subjects had frequent fever (84% had temperature  $\geq$  38.0°C) and very large areas of erythema (median, 313-367cm<sup>2</sup>, about the size of a standard tablet portable computer). Approximately 13% had diabetes. The median area of erythema among subjects in this clinical trial was substantially larger than that of patients who were hospitalized in our study (i.e., estimated median area ~48cm<sup>2</sup>). Among all clinical trial subjects, there was one case of necrotizing fasciitis and no septic deaths. Approximately 25% of subjects were treated entirely as outpatients.

Other alternatives to inpatient administration of intravenous antibiotics include peripherally inserted central catheters (PICC) for outpatient parenteral antibiotic treatment (OPAT).<sup>7</sup> One innovative approach is to administer a oncea-day parenteral agent prior to ED discharge, leaving the standard peripheral intravenous catheter for next day followup and repeat dosing in the ED or infectious diseases clinic.<sup>8,23</sup> Oral antibiotics, with good compliance, may also be an alternative in some cases. In a retrospective, propensity scorematched case-control study of adults with complicated SSTI, of whom about 20%-30% had diabetes and/or peripheral vascular disease, oral linezolid actually was associated with a greater chance of clinical cure than intravenous vancomycin.<sup>24</sup>

Some risk-stratification models based on hospital SSTI populations exist that might guide ED disposition decisions

but are limited by small size, selected patient populations and low rates of serious adverse events. Figtree et al.<sup>25</sup> reported outcomes among 395 adults admitted to a referral hospital; 2.5% of patients died, 5.1% had multi-organ failure, and 0.8% had amputation. A predictive model for adverse outcomes was derived consisting of a weighted score based on altered mentation, heart failure, wound discharge, hypoalbuminemia, and neutrophilia/neutropenia. Carralta et al.26 analyzed 332 adults hospitalized with SSTI. Thirty-day mortality was 5% and factors associated with death were male gender, comorbidities, heart failure, obesity, hypoalbuminemia, renal insufficiency, shock, and Pseudomonas cellulitis. The laboratory risk indicator for necrotizing fasciitis is a weighted risk-stratification scoring system based on abnormalities of serum sodium, glucose, creatinine, hemoglobin, WBC, and C-reactive protein derived among hospitalized SSTI patients to diagnose necrotizing fasciitis.27 Unvalidated expert-based disposition guidelines have been proposed, <sup>28-33</sup> one combining a graded scale of vital sign abnormalities and altered mentation, and presence of sepsis and/ or significant co-morbidities.31

# LIMITATIONS

In this study, physician survey responses and clinical correlates with hospitalization may not reflect the actual reason(s) an emergency physician decided that a patient required hospital care. Admission decisions may be influenced by factors not analyzed, such as by a patient's primary care physician, whose reasoning may not have been reflected by the emergency provider. However, other than asking the treating physician at the time of their care, and examining clinical findings present at the time for their association with admission, we are unaware of a better way to assess provider justification for hospitalization. We did not collect outcome data on discharged patients, although the risk of adverse outcomes would be expected to be substantially less than among admitted patients. Study sites were urban, university-affiliated hospitals that may not reflect practices in other settings. Admission rates varied greatly among sites, from 3% to 63%. This likely reflects sampling issues and case-mix, with a few sites enrolling a small number of patients. For example, the frequency of fever history among subjects at sites with the highest and lowest hospitalization rates was 47% and 9%, respectively. However, the rate of hospitalization predictors among admitted patients by site was similar. Variation in admission rates by site also suggests variation in practice patterns, perhaps related to availability outpatient care services and differences in payer models, and supports a range of acceptable approaches to SSTI management. Because another study purpose was bacteriological analysis, the study population was patients with purulent SSTI, mostly patients with abscesses and a minority of patients with cellulitis or wound infection, and some drainage,<sup>12</sup> who may be different than other SSTI patients. While our sample does not include patients with cellulitis without drainage, it would be expected that these patients would be more likely to be hospitalized for parenteral antibiotics and not for surgery or wound care than those with purulent drainage. Enrolled patients may be different from all eligible patients, although case finding audits have found these groups to be similar.<sup>2,12</sup> While our study population of ED patients with SSTI may therefore not reflect all such patients, importantly our admission and hospital mortality rates were similar to those of two large U.S. databases for patients with SSTI diagnoses.<sup>5,17</sup> Some univariate associations with hospitalization may have been artifactual, and therefore, we conducted a multivariate analysis to identify independent predictors. However, these independent associations may be an over-simplification of the factors that are the bases for provider admission decisions.

### CONCLUSION

ED patients with SSTI with fever, larger lesions, failed prior treatment, co-morbidities and advanced age tend to be hospitalized. The most common reason given by treating clinicians for admission is administration of intravenous antibiotics, which was frequently the only reason for hospitalization. Almost all these patients are admitted to noncritical care areas and rarely do they suffer serious adverse events. In light of the increasing availability of outpatient intravenous antibiotic therapy options, these results suggest that many hospitalized patients with SSTI could be managed safely and effectively as outpatients. Since this was not a clinical trial, we can only surmise based on other existing evidence that outcomes of low- and moderate-risk patients admitted only for intravenous antibiotics would be as good as if these patients had been discharged and treated with various outpatient parenteral antibiotic strategies or even oral antibiotics. It would be ideal to collect sufficient outcome data to develop a validated risk-stratification model, along the lines of the Pneumonia Severity Index.34 Implementation of these tools has been demonstrated to reduce CAP hospital admission rates.<sup>4,35</sup> Because of the relatively low rate of serious complications associated with SSTI, case series and clinical trials may be more appropriate than prospective cohort studies to address alternative management options to hospitalization and intravenous antibiotics for stable patients with SSTI.

Address for Correspondence: David A. Talan, MD 14445 Olive View Drive, North Annex, Sylmar, CA 91342. Email: eidnet@gmail.com.

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# Trauma Center Staffing, Infrastructure, and Patient Characteristics that Influence Trauma Center Need

Mark Faul, PhD, MA\* Scott M. Sasser, MD<sup>†</sup> Julio Lairet, DO<sup>†</sup> Nee-Kofi Mould-Millman, MD<sup>‡</sup> David Sugerman, MD, MPH\* \*Centers for Disease Control and Prevention, Atlanta, Georgia <sup>†</sup>Emory University, Department of Emergency Medicine, Atlanta Georgia <sup>‡</sup>University of Colorado, Department of Emergency Medicine, Aurora, Colorado

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**Introduction:** The most effective use of trauma center resources helps reduce morbidity and mortality, while saving costs. Identifying critical infrastructure characteristics, patient characteristics and staffing components of a trauma center associated with the proportion of patients needing major trauma care will help planners create better systems for patient care.

**Methods:** We used the 2009 National Trauma Data Bank-Research Dataset to determine the proportion of critically injured patients requiring the resources of a trauma center within each Level I-IV trauma center (n=443). The outcome variable was defined as the portion of treated patients who were critically injured. We defined the need for critical trauma resources and interventions ("trauma center need") as death prior to hospital discharge, admission to the intensive care unit, or admission to the operating room from the emergency department as a result of acute traumatic injury. Generalized Linear Modeling (GLM) was used to determine how hospital infrastructure, staffing Levels, and patient characteristics contributed to trauma center need.

**Results:** Nonprofit Level I and II trauma centers were significantly associated with higher levels of trauma center need. Trauma centers that had a higher percentage of transferred patients or a lower percentage of insured patients were associated with a higher proportion of trauma center need. Hospital infrastructure characteristics, such as bed capacity and intensive care unit capacity, were not associated with trauma center need. A GLM for Level III and IV trauma centers showed that the number of trauma surgeons on staff was associated with trauma center need.

**Conclusion:** Because the proportion of trauma center need is predominantly influenced by hospital type, transfer frequency, and insurance status, it is important for administrators to consider patient population characteristics of the catchment area when planning the construction of new trauma centers or when coordinating care within state or regional trauma systems. [West J Emerg Med. 2015;16(1):98–106.]

#### **INTRODUCTION**

In the United States, unintentional injury is the leading cause of death for people aged 0-44 years of age.<sup>1</sup> Treatment of severely injured persons at a Level I trauma center compared to a non-trauma center has been associated with a 25% reduction in mortality.<sup>2</sup> Published guidance from the U.S. Centers for Disease Control and Prevention (CDC) provides detailed prehospital transport recommendations for trauma center destination for severely injured patients meeting specific criteria.<sup>3</sup> A better understanding of how infrastructure, staffing and patient characteristics within a trauma center is impacted by the proportion of patients requiring advanced trauma care is critical for better trauma system management. Given the complexity of traumatic injuries, trauma centers are, by design, large, resource-intensive environments, capable of providing patients with a wide array of trauma and nontrauma care services, including access to complex diagnostic equipment, intensive care unit (ICU) beds, and trauma care clinical expertise through varied medical and surgical specialists.<sup>4</sup> These resources are readily available 24 hours a day, seven days a week. Although effective, the resources available at a trauma center can be costly. In one study, the cost of trauma center readiness (excluding trauma care costs) was \$2.7 million annually,<sup>5</sup> while another study reported the increased cost of treatment at a trauma center compared to a non-trauma center as being over \$7,264 per patient.<sup>6</sup>

The American College of Surgeons (ACS) delineates 108 specific criteria for formal trauma center verification, including the volume of trauma patients seen, volume of inpatient trauma admissions, continuous availability of specialty staff, and provider-to-patient ratios for every trauma center.<sup>7</sup> Trauma center verification criteria, in part, dictate resource allocation and use by trauma centers. However, the relationship between ACS trauma center verification criteria and patient use of those resources has not been fully explored.

In 2004, Laurent et al. studied and reported that higher trauma center patient volumes were not associated with improved patient outcomes,<sup>8</sup> thereby refuting previous findings suggestive of a mortality benefit at trauma centers with higher patient volumes.<sup>9-12</sup> Thus, the evidence of patient volume has been mixed. Part of the inconsistency may be due to differences in the proportion of patients that require the services of a trauma center. Additionally, trauma centers, like public safety agencies, require continuous staffing, regardless of patient volume, with an unclear costbenefit relationship. In terms of nursing, higher numbers of more experienced nursing staff confer a survival benefit to severely injured patients receiving trauma care in trauma centers, as opposed to using less experienced nursing staff as a resource-conserving mechanism.<sup>13</sup>

The American College of Surgeons Committee on Trauma (ACS-COT) recommends neurosurgery, orthopedic and trauma specialist availability 24 hours a day for Level I and II trauma centers. The value of these clinical specialties' involvement in trauma care has been well established.<sup>14</sup> Continuous neurosurgical care, for example, is generally required to apply the Brain Trauma Foundation treatment guidelines. Yet, the literature has raised the issue that the availability of neurosurgeons to care for the 1.5 million Americans with traumatic brain injuries is increasingly sparse, precipitating a nationwide crisis for neurosurgeon availability in trauma centers.<sup>15</sup> Similar influences hold true for the relative paucity of other subspecialists, such as orthopedic and trauma surgeons. It is feared that in an effort to maximize staffing efficiency at reduced costs, trauma centers may reduce staff coverage to meet the minimum ACS-COT requirements and trauma

center patient demand, with unclear implications to trauma patient's morbidity and mortality.

The future viability of trauma centers is vulnerable to the escalating cost of care provided to uninsured patients. The transfer of uninsured patients from smaller for-profit hospitals to larger nonprofit hospitals may result in a transfer of financial burden. Previous studies have shown that such transfers are not influenced by insurance status, but rather by injury severity and the presence of multiple injuries.<sup>16,17</sup> However, one three-year study estimates the proportion of uninsured trauma patients seen at an urban Level I trauma center was 37%. In that report, the trauma center lost \$37.5 million over three years, mostly attributable to patients without insurance, and Medicare and Medicaid beneficiaries.<sup>18</sup>

Unfortunately, despite the implementation of in-hospital evidence-based guidelines and standardized treatments and best practices to improve the quality of trauma care, substantial variation in patient outcomes occur across trauma centers.<sup>19,20</sup> Therefore, it is important to determine the most critical resources within a hospital that contribute to the treatment of patients with severe injuries. While some research has focused on patient volume in a trauma centers,<sup>21-23</sup> this study examines the proportion of critically ill patients that need the services of a trauma center. To date, no study has focused on the complex relationships between the critically injured patient needing major trauma center services and the hospital resource use, using data from a larger number of trauma centers throughout the U.S. Research in this topic may lead to more efficient trauma resource utilization, and an enhanced ability to meet future trauma care needs. Our primary objective in this study was to examine the how system characteristics impact the proportion of critically injured seen at a trauma center. We hypothesized that both trauma center infrastructure characteristics, patient characteristics and the trauma center staffing levels would be significant predictors in determining the proportion of patients who need care at a trauma center ("trauma center need"). Understanding the important characteristics related to trauma patient admissions to trauma centers may lead to a more efficient use of resources.

# METHODS

This study was a retrospective secondary data analysis using data from the 2009 National Trauma Data Bank (NTDB) Research Data Set. The 2009 NTDB contains trauma registrybased data from participating trauma centers across the U.S. These data are consolidated by the ACS-COT and are a voluntary, convenience sample of trauma center activity in the U.S. For this study, each hospital is the unit of analysis. There is no gold standard for the identification of patients who need the specialized services of a trauma center. To determine trauma center need, (or the portion of critically injured persons who required the services of a trauma center, the outcome variable), this study used a slightly modified version of the definition established by Lerner.<sup>24</sup> We defined trauma center need as a patient having one or more of the following characteristics: 1) death prior to hospital discharge, 2) ICU admission from the emergency department (ED); or 3) admission to an operating room from the ED for non-orthopedic surgical procedures. This definition was applied to each patient record and a proportion of trauma center need was calculated for each facility. We assigned each hospital a percentage based on the proportion of critically injured patients that required the services of a trauma center, divided by the total number of patients treated. That percentage of critically injured patients in a trauma center served as the outcome variable of the statistical models.

The independent variables that influenced trauma need were hospital infrastructure variables (total beds [adult and pediatric], ICU Beds [adult and pediatric], hospital profit type, trauma designation Level), and we obtained hospital staffing levels (number of neurosurgeons, trauma surgeons, and orthopedic surgeons) from the facility table within the NTDB. When ACS trauma center verification level information was not available, we substituted the state designation for the trauma center level. Other independent variables included staffing levels by specialty (number of trauma surgeons, neurosurgeons and orthopedic surgeons), infrastructure variables such as bed counts and ICU capacity, trauma center designation and hospital type. Variables used to define hospital characteristics, such as the percent of patients transferred and percent of patients insured, were calculated for each trauma center from all of the patients treated within each specific trauma center, and we merged those data with the trauma center.

We omitted patients with isolated orthopedic injuries from the sample, based on the procedural codes in patient records. The International Classification of Diseases, version 9, clinical modification (ICD-9-CM) procedure code range (76-83) was used to identify patients not requiring the services of a trauma center.<sup>25</sup> Consistent with Lerner's definition of trauma center need, critically injured patients who were admitted to the operating room from the ED only for operations on the musculoskeletal system were defined as not having a need for a trauma center.<sup>24</sup> However, if there was a single orthopedic procedure that involved an amputation following a traumatic injury to the limb, we considered those records as trauma related and included them in the trauma care need definition. Unlike Lerner et al., for non-orthopedic cases, we did not limit our analysis to patients receiving surgery within 24 hours of ED arrival. Analysis was performed with SAS, version 9.3.<sup>26</sup> We used a generalized linear model (GLM) procedure, which is an enhanced multiple regression procedure, to determine how much variance each independent variable contributed to trauma center need. Three models were run to evaluate factors that contribute to trauma center need for: 1) all trauma centers in the NTDB, 2) Level I and II

trauma centers, and 3) Level III and IV trauma centers. We performed a tolerance test with a cutoff Level of 0.4 for all three models, which revealed no multi-colinearity issues. Descriptive statistics and parameter statistics are reported.

# RESULTS

A total of 443 trauma centers were used in the statistical models. These trauma centers had 716,898 admissions as reflected in the trauma registries. When looking at all trauma centers, the average proportion of patients meeting one or more inclusion criteria for trauma center need was 31.7% (Table 1). The average percentage of trauma care need in Level I and II trauma centers was 35.3% and 18.6% in Level III and IV trauma centers. The average number of total beds within a Level I and II trauma center was 460 beds and 200 beds within a Level III and IV trauma center. ICU beds were more abundant in Level I and II trauma centers (mean=30.7) than in Level III and IVs (mean =12.7).

A slight majority of the sampled trauma centers were ACS verified or state designated as Level II (n=182 or 41%), followed by Level I (n=165, 37%), Level III (n=74, 17%), and Level IV (n=22, 5%). For all three models (Table 1), there was a higher proportion of nonprofit trauma centers (84%-93%) compared to for profit trauma centers. The percent of insured patients was consistent across the three models at 78-79%. The percent of transfers to a Level I and II trauma centers was almost twice as large when compared to Levels IIIs and IVs (24.1% and 12.2%, respectively).

Staffing with the trauma center groupings was also different. There were almost three times as many neurosurgeons at Level I and II trauma centers (mean=4.9) than at Level III and IV trauma centers (mean=1.8). Similarly, orthopedic surgeons in Level I and II trauma centers also outnumbered other orthopedic surgeons in Level III and IV trauma centers (mean=10.2, mean=6.9, respectively). There were almost twice as many trauma surgeons at Level I and II trauma centers (mean=6.1) than at Level III and IVs (mean=3.6). The overall generalized linear model predicting the proportion of acute trauma center need within all trauma centers (Levels I-IV) was significant ( $R^2 = 0.29$ , f=19.65, p < 0.001). While the overall model was significant, only certain factors contributed to explaining the proportion of trauma need at a hospital (Table 2). For example, when looking at all trauma centers, specific infrastructure variables such as total beds, ICU beds, and hospital profit type were not significant. We found that a higher percentage of inter-facility transfers (t=2.75, p=0.0061) and a lower percentage of insured patients (t=-2.11, p=0.0356) were associated with higher trauma center need. This model also showed that trauma center designation level category (Level I and IIs combined) was significantly associated with trauma care need (t=8.0, p< 0.0001). Across the entire trauma center care spectrum, staffing resources analyzed (orthopedics, neurosurgeons and trauma surgeons) did not significantly contribute to the predictability of trauma care need.

|                               | П         | Frauma centers |           | Level I and II tra | nd II trauma | uma centers | Level III a | Level III and IV trauma centers | a centers |
|-------------------------------|-----------|----------------|-----------|--------------------|--------------|-------------|-------------|---------------------------------|-----------|
|                               | number of |                | Standard  | Number of          |              | Standard    | Number of   |                                 | Standard  |
|                               | centers   | Mean           | deviation | centers            | Mean         | deviation   | centers     | Mean                            | deviation |
| Trauma center need*           | 443       | 31.7           | 13.9      | 347                | 35.3         | 12.2        | 96          | 18.6                            | 11.8      |
| Infrastructure                |           |                |           |                    |              |             |             |                                 |           |
| Total beds                    | 443       | 403.8          | 231.0     | 347                | 460.3        | 221.7       | 96          | 199.7                           | 124.1     |
| Intensive care unit beds      | 443       | 26.8           | 22.7      | 347                | 30.7         | 24.0        | 96          | 12.7                            | 7.2       |
| Trauma designation level      |           |                |           |                    |              |             |             |                                 |           |
| Level I                       | 165 (37%) | I              | I         | 165 (48%)          | ı            | I           | I           | ı                               | I         |
| Level II                      | 182 (41%) | I              | I         | 182 (52%)          | ı            | I           | I           | ı                               | I         |
| Level III                     | 74 (17%)  | I              | I         | I                  | ı            | I           | 74 (77%)    | ı                               | I         |
| Level IV                      | 22 (5%)   | ı              | ı         | ı                  | ı            | I           | 22 (23%)    | ı                               | ı         |
| Hospital type                 |           |                |           |                    |              |             |             |                                 |           |
| For profit                    | 40 (9%)   | ı              | ı         | 25 (7%)            | ·            | I           | 15 (16%)    | ı                               | ı         |
| Non profit                    | 403 (91%) | ı              | ·         | 322 (93%)          |              | I           | 81 (84%)    | ı                               | ı         |
| Patient characteristics       |           |                |           |                    |              |             |             |                                 |           |
| Percent insured               | 443       | 78.7           | 13.7      | 347                | 78.6         | 14.0        | 96          | 78.8                            | 12.5      |
| Percent transferred in        | 443       | 21.5           | 18.5      | 347                | 24.1         | 17.8        | 96          | 12.2                            | 18.0      |
| Staffing resources            |           |                |           |                    |              |             |             |                                 |           |
| Number of neurosurgeons       | 443       | 4.2            | 3.0       | 347                | 4.9          | 2.8         | 96          | 1.8                             | 2.6       |
| Number of orthopedic surgeons | 443       | 9.4            | 6.9       | 347                | 10.2         | 6.9         | 96          | 6.9                             | 6.4       |
| Number of trauma surgeons     | 443       | 5.6            | 2.7       | 347                | 6.1          | 2.4         | 96          | 3.6                             | 2.5       |

|   |                               | All trauma centers | ers  | Level I      | Level I and II trauma centers | centers    | Level III | Level III and IV trauma centers | a centers   |
|---|-------------------------------|--------------------|--|--------------|-------------------------------|------------|-----------|---------------------------------|-------------|
| 1   | f-value                       | t-value            | Probability  | f-value      | t-value                       | Probablity | f-value   | t-value                         | Probability |
| $^{\Delta}$ Trauma center need  | 19.65                         | 1                  | <0.001**   | 3.79         | ı                             | <0.001**   | 2.99      | ı                               | <0.01**     |
| Infrastructure  |                               |                    |  |              |                               |            |           |                                 |             |
| Total beds  |                               | -0.27              | 0.789  |              | -0.59                         | 0.557      |           | 1.34                            | 0.182       |
| Intensive care unit beds  |                               | 1.62               | 0.107  |              | 1.8                           | 0.073      |           | 0.74                            | 0.461       |
| Trauma designation level  |                               |                    |  |              |                               |            |           |                                 |             |
| Level I and II  |                               | 8                  | <0.0001**  |              | ı                             | ı          |           | ı                               | ı           |
| Level III and IV  |                               | ı                  | ·  |              | ı                             | ı          |           | ı                               | ı           |
| Hospital type   |                               |                    |  |              |                               |            |           |                                 |             |
| Non profit vs. for profit   |                               | -1.68              | 0.094  |              | -2.78                         | 0.0058**   | ı         | 0.64                            | 0.526       |
| Patient characteristics   |                               |                    |  |              |                               |            |           |                                 |             |
| Percent transferred in  |                               | 2.75               | 0.0061**   |              | 3.16                          | 0.0017**   |           | 1.68                            | 0.096       |
| Percent insured   |                               | -2.11              | 0.0356**   |              | -2.95                         | 0.0034**   |           | -0.03                           | 0.979       |
| Staffing resources  |                               |                    |  |              |                               |            |           |                                 |             |
| Number of neurosurgeons   |                               | 0.87               | 0.383  |              | 0.05                          | 0.962      | ı         | 1.15                            | 0.253       |
| Number of orthopedic surgeons   |                               | 0.71               | 0.477  |              | 1.1                           | 0.272      | ı         | -0.84                           | 0.401       |
| Number of trauma surgeons   |                               | 1.71               | 0.087  |              | 0                             | 0.999      | ,         | 2.02                            | 0.0464**    |
| $^{\Delta}$ Dependent variable of the models. Inference statistics for "Significant at the 0.05 probability level or lower. | erence statist<br>I or lower. | tics for Trauma    | Frauma Center Need are a summary of the entire model(s). | a summary of | the entire mo                 | del(s).    |           |                                 |             |
|   |                               |                    |  |              |                               |            |           |                                 |             |

When examining portion of critically injured patients requiring the services of a trauma center within Level I and II trauma centers only, three independent variables significantly contributed to estimating trauma care need. Nonprofit trauma centers (t = -2.78, p <0.0058) and trauma centers that had a higher percentage of transfers (t = 3.16, p <0.0017), meaning they received more patients transferred from other hospitals, were associated with a higher portion of trauma center need. These transfers were associated with greater need for trauma care. Finally, trauma centers with a lower percentage of insured patients were associated with greater need for trauma center care. (t = -2.95, p <0.0034).

The generalized linear model looking at Level III and IV trauma centers revealed that a larger proportion of patients requiring the resources of trauma center was associated with a larger number of trauma surgeons (t = 2.02, p <0.0464). This effect with not found when looking at orthopedic surgeons or neurosurgeons. This effect was not present when only looking at Level I and II trauma centers.

## DISCUSSION

In examining the data for Level I and II trauma centers, a significant predictor of trauma center need was nonprofit hospital status. This finding could be a result of a higher number of nonprofit trauma centers in the dataset, and across the U.S. Also, the characteristics of the patients in the catchment area and referral pattern of hospitals treating patients at risk for serious injuries are thought to be features more frequently associated with nonprofit trauma centers.

The percentage of transfers that a trauma center received was a clear factor in estimating the proportion of critically injured patients within a trauma center. This effect was significant in two of the three models and was marginally significant (p=0.096) when looking at Level III and IV trauma centers only. Patients are typically transferred to higher level trauma centers because those facilities offer a higher level of care through staffing, resources, and equipment that is not available at lower level trauma centers and non-trauma hospitals.

When we individually examined staffing and infrastructure, those factors were not typically found to be significantly associated with trauma center need. Thus, trauma center infrastructure and staffing levels at Level I and II trauma centers did not influence the proportion of severe trauma seen. Only within Level III and IV trauma centers was the number of trauma surgeons predictive of trauma care need.

## Staffing

Several factors may account for unexpected staffing findings at Level I and II trauma centers. First, the NTDB does not define the term "core trauma surgeon," which is used in the NTDB dictionary to identify trauma surgeons, and it is unclear how trauma centers interpret the term in their reporting. Therefore, this term may account for all general,

trauma, and critical care surgeons who may provide care at a particular facility. Complicating this definition is the fact that the ACS only requires general surgeons who meet specific criteria (board certified, clinical involvement, national and regional involvement, and education) to staff trauma centers. Support for this explanation of the findings can be found in a study where the performance of general emergency surgeons was compared to the trauma surgeons and there was no difference in mortality.<sup>27</sup> Secondly, this finding may be a reflection of the internal staffing practices and internal call rotations. Third, there is evidence that the use of "closed" ICU environments, with specialized critical care (intensivist) physicians managing patients, has had a positive impact on patient outcomes and resource utilization<sup>28,29</sup> and may impact trauma surgeon staffing patterns at facilities with a high volume of trauma. In a survey of 295 Level I and II trauma centers, Nathans, et al. found that 61% of Level I facilities and 22% of Level II facilities provided an intensivist model of critical care delivery.<sup>30</sup>

The number of neurosurgeons at a trauma center was not associated with trauma center need. This was a surprising finding. Intuitively, neurosurgeon availability should closely track with trauma center need because of the expertise necessary to treat traumatic brain injury (TBI), set forth in the established Brain Trauma Foundation guidelines.<sup>31</sup> Successful adherence to these guidelines requires immediate and continuous expertise in the management of TBI, most readily available in a Level I or II trauma center as a part of a comprehensive inclusive trauma system, where resources and staffing are an important part of the trauma center verification process.<sup>32</sup> This finding may be likely reflective of the limited number of neurosurgeons in the U.S. There are only 3,500 neurosurgeons to provide care for a population of 300 million, and closures of trauma centers have been reported to be due in part to a lack of neurosurgical coverage.33 Neurosurgeons also often provide care at multiple hospitals, perhaps further limiting the total numbers of neurosurgeons reported by any given facility. Future research using this definition of trauma care need might be useful in determining how staffing levels for neurosurgeons predict trauma care needs for traumatic brain injury.

## **Hospital Characteristics**

The lower the percentage of insured patients within a Level I or II trauma center, the higher the proportion of patients requiring trauma center resources. This may be reflective of the "safety net" role that many of our nation's trauma centers play, caring for a large number of uninsured patients. Because Level I and II trauma centers are primarily located in urban settings, these facilities receive patients where violence is widespread. It has been shown that up to 40% of the injuries treated were repeat victims of violence and most of these patients were uninsured (58%).<sup>34</sup> Additionally, inappropriate transfers to trauma centers may be impacting this finding as well. In a study of patients with orthopedic injuries transferred to Level I trauma centers, Thakur, et al. reported that 52% were inappropriate transfers, and that the majority of inappropriate transfers were uninsured.<sup>35</sup> This transfer effect was not found in Level III or IV trauma centers. Hospitals receiving a larger percentage of transferred patients also have higher proportions of patients requiring critical trauma resources. This is not surprising, as severely injured patients are typically transferred to higher levels of care for specialty expertise and for the management of complex injuries.<sup>36</sup>

Total beds and total number of ICU beds were not associated with trauma center need. One explanation of these findings is that the number of ICUs and the total number of beds within a hospital may not be solely dedicated to trauma care and are used for the treatment of non-injured patients. Another explanation is that the treatment reputation of a trauma centers may benefit from a "halo effect,"<sup>37</sup> as documented by trauma centers performing abdominal aortic aneurysm repairs in non-injured patients. The authors suggested that a trauma center has the ability to immediately mobilize both vascular and general surgeons for the patient requiring urgent operative intervention. Thus, the beneficial effects of a trauma center might extend beyond caring for the critically injured and might also enhance the trauma center reputation, which in turn may produce more transfers of critically injured patients to a specific trauma center.

Field triage decisions made by emergency medical services (EMS) personnel certainly impact the destination hospital for injured patients transported by ambulance and the critically ill are more frequently transported by ambulance. However, many injured patients are not transported by EMS resources. In 2010, there were approximately 130 million visits to EDs in the U.S. of which 16.3% were transported by ambulance.<sup>38</sup> In 2003, there were 40.2 million ED visits for injury and only 6.5 million EMS transports for injury.<sup>39</sup> A higher percentage of critically injured patients (i.e., those who require the services of a trauma center) are likely to arrive by ambulance, but many are transported to EDs by the public or other modes, such as the police,<sup>40</sup> and their hospital destination may not be influenced by field triage guidelines, local resources, or personnel of a formal EMS system. Also, the states and localities are free to modify the field triage guidelines or not follow them at all. In efforts to ensure the critically injured are transported to a trauma center, the ACS, in 1990, indicated that an acceptable rate of over triage is 50%. Good adherence to the field triage guidelines can reduce over triage. Thus, adherence to these guidelines, and the management of overtriage via ambulance transports was beyond the scope of this study.

In summary, trauma center need appears to be related to trauma center designation level, hospital type (profit vs. nonprofit), transfers, insurance status, and with the number of trauma surgeons and neurosurgeons in Level III and IV trauma centers. Staffing, bed count or ICU capacity had no significant influence on the proportion of trauma center need. Insurance status of patients and patients who are transferred may be two factors driving the need for trauma services. The results highlight the need for hospital administrators to have a thorough understanding of the patients they serve. The results also suggest that patient characteristics must be considered when deploying a trauma system within a state or region. Inclusive trauma systems help reimburse providers for the un-compensated care of uninsured trauma patients and help distribute trauma cost throughout the system. This study helps shed light on how uninsured patients disproportionately contribute to trauma center need and the importance of the accuracy of inter-facility transfer decisions in determining the proportion of patients admitted to a higher level of care.

## LIMITATIONS

The primary limitation of this study is its retrospective design, where trauma registry data with a limited set of hospital-level variables were available for analysis. Although each analysis model produced significant overall results, the portion of variance explained by the independent variables was low (29% or lower), despite the incompleteness of the NTDB. Thus, the data may not capture most of the factors that influence the portion of trauma need within a facility. Additional factors that influence trauma center need within a hospital may be geography, multiple trauma centers competing for patients and differences in field triage practices. These real world complexities would be difficult to capture in any study. This study also included mostly nonprofit Level I and II trauma centers, which may have impacted the accuracy of the volume of transfer and uninsured patients. Furthermore, using either the ACS-verified and state trauma center designations as a way to define the trauma designation level in this study introduces inconsistencies in defining a trauma center. Defining the trauma center need at the patient level involved a complex composite approach, which is not universally recognized by trauma researchers. As noted in previous trauma literature, trauma science would benefit from an established definition of "true trauma;" i.e. severe injuries requiring the resources of a trauma center, or an acceptable gold standard. We used a slightly modified version of trauma need, as established by previous researchers.<sup>24</sup> but this definition has not been validated. Finally, we were limited to the variables provided by the NTDB, providing few infrastructures, patient characteristic, and staffing variables for analysis. Information about patient populations served by a trauma center and the percentage electing to be transported to a particular center were unavailable.

## CONCLUSION

Trauma center need is more highly associated with patient characteristics (insurance or transfer status) than hospital facility characteristics. We identified that critically injured patients are often uninsured patients treated in non-profit trauma centers or transferred from lower levels of care. These results can have implications for the role of a trauma system in trauma center reimbursement for uncompensated care. This study may provide insights for hospital administrators and clinicians when planning the construction of new trauma centers or expansion/reduction in current center resources, or when adapting to changes in patient population catchment areas.

Address for Correspondence: Mark Faul, PhD, Centers for Disease Control and Prevention, 4770 Buford Highway, Atlanta, 30341 Email: mfaul@cdc.gov.

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## **Evaluation of Healthcare Use Trends of High-Risk Female Intimate Partner Violence Victims**

Robyn M. Hoelle, MD\* Marie-Carmelle Elie, MD\* Emily Weeks, MPH\* Nancy Hardt, MD<sup>†</sup> Wei Hou, MD<sup>‡</sup> Hui Yan, MS<sup>§</sup> Donna Carden, MD\*

- \*University of Florida, Department of Emergency Medicine, Gainesville, Florida <sup>†</sup>University of Florida, Family Data Center, Gainesville, Florida
- <sup>‡</sup>Stony Brook University Medical Center, Department of Preventative Medicine, Stony Brook, New York
- <sup>§</sup>University of Florida, Department of Biostatistics, Gainesville, Florida

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**Introduction:** Practitioners need more information about intimate partner violence (IPV) victims' healthcare use trends. We used a novel data-linkage method and complaint categorization allowing us to evaluate IPV victims healthcare use trends compared to the date of their victimization.

**Methods:** This was a retrospective case series using data-linking techniques cross-referencing databases of Medicaid-eligible women between the ages of 16 and 55 years, an IPV Case Database for 2007 and the Florida State Agency for Healthcare Administration, which tracks hospital inpatient, ambulatory and emergency department (ED) use within the State of Florida. We analyzed resulting healthcare visits 1.5 years before and 1.5 years after the women's reported IPV offense. Using all available claims data a 'complaint category' representing categories of presenting chief complaints was assigned to each healthcare visit. Analysis included descriptive statistics, correlation coefficients between time of offense and visits, and a logistic regression analysis.

**Results:** The 695 victims were linked with 4,344 healthcare visits in the four-year study period. The victims were young (46% in the 16-25 age group and 79% were younger than 35). Healthcare visits were in the ED (83%) rather than other healthcare sites. In the ED, IPV victims mostly had complaint categories of obstetrics and gynaecology-related visits (28.7%), infection-related visits (18.9%), and trauma-related visits (16.3%). ED use escalated approaching the victim's date of offense (r=0.59, p<0.0001) compared to use of non-ED sites of healthcare use (r=0.07,p=0.5817). ED use deescalated significantly after date of reported offense for ED visits (r=0.50,p<0.0001) versus non-ED use (r=0.00,p=0.9958). The victims' age group more likely to use the ED than any other age group was the 36-45 age group (OR 4.67, CI [3.26- 6.68]).

**Conclusion:** IPV victims use the ED increasingly approaching their date of offense. Presenting complaints were varied and did not reveal unique identifiers of IPV victims. This novel method of database matching between claims data and government records has been shown to be a valid way to evaluate healthcare utilization of at-risk populations. [West J Emerg Med. 2015;16(1):107-113.]

## **INTRODUCTION**

Intimate partner violence (IPV) occurs in two to five million intimate partner relationships in the United States each

year.<sup>1,2</sup> Healthcare use and costs are high during and after the abuse.<sup>3,4</sup> Several studies demonstrate that women experiencing IPV are more likely to use the emergency department (ED)

and hospital resources.<sup>5-9</sup> In one study, 18% percent of the victims in EDs reported seeking medical attention because of the abuse.<sup>10</sup> Frequently, female IPV victims present with a broad range of healthcare complaints rather than abuse-related traumatic injuries.<sup>11-13</sup> While IPV victims are likely to receive routine healthcare, they are also more likely to have been treated for an injury compared to other women.<sup>10</sup> IPV victim advocates consider these healthcare encounters valuable opportunities to identify and potentially intervene on behalf of the victim.

The practice of universal IPV screening during clinical encounters, however, remains controversial due to the extensive resources required to implement successful IPV screening tools and intervention programs. Such implementation is especially challenging in busy clinical environments such as the ED.<sup>1,14</sup> To create and sustain resourceful and cost-efficient programs, guidance is needed regarding the healthcare use practices of IPV victims including locations and types of treatments sought. Providers can assist in identifying IPV victims through recognition of use patterns or avoid under-diagnosis by relying on nonevidenced based methods. Further analysis of the timing of the index assault in the context of a clinical encounter may also provide important guidance regarding when healthcare providers have the greatest opportunity to intervene.

The methodology used to generate contemporary reports of IPV epidemiology are limited and can suffer from bias. Investigations are frequently based on a single healthcare encounter, rely on victim self-report, or legal convictions used in victim identification.<sup>15-17</sup> Factors such as the presentation of IPV victims to multiple healthcare facilities, the reluctance of victims to report abuse and the low ratio of abuse to legal conviction rate confound the accurate characterization of IPV and the rate of victim healthcare use. Despite these shortcomings, several studies have identified that women classified as receiving public assistance or in a lower socioeconomic group have a high prevalence of IPV.<sup>18,19</sup> The study population of Medicaid-eligible women are classified in lower socioeconomic groups in Florida and provided an accessible database for necessary cross-referencing. The healthcare use patterns of these women can be longitudinally tracked through administrative data. Further, the Florida State Attorney's Office of Victim Witness Services maintains a database of IPV victims obtained through sworn complaints, sexual assaults, arrests and IPV homicides within a six-county area. This database of IPV victims is much broader than those requiring legal conviction.

Visit-level information related to healthcare encounters with IPV victims is rarely reported: a critical factor in enhancing the recognition of IPV patients by advocates and healthcare providers. While analysis of diagnoses and population characteristics is important for recognizing healthcare use patterns, visit-level complaint data can assist physicians in recognition of IPV victims prior to final diagnosis. This study uses a complaint category-based assessment of IPV victims' visits to provide a more relevant evaluation of their presentation patterns to healthcare providers. Knowing presentation patterns of IPV victims can help emergency physicians with pattern recognition of victims, as well as dispel myths about IPV victims. The objective was to characterize healthcare use patterns in female IPV victims who were Medicaid-eligible and between the ages of 16 and 55 identified by the Office of Victim Witness Services in the Florida State's Attorney's Office (SAO), Eighth Judicial Court using database-linking methods.

## METHODS

## **Study Design**

We conducted a retrospective case series using datalinking techniques, cross-referencing databases of the Florida State Attorney's Office (SAO) of Victim Witness Services 2009 IPV victim database, Medicaid-eligible women between the ages of 16 and 55 years, and the Florida State Agency for Healthcare Administration, which tracks hospital inpatient, hospital-based ambulatory, and ED use within Florida. The local institutional review committee approved this study.

## **Study Setting and Population**

Our cohort included Medicaid-eligible female IPV victims identified through the State of Florida Attorney's Office of Victim Services in northern Florida including a six-county area. The women in our cohort were females in the SAO's adult IPV incident database whose IPV offense occurred between January 1, 2007 and December 31, 2007, and were between 16 and 55 years old. Victims included in the database were identified by law enforcement officers or victim advocates. Responding officers or victim advocates evaluated daily "offenses": sworn complaints, sexual assaults, arrests and IPV-related homicides. "Sworn complaints" are calls police officers receive by victims or bystanders that warrant a visit. For example, if a neighbor calls that he hears yelling next door, and the police investigate and determine the situation to be IPVrelated, this incident will be reported as an IPV-related sworn complaint, and added to the SAO's IPV database. Each law enforcement interaction, within the six counties of the Eighth Circuit Court, that the responding officer or victim advocate suspects to be IPV-related, are submitted to the SAO Office of Victim Services. The SAO reviews all reports and deems the events to be IPV-related or not. Seeking out these officer- or advocate-identified incidents ensured a variety of types of IPV and severities of IPVrelated victimization were included in the study rather than relying on higher-level court-determined incidents to validate IPV events. This created an inclusive population of the confirmed IPV victims recognized in this six-county region to study.

## **Study Protocol**

This cohort of confirmed IPV victims were linked to their healthcare visits within the state of Florida through the state's Agency for Healthcare Administration (AHCA) database records 1.5 years before and up to 1.5 years after the IPV victim's first IPV incident (index event). Researchers used a third-party data management group which received the list of victims from the SAO and cross-linked the victim identifiers to government databases. Their techniques involved a software program matching IPV victims to Medicaid-eligible women by first name, last name, and date of birth. The Social Security number from this cohort of women was then used to query the AHCA claims database. De-identified data was then delivered to the researchers by assigning each victim a unique identifier. These linkages resulted in robust claims data for each of the linked IPV victims.

The database includes financial, procedural and diagnostic data for all inpatient stays, ED visits, inpatient psychiatric visits, rehabilitations stays, and hospital-based ambulatory care medical records throughout the state. Each unique visit identified (most victims had several visits) was assigned a complaint category in order to evaluate trends in the women's presenting complaints over time. To assign this complaint category, researchers reviewed the claims data for each visit including patient diagnostic codes, reason for admission codes, reason for injury codes, and procedure codes. Category assignments included trauma, infectious, obstetric, gynecologic, dental, ophthalmologic, hematologic, endocrine, cancer, psychiatric, pulmonary, cardiac, gastroenterologic, neurologic, drugs/intoxication, orthopedic, dermatologic, and ears/nose/throat. We categorized all reproductive-related complaints as obstetricor gynecologic-related, including genital infections, instead of including these visits in the infectious category. Acute infectious complaints such as pneumonia, pharyngitis, or cellulitis were categorized to the infection-related complaints. For example, a visit with codes indicating vaginal bleeding would be categorized as a gynecologyrelated visit, and a visit with a diagnostic code indicating retinal tear would be categorized as an ophthalmologyrelated visit, while a visit indicating orbital cellulitis would be categorized under infectious. We constructed these categories to closer represent presenting complaints categories of ED patients to help identify trends in the undifferentiated patient as opposed to relying on the final diagnostic code evaluation. By tracking these complaint categories we hope to establish whether IPV victims present with complaints of one type prior to their date of offense more often than other complaints regardless of their traditional association with IPV.

## **Outcome Measures**

Outcome measures included healthcare use patterns. These specific variables included date of visit, site of visit, and reason for healthcare resource use, including complaint category of visit compared to date of offense.

## Data Analysis

We performed descriptive analysis for all variables, and median and IQR were reported for quantitative measures. We classified date of healthcare visit in relation to the date of reported offense, by number of weeks prior to or after the occurrence. This allowed for comparison of overall trends in healthcare use across the cohort of patients. Researchers compared dates of healthcare visits to the time of offense by calculating correlation coefficients to compare time interval and type of visits to the date of offense. We performed a logistic regression analysis comparing victims who used the ED versus victims who used other healthcare sites. Data was analyzed using SAS version 9.4 (Cary, NC), and a p-value less than 0.05 was considered significant.

## RESULTS

## **Descriptive Data**

There were 695 separate IPV offenses identifying 695 unique IPV victims within the six-county area, aged 16-55 years old, identified as victims of IPV by the State of Florida Attorney's Office in 2007. The cohort of 695 Medicaid-eligible IPV victims resulted in a total of 4,344 statewide healthcare visits found in 1.5 years before and after each victim's identifying offense. The median number of healthcare visits per victim was four (IQR=6), and the median number of ED visits per victim was three (IQR=5). However, there was great variability among victims as indicated by the IQR. The number of healthcare visits per IPV victim ranged from one visit to 98 visits. Fifty-three percent of the visits were before the date of the victim's offense versus 47% after the date of the victim's offense. Many victims fell into the 16-25 year old age group (46% of the victims), indicating a relatively young study population. Overall, 79% of the victims were 35 years old or younger at the time of the healthcare use. Most victims were Caucasian (52%) or African American (46%), reflecting the population of the study state.

Eighty-three percent of the total 4,344 healthcare visits by IPV victims occurred in the ED. Considering all healthcare visits, the most common complaint categories were obstetric-gynecology-related visits (28.7%), followed by infection-related visits (18.9%), and trauma-related visits (16.3%). Among only ED healthcare visits, the most common complaint categories of IPV victims were infection (22.4%), trauma (19.4%), and obstetric-gynecologic (18.8%).

## **Correlations Data**

Overall healthcare use by victims escalated approaching their individual dates of reported offenses, with a moderately

positive linear correlation (r=0.46, p<0.0001). ED visits also demonstrated a strongly strong positive linear correlation of escalating visits approaching the date of reported offense (r=0.50, p<0.0001) compared to non-ED healthcare visits (r=0.00, p=0.9958). Both total healthcare visits (r=-0.54, p<0.0001), and ED visits (r=-0.59, p<0.0001) demonstrated a strong linear correlation with declining visits after the date of reported offense compared to non-ED healthcare visits (r=-0.07, p=0.5817) (Figure 1-3).

Among all healthcare visits, those with the assigned complaint category of orthopedic (r=0.28, p=0.0266) and trauma (r=0.34, p=0.0024) had positive weak correlations with increasing number of visits up to the date of reported offense. Complaint categories with a weak correlation of declining visits following the day of the reported offense include trauma (r=-0.31, p=0.0060) and infection (r=0.38, p=0.0008) (Figure 4). While individuals within some of the smaller groups of complaints, like hematologic and endocrine, had significantly increasing visits up to or after date of offense, cohorts lacked power to report as an overall healthcare trend.

Psychiatric complaint category-related visits before (r=0.10, p=0.5347) and after (r=0.06, p=0.7202) date of reported offense, were not correlated with the time of reported IPV offenses. None of the other complaint categories had significant correlations to or from the time of reported offense.

#### **Logistic Regression Data**

We compared victims who used the ED to victims who chose non-ED healthcare settings. Victims were 40% more likely to use ED healthcare settings after the date of reported offense versus before, with an OR of 1.41 (95% CI [1.20-1.66], p<0.0001). The age group more likely to use the ED versus non-ED healthcare settings was the 36-45 age group compared to the youngest group of women (OR 4.67, CI [3.26- 6.68]). There were no significant differences between races in presenting in the ED versus non-ED healthcare settings.

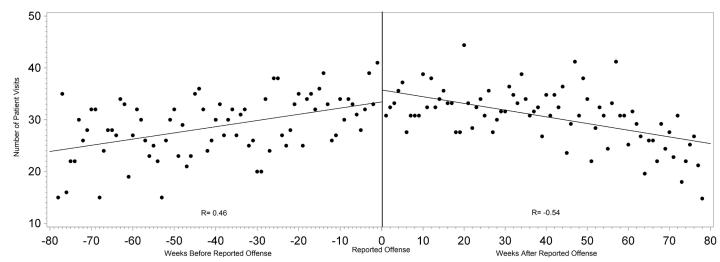
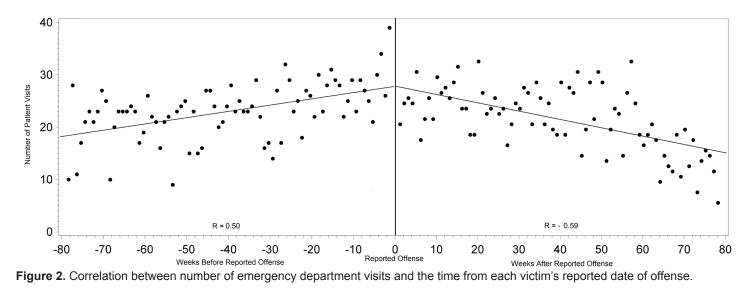


Figure 1. Correlation between number of all healthcare visits and the time from each intimate partner victim's reported date of offense.



Western Journal of Emergency Medicine

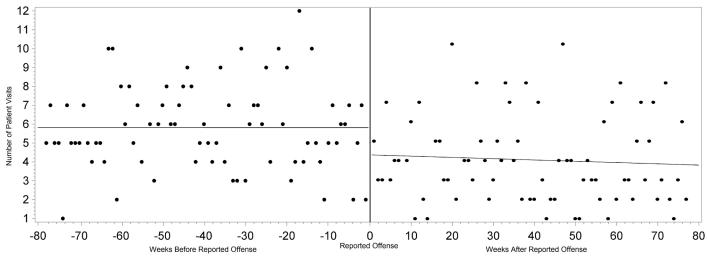


Figure 3. Correlation between number of non-emergency department visits and the time from each victim's reported date of offense.

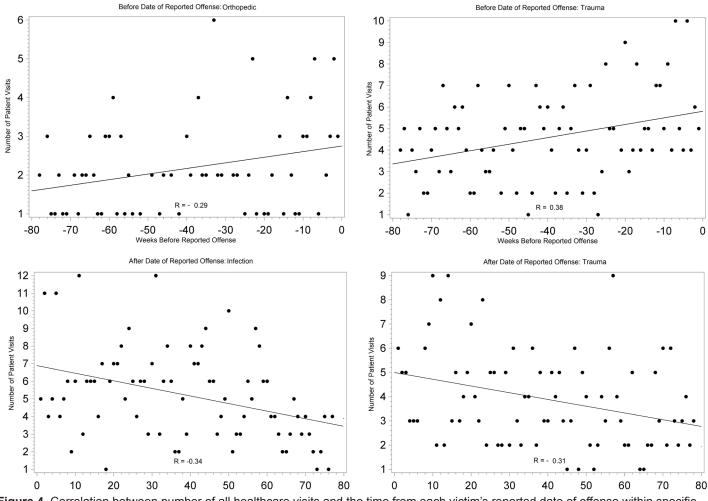


Figure 4. Correlation between number of all healthcare visits and the time from each victim's reported date of offense within specific complaint categories.

## DISCUSSION

This study offers healthcare providers insight into the healthcare use of IPV victims through an expanded analysis of a unique inclusive cohort of IPV victims' healthcare use. Most studies are limited to retrospective reviews of court-identified or self reports of victims and small local populations.<sup>15,16,20,21</sup> The first way this study is unique is that our data represent statewide-claims data capturing

statewide healthcare use by the confirmed IPV victims in the six-county area. Secondly, the cohort is distinct, including victims identified through sworn complaints, which is a call to the police or any police-reported IPV, and includes identification of IPV-related events prior to more severe occurrences (ie. arrest or fatality). One prior study (n=3,333), focusing on population-based healthcare use of IPV victims versus non-IPV victims, queried a large health-insured population in the northwest. The population of women studied was older and had private insurance, but researchers found women who reported IPV had 2.18 times the risk of using the ED compared to women who did not report IPV.<sup>3</sup> The cohort interestingly had increased mental healthcare use, where our cohort did not demonstrate correlation of mental health complaints and increased healthcare use related to the reported offense. The conflicting results may reflect differing populations and demonstrates greater need for a populationwide prospective study characterizing types of healthcare use by IPV victims.

The third way in which our analysis is unique is the assignment of the complaint category to each visit. Assessing victims by complaint category can lead to more clinically relevant analysis when trying to identify trends in patient presentations, compared to use of discharge diagnoses. The unique data-linkage methods used here paired state law enforcement data to healthcare use and resulted in robust claims data for analysis.

While victims used healthcare services frequently up to the date of the index offense and after, there was no single complaint category that successfully identified a majority of the victims. Ascending numbers of visits up to the date of IPV-related events is supported by a three-year county-wide study.<sup>18</sup> Healthcare providers may have increasing number of interactions to recognize and intervene for a victim prior to date of reported offense, but focused screening efforts cannot be supported with current research. Our paper shows that victims also came into contact with healthcare providers after IPV-related events, presenting with a myriad of complaints giving providers opportunities to identify victims. The findings in this study expand understanding of reasons victims seek medical care in the ED by demonstrating that together, obstetric-gynecologic related and infectious-related complaints represent almost half of the IPV victims' complaints. Supporting other studies, this is evidence that non-trauma related presentations are more common than trauma- related presentations for IPV victims and suggests complaints to incorporate into IPV screening strategies.<sup>17,21</sup> These visit patterns are key to understanding opportunities to identify IPV victims. While providers cannot focus screening strategies at this time to a specific presenting complaint, data suggest that clinicians have increasing contact with victims prior to their victimization and just after. Providers may consider adopting more in-depth

screening practices for patients presenting with obstetricgynecologic complaints. In the future, a prospective study characterizing complaints by category of IPV victims on presentation and comparing them to the non-IPV victims' presentations could help providers recognize patterns to assist in identifying IPV victims.

## LIMITATIONS

Like most research using claims data, conclusions about the diagnostic categories and reasons for visits are limited to the researchers' interpretation of and the strength of claims data. Retrospective data analysis also limited validity of results due to lack of control of confounding variables. The study also would have been able to make stronger conclusions about overall healthcare use had the claims data included primary care and private outpatient visits. The initial date of reported victimization in 2007 was chosen as the index offense, and it is possible that IPV occurred in prior years or after the index event in the same year. We did not analyze healthcare use trends associated with prior or repeat offenses, and this could have led to repeated measure bias. While Medicaid patients comprise an appropriate cohort for study, a larger study population across all socioeconomic categories would have strengthened external validity. Women who would not normally qualify for Medicaid can enroll when pregnant. This special population may have increased healthcare use associated with obstetric-gynecologic complaints.

## CONCLUSION

Female Medicaid-eligible IPV victims use the ED with increasing frequency as the date of the IPV abuse approaches. The women's presenting complaints varied and did not reveal unique presenting complaints that would allow narrowing screening practices. Frequent ED use in women between the ages of 16-55 years of age should prompt healthcare providers to consider IPV.

The successful cross-referencing of administrative and legal databases suggests this is a feasible methodology in investigating other use trends surrounding other types of victimization or criminal behavior. Identifying use patterns for child abuse victims, driving under the influence offenders or suicide victims may further assist practitioners on identifying at-risk patients.

*Address for Correspondence*: Robyn M. Hoelle, MD, c/o Research Group, 1329 SW 16th Street, Gainesville, FL 32610. Email: robyn. hoelle@gmail.com.

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## Low-Cost Alternative External Rotation Shoulder Brace and Review of Treatment in Acute Shoulder Dislocations

Kyle Lacy, MD, MS\* Chris Cooke, MD\* Pat Cooke, BA\* Justin Schupbach, BS<sup>†</sup> Rahul Vaidya, MD\* \*Detroit Medical Center, Department of Orthopaedic Surgery, Detroit, Michigan †Wayne State University, Detroit Medical Center, Detroit, Michigan

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Traumatic dislocations of the shoulder commonly present to emergency departments (EDs). Immediate closed reduction of both anterior and posterior glenohumeral dislocations is recommended and is frequently performed in the ED. Recurrence of dislocation is common, as anteroinferior labral tears (Bankart lesions) are present in many anterior shoulder dislocations.<sup>14,15,18,23</sup> Immobilization of the shoulder following closed reduction is therefore recommended; previous studies support the use of immobilization with the shoulder in a position of external rotation, for both anterior and posterior shoulder dislocations.7-11,19 In this study, we present a technique for assembling a low-cost external rotation shoulder brace using materials found in most hospitals: cotton roll, stockinette, and shoulder immobilizers. This brace is particularly suited for the uninsured patient, who lacks the financial resources to pay for a pre-fabricated brace out of pocket. We also performed a cost analysis for our low-cost external rotation shoulder brace, and a cost comparison with pre-fabricated brand name braces. At our institution, the total materials cost for our brace was \$19.15. The cost of a pre-fabricated shoulder brace at our institution is \$150 with markup, which is reimbursed on average at \$50.40 according to our hospital billing data. The lowcost external rotation shoulder brace is therefore a more affordable option for the uninsured patient presenting with acute shoulder dislocation. [West J Emerg Med. 2015;16(1):114-120.]

## **INTRODUCTION**

The acute traumatic shoulder dislocation is a frequent reason for presentation to emergency departments (EDs). Anterior dislocations compose up to 96% of all shoulder dislocations, and often result from excessive external rotation with the shoulder in a position of abduction and external rotation.<sup>13,25</sup> Posterior dislocations are less frequent, and may result from an excessive traumatic posterior force with the shoulder in internal rotation, flexion, and adduction.<sup>19</sup> Injury mechanisms for posterior shoulder dislocation include motor vehicle collision, fall, seizure, electrocution, and sportsrelated injury.<sup>1,19</sup> Immediate closed reduction of all shoulder dislocations is recommended, and is often performed in the ED. Anteroinferior labral tears (Bankart lesions) are present in many anterior shoulder dislocations, and contribute to instability and recurrent dislocation.<sup>14,15,18,23</sup> The presence of a large Hill-Sachs defect or reverse Hill-Sachs defect (>1.5cm<sup>3</sup>) also correlates with recurrent dislocation.<sup>19</sup> Age, sex, and athletic activity also contribute to recurrence, with higher rates of recurrent dislocation and need for surgical stabilization seen in younger patients, athletes, and male patient groups.<sup>3,4,14,15,18,22,23</sup> In acute traumatic shoulder dislocation, instability is seen in 19-67%, recurrence of dislocation in 15-57%, and immediate immobilization is therefore recommended.<sup>4,12,15,18</sup>

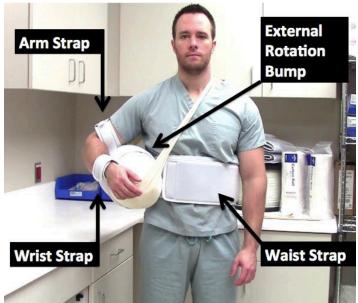
Over time, recurrent shoulder dislocations lead to higher rates of arthropathy.<sup>3,5</sup> Physical therapy after a period of immobilization is recommended, though motion restriction bands designed to avoid stretching the anteroinferior capsule have not been shown to reduce recurrence.<sup>11,22</sup>

Posterior dislocations are immobilized in external rotation or a "gunslinger" position of neutral rotation, abduction, and slight flexion.<sup>19</sup> The position of immobilization for anterior shoulder dislocations is somewhat controversial. External rotation tightens the anterior capsule and subscapularis tendon, which pull the medially displaced labroligamentous complex from the glenoid neck back up onto the rim; cadaveric studies have verified this coaptation effect as well as increased glenohumeral contact force with external rotation.<sup>7,16</sup> Magnetic resonance imaging studies of patients with anterior dislocations have confirmed this coaptation effect on the torn anteroinferior labrum, as well as a reduction in anterior capsule volume with external rotation.<sup>8,12,20,21,23</sup> Itoi et al., in a randomized controlled trial of 40 patients (average age of 37 years) with anterior shoulder dislocation, showed a recurrence rate of 30% with conventional internal rotation immobilization, and zero dislocations with external rotation immobilization.9 A second study of 198 patients randomized for three weeks of immobilization in either internal or external rotation, showed a recurrent dislocation relative risk reduction of 38.2% in favor of external rotation.<sup>10</sup> In a study of 33 patients with acute primary anterior dislocation comparing external and internal rotation immobilization, Taskoparan, et. al., found lower rates of recurrent dislocation with external rotation, which were significant in the 21-30 year age group.<sup>24</sup> However, larger randomized controlled trials, as well as meta-analyses comparing external and internal rotation immobilization for acute traumatic shoulder dislocation, have not shown a statistically significant difference in regards to recurrence of dislocation.<sup>2,15,17,26,27</sup> Although controversial, an external rotation shoulder brace can be used for both anterior and posterior shoulder dislocations.

At our institution, many of our patients lack medical insurance, or the financial resources necessary to pay for a prefabricated external rotation shoulder brace. Expensive shoulder braces are therefore not an option for many of our patients. This impetus has led us to develop a low-cost alternative shoulder immobilizer brace, using materials found in most hospitals. The following is a technique guide for assembling a low-cost alternative external rotation shoulder brace.

## TECHNIQUE

The low-cost external rotation shoulder brace consists of four components: the waist strap, the arm strap, the wrist strap, and the external rotation bump (Figure 1, Video). Materials for the external rotation shoulder brace include: two 14" practical cotton rolls, four feet of 4" stockinette roll (Figure 2), two standard shoulder immobilizer sets. To make the external rotation bump, the two 14" cotton rolls are rolled together into one thicker roll. The 4" stockinette is then rolled in on itself in a cuff-like fashion, leaving roughly two feet free of the cuff (Figure 3). An end of the cotton roll is then stuffed into the cuffed opening of



**Figure 1.** The assembled low-cost external rotation shoulder brace. The four components consist of the waist strap, the arm strap, the wrist strap, and the external rotation bump.

the stockinette, for a snug fit. The stockinette cuff is then rolled over the cotton roll, engulfing it entirely (Figure 4). A waist strap from the first shoulder immobilizer set is then cut to size, wrapped around the cotton-stuffed stockinette, and fastened. This serves as the external rotation bump (Figure 5). The cotton within the bump can be molded with compression over the posterior aspect, so as to create the desired degree of external rotation.

The waist strap from the shoulder immobilizer (Figure 6) is then fitted around the patient's waist and fastened. The arm strap is placed around the patient's arm, while the slightly shorter wrist strap (Figure 7) is placed around the patient's wrist; both are fastened. The fasteners of these straps then adhere to the foam exterior of the external rotation bump, thus supporting the arm. The free stockinette ends of the external rotation bump are then tied around the patient's neck. The external rotation bump can be further molded, to an ideal shoulder position of 10 degrees of external rotation, and 20 degrees of abduction (Figure 8).

We obtained itemized materials cost information for the low-cost brace from our hospital's operative room billing data. Additionally, the cost of a pre-fabricated external rotation shoulder brace at our institution was also obtained; this included our institutional mark-up as well as the average payer reimbursement for the pre-fabricated brace. These numbers represent the price our institution pays to the supplier, and therefore accounts for cost discounts attributed to economies of scale, as these materials are purchased in bulk. We obtained the prices for eight different brand-name prefabricated external rotation shoulder braces through a simple search on Amazon.com using the criteria "external rotation shoulder brace."



Figure 2. Two 14-inch cotton rolls and 4 feet of 4 inch stockinette are prepared.



Figure 3. The stockinette is cuffed, to allow for insertion of the cotton roll.

## RESULTS

Material costs for the supplies needed to construct an external rotation shoulder immobilizer are listed in Table 1. The total material cost for our external rotation shoulder brace = 2 standard shoulder immobilizers (\$10.58) + stockinette 4" x 4' (\$2.21) + 2 practical cotton rolls (\$6.36) = \$19.15. Our hospital is contracted with DJO Global (Vista, CA) for the Donjoy® Ultrasling<sup>TM</sup> shoulder braces; price for the braces with mark-up included at our institution was \$150 per brace; Medicare reimbursement for each brace was quoted at \$50.40, as only roughly one-third of the total cost is reimbursed to the hospital. The listed prices on Amazon.com of eight different brand-name prefabricated external rotation shoulder braces are listed in Table 2. Throughout this search, we did not find a prefabricated external rotation shoulder brace whose listed price was lower than the total materials cost of our brace. In comparison, the average Internet-listed price for a

prefabricated shoulder brace was 4.6 times that of the total materials cost of our brace.

## DISCUSSION

The low-cost alternative external rotation shoulder brace is useful for the acute immobilization of the reduced anterior or posterior shoulder dislocation. This low-cost brace can be easily assembled in the ED using materials commonly found in most hospitals. An advantage to this brace is that assembly only takes a few minutes, and can be performed by on-call residents or attending physicians at any hour of the day. The brace therefore does not require the assistance of an orthotics vendor or technician for fitting and sizing, which is also an advantage. At our institution, the orthopaedic surgery resident on-call fits the brace, and therefore this creates no additional cost. In the event that an uninsured patient cannot afford to pay for a shoulder brace out of pocket, our hospital then absorbs the cost. Therefore, the brace offers the potential for cost savings to both the patients and the hospital.

Anterior dislocations are commonly associated with anteroinferior labral tears (Bankart lesions), which often displace medially onto the glenoid neck. The resultant loss of the bumper effect created by the anteroinferior labrum leads to recurrent instability (subluxation or dislocation) of the humeral head off the anterior glenoid. In both cadaveric and human studies, a position of shoulder external rotation has been shown to have a "coaptation effect" on the anteroinferior labral tear. Tension of the subscapularis and anterior capsule in external rotation reduces the capsular volume, and mobilizes the displaced anteroinferior labral tear off the medial glenoid neck, thus reducing it back up onto the anterior glenoid rim.<sup>7,8,12,16,20,21,23</sup> Randomized clinical outcomes studies have shown reduced rates of recurrent shoulder dislocation after immobilization in external



Figure 4. The cotton roll is inserted into the stockinette.



**Figure 5.** A waist strap is wrapped around the bump and fastened, completing the external rotation bump.

rotation.<sup>9,10,24</sup> However, larger randomized controlled trials and meta-analyses comparing positions of internal and external rotation for shoulder immobilization following reduction after shoulder dislocation have shown no difference in rates of dislocation recurrence.<sup>2,15,17,26,27</sup> Although a controversial topic, immobilization of the shoulder in a position of external



Figure 6. The waist strap.

rotation is a safe and effective treatment option for both anterior and posterior shoulder dislocations.

## LIMITATIONS

We did not compare the clinical efficacy of our brace with that of the brand-name prefabricated external rotation shoulder



Figure 7. The arm strap and the slightly smaller wrist strap.



Figure 8. The ideal shoulder immobilization position of 10 degrees of external rotation and 20 degrees of abduction.

**Table 1.** Itemized materials cost for the low-cost external rotation shoulder brace.

| Item                                | Cost    |
|-------------------------------------|---------|
| 2 Shoulder immobilizers             | \$10.58 |
| Stockinette 4"x4'                   | \$2.21  |
| 2 Cotton rolls                      | \$6.36  |
| Total shoulder brace materials cost | \$19.15 |

braces. Rates of recurrence of shoulder dislocation with the use of this low-cost brace were not assessed, nor was the comparative durability of our brace assessed. Additionally, we did not assess ease of use and patient satisfaction with our brace. The listed materials cost of our low-cost external rotation shoulder brace is only directly applicable to our institution (Detroit Receiving Hospital); the materials cost may differ among hospitals due to differences in patient volume and economies of scale. In spite of these limitations, for uninsured patients at our institution who cannot afford to pay for a brace out-of-pocket, this low-cost alternative brace is often the preferred option.

## CONCLUSION

For the self-pay patient without adequate funds to pay for a shoulder brace out of pocket, our low-cost external rotation brace is a useful alternative. The external rotation brace can be fitted to create the desired degree of abduction and external rotation. The brace can be easily assembled using materials found in most hospitals, and can assist in the immobilization of patients with acute anterior and posterior shoulder dislocations at a fraction of the cost.

## ACKNOWLEDGMENTS

John Bauer – Detroit Receiving Hospital, OR Supply Manager.

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|---------------------|----------------|-----------------|---------------------|-------------------|
| Table 2. Itemized r | naterials cost | for the low-cos | t external rotatioi | n shoulder brace. |

| Item   | Cost     | Source                       |
|--|----------|------------------------------|
| Donjoy® Ultrasling™ DRH Cost                     | \$50.40  | Detroit Receiving or Billing |
| Donjoy® Ultrasling™ with Markup                  | \$150.00 |                              |
| Breg® Neutral Wedge Shoulder Brace               | \$136.99 | Amazon.com                   |
| Donjoy® Ultrasling™ III ER 30in                  | \$89.00  |                              |
| Donjoy® Ultrasling™ II                           | \$75.00  |                              |
| Donjoy® Ultrasling™ III X-Large                  | \$114.99 |                              |
| Corflex® Shoulder Abduction Pillow Sling         | \$69.99  |                              |
| Corflex® ER Shoulder Abduction Pillow with Sling | \$79.99  |                              |
| Maxar® AS-300™ Super Arm Sling                   | \$104.75 |                              |
| AlphaBrace® Shoulder Immobilizer and Sling       | \$35.65  |                              |
| Average shoulder brace price                     | \$88.30  |                              |

Address for Correspondence: Kyle Lacy, MD, MS, Orthopaedic Surgery Offices, UHC -4G, Detroit Receiving Hospital, 4201 St. Antoine St, Detroit, MI 48067. Email: kylelacymd@gmail.com.

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**Video.** Low-cost alternative external rotation shoulder brace assembly technique guide.

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# **Objective Structured Clinical Examinations Provide Valid Clinical Skills Assessment in Emergency Medicine Education**

Joshua Wallenstein, MD Emory University, Dep Douglas Ander, MD

Emory University, Department of Emergency Medicine, Atlanta, Georgia

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**Introduction:** Evaluation of emergency medicine (EM) learners based on observed performance in the emergency department (ED) is limited by factors such as reproducibility and patient safety. EM educators depend on standardized and reproducible assessments such as the objective structured clinical examination (OSCE). The validity of the OSCE as an evaluation tool in EM education has not been previously studied. The objective was to assess the validity of a novel management-focused OSCE as an evaluation instrument in EM education through demonstration of performance correlation with established assessment methods and case item analysis.

**Methods:** We conducted a prospective cohort study of fourth-year medical students enrolled in a required EM clerkship. Students enrolled in the clerkship completed a five-station EM OSCE. We used Pearson's coefficient to correlate OSCE performance with performance in the ED based on completed faculty evaluations. Indices of difficulty and discrimination were computed for each scoring item.

**Results:** We found a moderate and statistically-significant correlation between OSCE score and ED performance score [r(239) = 0.40, p<0.001]. Of the 34 OSCE testing items the mean index of difficulty was 63.0 (SD =23.0) and the mean index of discrimination was 0.52 (SD =0.21).

**Conclusion:** Student performance on the OSCE correlated with their observed performance in the ED, and indices of difficulty and differentiation demonstrated alignment with published best-practice testing standards. This evidence, along with other attributes of the OSCE, attest to its validity. Our OSCE can be further improved by modifying testing items that performed poorly and by examining and maximizing the inter-rater reliability of our evaluation instrument. [West J Emerg Med. 2015;16(1):121–126.]

## **INTRODUCTION**

The unpredictable nature of emergency department (ED) patient encounters limits the standardization of EDbased clinical evaluation, particularly when that evaluation is focused upon defined tasks and competencies, or when it must be completed within a short time period. Emergency medicine (EM) educators typically must perform both comparative assessments of multiple learners as well as progressive evaluation of individual learners. Reproducibility of clinical scenarios and encounters enhances the objectivity of such evaluations. This, however, can be a challenge given the random nature of ED encounters, particularly when the time period for assessment is relatively brief. The provision of safe and high-quality patient care further limits the ability to assess decision-making among novice learners in highrisk situations. To overcome these challenges, EM educators have increasingly turned to additional methods of clinical evaluation that are reproducible, non-threatening to patient safety, and provide standardized assessment of defined skills in specific encounter types. As with all forms of assessment in medical education, these methods must demonstrate evidence of validity to be interpreted in a meaningful manner. Patient simulation has emerged as one such tool that can evaluate performance in specific encounters and competencies in multiple learners over an extended time period. While the term simulation generally is used in reference to highfidelity mannequins, the "human" model of simulation obtained through the use of standardized patients (SPs) has emerged as a standard of assessment in undergraduate and graduate medical education. The objective structured clinical examination (OSCE) first introduced in 1975<sup>1</sup> has become a staple of competency evaluation in medical education<sup>2</sup> and is also a component of the U.S. medical licensure process. The newly-released EM milestones, part of the Accreditation Council of Graduate Medical Education's (ACGME) New Accreditation System (NAS), lists the OSCE as a suggested evaluation method in multiple performance areas.<sup>3</sup>

The OSCE and high-fidelity simulation share much in common. They are both able to recreate specific patient-care scenarios for multiple learners and evaluate specific competencies among those learners. They are both reproducible, allowing for standardized evaluation of multiple groups of learners, and for evaluating performance over time in individual learners. While high-fidelity simulation has the added capabilities of simulating and modifying abnormal physical exam findings, the OSCE is superior in evaluating diagnostic skills, such as the history and physical, and in evaluating communication and interpersonal skills. A growing body of literature supports the use of OSCEs and SPs in EM education. EM-based OSCEs have been used to evaluate a diverse range of skills, including advanced communication tasks such as death disclosure<sup>4</sup> and intimate partner violence counseling.<sup>5</sup> OSCEs have also been used in EM to evaluate educational interventions by comparing learner performance in intervention and control groups<sup>6</sup> and to predict future trainee performance among post-graduate trainees.<sup>7</sup>

In 2007 we developed a management-focused OSCE as a tool for clinical assessment of students in our required fourthyear EM clerkship. One of the limitations of the traditional OSCE format is that it is not particularly well suited for evaluating patient management skills or clinical decisionmaking, both of which are core learning objectives of our clerkship. To better evaluate the acquisition of these skills we made a substantive change to the traditional OSCE format that can best be described as a blending of the traditional SP encounter and the interactive "role-play" style of patientmanagement typified by the American Board of Emergency Medicine (ABEM) oral certification examination. In our OSCE students interact not only with an SP, but also with a case facilitator who through role-play portrays multiple individuals (patient, family member, resident nurse, consulting physician), and provides additional data (vital sign changes, laboratory and radiographic test results) based on studentinitiated management steps. The case facilitator additionally evaluates student performance using a standardized evaluation instrument. SPs and facilitators receive both formal initial training and ongoing evaluation and feedback to maximize the

standardization of patient portrayal and student evaluation.

While multiple studies have demonstrated the validity of the OSCE as an assessment method, it has been suggested that the validity of a particular OSCE depends on the *application* of the test, including its accuracy of reflection, scoring measures, and characteristics of the participating subjects.<sup>8</sup> In that regard, it is important to determine if our unique and non-traditional OSCE format is indeed a valid assessment of clinical skills in EM trainees.

A key component of a test's validity is evidence of correlation with other established evaluation methods. In both undergraduate and graduate EM training the most established clinical evaluation method is the ED performance evaluation completed by supervising faculty based on a subject's clinical performance over the course of one or more ED shifts. We hypothesized that student performance on our EM OSCE would correlate with their clinical performance in the ED, as determined by the cumulative evaluation of all "end-of-shift" evaluations completed by faculty and residents. An additional source of a test's validity is the characteristics of its individual components or items, particularly the indices of difficulty and discrimination. These indices are valuable measures of the "usefulness" of individual testing items in differentiating high and low performers. We further hypothesized that our OSCE test-item analysis would demonstrate adherence to published best-practice guidelines for these measures.

## **METHODS**

This was a prospective cohort study. We submitted the study to our local institutional review committee, which determined that it met criteria for exemption of further review.

Our study population was comprised of medical students in our institution's required EM clerkship between September 2009 and February 2011. The OSCE was administered in simulated exam rooms at our institution's Clinical Skills Center. Clinical evaluation during the clerkship took place at up to five of our affiliated hospitals, which include a tertiary care referral center, an urban county hospital, a mixed academic/community hospital, and two pediatric centers.

An EM clerkship OSCE program was developed under the leadership of the EM clerkship director and the associate director of our center's clinical skills program who oversees SP recruitment, training, and oversight. Cases were developed by the Department of Emergency Medicine Education Committee and designed to represent the broad spectrum of disease, acuity, and patient demographics that would typically be encountered during our EM clerkship (Table). The cases were further designed to align with the learning objectives specified in a national curriculum guide for EM clerkships.<sup>9</sup>

The OSCE is a required component of our EM clerkship and is administered during the final week of each clerkship block. Performance on the examination constitutes 15% of a student's final grade. Students receive an orientation to the nature of this OSCE by the clerkship director and the associate

#### Table. OSCE case description.

| Title             | Chief complaint or<br>presenting sign/symptom | Patient demographic               | Final diagnosis                              | Critical actions  |
|-------------------|---|-----------------------------------|--|---|
| Sepsis            | Altered mental status                         | Elderly male or female            | Septic shock                                 | Oxygen delivery<br>2 Liter IV fluid bolus<br>Antibiotic therapy       |
| Seizure           | Confused after having seizure                 | College-age male<br>or female     | Bacterial meningitis                         | Fingerstick glucose<br>Lumbar puncture<br>Antibiotic therapy          |
| Overdose          | "Took pills"                                  | Varies                            | Acetaminophen overdose<br>Depression         | Activated charcoal<br>Acetaminophen level<br>NAC therapy              |
| Abdominal<br>pain | Abdominal pain and vaginal bleeding           | Young female, 6<br>weeks pregnant | Missed abortion<br>Intimate partner violence | Ultrasound<br>Communication of bad news<br>IPV Detection & Counseling |
| MI                | Indigestion                                   | Middle-age male                   | ST elevation MI<br>Ventricular tachycardia   | EKG<br>"Cath lab activation"<br>Synchronized cardioversion            |

OSCE, objective structured clinical examination; *IV*, intravenous; *NAC*, N-acetylcysteine; *IPV*, intimate partner violence; *MI*, myocardial infarction; *EKG*, electrocardiogram

director of the clinical skills program. At the start of each case students are provided with a triage report, listing the chief complaint, vital signs, and pertinent demographic and medical history. Students are given 15 minutes to perform patient evaluation and management and reach a disposition. In several of the cases performance of early resuscitative measures is indicated, and students perform these and other management tasks through verbalization of patient care orders to the case facilitator. Pre-scripted updates in vital signs and clinical status are given to the students based on the management steps they perform. Students may request diagnostic tests, such as laboratory and radiographic studies, the results of which are provided in a simulated real-time manner. Each case requires a patient disposition decision by the conclusion of the case.

At the core of each of the five cases in our OSCE are pre-selected key historical features and physical exam findings, 3-5 critical actions (including diagnostic and therapeutic tasks), and specific communication objectives (such as giving bad news, discussing advance directives, and obtaining informed consent). Our task-based evaluation instrument is anchored to both quantitative and qualitative assessment of these specific tasks. Performance of the history and physical is scored based upon the number of key features and exam findings elicited. Performance of critical actions is evaluated based upon the number of actions performed, as well as the completeness and timeliness of each task. Communication and interpersonal skills is evaluated based on performance in relation to a specific goal or task. A descriptive example of the evaluation instrument is shown in Figure 1. While we recognize the value of a global rating scale as an assessment tool, we specifically did not include global ratings in our assessment as student performance was assessed by our case facilitators. We felt that they received

appropriate training to perform task-based assessment but did not have the background or training to perform a global assessment of performance.

All testing items in each case were weighted equally, and all cases within the OSCE were weighted equally (each case constituted 20% of the final OSCE grade). The ratio of total points earned to total points possible to earn determined a student's final grade, and was expressed on a 0-100 scale.

We recruited our case facilitators from our institution's pool of SPs. As our non-physician evaluators are assessing performance of medical tasks, we specifically sought evaluators with a healthcare background. Our cohort of casefacilitators includes retired nurses, paramedics and emergency medical technicians. Regardless of background, all SPs and evaluators complete a formal training program that includes presentation of case goals and objectives, review of case scripts, overview and use of the evaluation instrument, and detailed description of full and partial performance for each critical action. To maintain standardization of patient portrayal and evaluation standards, SPs and evaluators are regularly observed (via remote video feed) by both EM faculty and our clinical skills program leadership. They receive individual feedback on their performance and also participate in regular group conferences.

Students' clinical performance in the ED is measured using our institution's clinical evaluation assessment tool which is uniformly used by all clinical clerkships. This tool utilizes a 9 item anchored 1-5 Likert scale to assess competencies related to medical knowledge, clinical practice, procedural skills, and communication, and a 5 item scale to assess professionalism. Based on an equal weighting of all completed faculty and resident evaluations, students receive a final clinical score as well as sub-scores in each competency area.

Using Pearson's coefficient we assessed the correlation

|   |                      | U.                     |              |
|---|----------------------|------------------------|--------------|
| 1. Obtains HPI, PMH, medications allergies.<br><i>Notes</i> : HPI: fever, cough, difficulty breathing x2 days   | () Correct Technique | () Incorrect Technique | () Not Done  |
| 2. Fingerstick glucose or D50 IV given early for full credit.<br><i>Notes</i> : Fingerstick glucose obtained early in case or alternatively D50 given IV early in case. | () Correct Technique | () Incorrect Technique | () Not Done  |
| 3. Oxygen via non-rebreather mask or intubation.<br><i>Notes</i> : Non-rebreather mask may also be called 100% 02 or face mask.   | () Correct Technique | () Incorrect Technique | ( ) Not Done |
| Partial credit for less oxygen (nasal cannula, 2 liters, etc.) or if administered late.   |                      |                        |              |
| 4. IV fluids given via 2 IV lines running wide open.<br><i>Notes</i> : Partial credit if fluid given through one line slowly or if late.                                | () Correct Technique | () Incorrect Technique | () Not Done  |
| 5. Antibiotics given early (before determining source of infection). <i>Notes</i> : Partial credit if done after determining source of infection.                       | () Correct Technique | () Incorrect Technique | () Not Done  |
| 6. Communication & bedside manner<br><i>Notes</i> : Explains patient's condition clearly to spouse. Honest but<br>compassionate with regard to severity of illness.     | () Correct Technique | () Incorrect Technique | () Not Done  |

Figure 1. Descriptive example of OSCE evaulation instrument (Altered mental status/sepsis case)

HPI, history of the previous illness; PMH, past medical history; IV, intravenous; OSCE, objective structured clinical examination

between final OSCE score and final clinical score. Index of difficulty and index of discrimination were computed for each scoring item and compared to best-practice standards.

## RESULTS

We enrolled 278 medical students in the study. Five students did not participate in the OSCE due to unresolvable schedule conflicts, and others were found to have missing or incorrect data. Complete data from all five cases was available for 239 students. All students received a final ED clinical score representing an equal weighting of all completed shift evaluation forms.

Mean OSCE score was 75.0 (SD =7.8), and mean ED performance score was 81.6 (SD =5.4). A positive correlation was found between OSCE score and ED performance score [r(239) = 0.40, p <0.001], indicating a statistically-significant linear relationship between the two (Figure 2).

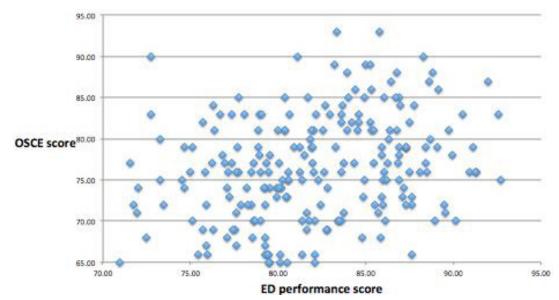
Of the 34 evaluation items within the five-station OSCE, the mean index of difficulty was 63.0 (SD = 23.0 ) and the mean index of discrimination was 0.52 (SD = 0.21 ). Mean indices of individual cases are demonstrated in Figure 3.

## DISCUSSION

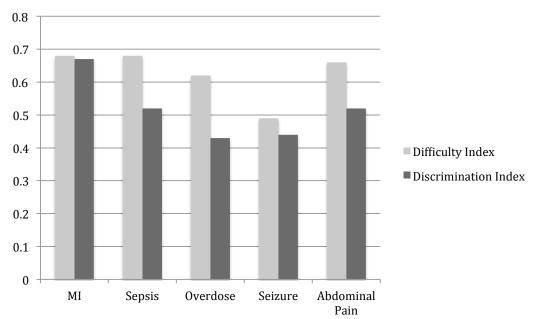
In our EM clerkship, students' OSCE scores showed a positive and statistically significant correlation with their clinical scores. Based on the computed Pearson's coefficient the strength of the correlation is moderate. Comparison of difficulty and discrimination indices to best-practice standards show that the majority of our testing items demonstrate ideal characteristics and validates the internal structure of our OSCE evaluation instrument. With regard to difficulty index, 24 (70%) of the total testing items are in the most recommended level I (mid range) and level II (easy) classes, with the remainder in levels III (difficult) and venous line (IV) (extremely difficult or easy), acceptable if used sparingly and in relation to key material.<sup>10</sup> With regard to discrimination index, 26 (76%) demonstrate "very good" discrimination between high and low performers with an additional five (15%) items demonstrating "reasonably good" discrimination. The remaining three (9%) are marginal or poor and should be revised or eliminated.<sup>11</sup>

A useful model of validity-determination for OSCEs was provided in a 2003 paper by Downing in which he discussed five sources of validity evidence, for each listing examples pertinent to SP-based assessment.<sup>12</sup> These areas (and SP-relevant examples) include content (selection of cases), response process (evaluation methodology and data integrity), internal structure (test item analysis), relationship to other variables (performance correlation) and consequence (use of method in high-stakes evaluation). The current use of OSCEs as part of the U.S. medical licensure process provides evidence of its consequence validity, and we believe that the deliberate design and implementation of our OSCE program provides evidence of its content and response process validity. Our cases were selected by content-experts and aligned with a national curriculum guideline for EM clerkships. Exacting specifications for patient portrayal were developed, and comprehensive actor training was provided by professional SP educators. Quality control measures were put into place to maximize evaluator accuracy and data integrity.

In this study we have demonstrated the remaining two sources of validity discussed by Downing: internal structure and relationship to other variables. Performance on our OSCE correlates with performance in what is arguably the most common and well-established evaluation method of clinical EM skills, and item-analysis of the OSCE demonstrates characteristics aligned with best-practice testing standards.



**Figure 2.** OSCE and ED performance score correlation. *OSCE*, objective structured clinical examination; *ED*, emergency department



**Figure 3.** Difficulty and discrimination indices of individual OSCE cases. *OSCE*, objective structured clinical examination; *MI*, myocardial infarction

These data, along with the above-mentioned OSCE characteristics, provide valuable validity evidence for use of an OSCE as an assessment tool for EM clinical skills.

While this study was conducted on undergraduate medical education level, we believe our results are readily generalizable to post-graduate EM education as well. In a clinical environment in which it is difficult to provide standardized and reproducible experiences, the OSCE is a valuable tool that clerkship and program directors can use to asses specific skills in multiple groups of learners. As accrediting and licensing bodies rightfully demand more formal evidence of the acquisition of clinical skills, the need and role for objective, standardized, reproducible and valid assessment such as the OSCE will only increase.

## LIMITATIONS

There are a number of study limitations that may have affected our results. We put significant effort into standardizing the evaluation process during the OSCE. Formal evaluator training was provided and ongoing monitoring was conducted. To promote accuracy of evaluation, we anchored most testing items to the performance of specific tasks rather that a more global assessment of a competency. However, we did not rigorously assess evaluator accuracy nor did we study the inter-rater reliability of the evaluation instrument. This was primarily due to manpower and other practical limitations, although future studies could use video review by multiple evaluators to ensure more accurate performance assessment.

Secondly, our demonstrated correlation between OSCE and ED clinical score, while statistically significant, is only moderate. Sub-optimal inter-rater reliability is one potential variable that may have prevented the demonstration of a stronger correlation, though it may be also be due to the fact that the OSCE and ED performance evaluation, while theoretically similar, in fact evaluate independent performance variables. Additionally, ED performance evaluations by faculty, while well-accepted and established assessment methods in EM education, are subject to numerous biases and limitations, and may not represent a true criterion standard in assessment of clinical skills. Future studies could compare OSCE performance with other measures of clinical skills such as direct observation in the clinical setting and high-fidelity simulation encounters.

Finally, our institution has a well-developed OSCE/SP program, which includes dedicated facilities and technical support, as well a professional SP educator and trainer. These resources, which greatly facilitate our EM OSCE program, may not be available at all institutions. A collaborative multi-center study would both increase our sample size and demonstrate reproducibility at multiple sites.

## CONCLUSION

A management-focused OSCE modified to assess clinical skills relevant to the practice of emergency medicine has validity evidence to support its use in undergraduate EM learners.

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Address for Correspondence: Joshua Wallenstein, MD, Emory University, 68 Armstrong St., Atlanta, GA 30303. Email: jwalle2@ emory.edu. *Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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## **Change to an Informal Interview Dress Code Improves Residency Applicant Perceptions**

H. Gene Hern, Jr., MD, MS Charlotte P. Wills, MD Brian Johnson, MD, MPH Alameda Health System, Highland Hospital, Department of Emergency Medicine, Oakland, California

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**Introduction**: Residency interview apparel has traditionally been the dark business suit. We changed the interview dress code from a traditionally established unwritten 'formal' attire to an explicitly described 'informal' attire. We sought to assess if the change in dress code attire changed applicants' perceptions of the residency program or decreased costs.

**Methods:** The authors conducted an anonymous survey of applicants applying to one emergency medicine residency program during two application cycles ending in 2012 and 2013. Applicants were asked if the change in dress code affected their perception of the program, comfort level, overall costs and how it affected their rank lists.

**Results:** We sent the survey to 308 interviewed applicants over two years. Of those, 236 applicants completed the survey for a combined response rate of 76.6% (236/308). Among respondents, 85.1% (200 of 235) stated they appreciated the change; 66.7% (154 of 231) stated the change caused them to worry more about what to wear. Males were more uncomfortable than females due to the lack of uniformity on the interview day (18.5% of males [25/135] vs. 7.4% of females [7/95], collapsed results p-value 0.008). A total of 27.7% (64/231) agreed that the costs were less overall. The change caused 50 of 230 (21.7%) applicants to rank the program higher on their rank list and only one applicant to rank the program lower.

**Conclusion:** A change to a more informal dress code resulted in more comfort and fewer costs for applicants to a single residency program. The change also resulted in some applicants placing the program higher on their rank order list. [West J Emerg Med. 2015;16(1):127-132.]

## INTRODUCTION

The interview for residency remains a rite of passage for physicians seeking specialty training throughout the country. Usually during their last year of medical school, students apply to residency programs in the specialty of their choice. During the months of November through January they interview at multiple residency training programs, and then list the programs they prefer in the rank order list (ROL). One tradition of the interview, which has remained across specialties, is the formal business attire. However in recent years, the dress code of medical schools has become more relaxed to even allow fleece jackets or 'sneakers'.<sup>1,2</sup> It is less common for medical students whether in the classroom, clinic, or wards to be dressed in formal business attire, especially if 'on call' or doing a rotation in the emergency department or intensive care unit.<sup>3</sup>

Few articles about dress codes for physicians exist and what does exist does not describe residency interviews. Furthermore, few articles actually study any dress attire phenomena beyond patient perceptions. No study to date has addressed cost or physician perceptions with dress code. What does exist concerns the dress code for medical student or physicians while seeing patients.<sup>4,5</sup> In 2007, the United Kingdom's National Health Service proposed a 'Bare Below the Elbows' dress code for infection control, which was met with some resistance.<sup>6-8</sup>

We challenged the dominant paradigm of "a residency interview requires business attire" by explicitly changing the dress code expectations for applicants on their interview day at our emergency medicine (EM) residency training program. We then explored whether changing the dress code for residency interviews also changed applicants' perceptions of the program, comfort level, or decreased the cost of the interview season. Furthermore, we surveyed applicants about their opinions as to whether EM residency programs should adopt this practice.

## METHODS

During the initial interview offers to applicants of our residency program in the 2011-12 and 2012-13 seasons, we stated in the letter that formal business attire was not required. The letter stated, "We don't want you to wear suits to the interview day, unless you absolutely love wearing suits. We will all be dressed in some version of jeans, scrubs, and at the most, business casual." We reiterated this new policy in our follow-up communication and provided examples of appropriate but more casual attire. Once the interviewees had submitted their match list and the program had also submitted the match list, we surveyed applicants who had interviewed at our program using a commercially available survey website (SurveyMonkey.com). The survey was submitted to the institutional review board at our home institution, Alameda Health System, and was approved.

We developed and then piloted our survey with departmental education faculty with a combined total of 40 years of residency leadership experience. In addition, the survey was piloted with residents within our own program (a group generally similar in age to our target population and who went through the interview process recently.) The pilot and revisions were in accordance with survey design methodology to maximize validity and reliability.<sup>9</sup> No prior studies of this topic exist to adapt survey instrument questions from.

The survey was emailed to residency applicants twice after the deadline to submit rank order lists for both programs and applicants had passed. The option to respond was closed prior to the release of match results to either applicant or program. Respondents were allowed to not answer all of the questions. We surveyed applicants about demographic information including age, gender, and geographic location. In addition, applicants were queried about their impressions of the change in dress code expectations. For an example of the instrument, see attached survey.

We collapsed the five-point Likert scale anchored by "1-disagree" and "5-agree" into 1 to 2 (disagree), 3 (neutral), and 4 to 5 (agree). A general comments section was included at the end of the survey. We performed statistical analysis using SAS (Version 9.3, SAS Inc; Cary, NC). Each survey question was analyzed by gender, age, and medical school region. We calculated differences using chi square analysis for categorical variables (age, medical school region) and t-test for age.

## RESULTS

We sent the survey to all 150 interviewed applicants the first year and all 158 the second. It was completed by 120 applicants the first year and 116 applicants the second year for a combined response rate of 76.6% (236/308) (Table 1 contains respondent demographic information). Most respondents felt comfortable with the change in dress code expectation. Among respondents, 85.1% (200 of 235) stated they appreciated the change to a more casual dress code. The majority of applicants did not feel less comfortable as compared to their experiences at other programs (75.5%, 173/229). Of note, when asked if the change in the dress code caused them to worry more about what to wear, 66.7% (154 of 231) replied 'yes;' however, during the interview day, the majority were not uncomfortable by the lack of uniformity in apparel (74.9%, 173/231) (Table 2). There was no difference in response by gender except more males were uncomfortable than female applicants due to the lack of uniformity on the interview day (18.5% of males [25/135] vs. 7.4% of females [7/95], collapsed results p-value 0.008) (Table 3).

Overall, a minority of applicants stated that a change in dress code cost them less money overall in the interview process. Only 27.7% (64/231) agreed that the costs were overall less compared to costs incurred interviewing at other residency training programs.

Regarding perceptions of the residency program itself, 212 of 234 (90.6%) 'disagreed' or 'somewhat disagreed' with the statement "The change in dress expectation lowered [program] in my esteem." A confirmatory question later in the survey asked whether the dress code change improved their feelings of the program. Of respondents, 150 of 229 (65.5%) stated the change in dress code improved their feelings about the program and an additional 66 (28.8%) stated it

**Table 1.** Demographics of surveyed applicants with regard to interview dress code (mean age 27.7).

| Variable              | n (%)      |
|-----------------------|------------|
| Gender                |            |
| Male                  | 137 (58.3) |
| Female                | 98 (41.7)  |
| Medical school region |            |
| East Coast            | 77 (33.5)  |
| Midwest               | 34 (14.8)  |
| Rocky Mountain        | 14 (6.1)   |
| South                 | 24 (10.4)  |
| West Coast            | 81 (35.2)  |
| Age                   | -          |
|                       |            |

| Table 2. Frequency of responses for each questions asked.   |            |                      |                               |                |            |
|---|------------|----------------------|-------------------------------|----------------|------------|
|   |            |                      | u (%)                         |                |            |
| Question  | Disagree   | Somewhat<br>disagree | Neither agree nor<br>disagree | Somewhat agree | Agree      |
| I appreciated the change to more casual dress.  | 6 (2.6)    | 14 (6)               | 15 (6.4)                      | 21 (8.9)       | 179 (76.2) |
| Compared to my experience at other programs, the change to more casual dress caused me to worry more about what to wear.          | 41 (17.7)  | 18 (7.8)             | 18 (7.8)                      | 81 (35.1)      | 73 (31.6)  |
| Compared to my experience at other programs, the change made me feel less comfortable.  | 134 (58.5) | 39 (17)              | 29 (12.7)                     | 14 (6.1)       | 13 (5.7)   |
| Compared to my experience at other programs, the change cost me less money.   | 54 (23.4)  | 16 (6.9)             | 97 (42)                       | 11 (4.8)       | 53 (22.9)  |
| The change in dress expectation lowered Highland in my esteem.  | 198 (84.6) | 14 (6)               | 14 (6)                        | 6 (2.6)        | 2 (0.9)    |
| I feel that other programs should change their dress requirements.  | 21 (9.1)   | 12 (5.2)             | 51 (22)                       | 43 (18.5)      | 105 (45.3) |
| The lack of uniformity among applicants' dress made me feel uncomfortable.  | 144 (62.3) | 29 (12.6)            | 26 (11.3)                     | 26 (11.3)      | 6 (2.6)    |
| The change reflected the attitudes and demeanor of the Highland Attendings and Residents.   | 6 (2.6)    | 2 (0.9)              | 23 (9.8)                      | 49 (20.9)      | 154 (65.8) |
| While interviewing at other programs, other applicants discussed<br>the Highland Dress Expectation (I didn't bring up the topic). | 22 (9.4)   | 6 (2.6)              | 11 (4.7)                      | 57 (24.4)      | 138 (59)   |
| While interviewing at other programs, I mentioned the Highland Dress Expectation initially to other applicants.                   | 58 (24.9)  | 19 (8.2)             | 27 (11.6)                     | 59 (25.3)      | 70 (30)    |
| Compared to my experience at other programs, the change improved my feelings about Highland.                                      | 9 (3.9)    | 4 (1.7)              | 66 (28.8)                     | 48 (21)        | 102 (44.5) |

#### Table 3. Response frequency to each survey question stratified by gender.\*

|  |            | n (%                  | )          |         |
|--|------------|-----------------------|------------|---------|
|  |            | Neither               |            |         |
| Question   | Disagree   | agree nor<br>disagree | Agree      | p-value |
| appreciated the change to more casual dress.   |            |                       |            | ·       |
| Male   | 14 (10.2)  | 9 (6.6)               | 114 (83.2) | 0.54    |
| Female   | 6 (6.2)    | 6 (6.2)               | 85 (87.6)  |         |
| Compared to my experience at other programs, the change to more casual dress caused me to worry amore about what to wear.      |            |                       |            |         |
| Male   | 36 (27.1)  | 8 (6)                 | 89 (66.9)  | 0.45    |
| Female   | 23 (23.7)  | 10 (10.3)             | 64 (66)    |         |
| Compared to my experience at other programs, the change made me feel less comfortable.   |            |                       |            |         |
| Male   | 97 (71.9)  | 18 (13.3)             | 20 (14.8)  | 0.21    |
| Female   | 75 (80.6)  | 11 (11.8)             | 7 (7.5)    |         |
| Compared to my experience at other programs, the change cost me less money.  |            |                       |            |         |
| Male   | 42 (31.6)  | 59 (44.4)             | 32 (24.1)  | 0.32    |
| Female   | 28 (28.9)  | 37 (38.1)             | 32 (33)    |         |
| The change in dress expectation lowered Highland in my esteem.   |            |                       |            |         |
| Male   | 122 (89.7) | 10 (7.4)              | 4 (2.9)    | 0.54    |
| Female   | 89 (91.8)  | 4 (4.1)               | 4 (4.1)    |         |
| feel that other programs should change their dress requirements.   |            |                       |            |         |
| Male   | 23 (17)    | 28 (20.7)             | 84 (62.2)  | 0.36    |
| Female   | 10 (10.4)  | 22 (22.9)             | 64 (66.7)  |         |
| The lack of uniformity among applicants' dress made me feel<br>uncomfortable.  |            |                       |            |         |
| Male   | 91 (67.4)  | 19 (14.1)             | 25 (18.5)  | 0.008   |
| Female   | 81 (85.3)  | 7 (7.4)               | 7 (7.4)    |         |
| The change reflected the attitudes and demeanor of the Highland attendings and residents.                                      |            |                       |            |         |
| Male   | 4 (2.9)    | 14 (10.3)             | 118 (86.8) | 0.87    |
| Female   | 4 (4.1)    | 9 (9.3)               | 84 (86.6)  |         |
| While interviewing at other programs, other applicants discussed the Highland Dress Expectation (I didn't bring up the topic). |            |                       |            |         |
| Male   | 17 (12.5)  | 6 (4.4)               | 113 (83.1) | 0.94    |
| Female   | 11 (11.3)  | 5 (5.2)               | 81 (83.5)  |         |
| While interviewing at other programs, I mentioned the Highland Dress<br>Expectation initially to other applicants.             |            |                       |            |         |
| Male   | 45 (33.6)  | 15 (11.2)             | 74 (55.2)  | 0.94    |
| Female   | 31 (31.6)  | 12 (12.2)             | 55 (56.1)  |         |
| Compared to my experience at other programs, the change improved my feelings about Highland.                                   |            |                       |            |         |
| Male   | 7 (5.2)    | 46 (34.3)             | 81 (60.4)  | 0.1     |
| Female   | 6 (6.4)    | 20 (21.3)             | 68 (72.3)  |         |

\*"Agree" and "Somewhat agree" responses were consolidated. "Disagree" and "Somewhat disagree" responses were consolidated. Statistical significance did not change when responses were not consolidated. had no change on their feelings about the program. Only six applicants of the 234 (2.6%) 'somewhat agreed' that the change in dress code lowered their esteem of the program and two applicants took the stronger position of 'agreed' (0.9%). When asked if the change in dress code reflected the attitudes and demeanor of the programs' attendings and residents, 203 of 234 (86.8%) responded in the affirmative.

Per survey responses, the dress code change during the interview season increased discussion with other applicants also in the residency interview process. When asked if other applicants discussed the dress code change while interviewing at other programs, 195 of 234 (83.3%) stated that other applicants brought up the topic. The question expressly stated that they, the applicant, did not bring up the topic in conversation.

When asked if other residency programs should change their dress code, 148 of 232 (63.8%) stated they agreed or somewhat agreed. Additionally, another 51 (22%) stated they neither agreed nor disagreed. There were no statistical differences by school region or age for those in favor of dress code change. Only 4.2% of applicants from the Southern region (1/25) and one of 13 applicants (7.7%) from the Rocky Mountain region were not in favor of a dress code change. (Perhaps we should explicitly say there were no differences by school region or age.)

The change in dress code caused 50 of 230 (21.7%) applicants to rank the program higher on their rank list. Only one applicant indicated the dress code change caused him or her to rank the program lower. We found no significant difference in response to any dress code question by age or medical school region.

Anecdotally, there were a few applicants (less than 10) who still wore formal business attire to the interview. Applicants who interviewed earlier in the season seemed to have more apprehension with the new dress code than later applicants. It may be that later applicants heard about the dress code from fellow interviewees at other programs or their own medical school and had more time to confirm the information being sent from the program itself.

The authors do not believe there were negative affects on the program itself. The program's rank list was filled within three spots of prior years' matches, so it appears that at least for those years' rank lists, there was no negative impact to the program.

## DISCUSSION

Our experience demonstrated that changing dress code expectations from formal to more casual did not negatively impact the interview process for either applicant or program at our single institution. The results of our survey demonstrate the majority of applicants to our EM residency preferred to have a more casual interview dress code.

This result must be taken in the context of the study. This was a change in dress code in one EM program over two years. While the results suggest relatively little impact upon the program reputation or the ranking of the program by applicant, one must consider the setting.

EM is a relatively newer specialty that does not have a 'clinic' type setting, and thus the practitioners tend to wear surgical scrubs in the emergency department. A change in interview attire may not be seen as acceptable to more traditional specialties who retain a clinic or office based setting. These specialists often have more formal attire during these clinical settings.

In terms of cost savings, a change in dress code may not provide dramatic cost savings. Anecdotally, many applicants have commented over the years on the cost of flying all over the country doing interviews. Some have applied for additional credit cards or applied for loans from their medical schools to help defray the costs of interviewing. We had hoped the change in dress code might limit some of the costs of cleaning or maintaining their formal business attire but that may not be the case. Applicants still have to have their formal business attire for interviewing. More money is likely saved by staying overnight with current residents/friends and taking public transit/carpooling (all practices we encourage), rather than hotels and rental cars.

## Limitations

The study suffers from a number of limitations common to surveys. Recall bias is a clear limitation as surveys were completed perhaps more than a month after the actual interview. In addition, despite the anonymous survey being sent in the 'quiet period' when the National Resident Matching Program has each program's and applicant's list, it is possible that applicants felt their response was perhaps traceable back to them or might negatively influence their application or their ranking.

While the response rate was 76.6%, it is also possible the applicants who did not answer the query had more negative feelings about the dress code change and might have lowered the favorable percentages or have resulted in applicants stating they lowered the program on their rank lists.

Additionally, the residency program where this change in dress code was implemented trains EM residents. This is a specialty that does not have 'clinic days' or any standard outpatient office setting. Applicants who prefer this specialty may also tend to prefer acute care settings in which scrubs are more favored. Finally, the program is also located in a county hospital in California and where the 'formality' of the hospital and the faculty might be more informal than other institutions located in other parts of the country. As an example, most faculty do not wear white coats and some have tattoos visible.

Another potential limitation is that we did not explicitly notate which applicants did not follow the new dress code and were dressed in a more traditional fashion. We, therefore, could not exclude them from the study as the survey was sent anonymously to all applicants who interviewed.

## CONCLUSION

Changing the dress code for the residency interview does not appear to negatively affect the program's reputation or rank order list results. Most applicants prefer a less formal dress code. It appears to make them more comfortable and, for a minority, incurs less cost. The change in dress code at the single study site was associated with some applicants raising the program on their rank lists and very few lowering it. Further investigations should study how individual applicants are perceived by their interpretation of the dress code and if some are ranked higher or lower based on their actual apparel or their 'following' the suggested dress code.

Address for Correspondence: H. Gene Hern, Jr., MD, MS, Residency Director, Dept. of Emergency Medicine, Alameda County Medical Center, 1411 E. 31st St. Email: emergentt@gmail.com.

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# Educational Technology Improves ECG Interpretation of Acute Myocardial Infarction among Medical Students and Emergency Medicine Residents

Ali Pourmand, MD\* Mary Tanski, MD<sup>†</sup> Steven Davis, MD\* Hamid Shokoohi, MD\* Raymond Lucas, MD\* Fareen Zaver, MD\* \*George Washington University, Department of Emergency Medicine, Washington, District of Columbia

<sup>†</sup>Oregon Health & Science University, Portland, Oregon

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**Introduction:** Asynchronous online training has become an increasingly popular educational format in the new era of technology-based professional development. We sought to evaluate the impact of an online asynchronous training module on the ability of medical students and emergency medicine (EM) residents to detect electrocardiogram (ECG) abnormalities of an acute myocardial infarction (AMI).

**Methods:** We developed an online ECG training and testing module on AMI, with emphasis on recognizing ST elevation myocardial infarction (MI) and early activation of cardiac catheterization resources. Study participants included senior medical students and EM residents at all post-graduate levels rotating in our emergency department (ED). Participants were given a baseline set of ECGs for interpretation. This was followed by a brief interactive online training module on normal ECGs as well as abnormal ECGs representing an acute MI. Participants then underwent a post-test with a set of ECGs in which they had to interpret and decide appropriate intervention including catheterization lab activation.

**Results:** 148 students and 35 EM residents participated in this training in the 2012-2013 academic year. Students and EM residents showed significant improvements in recognizing ECG abnormalities after taking the asynchronous online training module. The mean score on the testing module for students improved from 5.9 (95% CI [5.7-6.1]) to 7.3 (95% CI [7.1-7.5]), with a mean difference of 1.4 (95% CI [1.12-1.68]) (p<0.0001). The mean score for residents improved significantly from 6.5 (95% CI [6.2-6.9]) to 7.8 (95% CI [7.4-8.2]) (p<0.0001).

**Conclusion:** An online interactive module of training improved the ability of medical students and EM residents to correctly recognize the ECG evidence of an acute MI. [West J Emerg Med. 2015;16(1):133–137.]

## **INTRODUCTION**

Cardiovascular disease, particularly ischemic heart disease, is a leading cause of death and disability in the United States.<sup>1,2</sup> Diagnosis of ischemic heart disease and specifically ST segment elevation myocardial infarction (STEMI) relies heavily on accurate electrocardiogram (ECG) interpretation.<sup>3,4</sup> While the ECG is a simple, safe, reproducible and powerful tool, prior studies have shown that faulty interpretations can lead to inappropriate clinical decision making. Unfortunately, too many physicians have an inaccurate perception of their

limitations when interpreting ECG readings.<sup>5,6</sup> The only way to combat such deficiencies is through education, necessitating training in ECG interpretation as an essential part of medical education.<sup>6</sup> To determine the methodology that best teaches the skill of ECG interpretation, several uncontrolled studies of residents and students have demonstrated improvement in ECG interpretation skills after structured ECG interpretation seminars.<sup>6,7</sup> The tentative conclusion from these studies is that didactic learning can reinforce and prepare trainees for clinical learning using a variety of methods, including problem-based learning, small group sessions, simulation, etc.<sup>8</sup>

With the advent of new technology from nanoparticles to microchips and from multimedia devices to computer assisted learning, a greater emphasis is being placed on using interactive online modules to promote distance learning in medical education.<sup>8-10</sup> This focus is built upon the studies of Michael Graham Moore, wherein he codified a framework for distance learning depending on paper, a physical medium.<sup>11</sup> With the telecommunication technology available today however, the educator can take Moore's studies one step further as true asynchronous learning is now possible. Asynchronous online module forums are increasingly being used as an adjunct to didactics and basic medical training in blended learning environments. Previously, education depended on scheduling and supporting instructors with an emphasis on using classroom time to promote retention of already-learned facts. The advent of distance learning techniques provides instructors with the tools of contextual learning, active and individualized learning, and can reduce the burden of promoting fact retention.<sup>9,12,13</sup>

## **Goals of This Investigation**

The purpose of our study was to evaluate the impact of an online asynchronous training module on the ability of medical students and emergency medicine (EM) residents to detect ECG abnormalities of acute myocardial infarction (AMI).

## METHODS

#### Study design

This is a prospective study involving senior medical students in their EM rotations as well as EM residents at the George Washington University Hospital. The institutional review board approved this study.

## **Study Setting and Population**

We performed the study at an academic medical center with tertiary cardiac care including 24/7 availability of cardiac catheterization. The annual emergency department (ED) census is 76,000 patients per year, and the EM residency-training program is a postgraduate year (PGY) 1–4 format.

Volunteer medical students during their ED rotations and all levels of EM residents (PGY 1-4) were evaluated on their interpretation of ECG abnormalities.

#### **Study Protocol**

We developed a learning module using 10 ECGs that represented common findings and used them for evaluation in this study. The module consisted of integrated multimedia related to ECGs interpretation. A cardiologist and two board-certified emergency physicians independently validated the standardized exam of the 10 ECGs. The testing module consisted of four normal ECGs, three ECGs meeting classic STEMI criteria and three with subtle STEMIs. The ECGs were obtained from records of patient records who had a confirmed acute coronary thrombus during cardiac catheterization.

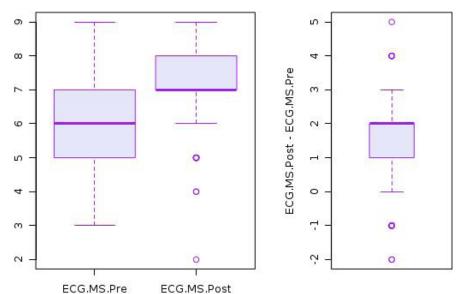
First, we established baseline aptitude regarding ECG interpretation by evaluating participants with 10 ECGs prior to the presentation of the online training module. No patientspecific clinical information was provided for the ECGs in the pre-test. For each ECG, participants were asked to interpret the ECG on a scoring sheet as either no STEMI or STEMI with a need for cardiac catheterization. The answers were anonymous with only the year of residency and sex of the participants collected. The participants then completed an online interactive multimedia module, which contained two sections. The first section discussed the basic principles of electrocardiography and the ECG criteria for STEMI based on American Heart Association/American College of Cardiology guidelines.<sup>14</sup> The second section covered the pathological ECGs, specifically the types of changes seen in STEMI including reciprocal changes. The participants were then asked to complete a post-test within 24 hours of completion of the online module to measure their ability to diagnose STEMI using the same 10 ECGs administered during the pre-test.

## Data Analysis

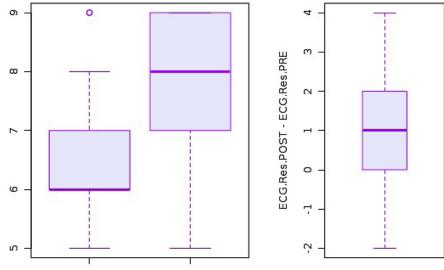
We performed a repeated-measures analysis of test scores using a Wilcoxon signed-rank test to assess for the changes in each individual test score after completion of the asynchronous training module. We then also evaluated the association between trainees' scores and the year of training for residents by using multivariate regression analysis. The changes in scores before and after the online training were analyzed using Stata 12.1 (Stata Corp, College Station, TX) to perform parametric tests of association and descriptive statistics as appropriate. A p-value less than 0.05 was considered significant.

## RESULTS

A total of 148 students and 35 EM residents were enrolled in the 2012-2013 academic year. The medical students had a mean pre-test score of 5.9 (95% CI: [5.7-6.1]). Figure 1 shows the histogram of pre- and post-test scores for students. Test scores significantly improved after the online asynchronous training, as the mean score on the post-test was 7.3 (95% CI: 7.1-7.5]), and the mean difference was 1.4 (95% CI: [1.12-1.68), which represents a statistically significant improvement



**Figure 1.** Histogram on medical students' pre and post-test scores on ECG interpretations. *ECG*, electrocardiogram; *MS*, medical student; *Pre*, pre-test scores; *Post*; post-test scores



ECG.Res.PRE ECG.Res.POST

**Figure 2.** Histogram on emergency medicine residents' pre and post-test scores on ECG Interpretations. *ECG*, electrocardiogram; *Res*, resident; *PRE*, pre-test scores; *POST*, post-test scores

to the mean scores pre- to post-training. p<0.0001) (Figure 1).

The mean score on the pre-test for the EM residents was 6.6 (95% CI: [6.2-6.9]). Figure 2 shows the histogram of pre-test and post-test scores for EM residents. The mean post-test score improved to 7.8 (95% CI: [7.4-8.2]) among EM residents, representing a significant improvement among EM residents after online asynchronous training (p<0.0001) (Figure 2).

Multivariate regression analysis did not demonstrate any dependence on the year of training, or status as a medical student versus a resident for test score improvement.

## LIMITATIONS

This study involved students and EM residents in a single

residency program. The content of the lectures were developed from our program resources and have not been formally validated for this purpose. The small sample size, single site and site-specific resources may limit its generalizability to other institutions.

## DISCUSSION

This study demonstrated that delivery of medical training via an online, asynchronous resource could significantly improve medical students' and EM residents' ability to accurately interpret ECGs.

The results of our study have built upon previous studies regarding the effectiveness of asynchronous medical education. It has previously been demonstrated that online medical education can favorably influence learning outcomes.<sup>15-17</sup> Our study further illustrates benefits from this type of learning and demonstrates the need for the adjustment of medical education to best take advantage of online learning, especially as hospital resources become more and more scarce.<sup>18,19</sup>

Asynchronous learning also provides flexibility for learners to review curricular content at the most appropriate, and most convenient, time and place.<sup>20,21</sup> A small but growing body of EM literature supports inclusion of asynchronous online education into EM curricula for both student and resident learners.<sup>22</sup> Recent literature suggests, however, that educators should approach asynchronous EM education with discretion.<sup>23</sup> We believe an asynchronous online format that is both accessible and iterative is ideal for learning ECG interpretation, which requires repetition to obtain mastery. We believe this study supports a blended approach to clinical education where lower-level learning objectives ( i.e. knowledge acquisition) can be done asynchronously online; and higher level objectives (i.e. synthesis, analysis) can be done face-to-face, optimizing the use of faculty expertise in interactive settings.

The online nature of the module allows easy access for those learners who wish to view the material for future review and reference. An additional benefit is the standardization of content of web-based teaching modules,<sup>18</sup> which cannot always be assured when core content may be taught by a variety of clinical instructors. This uniformity of presentation both ensures coverage of basic informational content and thereby ensuring no relevant details are overlooked, as well as removes the risk of variation seen in face-to-face lectures. Moreover, the content of the module can be easily updated as information changes.

Being a good caregiver depends on maintaining one's knowledge on the most recent advances in medicine. The asynchronous method of delivery provides the flexibility to allow learners to absorb the information at a time of their choosing, at their own pace in a learning environment of their choice.<sup>20,21</sup> Due to varying shifts and schedules in the ED, it is nearly impossible for learners to be able to attend every scheduled lecture. Using asynchronous learning, attendance would also no longer be an issue. The online medium frees learners from the burden of rescheduling or being forced to choose between equally important lectures being held in the same timeslot.

This study compared two major groups of trainees – medical students and EM residents – and both of those groups demonstrated improvement from the same online module. As asynchronous learning develops, such versatility to affect such a large proportion of learners at such different levels is most likely be its greatest strength.

It has been demonstrated that the most effective teaching and greatest improvement of performance and retention is dependent on using different learning styles.<sup>21</sup> Web-based asynchronous

learning is another method of education that may easily adjust for variations in cognitive styles of learning. Web-based modules can incorporate numerous methodologies including interactive tools, which can be set to activate upon learner request, allowing for individualized preferences to be utilized.

## CONCLUSION

Educators should consider the broad range of needs of their learners and choose multiple learning strategies to teach medical content. Our study demonstrated that an online interactive module of training improved the ability of medical students and EM residents to correctly recognize the ECG evidence of an acute MI. It is a valuable tool to facilitate repetition, enhance curriculum, and potentially provide direct feedback for learners.

Address for Correspondence: Ali Pourmand, MD, MPH, Department of Emergency Medicine, George Washington University Medical Center, 2120 L St., NW, Suite 450, Washington, DC 20037. Email: Pourmand@gwu.edu.

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# Correlation of the NBME Advanced Clinical Examination in EM and the National EM M4 exams

| Katherine Hiller, MD, MPH*<br>Emily S. Miller, MD <sup>†</sup><br>Luan Lawson, MD, MAEd <sup>‡</sup><br>David Wald, DO <sup>§</sup><br>Michael Beeson, MD, MBA <sup>¶</sup><br>Corey Heitz, MD <sup>∥</sup><br>Thomas Morrissey, MD, PhD <sup>#</sup><br>Joseph House, MD**<br>Stacey Poznanski, DO <sup>††</sup> | *University of Arizona, Department of Emergency Medicine, Tucson, Arizona<br><sup>†</sup> Harvard University, Department of Emergency Medicine, Boston, Massachusetts<br><sup>‡</sup> Brody School of Medicine at East Carolina University, Department of Emergency<br>Medicine, Greenville, North Carolina<br><sup>§</sup> Temple University School of Medicine, Department of Emergency Medicine,<br>Philadelphia, Pennsylvania<br><sup>¶</sup> Northeastern Ohio Medical University, Department of Emergency Medicine,<br>Rootstown, Ohio<br><sup>¶</sup> Virginia Tech Carilion School of Medicine, Department of Emergency Medicine,<br>Roanoke, Virginia<br><sup>#</sup> University of Florida Health Sciences Center, Department of Emergency Medicine,<br>Jacksonville, Florida<br>**University of Michigan School of Medicine, Department of Emergency Medicine, Ann<br>Arbor, Michigan<br><sup>†</sup> Wright State University Boonshoft School of Medicine, Department of Emergency |
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|   | <sup>+†</sup> Wright State University Boonshoft School of Medicine, Department of Emergency Medicine, Dayton, Ohio   |

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**Introduction**: Since 2011 two online, validated exams for fourth-year emergency medicine (EM) students have been available (National EM M4 Exams). In 2013 the National Board of Medical Examiners offered the Advanced Clinical Examination in Emergency Medicine (EM-ACE). All of these exams are now in widespread use; however, there are no data on how they correlate. This study evaluated the correlation between the EM-ACE exam and the National EM M4 Exams.

**Methods**: From May 2013 to April 2014 the EM-ACE and one version of the EM M4 exam were administered sequentially to fourth-year EM students at five U.S. medical schools. Data collected included institution, gross and scaled scores and version of the EM M4 exam. We performed Pearson's correlation and random effects linear regression.

**Results**: 303 students took the EM-ACE and versions 1 (V1) or 2 (V2) of the EM M4 exams (279 and 24, respectively). The mean percent correct for the exams were as follows: EM-ACE 74.8 (SD-8.83), V1 83.0 (SD-6.41), V2 78.5 (SD-7.70). Pearson's correlation coefficient for the V1/ EM-ACE was 0.51 (0.42 scaled) and for the V2/EM-ACE was 0.59 (0.41 scaled). The coefficient of determination for V1/EM-ACE was 0.72 and for V2/EM-ACE = 0.71 (0.86 and 0.49 for scaled scores). The R-squared values were 0.25 and 0.30 (0.18 and 0.13, scaled), respectively. There was significant cluster effect by institution.

**Conclusion**: There was moderate positive correlation of student scores on the EM-ACE exam and the National EM M4 Exams. [West J Emerg Med. 2015;16(1):138–142.]

## INTRODUCTION

Clerkship directors employ numerous methods to assess medical student performance during clinical rotations. These methods include direct observation, clinical feedback from supervisors, performance on written and/or oral examinations, simulation, and case presentations. A 2010 survey of emergency medicine (EM) clerkship directors revealed that the most commonly used methods in determining a medical student's clerkship grade are clinical performance assessment forms (used by 94% of clerkships) and written exams (used by 57% of clerkships).<sup>1</sup> On average, written exam scores count for 24.5% of students' grades on an EM clerkship.1 Unlike most other core clerkships (Surgery, Pediatrics, Obstetrics/Gynecology and Internal Medicine), until recently, EM has not had a nationally accepted, standardized exam such as the National Board of Medical Examiners "shelf exam," or Advanced Clinical Exam in Emergency Medicine (NBME EM-ACE). Historically, clerkship directors relied on creating their own exams for an end-of-rotation written assessment of medical knowledge. Most clerkship directors have no formal training in exam item writing, making the level of quality of these internal exams difficult to ascertain. Further, until 2006, when a standardized national fourth-year curriculum was published, there had been significant variability in the "core content" material for rotations at different venues.<sup>2</sup> This curriculum was updated in 2010.<sup>3</sup>

With a new national curriculum in place, the Clerkship Directors of Emergency Medicine (CDEM) released the first version (V1) of a national, standardized, end-ofrotation exam for fourth-year students in 2011 entitled the National EM M4 Exam (referred to by some as the CDEM Exam or Society for Academic Emergency Medicine tests exam).<sup>4,5</sup> This exam was created to assess content in the published EM curriculum and consists of items written according to published item-writing guidelines.<sup>5</sup> CDEM released a second version (V2) of the National EM M4 Exam in 2012.<sup>6</sup> Both versions of the National EM M4 Exam are available online free of charge to all U.S. clerkship directors (www.saemtests.org).

In 2013, the NBME introduced the Emergency Medicine Advanced Clinical Exam (EM-ACE), which was written and developed by an NBME task force consisting of CDEM members with formal training in item writing. The EM-ACE was made available free of charge from its initial release in April 2013 until June 2014. Like the National EM M4 Exams, the NBME EM-ACE is based on content in the published fourth-year EM curriculum, making the curricula covered theoretically identical.<sup>2,3</sup>

Before a stable national curriculum was agreed upon, it was not possible to generate a standardized end-of-rotation assessment tool for EM students, and comparison of student performance across institutions was not feasible. The release of these end-of-rotation examinations represents the first opportunity for EM clerkship directors to be able to assess their students with a standardized, nationally available assessment tool. Although both exams are based on the same national curriculum, it is unknown whether student performance on the NBME EM-ACE correlates with performance on the National EM M4 Exams. End-ofrotation exam scores are typically included in a student's summative grade report and may also be included in letters of evaluation for residency application. Understanding how scores on the NBME EM-ACE correlate with scores on the National EM M4 Exams would help inform educators and program directors about individual students and more importantly, enable comparison of students who have taken different exams. The objective of this study was to correlate medical student performance on the NBME EM-ACE with medical student performance on V1 and V2 of the National EM M4 Exams.

## METHODS

This multicenter, prospective, paired comparison study was performed across five U.S. allopathic medical schools from May 2014 to April 2014. All fourth-year medical students participating in a fourth-year EM rotation at the study sites were administered both the NBME EM-ACE and an EM M4 exam. The study sites varied with regard to having mandatory, selective or elective EM rotations, but were all four weeks long and used the standardized curriculum recommended by CDEM. Study sites administered either V1 or V2 of the EM M4 exam based upon site preference. Exams were taken consecutively within one day of each other, at the end of the rotation. Individual study sites determined which exam was administered first. Both exams were administered by the same clerkship coordinator or other administrator according to respective protocols developed by the NBME and CDEM. At all sites, students were aware that the EM M4 exam would count towards their grade, as per local institution protocol. Without longitudinal performance data or norms, most sites did not count NBME exam towards the final rotation grade; however, to encourage students to take the NBME exam seriously, some institutions advised students that although the NBME exam could not lower their grade, a strong performance would be reflected in their final evaluation. One institution used the NBME score for a small portion (5%) of the final course grade.

The clerkship director or coordinator collected deidentified data, which included institution, NBME gross score (percent correct, when available), NBME scaled score, the version of the EM M4 exam administered (V1 and V2) and the gross score on that exam. We pooled the data and calculated Pearson correlation coefficients for the NBME (gross and scaled) and EM M4 (V1 and V2) exam scores. Random effects linear regression with institution as the cluster variable was performed for both EM M4 versions.

We performed data collection in Microsoft Excel 2007. Data analysis was performed with StataMP 11.0 (College Station, TX). This project was determined to be exempt from human subjects review by the University of Arizona Institutional Review Board.

#### RESULTS

Five institutions administered both the NBME EM-ACE and one version of the EM M4 exam to 303 fourthyear students at the end of their EM rotation. V1 of the EM M4 was administered to 279 students, and V2 to 24 students. This profile is similar to the national distribution of students who took V1 and V2 in 2013-14 (5060 and 787, respectively).<sup>7</sup> The mean NBME raw score was 74.8 (n=216; SD 8.83). The mean NBME scaled score for the entire cohort was 68.2 (SD 12.8). The mean EM M4 V1 raw score was 83.0 (n=279; SD 6.41), and the mean EM M4 V2 raw score was 78.5 (n=24, SD 7.80). We performed Pearson's correlations and linear regression on the NBME raw and scaled scores and V1 and V2 of the EM M4 exams. There was moderate positive correlation for all comparisons (Figures 1 and 2). There was a cluster effect for institution, so it was retained in the linear regression analysis for both the EM M4 versions (Table 1).

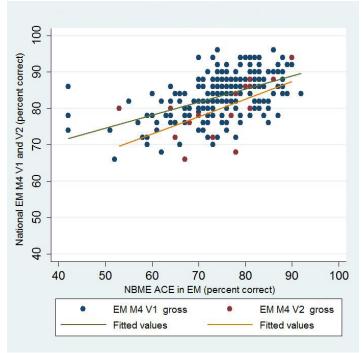
### DISCUSSION

The availability of the NBME EM-ACE this past year is of great importance to our specialty. The NBME has provided internal validity data for the EM-ACE. However, the impact the NBME EM-ACE will likely have necessitates assessment of external validity and reliability compared to what historically has been used as the assessment standard. This study represents the first step in this evolving process.

End-of-rotation exams play a high stakes role in medical student evaluations. Although they are imperfect tools in that they provide only partial assessment of a student's level of competence (namely, medical knowledge and problem solving), they remain one of few objective quantifiable tools available to medical student educators for assessment of a student's performance. A 2009 survey revealed that 88% of U.S. and Canadian internal medicine clerkships administer the NBME subject exam in medicine.<sup>8</sup> Final exam scores are often reported in a student's summative evaluation.

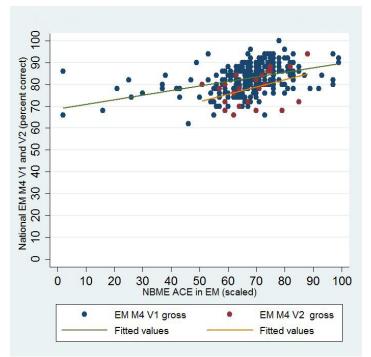
EM differs from other core clerkships in its position and timing in the medical school curriculum; not all schools require an EM rotation, and most EM rotations occur in the fourth year.<sup>1</sup> A 2014 survey of EM clerkship directors revealed that EM is a required rotation at 52% of medical schools.<sup>1</sup> This percentage has risen from a similar survey in 2007, in which EM was a required rotation at only 36% of medical schools.<sup>9</sup> As medical schools increasingly adopt EM as a core clerkship, the need for standardized end-of-rotation exam options will likely continue to rise.

Many EM rotations are completed away from a student's home institution, either because the home institution lacks a robust academic EM training program, or because the student



**Figure 1.** Correlation of NBME EM-ACE and National EM M4 V1 and V2.

*EM*, emergency medicine; *V1*, first version; V2, second version; *NBME*, National Board of Medical Examiners; *EM-ACE*, Advanced Clinical Exam in Emergency Medicine



# Figure 2. Correlation of NBME EM-ACE and National EM M4 V1 and V2.

*EM*, emergency medicine; *V1*, first version; V2, second version; *NBME*, National Board of Medical Examiners; *EM-ACE*, Advanced Clinical Exam in Emergency Medicine

| Comparison                     | Pearson's Correlation coefficient | R-squared value |
|--------------------------------|-----------------------------------|-----------------|
| NBME (raw) version V1 EM M4    | 0.51                              | 0.26            |
| NBME (scaled) version V1 EM M4 | 0.42                              | 0.18            |
| NBME (raw) version V2 EM M4    | 0.58                              | 0.30            |
| NBME (scaled) version V2 EM M4 | 0.41                              | 0.13            |

| Table 1. Pearson's correlation coefficient and R-squared values for the NBME EM-ACE (raw and scaled scores) and V1 and V2 of the |
|--|
| EM M4 exam.  |

*NBME,* National Board of Medical Examiners; *EM-ACE,* Advanced Clinical Exam in Emergency Medicine; *EM,* emergency medicine; *V1,* first version; V2, second version

chooses externships as audition rotations in preparation for entering the residency match. Scores from end-of-rotation exams are not only reported in end-of-rotation summative evaluations, but also frequently reflected in letters of recommendation from these externships. With EM being a popular specialty choice and competition for EM residency positions increasing, any objective measure of student performance has the potential to have a profound effect on a student's candidacy for residency.<sup>10</sup> Correlation and comparison data between the NBME and EM M4 exams provides the ability to compare applicants who have taken different exams.

Importantly, cost is also a factor. As more medical schools require students to complete an EM clerkship, there may be increased use of the NBME EM-ACE. The exam was provided free to clerkships for the first year. Starting in July 2014, there has been a \$41 per student fee for use of this exam.<sup>11</sup> Some EM clerkships may have funding through their medical school or department to cover such expenses; however many EM clerkships likely do not have a readily available funding source for student exam fees. Schools may be even less likely to fund the exam for visiting externs. If the cost of the exam is deferred to students, this may limit a student's ability to accept externships. The National EM M4 Exams have been offered free of charge since their release and would remain a viable option for clerkship directors without access to funding for the NBME EM-ACE. The usage of the National EM M4 Exams is likely to remain common. It is notable that nationwide usage of the National EM M4 Exams has remained steady since the release of the NBME EM-ACE, reflecting a continued need for these exams.<sup>7</sup> Given the high likelihood that both the NBME EM-ACE and the National EM M4 Exams will continue to be used to assess EM students, the ability to compare student performance on these exams is advantageous.

While it is not surprising that exams based on the same core curriculum and written by trained item writers would yield a positive correlation, the documentation of this correlation is helpful for the reasons discussed above. The observed positive correlation between student performance on the National EM M4 Exams and the NBME EM-ACE is also encouraging because it suggests that the National EM M4 Exams, which were created on a limited budget by national EM educators who volunteered their time and efforts, are able to effectively assess medical student knowledge comparably to the EM exam offered by the NBME, which is considered the gold standard for student exams.

## LIMITATIONS

The first limitation to acknowledge is the validity of multiple-choice questions as a tool in the assessment of student performance. While multiple-choice written exam questions may only provide a partial assessment of medical knowledge and perhaps basic clinical reasoning skills, they are a routine part of assessment at virtually every level of training from grade school and high school, through college, medical school, residency, and the board certification and recertification processes. Even as newer assessment techniques, such as simulation and online interactive cases, continue to be developed, the multiple-choice question remains a frequently used assessment tool and piece of a student's overall assessment.

Another possible limitation of this study is that all of the authors were involved in the development of the National EM M4 Exams, and several were involved in the development of the NBME EM-ACE (KH, EM, LL, DW, CH). Theoretically, this could bias the results towards a positive correlation. It is unlikely that this bias, if present, altered the results of the study, as the population who took the test was heterogenous, geographically diverse, and the conclusion robust. Additionally, though the same item-writers were working with the same curriculum and core content, the items themselves were vetted and edited by an outside organization (NBME) and the process of item writing itself was significantly different in the two systems.

An additional limitation of this study is that the data provided by the NBME came in the form of raw data (percent correct) for the first six months of the study, but was not available as such for the last half of the study. Scaled scores were available retrospectively for the first half of the study and from October until completion of data collection. We chose to report both the raw and scaled score correlations, however, the NBME will only be reporting scaled scores going forward. As noted above, correlation existed for both raw score and scaled score data.

The number of students completing V2 was low (n=24) compared the number of students completing V1 (n=279). This ratio is in line with the ratio of V1 and V2 exams that have been completed since inception, 5,060 and 787, respectively.<sup>7</sup> Future

studies could obtain more data for V2 examinees.

Another potential limitation to our study is that the number of EM rotations completed by a student was not collected as a potential confounding variable. Many students, especially those applying in EM, complete more than one EM rotation. A more experienced student could be expected to perform better on an end-of-rotation exam than a student who has completed only one EM rotation. It is unlikely that greater EM experience would introduce a systematic bias when comparing exam performance on two exams by the same student, however. This represents an area for future study.

One last potential limitation is how students' scores were used, i.e. students' grades were derived almost exclusively from their scores on the National EM M4 Exams, while performance on the NBME EM-ACE was not "high stakes." Students may have been more motivated to score well on the EM M4 exam as compared to the NBME exam, which could have resulted in lower scores on this exam.

#### CONCLUSION

Two standardized, end-of-rotation exam options for fourth-year EM students currently exist, the National EM M4 Exams and the NBME EM-ACE. There is a modest positive correlation in student performance on these exams, suggesting that both exams are effective in assessing EM student knowledge of the published fourthyear EM student curriculum, and enabling comparison of student performance between students completing different exams. While this correlation does not completely address whether either exam is effective at assessing students' comprehension of the EM core curriculum, it is encouraging and does suggest that either exam is effective as an end of rotation assessment method.

Address for Correspondence: Katherine Hiller, MD, MPH, 1501 N. Campbell Ave, Tucson, AZ 85724. Email: khiller@aemrc.arizona. edu.

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# Ultrafest: A Novel Approach to Ultrasound in Medical Education Leads to Improvement in Written and Clinical Examinations

University of California, Irvine, School of Medicine, Irvine, California

Kiah Connolly, MD Lancelot Beier, BS Mark I. Langdorf, MD, MHPE, RDMS Craig L. Anderson, PhD, MPH John C. Fox, MD, RDMS

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**Introduction:** Our objective was to evaluate the effectiveness of hands-on training at a bedside ultrasound (US) symposium ("Ultrafest") to improve both clinical knowledge and image acquisition skills of medical students. Primary outcome measure was improvement in multiple choice questions on pulmonary or Focused Assessment with Sonography in Trauma (FAST) US knowledge. Secondary outcome was improvement in image acquisition for either pulmonary or FAST.

**Methods:** Prospective cohort study of 48 volunteers at "Ultrafest," a free symposium where students received five contact training hours. Students were evaluated before and after training for proficiency in either pulmonary US or FAST. Proficiency was assessed by clinical knowledge through written multiple-choice exam, and clinical skills through accuracy of image acquisition. We used paired sample t-tests with students as their own controls.

**Results:** Pulmonary knowledge scores increased by a mean of 10.1 points (95% CI [8.9-11.3], p<0.00005), from 8.4 to a posttest average of 18.5/21 possible points. The FAST knowledge scores increased by a mean of 7.5 points (95% CI [6.3-8.7] p<0.00005), from 8.1 to a posttest average of 15.6/ 21. We analyzed clinical skills data on 32 students. The mean score was 1.7 pretest and 4.7 posttest of 12 possible points. Mean improvement was 3.0 points (p<0.00005) overall, 3.3 (p=0.0001) for FAST, and 2.6 (p=0.003) for the pulmonary US exam.

**Conclusion:** This study suggests that a symposium on US can improve clinical knowledge, but is limited in achieving image acquisition for pulmonary and FAST US assessments. US training external to official medical school curriculum may augment students' education. [West J Emerg Med. 2015;16(1):143–148.]

## INTRODUCTION

Physician-performed bedside ultrasound (US) for diagnosis and procedural guidance is valuable, with studies from many specialties showing improved evaluation of patient pathology.<sup>1,2</sup> US is portable, relatively inexpensive, and has no radiation or health risks. Furthermore, technology advances and declining machine costs have improved bedside applicability.<sup>3</sup> The major limitation to physician-performed US in standard practice is proficiency at image acquisition and interpretation. Integration of US training into medical education is a next critical step. While some medical students already receive limited or even advanced US training as part of their curriculum, most do not. This study evaluated the effectiveness of hands-on training at a bedside US symposium

("Ultrafest") in improving clinical knowledge and image acquisition skills of medical students.

## **METHODS**

"Ultrafest," created in May 2012, was the nation's first multidisciplinary bedside US symposium directed to medical students who lacked formal curricula in their native schools. Attendance reached over 200 student attendees in 2012, so the conference was repeated in February 2013 where we studied the educational impact of the symposium reported here.

The conference was free and accepted students from allopathic, osteopathic and physician assistant programs. The symposium was tailored to the interests of each student, allowing them to choose five of 12 workshops to most effectively build skills and meet their peak interests. All students were instructed to watch subjectspecific online tutorials created by the US director prior to arrival to maximize hands-on experience at the event. Workshops offered were cardiology, anesthesia, pulmonary, male genitourinary, female pelvis, question-and-answer image review, pediatrics, obstetrics, musculoskeletal, trauma simulation, hepatobiliary and vascular. Workshops featured 32 live models including multiple live pelvic, pregnant, and male genitourinary models, as well as musculoskeletal and hepatobiliary pathology. Thirty-six US machines were used in addition to multiple "Sonosim" ultrasound simulators to depict real-time trauma and cardiac pathology. Phantom task trainer models were used to enable procedure practice (central line placement and thoracentesis), and viewing of pathology in transvaginal, Focused Assessment with Sonography in Trauma (FAST), and pleural effusion.<sup>4</sup>

More specifically the technology utilized included Sonosim "Editions" (Santa Monica, CA), Blue Phantom Combination IUP Ectopic Pregnancy Transvaginal Model (item #BPOB1227), Blue Phantom FAST Exam Real Time Training Model (item #: BP-FAST1800), Blue PhantomTransparent Internal Jugular Central Line (item #: BPIJ500-C), Blue Phantom Regional Anesthesia and Central Line Model (item #: BPHNB670), Blue Phantom Midscapular thoracentesis model (item #: BPTT2-1005), and the CAE/ VIMEDIX: Transthoracic ECHO simulator.

In February 2013, 208 students from eight medical and allied health schools attended Ultrafest (University of California, Irvine, Los Angeles, Davis and San Diego, University of Southern California, Loma Linda University, Touro University and Western University). All participating students were enrolled in MD (155, 75%), DO (38, 18%), or PA (15, 7%) programs. Twenty physicians from obstetrics and gynecology, anesthesia, emergency medicine, and internal medicine from UC Irvine, Davis and San Francisco, Stanford and Loma Linda served as workshop leaders. Twenty-four well-trained UC Irvine medical students served as small group instructors, with student to instructor ratio <5:1. All attendees participated in five one-hour workshops in addition to four hours of didactic online preparatory training, for nine total instructional hours.

Forty-eight students (38 MD, 8 DO, 2 PA) consented to this cohort study to evaluate change in practical knowledge and clinical skills in US before and after Ultrafest. Students were randomly assigned to be evaluated for proficiency in Pulmonary US or FAST, assessing clinical knowledge through written exam and image acquisition. We did not assess prior US training for the volunteer subjects. These volunteers were required to participate in the Pulmonary US or FAST course, which required some volunteers to change their preferences to include one of these courses. All students in the study were assigned to review the pre-course online didactic material for Pulmonary US and FAST.

The instruction at all stations, including the Pulmonary US and FAST stations was standardized to include specific information detailed in handouts given to each of the instructors prior to Ultrafest. This ensured that each instruction goal was met during their hands on course, and provided appropriate training to perform and interpret point of care ultrasound.

#### Course Content

Each station included instruction on the ideal probe to use, optimal probe placement for image acquisition and the interpretation of relevant anatomy for each ultrasound study. The Pulmonary US station also included specific instruction on the identification and clinical significance of A lines and B lines, how to identify a pneumothorax using both "b" and "m" modes, the recognition of lung sliding and various signs including the "sky, ocean, beach" sign and the "barcode" sign, as well as how to identify pleural effusions and to recognize significant artifact including mirror imaging. While the live models did not have pulmonary pathology, the students were able to identify pathology of pleural effusion through phantom models and were provided images of pneumothorax examples. The FAST US focused on acquisition of the four windows of the FAST exam, including subxiphoid cardiac window, hepatorenal recess, splenorenal recess, and suprapubic views. The FAST exam also emphasized identifying anechoic free fluid as well as the recognition of clinically relevant artifacts including reverberation, mirror image artifact, posterior enhancement and edge artifact. While the live models did not have pathology in the FAST stations, phantom models with positive FAST scans in addition to image clip examples were provided for the students.

Pre-Ultrafest examinations were done during the hour prior to the conference, with post examinations immediately after. All testing was proctored. Students from the host university were excluded due to high baseline exposure to US and teaching materials. Students who completed the study were compensated with an US textbook. The study was approved by the local institutional review board. Primary outcome measure was improvement in multiple-choice questions focused on pulmonary or FAST US knowledge. Secondary outcome was improvement in image acquisition for four windows on standardized models in either pulmonary US or FAST.

## Clinical Knowledge

Clinical knowledge was assessed by 21 written multiplechoice questions for either Pulmonary US or FAST. Questions were written by the US director and focused on practical knowledge for diagnosis and image interpretation. Paired t-test analysis was done on total scores of the pre- and postexaminations for both the Pulmonary US and FAST groups.

### Clinical Skills

We assessed clinical skills by ability of students to acquire four windows each in pulmonary US and FAST. For FAST, participants were instructed to scan the right upper quadrant, left upper quadrant, subxiphoid and suprapubic windows. For pulmonary US, participants scanned windows to evaluate pleural effusion, A and B lines, pneumothorax in 2D and then M-mode. Proctors saved image clips when students expressed verbal satisfaction with image quality. Participants were not given feedback about quality of images or instructed how to improve. Images were saved with a coded label to identify and match students.

Images were scored by the US director, blinded to student identification and timing of assessment, as unacceptable, acceptable, or excellent. We calculated overall score for each exam as the sum of four window components of each exam, with 0 points (unacceptable), 2 points (acceptable), and 3 points (excellent) assigned. An image was "unacceptable" if it could not reveal potential pathology. Acceptable images visualized the organs of importance to identify pathological changes if present. An additional point was given for an excellent image with proper gain, depth, location and scanning technique. The scoring reflected a larger difference between an unacceptable [0] and acceptable [2] image, than between acceptable and excellent [3], to reflect greater clinical import of an optimum diagnostic image. We conducted paired t-tests on pre- and post-data, with students as their own controls.

### RESULTS

#### Clinical Knowledge

We analyzed data for 46/48 subjects (two excluded for incomplete written exams). Twenty-four (of 46) completed pre- and post-Ultrafest pulmonary US written exams. Pulmonary knowledge scores increased by mean 10.1 points (95% CI [8.9-11.3], p<0.00005), from a pretest average 8.4, to posttest average 18.5 of 21 possible points (Figure 1). Twentytwo students completed the FAST pre- and post-Ultrafest written exams. FAST knowledge scores increased by mean 7.5 points (95% CI [6.3-8.7] p<0.00005), from pretest average 8.1 to posttest average 15.6 of 21 possible points (Figure 1). For neither application were there statistically significant pre-post differences by medical student year of training.

## Clinical Skills

We analyzed image acquisition data on 32/48 students (66%, 16 each in pulmonary US and FAST) by both paired t-test and overall percent improvement. Mean score improved from 1.7 pre- to 4.7 posttest (of 12 possible

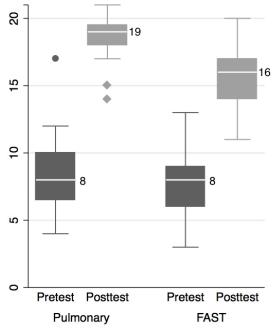


Figure 1. Boxplot of written Clinical Knowledge pre- and post-Ultrafest scores for Pulmonary Exam and FAST (Focused Assessment of Sonography for Trauma) n =22.

points). Therefore, the average posttest performance did not meet the eight points needed for adequate image acquisition in all four windows (2 points each). For both studies combined, mean improvement was 3.0/12 (95% CI [2.0-3.9], p<0.00005), FAST exam alone improved by 3.3 (95% CI [2.0-4.6], p=0.0001), and pulmonary exam improved by 2.6 (95% CI [1.1-4.2], p=0.003). The data show that image acquisition on both exams combined improved from 80% unacceptable, 19% acceptable, and 2% excellent, to 47% unacceptable, 43% acceptable, and 10% excellent. The views for the two modalities are separated in Figure 2.

## LIMITATIONS

These data are limited by small sample size and moderate drop-out rate for 16 inadequate image clips. The 48 volunteers recruited may have had additional interest, aptitude or experience with US, and could have inflated the measured improvement. We made no attempt to determine whether and to what extent students carried these skills to the clinical bedside after training, or whether they retained what they learned. Image quality assessments of "unacceptable," "acceptable" and "excellent" were subjective and unvalidated. Student preceptors may have coached students contrary to instruction. We did not check or validate students' viewing of pre-course materials.

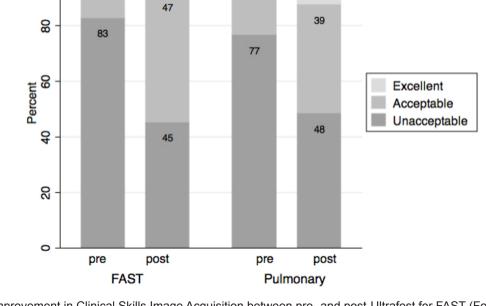
We did not assess prior US training or expertise in our volunteer subjects. This would be a confounding variable in our assessment methods. Our study design did not discriminate between the value of the pre-course didactics, the one- hour lecture and the hands-on training.

17

8

Research on the efficacy of ultrasound in both medical education and patient care is expanding. Results from multiple studies support using ultrasound to facilitate and supplement anatomy courses in medical education.<sup>5,6</sup> Additional research suggests direct clinical benefit from bedside US, demonstrating improved physical exam skills and overall increased confidence in medical students using US.<sup>7</sup> Furthermore, one study showed medical students who were taught US achieved greater accuracy collecting specific physical exam data when compared to experienced physicians not using US.8 Such studies suggest that physician-performed bedside US may enhance diagnostic accuracy and therefore lead to more informed treatment decisions. However, most medical schools in the United States do not have integrated US curricula, leaving most students without instructors or machines to learn on. While many medical schools may be interested in including such training, there are many limitations, including lack of funding and faculty resources to support such an endeavor.

This study sought to determine whether hands-on US training, outside traditional medical school curricula in a day-long symposium, could improve student knowledge and skills. The effectiveness of similar short (<6 hours) hands-on training models in medical education has been supported by other studies in a variety of fields including surgery and BLS.<sup>9,10</sup> Student interest in US training symposia is demonstrated by robust attendance for two consecutive years. Subjective evaluations of the symposium have also been overwhelmingly positive.<sup>4</sup>



3

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12

8

Figure 2. Percent improvement in Clinical Skills Image Acquisition between pre- and post-Ultrafest for FAST (Focused Assessment of Sonography for Trauma) and Pulmonary Ultrasound exams. N=16 for each ultrasound application.

Our cohort study on Ultrafest suggests that a daylong symposium on US is effective in improving clinical knowledge but not in achieving adequate image acquisition for pulmonary and FAST ultrasound assessments. We found significant improvement in written clinical knowledge exam by almost every student, suggesting students achieved clear advances in understanding of the US examinations and interpretations. Although we found significant improvement in practical image acquisition, almost half of these were still judged inadequate after training. This implies that most students were poorly skilled at image acquisition prior to training, and that the one-hour subject-specific workshop was insufficient to achieve proficiency. Further studies are needed to assess clinical applicability of these US techniques, and those from the other workshops, in clinical practice.

The complexity of hands-on training in US for large groups presents many challenges, including assessing student improvement and proficiency, and evaluating integration of new skills with patient care. As each patient is unique in body habitus, pathology and cooperation, each US application requires integration of many user skills that are difficult to assess. In addition, skill in image acquisition does not reliably generalize across different US examinations, as each requires training on required windows.<sup>11</sup> The amount of training required to become proficient in each examination also seems to differ.<sup>12</sup>

While free US symposia for hundreds of students may offer significant benefits, they require extensive preparation, experienced volunteers, and funding. Therefore, such symposia may be unsustainable. This symposium included 36 ultrasound machines, seven phantom models, finances for food and special pelvic and genitourinary models (\$200-\$400 each), 32 live volunteer models, 20 volunteer physician instructors, 24 trained US medical student instructor volunteers, and adequate space to hold workshops in 15 breakout rooms. However, the paucity of US training capability among medical schools may make central training at centers of excellence viable, with pooling of financial resources.

Although the hands-on component of training was the primary purpose of Ultrafest, we used a written examination with questions focused on the acquisition and interpretation of the corresponding ultrasound study as a primary outcome measure. Practical examinations in the two modalities were used as secondary endpoints, as this is a non-traditional way of assessing ultrasound skills. There is no practical examination validated at this time to evaluate a clinician's ultrasound skills.

For example, the national American Registry of Diagnostic Medical Sonographers credential assessment is a multiple-choice format written examination, though it seeks to measure knowledge on performing and interpreting ultrasound images. We did not similarly grade US images for Ultrafest, as models had different anatomy, no pathology, and image grading is subjective. The written exam we used by contrast, is more objective and reflects pathology. We have attached the test questions as Appendix I. There has been a recent transition of teaching ultrasound at the bedside as opposed to in a lecture hall which has been shown to improve learning.<sup>14</sup>

Future symposia may foster greater proficiency in US skills by lengthening the hands-on workshops and expanding the symposium to two or more days. One small study supports a two-day model where PGY 1 residents, novice to ultrasound, participated in two, four-hour blocks over two days in physics, FAST, cardiac, aorta, renal, gallbladder, and pelvic sonography. Although the study was limited by sample size (n =12), they found significant improvement which persisted for six months without additional training.<sup>13</sup>

Future studies should evaluate students longitudinally for shor-t and long-term (3-6 months) retention of knowledge and psychomotor skills.

#### CONCLUSION

Physician performed bedside US is a promising adjunct to traditional physical examination. Its major limitation is physician training, as most medical schools have not yet integrated US. A one-day, nine-hour, small group instruction and practice symposium improved student knowledge on trauma and pulmonary US, and improved image acquisition, but the latter fell short of significant proficiency. While many improvements can be made to this symposium, this model suggests that central training centers of excellence may be a viable option for US training in medical education.

#### ACKNOWLEDGEMENTS

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Address for Correspondence: Kiah Connolly, MD, UC Irvine Emergency Medicine, Rt. 128-01, Orange, CA 92868. Email: kcc@ uci.edu.

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## 13-Year-Old with Cryptic Abdominal Pain

Stephanie Spring, DO\* Richard Anderson, MD\* Jestin N. Carlson, MD, MSc\*† \*Saint Vincent Health System, Department of Emergency Medicine, Erie, Pennsylvania <sup>†</sup>Unviersity of Pittsburgh School of Medicine, Department of Emergency Medicine, Pittsburgh, Pennsylvania

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A 13-year old female patient presented to the emergency department (ED) with four days of intermittent non-radiating, left upper quadrant pain, associated with non-bloody, nonbilious emesis and decreased appetite. The patient had been evaluated by a gastroenterologist three months prior for abdominal pain. At that time an esophagogastroduodenoscopy revealed a trichobezoar in the stomach too large for endoscopic removal. Elective surgical removal had been offered to the patient, although surgery had not yet been scheduled.

Vital signs were within reference limits for the patient's age. The patient had tenderness throughout the left upper quadrant, however there was no guarding or rebound tenderness. The patient underwent computed tomography (CT) of the abdomen and pelvis, which confirmed the thichobezoar in the stomach and intussusception of the bowel (Figures 1 and 2) consistent with Rapunzel Syndrome.

#### DISCUSSION

Rapunzel Syndrome, named after the Brothers Grimm's

fairy tale princess with long hair by the same name, is a rare disorder resulting from trichobezoar formation and subsequent extension of the tail of the bezoar into small bowel associated with trichophagia (Figure 1).<sup>1</sup> The tail of the hair acts as a lead point, causing intussusception of the bowel (Figure 2). Bezoars are rare, occurring in less than 1% of patients undergoing upper gastrointestinal endoscopy and only a small number of patients have been reported with Rapunzel Syndrome.<sup>1-3</sup> While many patients may undergo CT scans, ultrasound and plain radiographs have also been used to establish the diagnosis.<sup>4,5</sup> Management includes removal via endoscopy or elective surgery although complications including gastric perforation has been reported.<sup>6,7</sup> The patient was transferred to a pediatric hospital where she underwent an exploratory laparotomy including bezoar removal from both the stomach and jejunum. Over the next 48 hours the patient's diet was advanced and was discharged home on post-operative day five.

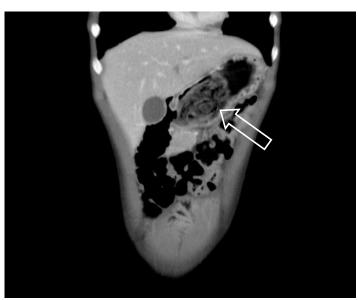


Figure 1. Bezoar in the stomach.



**Figure 2.** Target sign signifying intussusception. The arrow points to the tail of the bezoar acting as a lead point for the intussusception.

Address for Correspondence: Jestin Carlson, MD, MSc, Saint Vincente Health Center, 232 West 25th St. Erie, PA 16544. Email: jcarlson@svhs.org.

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# Delayed Diagnosis of Gastric Outlet Obstruction from Bouveret Syndrome in a Young Woman

Zachary Smith, DO\* Jodie Totten, MD<sup>+</sup> Adrienne Hughes, MD<sup>+</sup> Jared Strote, MD<sup>+</sup> \*Madigan Army Medical Center, Department of Emergency Medicine, Tacoma, Washington

<sup>†</sup>University of Washington-Seattle Campus, Division of Emergency Medicine, Seattle, Washington

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Bouveret syndrome is a rare presentation of gastric outlet obstruction caused by a gallstone in the proximal duodenum via a bilioenteric fistula. This is an infrequent although clinically significant cause of abdominal pain, almost exclusively in the elderly. The clinical presentation is similar to that of a small bowel obstruction with abdominal pain, nausea and vomiting. Surgery or endoscopy is often required for definitive diagnosis and therapy. We describe the case of a young woman with this condition who had a delayed diagnosis in part because of her age and the rarity of the condition. [West J Emerg Med. 2015;16(1):151-153.]

#### INTRODUCTION

Bouveret syndrome is a rare presentation of gastric outlet obstruction caused by a gallstone in the proximal duodenum via a bilioenteric fistula. Gallstone ileus is uncommon itself, accounting for only 1-4% of intestinal obstructions and Bouveret syndrome is seen in only 1-3% of gallstone ileus cases. Presentations of Bouveret syndrome are at risk of being missed, as symptoms are frequently non-specific and presentations are often benign. The disease is almost exclusively one of the elderly, increasing the likelihood of missed diagnosis when it occurs in younger patients.<sup>1</sup> We describe the case of a young woman with this condition who had a delayed diagnosis in part because of her age and rarity of the condition.

#### **CASE REPORT**

A 26-year-old female presented to our emergency department (ED) complaining of abdominal pain. The pain was located in the right upper quadrant; it was described as severe, achy, constant, non-radiating, and associated with nausea and non-bilious, non-bloody vomiting. She had experienced intermittent pain and vomiting for several months but had not sought medical attention until the day of presentation. She denied any fever, chills, hematemesis, diarrhea, melena, pruritis, abnormal vaginal bleeding or discharge. She had a chronic hepatitis C virus infection and a history of prior intravenous heroin use but was currently on methadone maintenance therapy. She smoked approximately 5-10 cigarettes per day and denied any active drug or alcohol use. She did not take any medications and had no allergies.

On examination, her vital signs were all within normal limits. The patient had moderate abdominal tenderness to palpation in the right upper quadrant and mid-epigastrium and an equivocal Murphy's sign. The remainder of her examination was notable for a lack of abdominal distension, rebound, guarding or any palpable masses. Laboratory studies demonstrated a slight transaminitis (aspartate aminotransferase [AST] 82 [normal range 15-40] units/L, alanine aminotransferase [ALT] 84 [normal range 6-40] units/L, and alkaline phosphatase 135 [normal range 25-100] units/L). Blood glucose, lipase, bilirubin, hematocrit, white blood count, electrolytes, renal function and coagulation function tests were all normal, and urine pregnancy test was negative. An abdominal plain film showed no free air and normal bowel gas pattern. An abdominal ultrasound revealed no biliary ductal dilation, although the gallbladder was unable to be visualized. Repeat evaluations after treatment with aluminum and magnesium hydroxide demonstrated a benign abdomen with improved symptoms. Omeprazole and odansetron were prescribed and the patient was discharged home.

Three days later, the patient returned to the ED. She reported worsening abdominal pain and increased nausea despite taking the prescribed medications. On exam, her vitals were still normal. She again demonstrated moderate right upper quadrant and mid-epigastric tenderness without distention, masses, Murphy's sign, guarding, or rebound. The remainder of the examination was unchanged and normal. Laboratory studies revealed an AST of 252 units/L, ALT of 272 units/L, and alkaline phosphatase of 133 units/L. The patient's urine pregnancy test, lipase, bilirubin, hematocrit, white blood count, electrolytes, renal function and coagulation function tests remained within normal limits. A computed tomography (CT) of the abdomen/pelvis was obtained and demonstrated mild thickening of the gallbladder wall, circumferential wall thickening and mucosal enhancement of the first part of the duodenum, with surrounding omental stranding and an associated visualized fistulous tract to the gallbladder. There were no gallstones identified in the bowel lumen and no clear evidence of gastric obstruction (Figure).

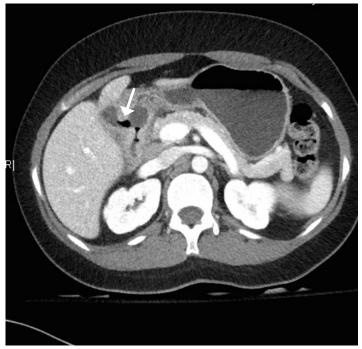
Despite the lack of radiologic evidence of obstruction, the patient was admitted to the general surgery service with the clinical diagnosis of presumed gastric outlet obstruction likely secondary to proximal gallstone ileus. A nasogastric tube was placed to decompress the stomach. Initial treatment included administration of intravenous fluids, anti-emetics, and pain medications.

During her admission, the patient underwent fluoroscopic examination of the duodenum with gastrograffin which demonstrated complete obstruction between the duodenum and gastric antrum. Subsequent esophagogastroduodenoscopy (EGD) demonstrated a large gallstone occluding the lumen of the pylorus and the patient was subsequently scheduled for endoscopic removal of gallstone impaction the following day under general anesthesia. Repeat EGD demonstrated severe inflammation at the level of the pylorus and a fistulous tract between the gallbladder and duodenum consistent with cholecystoduodenal fistula. The previously noted gallstone was no longer present. Serial balloon dilation was performed with partial but incomplete resolution of the duodenal bulb gastric outlet obstruction. A nasojejunal feeding tube was placed, and the patient was started on enteral nutrition. Her diet was slowly advanced and no further interventions were performed.

## DISCUSSION

Bouveret syndrome is named after Leon Bouveret who published two case studies of this condition in 1896.<sup>1</sup> It is defined as gastric outlet obstruction by a gallstone in the duodenum, which occurs via gallstone erosion through the intestinal wall. This creates a bilioenteric fistula, most commonly cholecystoduodenal.<sup>2</sup> The proposed mechanism involves chronic inflammation leading to intra-abdominal adhesions as well as acute cholodocolithiasis. This, in turn, creates increased pressure and ultimately gallbladder ischemia, necrosis, and subsequent bilioenteric fistula.<sup>2</sup> Duodenal diverticula may also place patients at higher risk.<sup>3</sup>

Bouveret syndrome occurs more frequently in females than males, which is consistent with the higher frequency of gallstones in women.<sup>3</sup> It is overwhelmingly a disease of the



**Figure.** Transverse computed tomography of air passing from duodenum through a fistula into the gallbladder.

elderly; a recent review, which examined all published reports of Bouveret syndrome from 1974 (128 patients), described a mean age of 71 years with a standard deviation of 11.

Patients with Bouveret syndrome present with symptoms similar to small bowel obstruction: nausea, vomiting and epigastric abdominal pain, often waxing and waning with resolution of symptoms intermittently, making diagnosis particularly challenging. Common exam findings include abdominal tenderness, dehydration, and abdominal distention.<sup>1</sup> Hematemesis may be present due to erosion of the cystic artery and fever is not uncommon.<sup>1,2</sup>

Abdominal plain radiographs are often the first imaging study obtained and may illustrate Rigler's triad of gallstone ileus of ectopic gallstones, pneumobilia, and small bowel obstruction.<sup>4</sup> Plain films, however, are diagnostic of Bouveret's syndrome in only approximately 21% of patients, and further imaging usually occurs.3 Ultrasound can be helpful to show biliary pathology, but ultimately CT is needed to confirm the diagnosis of obstruction and stone, even though a fistula is rarely visualized on CT.<sup>1,3,5</sup> Endoscopy is an appealing combined diagnostic and therapeutic option as these patients frequently have multiple co-morbidities and the obstructing stone is seen in 69% of endoscopies; however, removal is only successful in 10%.<sup>1,3</sup> Various types of lithotripsy procedures have also been used. Up to 91% of patients may ultimately require surgical repair;<sup>3</sup> enterolithotomy or gastrotomy are the most common options, frequently including a cholelcystectomy.<sup>1</sup> The mortality rates are now estimated at 12%, in great part due to the advanced age and frequent comorbidities of the patients who develop this condition.<sup>3</sup>

Although rare, and generally thought of as a disease of

the elderly, we suggest that Bouveret syndrome be considered in younger patients presenting with signs and symptoms suggestive of small bowel obstruction but without a clear cause.

Address for Correspondence: Jared Strote, MD, Division of Emergency Medicine, Box 356123, 1959 NE Pacific St., Seattle WA 98195. Email: strote@u.washington.edu.

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## **Complications of New Medications**

Carlos J. Roldan, MD Linda Paniagua, MD The University of Texas Health Science Center at Houston, Department of Emergency Medicine, Houston, Texas

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Numerous mandibular pathologies are diagnosed in the emergency department (ED). We present the case of a woman with severe right-sided mandibular pain who was found to have a pathological fracture and osteonecrosis of the jaw (ONJ). The etiology of ONJ was found to be associated to previous use of zoledronic acid to treat osteoporosis. The aim of this case report is to discuss the etiology, diagnosis and treatment of ONJ secondary to the use of zoledronic acid and to outline a clinical condition rarely seen in the ED whose incidence might rise with the increasing use of bisphosphonates. [West J Emerg Med. 2015;16(1):154-156.]

#### **INTRODUCTION**

Osteonecrosis, the destruction and death of bone tissue, has traditionally been attributed to ischemia, infection, neoplastic disease and trauma. Reports in the medical literature have begun to establish a direct correlation with the use of pharmacological agents intended to prevent skeletal fractures in patients with malignancies such as multiple myeloma and prostate cancer.<sup>1</sup> Among those pharmacological agents, bisphosphonates (BPs) have gained popularity in the non-cancer population for the treatment of postmenopausal osteoporosis. The intended clinical benefits are not risk free. Among other effects, BPs have been shown to stimulate the gamma-delta T cells, which can potentially contribute to indiscriminate cytotoxicity against tumor cells and normal cells.<sup>2</sup> A wide range of additional systemic side effects have been described. Of particular concern is structural bone disease manifested as increased risk of fractures of the hip and pelvis and osteonecrosis of the mandible. It is unknown whether the risk continues after stopping the therapy. Localized pain is an early manifestation of bone compromise. In patients using BPs this is considered a warning sign of bone complications.

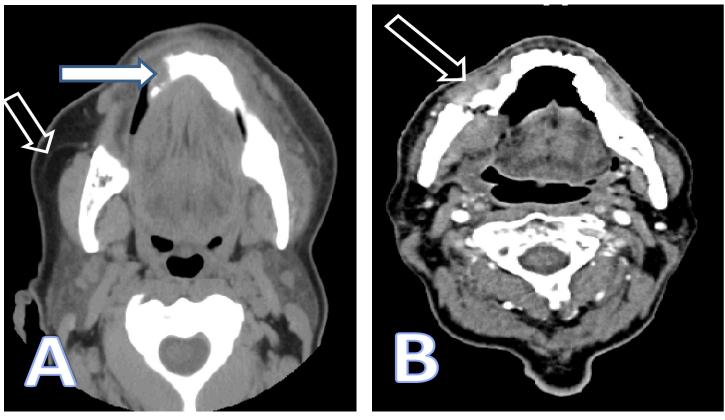
#### **CASE REPORT**

A 73-year-old woman with history of hypertension and osteoporosis presented to a suburban emergency department (ED) complaining of right-sided mandibular pain and gum swelling for one week. She was diagnosed with gingivitis and discharged home on oral antibiotics, analgesics and a mouth rinse solution. She was advised

to follow up with the dental service. After two weeks the symptoms continued to progress. She presented to our ED once the pain became unbearable after feeling a "pop" while trying to chew peanuts with the left side of her mouth. She denied malaise, fever, anorexia or any history of trauma. Our evaluation revealed a very uncomfortable-appearing female. She was afebrile (temperature 98.2°F) and had normal vital signs other than a blood pressure of 169/92mm Hg and heart rate 104 beats per minute. Her physical exam was remarkable for right mandibular edema, tenderness and crepitance to palpation. Her dentition was in fair condition and she had scattered fillings. A gravish discoloration of the gingiva was evident in the premolar zone with no apparent drainage. Laboratory values were within normal limits, including a white blood cell count of 8,000 cells/uL with 60% neutrophils. A computed tomography demonstrated "osteonecrosis of the jaw and a pathological fracture of the right ramus" (Figure). Further chart review established that the patient had been previously treated for osteoporosis with intravenous zoledronic acid once a year for two years. The most recent dose was one month earlier. The patient was hospitalized by ear nose throat surgery, and surgical reconstructive therapy was performed. Seven days later, her pain had nearly resolved and she was discharged home.

#### DISCUSSION

In 1995, the U.S. Food and Drug Administration approved the first BP agent. Since then several oral and intravenous BPs have been released to the market. BPs are used to inhibit resorption of bone mass in patients with bone metastases,



**Figure.** Computed tomography of the face without (A) and with (B) intravenous contrast. (A) Mandibular sclerosis with periosteal reaction of the mandibular body extending to the parasymphyseal region; given history of bisphosphonates therapy most likely osteonecrosis (full arrow). Diffuse subcutaneous edema and submental soft tissue swelling reflecting focal inflammatory changes (hollow arrow). (B) Osteoradionecrosis of the mandible with pathologic fracture of the right horizontal mandibular ramus (arrow).

bone primary lesions and for the treatment of osteoporosis.<sup>3</sup> With our aging population osteoporosis is becoming a matter of public health. This bone deficiency is estimated to result in two million fractures every year.<sup>4</sup> The estimated annual expenditure is between \$12.2 to 17.9 billion.<sup>5</sup>

Zoledronic acid, currently the most-prescribed intravenous BP for the treatment of osteoporosis, is also used for the treatment of hypercalcemia associated with malignancy, multiple myeloma and bone metastases from solid tumors. Despite being highly effective in reducing the risk of osteoporotic fractures, a number of safety concerns have surfaced. Atypical subtrochanteric and femoral fractures and osteonecrosis of the jaw have sparked debate over the safety issues associated with long-term use of these drugs.

Osteonecrosis of the jaw (ONJ), also known as avascular or aseptic necrosis of the mandible, jaw death, dead jaw disease, or bisphossy jaw, was first described by Marx et al. a decade ago.<sup>6</sup> It is a disfiguring and disabling condition under which the mandible bones suffer literal death. Although the exact pathophysiology of how ONJ relates to BP use has not been found, several pathogenic mechanisms have been proposed. The low bone turnover induced by BPs can lead to decreased blood flow, bone cell necrosis and apoptosis.<sup>6,7</sup> In conjunction with infection, decreased blood flow can lead to the development of non-healing exposed bone in the mouth.<sup>6,7</sup> Recent data suggest that mucosal damage is the event preceding infection and subsequent bone necrosis. A retrospective chart review of oncology patients (n= 4,000) treated with BPs suggested that mucosal damage was an important precipitating factor of ONJ.<sup>8</sup> The higher incidence of ONJ in cancer patients might be explained by the higher frequency of concomitant immunosuppression and the use of anti-cancer drugs and corticosteroids. The increasing evidence in the literature tying BPs and infection together cannot be dismissed.<sup>9</sup>

It is important to mention that the high levels of nitrogen content of some BPs, zoledronic acid among them, have been tied to ONJ to a much higher degree than the less nitrogen containing BPs.<sup>10</sup> In support of this, a review of 368 cases of BPs-cancer associated ONJ found that patients receiving intravenous nitrogen-containing BPs are at greatest risk for ONJ.<sup>11</sup>

In light of the current literature, it is imperative that clinicians be aware of the risk and benefits of BPs. There has been evidence suggesting that dental trauma, surgical procedures and extractions and increased dosage of BPs could increase the risk of ONJ.<sup>12,13</sup> It is also presumed that diabetes, autoimmune conditions, periodontal disease, poor oral hygiene and poorly fitting dentures may increase the risk of developing ONJ.<sup>14</sup> A close dental examination and preventive dentistry prior to beginning zoledronic acid is recommended. A stricter patient selection and education with close follow up might be a reasonable strategy to monitor the development of these complications.

The role of the emergency physician is to be aware of the clinical significance of localized bone pain, even in the absence of trauma, in patients under current or past therapy with BPs. Clinical suspicion should be followed by diagnostic imaging and proper referral for definitive treatment. The current treatment of ONJ belongs to the surgical specialties; although treatment protocols have been outlined, there has been no randomized clinical trial assessing management strategies. Thus, management of ONJ remains controversial.

Address for Correspondence: Carlos J. Roldan, MD, The University of Texas Medical School of Houston, Department of Emergency Medicine, 6431 Fannin Street, JJL 450 G, Houston, TX 77030. Email: Carlos.J.Roldan@uth.tmc.edu.

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## **Bilateral Inferior Shoulder Dislocation**

Erica Cacioppo, MD James R. Waymack, MD Southern Illinois University School of Medicine, Division of Emergency Medicine, Department of Surgery, Springfield, Illinois

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A 42-year-old male with a history of multiple shoulder dislocations presented to the emergency department via emergency medical services with both arms locked above his head, stating that he had been jumped at a bar and had since been unable to move his arms. A single anteroposterior chest radiograph (Figure) demonstrates bilateral inferior shoulder dislocations. The humeral head (white arrow) is displaced from the glenoid (yellow arrow) on each side.

Inferior shoulder dislocations are the rarest of all glenohumeral joint dislocations, accounting for less than 1%; and bilateral inferior dislocations are therefore extremely infrequent. The classic presentation is the patient whose arm is locked above his head in a hyper-abducted fashion. The inferior dislocation must first be converted to an anterior dislocation by slowly adducting the arm. The anterior dislocation can then be reduced using routine maneuvers.

In our case the patient underwent reduction with propofol sedation and was placed in bilateral shoulder slings. He was observed overnight by the orthopedic service for ethanol metabolism and was safely discharged home the next day in bilateral arm slings.

Address for Correspondence: James R. Waymack, MD, Southern Illinois University School of Medicine. Email: jwaymack@siumed.edu.

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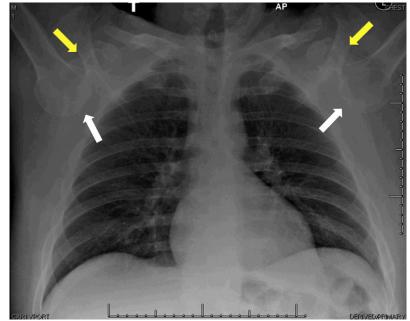


Figure. Radiograph of bilateral inferior shoulder dislocations. Humeral head (white arrow), displacement from glenoid (yellow arrow).

# Acute Idiopathic Compartment Syndrome of the Forearm in an Adolescent

Kelley Smith, MD Robert W. Wolford, MD, MMM University of Illinois College of Medicine at Peoria, Department of Emergency Medicine, Peoria, Illinois OSF Saint Francis Medical Center, Department of Emergency Medicine, Peoria, Illinois

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Acute compartment syndrome (ACS) is a condition typically associated with long bone fractures or severe trauma; however, non-traumatic etiologies also occur. We describe a case of an otherwise healthy female pediatric patient presenting with unilateral forearm pain without an inciting injury. Intracompartmental pressures of the forearm were measured and she was diagnosed with idiopathic compartment syndrome. Our goal is to encourage clinicians to consider acute compartment syndrome even in the absence of trauma. [West J Emerg Med. 2015;16(1):158-160.]

#### INTRODUCTION

Acute compartment syndrome (ACS) is an orthopedic emergency that develops when the pressure within a closed fascial space rises and compromises the perfusion to that compartment. It is most commonly seen in the limbs but can occur in other parts of the body. Fractures are the most common etiology of ACS (nearly 75%), and the most common associated with ACS is the tibia.<sup>1</sup> However, ACS can occur in the absence of fracture or other injury.

#### **CASE REPORT**

A 17-year-old Caucasian female presented to the emergency department with the complaint of left forearm pain. She initially noted paresthesia of the left hand and then left forearm pain. The pain had been progressive over the previous 10 hours and was exacerbated with flexion or extension of the wrist. She could not recall any injury or inciting event. She was otherwise healthy and without any significant past medical history. Her family history was unremarkable with the exception of her mother's brother who died of Duchenne muscular dystrophy. Her mother had been tested for Duchenne carrier status and was negative. Her only medication was an oral contraceptive. She denied the use of tobacco, alcohol, and illicit drugs. Her initial vital signs were an oral temperature of 36.8°C, pulse of 76 beats per minute, blood pressure of 144/96 mm Hg, respiratory rate of 16 breaths per minute, and room air pulse oximetry of 100%. The physical examination of the left forearm revealed it to be firm and tender to palpation, and it measured 2cm larger in circumference than the right. Her radial pulse was palpable and her fingertip capillary refill was less than two seconds. The skin appeared normal without overlying erythema or calor. The patient experienced pain with flexion or extension of the digits and wrist. No sensory deficits of the hand or forearm were noted. Her initial laboratory evaluation showed the following: leukocytosis of 15,300 10(3)/mcL, blood glucose of 93mg/dl, elevated creatine phosphokinase of 15, 750U/L, normal erythrocyte sedimentation rate, and slightly elevated c-reactive protein at 1.27mg/L. No coagulation studies were obtained. A radiograph of the forearm was obtained and demonstrated only soft tissue swelling. Venous and arterial duplex studies of the extremity were performed. The arterial duplex demonstrated no evidence of arterial thrombosis, stenosis, or occlusion. The venous studied showed normal flow and compressibility, but the waveforms were continuous. Compartment pressures were measured in the volar and dorsal compartments of the forearm with a Stryker Needle™ (Stryker Intra-Compartmental Pressure Monitor, Stryker Corporation, USA) and found to be 86mmHg and 62mmHg, respectively. The patient was taken to the operating suite and underwent an emergent 10cm long fasciotomy of both the volar and dorsal compartments of her left upper extremity. Intraoperative cultures were obtained and showed no growth. Fortunately, the

patient required minimal debridement. Total hospital course was four days. A precipitating cause could not be identified. The patient's fasciotomy sites were surgically closed and she was discharged home with a diagnosis of idiopathic compartment syndrome. At 18-month follow up, the etiology of the compartment syndrome has not been identified, although she has been found to have a chronically elevated creatine phosphokinase (1,500U/L).

### DISCUSSION

As emergency physicians, we must be vigilant and consider ACS. ACS occurs in a variety of clinical situations and in various anatomic locations. It is most commonly associated with a fracture or other traumatic injury, such as a crushing mechanism. It can also develop in the setting of hereditary bleeding disorders, therapeutic anticoagulation, septicemia, animal bites, or venous cannulation.<sup>2</sup> As our case demonstrates, it may even be idiopathic (Table).

ACS was first described in 1881, when Richard von Volkmann defined the contracture that is commonly seen as a complication.<sup>3</sup> About 1%-10% of patients with ACS may go on to develop Volkmann's ischemic contracture.<sup>4</sup> ACS develops whenever the pressure inside the fascial compartment increases, whether that is caused from external compression, internal edema, or reperfusion. As the pressure rises, venous outflow is compromised first, followed eventually by arterial flow. Ischemia to the nerves and muscle develops. Vasodilatation is a compensatory mechanism to increase perfusion, but eventually leads to increased vascular permeability. The lymphatic system is overwhelmed and the compartmental pressure increases, resulting in decreased perfusion and eventually necrosis.

In most cases, ACS develops in the setting of a closed fracture. In a systematic review by Kalyani et al.,<sup>5</sup> the most common cause of ACS in the upper extremity in adults is a fracture of the distal radius; however, in pediatrics the most common etiology is a supracondylar fracture of the humerus. Other locations for ACS include the hand, forearm, arm, shoulder, back, buttocks, thigh, and foot.<sup>1</sup> It should also be noted that 23% to 31% of ACS cases occur in the setting of soft

tissue injuries without the presence of a fracture.<sup>2,5-7</sup>

Classically, ACS is associated with "The 5 Ps:" Pain, pallor, paresis, paresthesias, and pulselessness. Of these signs, pain out of proportion to the injury is the first to develop and is more commonly seen; however, the loss of normal neurologic sensation is the most reliable sign.<sup>1</sup> In one study of 90 patients by Duckworth et al.,<sup>6</sup> edema was noted in 100% of cases, followed next by pain in 79%, and then by paresthesias in 52% of patients. In the case of our patient, she had swelling along with pain with passive extension or flexion of the wrist. She also had a very tense and tender forearm to palpation. A pediatric study by Bae et al.,8 found that 90% of patients reported pain. Seventy percent had pain associated with one other "P," leaving 30% of patients with pain as the only symptom. They suggested close monitoring of the analgesic requirement by the child, as this could serve as an additional indicator of the development of ACS. They found that the need for increased pain medication preceded other clinical symptoms of ACS by an average of 7.3 hours in a sub-set of patients who had access to patient-controlled analgesia. Gelberman et al.,9 found that diminished two-point discrimination was a reliable finding and was sensitive in differentiating ACS from a less acute injury.

Compartment pressures should be measured whenever ACS is considered. ACS in the setting of soft tissue injury alone is more likely to result in delay of treatment and the development of complications. One study found that ACS patients without a fracture had an average delay to fasciotomy that was longer by 12.4 hours.7 Our patient's compartment pressures were measured using the Stryker Needle<sup>TM</sup>. Normal pressure is usually considered to be <10mmHg. Patients typically notice pain as pressures increase to 20-30mmHg.<sup>3</sup> Capillary blood flow is compromised as pressures approach 25-30mmHg. Mubarak et al.,<sup>10-12</sup> recommend using an intracompartmental pressure (ICP) of more than 30mmHg as an indication for performing fasciotomy, stating that once the critical ICP of 30 mmHg is reached, permanent damage can occur in as little as 6-8 hours. Management of ACS focuses on the maintenance of adequate perfusion pressure (diastolic blood pressure minus the ICP).

Table. Etiology of acute compartment syndrome

| External compression                  | Internal compression              |  |
|---------------------------------------|-----------------------------------|--|
| Circumferential cast or dressing      | Hematoma/coagulopathy             |  |
| Burn eschar                           | Fracture                          |  |
| Military anti-shock trousers (MAST)   | Overexertion of muscles (seizure) |  |
| Compression from prolonged immobility | Post-ischemic time/reperfusion    |  |
|                                       | Animal bite/envenomation          |  |
|                                       | Soft tissue injury                |  |
|                                       | Vascular injury                   |  |
|                                       | Deep venous thrombosis            |  |
|                                       | Idiopathic                        |  |

A pressure difference less than 30mmHg for more than two hours is considered diagnostic of a compartment syndrome.<sup>6</sup> Hypotension must be prevented in patients with ACS. Once ACS is diagnosed, any source of external compression, such as a splint or cast, should be removed immediately. If a cast is bivalved, the compartment pressures may decrease as much as 55%, and if the cast is entirely removed, the pressure may be reduced as much as 85%.<sup>1</sup> The limb should be placed at the level of the heart and adequate analgesia and supplemental oxygen provided as needed. ICP should be measured in all compartments of the extremity. Other complications of ACS, including rhabdomyolysis, hyperkalemia, and myoglobinuria should be sought.

In summary, our patient had acute compartment syndrome of the forearm without a history of trauma or other identifiable cause. Other reports of "idiopathic" ACS have involved adults and the leg.<sup>13-15</sup> A retrospective study of pediatric patients, with upper extremity compartment syndrome without a fracture, cared for at a large academic center over a 22-year period, found the majority to be iatrogenic (ex. infiltrated intravenous line) or to be associated with an infection.<sup>16</sup> None were "idiopathic," as in this case.

Acute compartment syndrome is frequently not considered in patients without a fracture or other traumatic injury. ACS is a clinical diagnosis. Care providers must have a high clinical suspicion for compartment syndrome in patients without injuries but with pain out of proportion to clinical findings, as demonstrated by our patient, to prevent irreversible damage.

Address for Correspondence: Robert W. Wolford, MD, MMM, Department of Emergency Medicine, OSF Saint Francis Medical Center, 530 NE Glen Oak Ave., Peoria, IL, 61550. Email: robert.w.wolford@osfhealthcare.org.

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## **Achilles Tendon Rupture**

Sean P. Stickles, MD\* Larry Friedman, MS, PA-C<sup>†</sup> Michael Demarest, MHA, PA-C<sup>†</sup> Christopher Raio, MD, MBA<sup>‡</sup> \*University of Missouri, Department of Emergency Medicine, Columbia, Missouri\* <sup>†</sup>Lenox Hill Hospital, Department of Emergency Medicine, New York, New York <sup>‡</sup>North Shore University Hospital, Department of Emergency Medicine, Manhasset, New York

Supervising Section Editor: Sean O. Henderson, MD Submission history: Submitted October 1, 2014; Accepted October 22, 2014 Electronically published November 26, 2014 Full text available through open access at http://escholarship.org/uc/uciem\_westjem DOI: 10.5811/westjem.2014.10.24127 [West J Emerg Med. 2015;16(1):161–162.]

A 60-year-old man presented to the emergency department complaining of acute onset posterior ankle pain. He reported playing tennis earlier in the afternoon when he suddenly stopped and pivoted, noting a "pop" sensation and pain to the right posterior ankle. The pain was sharp and increased with movement. The patient also experienced difficulty weight bearing and ambulating. There was a palpable defect at the distal end of the expected course of the Achilles tendon and lack of plantar flexion with squeezing the affected calf (Figure A). Point-of-care ultrasound (POCUS) was performed for further evaluation, and noted a discontinuity of the Achilles tendon with retracted proximal and distal ends, consistent with rupture (Figure B; Video). Orthopedics was consulted, and the patient was admitted for operative repair.

Achilles tendon rupture typically occurs by pushing off the weight-bearing foot with knee extended, sudden

dorsiflexion of the ankle, or forceful dorsiflexion of a plantarflexed foot.<sup>1,2</sup> Physical examination may reveal a palpable defect at the tendon injury site, loss of strength with voluntary plantar flexion, increased passive dorsiflexion, and loss of plantar flexion with squeezing of the calf when the patient is lying prone (Simmonds-Thompson test).<sup>3-5</sup> POCUS using a high-frequency transducer has been shown to be effective at visualizing Achilles tendon rupture, noting loss of the tightly arranged fibrillar pattern of the tendon fibers and an area of hypoechogenicity at the site of tendon defect.<sup>6,7</sup> Additional ultrasound findings of tendon rupture include hematoma formation at the site of rupture and posterior acoustic shadowing at the retracted rupture margins.8 To avoid misdiagnosis of tendon injury due to the effect of anisotropy as the tendon fibers insert on the calcaneus, one should completely scan through the tendon course and insertion point in different planes.7



**Figure A and B**. (A) Comparison of both posterior ankles in patient with right posterior Achilles tendon rupture. (B) Longitudinal ultrasound image of the area of pain to the posterior right ankle, noting retracted ends of the Achilles tendon (arrows) and hematoma in-between (\*).

**Video.** Ultrasound video of the Achilles tendon using a linear transducer demonstrating retracted proximal and distal tendon ends, separated by a mixed echogenic focus (hematoma), consistent with complete tendon rupture.

Address for Correspondence: Sean P. Stickles, MD. University of Missouri, Department of Emergency Medicine, Columbia, MO. Email: spstickles@gmail.com.

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## Tense Bullae and Urticaria in a Woman in Her Sixties

Katherine C. Wurlitzer, BS\* Caleb P. Canders, MD<sup>+</sup> Angelique S. Campen, MD, MBA<sup>+</sup> \*Sydney Kimmel Medical College, Philadelphia, Pennsylvania <sup>†</sup>UCLA Medical Center, Department of Emergency Medicine, Los Angeles, California

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#### CASE

A 68-year-old woman presented with a pruritic, blistering rash. Three months prior, she had developed itchy lesions on her hands and feet, spreading to her chest and abdomen. For the past week, she had developed painful, tense blisters. The patient had seen her primary care doctor at symptom onset and failed to improve with topical clobetasol proprionate and hydroxyzine. She took amlodipine for blood pressure and denied any new medications or exposures. Physical examination was notable for bullae with mucosal-sparing, urticaria, negative Nikolsky's sign, and the absence of scarring over ruptured bullae (Figures 1-3). Her complete blood cell count showed an increased number of eosinophils.

#### DIAGNOSIS

Bullous pemphigoid, first identified in 1953, is the most common autoimmune blistering disorder.<sup>1</sup> It has an annual incidence of 6-7 new cases per one million persons, occurs equally in men and women, and typically develops in the seventh or eighth decade of life.<sup>1-3</sup> The disease is characterized by IgG auto-antibodies against the basement membrane hemidesmosome, located at the dermal-epidermal junction.<sup>3-4</sup> Circulating and tissue-bound auto-antibodies bind to target antigens, leading to complement activation. mast cell degranulation, and the release of proteolytic enzymes along the basement membrane, ultimately leading to blister formation.<sup>4</sup> Risk factors include mechanisms that disrupt the basement membrane, including ultraviolet light, radiation therapy, burns, vaccines, and surgical and accidental traumas.<sup>4</sup> Certain medications have also been found to induce the disease.<sup>4</sup> However in 85% patients, no precipitating factor is identified.<sup>4</sup>

In the early, non-bullous phase, patients develop eczematous or urticarial lesions associated with severe pruritus, lasting weeks or months.<sup>1,3-4</sup> Patients eventually develop tense blisters that are localized or generalized, and may rupture.<sup>1,3</sup> Only 10-30% of patients have oral involvement.<sup>3</sup> Proposed diagnostic criteria for bullous



**Figure 1.** Skin findings include tense bullae on erythematous bases, pruritic plaques on the hands, and urticaria.



**Figure 2.** Skin findings include tense bullae on erythematous bases and urticaria on the right inner thigh.

pemphigoid include tense blisters or erosions, histologic findings of subepidermal blisters with eosinophil infiltration, and direct immunofluorescence showing linear deposits of IgG and complement along the basement membrane.<sup>1</sup> Indirect immunofluorescence can also be performed to detect circulating serum auto-antibodies.<sup>3</sup>

First-line treatment consists of topical and systemic corticosteroids and azathioprine. Other treatments include mycophenolate mofetil, leflunomide, cyclophosphamide, methotrexate, dapsone, intravenous immunoglobulin, and plasmapharesis.<sup>5</sup> Bullous pemphigoid is typically chronic with spontaneous exacerbations and remissions.<sup>5</sup> It predisposes patients to secondary infections and sepsis, and mortality of bullous pemphigoid ranges 10-40% in the first year following diagnosis.<sup>6</sup>

Our patient was fluid resuscitated and admitted for intravenous steroids. A skin biopsy confirmed the diagnosis. She was eventually discharged home on oral prednisone and mycophenolate mofetil.

Address for Correspondence: Caleb P. Canders, MD, Department of Emergency Medicine, David Geffen School of Medicine at UCLA, 924 Westwood Blvd., Suite 300 | Box 951777 Los Angeles, CA 90095-1777. Email: ccanders@mednet.ucla.edu.



**Figure 3.** Skin findings include tense bullae on erythematous bases and urticaria on the left anterior thigh.

*Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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# Necrotizing Fasciitis Caused by Hypermucoviscous *Klebsiella pneumoniae* in a Filipino Female in North America

Daniel Ng, MD Brad Frazee, MD Highland Hospital – Alameda Health System, Department of Emergency Medicine, Oakland, California

Supervising Section Editor: Rick A. McPheeters, DO

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Necrotizing fasciitis caused by *Klebsiella pneumoniae* has been described in Southeast Asia, but has only recently begun to emerge in North America. The hypermucoviscous strain of *K. pneumoniae* is a particularly virulent strain known to cause devastatingly invasive infections, including necrotizing fasciitis. Here we present the first known case of necrotizing fasciitis caused by hypermucoviscous *K. pneumoniae* in North America. [West J Emerg Med. 2015;16(1):165–168.]

### INTRODUCTION

*Klebsiella pneumoniae* is a member of the enterobacteriacea family of gram-negative rods that are found primarily in the human gastrointestinal tract. The most common forms of Klebsiella infection are hospital- acquired urinary tract infections, pneumonia, and bacteremia. Much of the recent literature surrounding *K. pneumoniae* has been in regards to its role as a carrier of extended spectrum beta-lactamase (ESBL), and more recently, as the predominant carbapenem resistant enterobacteriaceae (CRE) species. CRE is a new class of multidrug resistant species that tend to infect elderly patients after prolonged hospital stays or in long-term care facilities.<sup>1</sup> The substantial mortality associated with CRE infections is likely due the lack of effective treatments and underlying vulnerability of the patients, rather than virulence of the bacteria.<sup>1</sup>

This case report describes a strain of *K. pneumoniae*, referred to as hypermucoviscous, that is distinctly different from CRE. Hypermucoviscous *K. pneumoniae*, unlike CRE, is community acquired, highly virulent and essentially pansensitive.<sup>2</sup> Hypermucoviscous *K. pneumoniae* causes invasive infections, including liver abscess, endopthalmitis, meningitis, empyema, and necrotizing fasciitis, that occur primarily in Southeast Asia. Here we report a case of monomicrobial necrotizing fasciitis caused by hypermucoviscous *K. pneumoniae* in a Filipino woman who presented to our public hospital in Oakland, California. While there have been limited reports of infection with this unusual *K. pneumoniae* strain outside of Asia, to our knowledge this is the first report of necrotizing fasciitis caused by confirmed hypermucoviscous *K. pneumoniae* in North America.

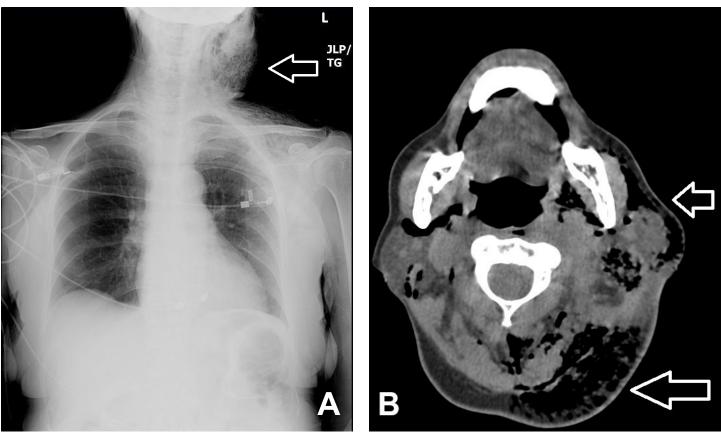
## **CASE REPORT**

A 71-year-old Filipino female with no known past medical history presented to an emergency department in Oakland, California, for neck swelling, fever, and difficulty breathing. She had been experiencing these symptoms for two weeks, with the neck swelling becoming progressively worse. On physical exam the patient appeared ill with a heart rate of 139, blood pressure of 87/36 and temperature 101.1, indicating septic shock. Physical exam revealed a large fluctuant mass over the left lateral neck. The center of this mass exhibited blackish discoloration and skin necrosis. Swelling and crepitus extended to the anterior and posterior neck, left shoulder and anterior chest wall.

Initial laboratory evaluation showed a white blood cell count of 22.9thou/mcL, Hemoglobin of 14.8g/dL, and platelets of 359thou/mcL. Notable chemistries were sodium of 125mmol/L, potassium 4.9mmol/L, chloride 110mmol/L, bicarbonate less than 5mmol/L, blood urea nitrogen 41mg/ dL, creatinine 2.5mg/dL, glucose 917mg/dL, and lactic acid 3.5mmol/L. Urinalysis showed glucosuria and ketonuria. CT of chest and neck revealed extensive subcutaneous emphysema throughout the left lateral upper chest wall, left shoulder region, anterior mediastinum and throughout the superficial and deep spaces of the neck (Figure 1).

The patient was taken to the operating room for debridement and was discovered to have necrotic deep muscle tissue and fascia. Intraoperative biopsies confirmed the diagnosis of necrotizing fasciitis, with necrotic and purulent material found in the dermis, subcutaneous tissues, and fascia.

During the patient's hospital stay, she required numerous



**Figure 1.** *A*, Chest radiograph and *B*, neck computed tomography image at level of C2, both demonstrating left-sided neck mass with extensive subcutaneous emphysema (open arrows).

vasopressors and steroids for refractory hypotension, hemodialysis for refractory acidosis and uremia, and was taken to the operating room for debridement a total of three times. The patient expired on her seventh hospital day due to overwhelming sepsis and acidosis.

Cultures of blood, urine, and surgical specimens all grew *K*. *pneumoniae*. These isolates were string-test positive, indicating that this was the hypermucoviscous strain. All cultures were resistant to ampicillin, but otherwise were pan susceptible.

#### DISCUSSION

The distinctive clinical syndrome of invasive hypermucoviscous *K. pneumoniae*, consisting of liver abscesses, bacteremia, and metastatic infection, particularly of the central nervous system, is now well described. To a large extent, the syndrome has been geographically restricted to Southeast Asia. The association of this pathogen with a wider range of invasive infections, including soft tissue abscesses and necrotizing fasciitis has only been recognized more recently with the first description of necrotizing fasciitis appearing in 1996.<sup>3</sup> While much of the existing literature consists of case reports,<sup>4-8</sup> a recent large case series from Taiwan systematically evaluated *K. pneumoniae* necrotizing fasciitis.<sup>9</sup> In this single hospital study, *K. pneumoniae* accounted for 17% of monomicrobial necrotizing fasciitis cases as compared to 22% due to *S. aureus* and 18% due to group A *Streptococcus*. Fifteen *K. pneumoniae* cases were compared to a similar number caused by group A Streptococcus – an organism more traditionally associated with necrotizing fasciitis. The investigators found that *K. pneumoniae* cases exhibited higher mortality and higher rates of bacteremia and that patients were more likely to be immunocompromised, with 80% having diabetes.

Outside of Asia, *K. pneumoniae* has just begun to emerge as a cause of necrotizing fasciitis. Three cases have been described in Europe.<sup>10-12</sup> The first case of *K. pneumoniae* necrotizing fasciitis described in North America was in 2007, in which a Cambodian man with travel to Cambodia six months prior was diagnosed with necrotizing fasciitis and died in three days.<sup>13</sup> Two subsequent reports described *K. pneumoniae* necrotizing fasciitis in patients who had no recent travel to Asia and were not of Asian descent.<sup>14,15</sup> A recent North American case series reported on six liver transplant recipients, who developed *K. pneumoniae* necrotizing fasciitis, all of whom died.<sup>16</sup> There is one report specifically of *K. pneumoniae* cervical necrotizing fasciitis, similar to our case, that required 12 surgical debridements with the patient surviving.<sup>17</sup>

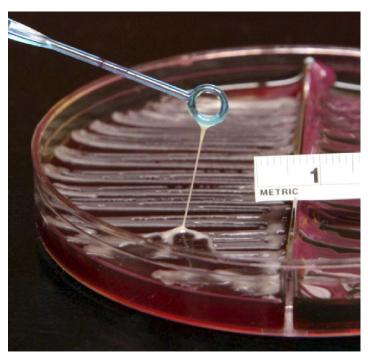
Ours is the first case report of *K. pneumoniae* necrotizing fasciitis in the North America to confirm the hypermucoviscous phenotype. Hypermucoviscous strains are identified in the laboratory with a simple string test, in which a colony is lifted

with a loop, producing a string longer than 5mm (Figure 2). The phenotype is associated with the rmpA and magA genes;<sup>18</sup> although we did not perform genotyping in this case, we have previously shown the hypermucoviscous K. pneumoniae isolates from our hospital were rmpA positive.<sup>19</sup> The hypermucoviscous phenotype is thought to confer virulence by a number of mechanisms, including its ability to resist phagocytosis, and both complement and neutrophil-mediated killing, and its ability to more efficiently acquire iron.<sup>20,21</sup> These virulence factors lead to a destructive clinical syndrome, often with multiple infectious metastases.<sup>20-22</sup> It is likely that most of the community-acquired invasive K. pneumoniae infections recently reported in North America, including the previously reported necrotizing fasciitis cases, were also due to the hypermucoviscous strain, but that string testing was simply not performed. Hypermucoviscous K. pneumoniae strains are invariably cephalosporin susceptible, so the finding of broad antibiotic susceptibility in a K. pneumoniae isolate from a community-acquired invasive infection represents indirect evidence that it is a hypermucoviscous strain. As expected, most of the studies of K. pneumoniae necrotizing fasciitis outside of Asia reported similar antibiotic susceptibility profiles that fit this pattern.<sup>10,13-15</sup>

We previously reported 13 cases of invasive infection caused by hypermucoviscous *K. pneumoniae*.<sup>19,23</sup> In our series, multiple types of infectious were found, including neck abscesses, pyelonephritis, brain abscesses, pneumonia, liver abscesses, and cholecystitis. Including the current case,four patients with skin and soft tissue infections due to hypermucoviscous *K. pneumoniae* have been seen since 2007 at our urban public hospital in Northern California.

Interestingly, hypermucoviscous *K. pneumoniae* still remains largely confined to Asia and cases in North America have occurred disproportionately in patients of Asian descent. This has raised speculation as to a genetic susceptibility to colonization and/or infection.<sup>21</sup> Data from stool samples from healthy Chinese and Korean adults residing throughout Asia have also suggested that a small percentage of Asians are colonized with hypermucoviscous *K. pneumoniae*.<sup>21</sup> Alternatively, patients may simply acquire hypermucoviscous *K. pneumoniae* from living in or traveling to endemic areas. Regardless, it seems that being of Asian descent and recent travel to Asia are the most important risk factors, along with diabetes mellitus, for developing a hypermucoviscous *K. pneumoniae* infection.

Our West Coast urban safety net hospital serves a large Southeast Asian population, including recent immigrants, which likely accounts for the large number of cases we have seen. Yet it is also likely that hypermucoviscous *K. pneumoniae* has made an unrecognized emergence elsewhere in northern California and perhaps elsewhere in North America. While we predicted in 2009 that this pathogen was likely to emerge dramatically in the U.S., subsequent reports have been limited. Ultimately, routinely testing for and identifying hypermucoviscosity in *K. pneumoniae* isolates has limited clinical importance in changing early management, especially for necrotizing soft



**Figure 2.** Example of a positive string test (>5mm string) indicating the hypermucoviscous phenotype.

tissue infections, as aggressive sepsis care, early empiric broad spectrum antibiotics, and prompt source control remain priorities in the treatment of necrotizing soft tissue infections, regardless of etiology. On the other hand, microbiologic surveillance for emerging pathogens is a potentially important role of emergency departments, especially those located in communities with large immigrant populations.<sup>24,25</sup> The appearance of a new and virulent pathogen here in North America will certainly have public health implications; however, it is difficult to predict what these might be, as confirmed cases are sparse in number and based on our suspicions, other cases are potentially not being recognized. We therefore advocate that string testing be performed routinely on all K. pneumoniae isolates. In addition to identifying this clinically distinctive syndrome and thereby prompting a search for metastatic infections, routine string testing of K. pneumoniae isolates might illuminate the connection with the Southeast Asian data and clarify whether this pathogen is emerging rapidly outside of Asia.

Address for Correspondence: Daniel Ng, MD, Department of Emergency Medicine, 1411 E. 31st Street, Oakland, CA, 94602. Email: daniel.ktng@gmail.com.

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## Herpes Zoster Ophthalmicus Extending to the Palate

Todd Schneberk, MD, MA Edward J. Newton, MD Los Angeles County/University of Southern California Medical Center, Department of Emergency Medicine, Los Angeles, California

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A 57-year-old female presented to the emergency department with left sided facial rash with associated pain, blurred vision and oral discomfort. Past medical history included hypertension, and remote scleroderma (untreated). There was no history of neck stiffness, ear pain, environmental exposures, trauma, or immunosuppressive medications. Her facial pain was sharp in quality and extended to her mouth, localizing to her palate. She was mildly hypertensive and other vitals were normal. Physical exam revealed vesicular rash of the left side of her face. along with swelling and periorbital inflammation. There were also multiple vesicular lesions on the left side of her hard palate. Ocular exam showed a small area of fluorescein uptake infranasally concerning for a pseudodendrite, with mild cell and flare of the anterior chamber. There were no vesicles in the ear or tip of her nose.

She was diagnosed with herpes zoster ophthalmicus involving the V1-V2 distribution of the trigeminal nerve, was put on oral acyclovir with opiates for pain control, and referred to ophthalmology. The oral mucosal lesions do not represent another dermatomal involvement, and are extensions of the V2 branch. These lesions are associated with involvement of the palatine nerves, greater and lesser, as well as the nasopalatine nerve, which are extensions of the V2 branch of the trigeminal nerve via the pterygopalatine ganglion.<sup>1</sup> This distribution of lesions is not uncommon in nonimmunocompromised patients with zoster.<sup>2</sup> Herpes zoster can also begin on the palate and should be considered in patients presenting with oral lesions and pain.

Address for Correspondence: Todd Schneberk, MD, MA, 1200 N. State St. Rm 1060H, Los Angeles, CA 90033 Email: tschneberk@gmail.com.



Figure. Multiple vesicles on the palate.

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## **Persistent Pain After Lithotripsy**

| Ellen Jones, MD |    |
|-----------------|----|
| Kenneth DeKay,  | MD |

Carl R. Darnall Army Medical Center, Department of Emergency Medicine, Fort Hood, Texas

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A 36-year old man presents to the emergency room five days after undergoing extracorporeal shock wave lithotripsy (ESWL) for a symptomatic 11mm left renal pelvis stone. The patient has persistent symptoms of severe left flank pain at presentation.

Plain abdominal radiography is obtained and shows a steinstrasse pattern of urolithiasis. In the 1980s, the German developers of ESWL observed that stone fragments could stack in a column formation in the ureter in a radiographic pattern that resembled a "stone street," or steinstrasse in German (plural is *steinstrassen*) (Figure).<sup>1</sup> This phenomenon is observed in 2-20% of ESWL patients and is a unique cause of ureteral obstruction that may present to the emergency

department.<sup>2</sup> Risk factors for the development of steinstrasse include large proximal stones, staghorn calculi, and preexisting ureteral obstruction that may have caused permanent kinking of the ureter. Eighty-seven percent of steinstrassen occur in the distal ureter.

For asymptomatic cases of steinstrasse, conservative management is preferred with observation and serial imaging with plain radiography to follow progression of the stones and ultrasonography to evaluate for hydronephrosis. Sixty-five percent of steinstrassen will pass spontaneously over days to weeks.<sup>2</sup> Tamsulosin has been more recently added as adjunctive therapy to improve outcomes in these asymptomatic cases. For symptomatic cases characterized



Figure. Steinstrassen seen in the left ureter.

by pain, fever, or hydronephrosis, more urgent urologic intervention is required through percutaneous nephrostomy or ureteroscopy with stent placement.

This particular patient underwent urgent ureteroscopy with stent placement the following day and had an uneventful recovery thereafter.

Address for Correspondence: Ellen Jones, MD, 3105 Legend Oaks Blvd, Belton, TX. Email: ellencgiles@gmail.com.

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## Survival from Cervical Necrotizing Fasciitis

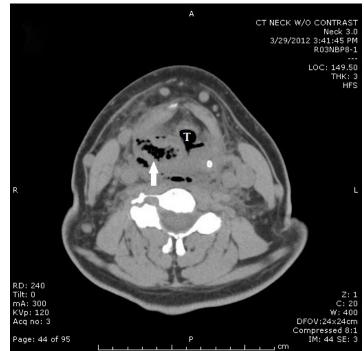
Jeniffer S. Gausepohl, MD Jonathan G. Wagner, MD Los Angeles County + University of Southern California Health Network, Department of Emergency Medicine, Los Angeles, California

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Cervical necrotizing fasciitis (CNF) is an uncommon, yet clinically significant infection that rapidly progresses to involve the deep neck spaces. Early recognition and aggressive surgical intervention and debridement are important, as this disease is associated with a high morbidity and mortality. In this report, we present a case of CNF and descending mediastinitis from a non-odontogenic source in a patient presenting with neck swelling and odynophagia. [West J Emerg Med. 2015;16(1):172–174.]

### **CASE REPORT**

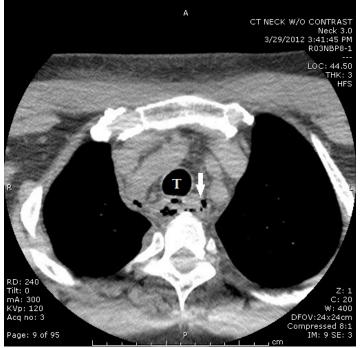
A 59-year-old Caucasian man with past medical history significant for hypertension and hyperlipidemia presented to the emergency department with a four-day history of increasing throat pain and bilateral neck swelling. Associated symptoms included voice hoarseness, shortness of breath, dysphagia, and odynophagia. He denied recent dental procedures, upper respiratory tract infection or history of similar symptoms. Patient's social history was negative for smoking, alcohol and illicit drug use. Initial vital signs were Blood Pressure 109/68, Pulse 101, Repiratory Rate 16, Temperature 98.1, and O<sub>2</sub> saturation of 100% on room air. On exam, the patient was noted to have edema and tenderness to palpation of his entire right neck, with erythema tracking from the superior border of his right clavicle to the angle of the jaw on the right. No induration, crepitus or bullae were noted on the skin. Oral examination was remarkable for edema and erythema of the right anterior tonsil, without exudates or fluctuance, with mild deviation of the uvula to left. The laboratory values were significant for elevated leukocyte count of 29,000 with 89.9 % neutrophils and blood urea nitrogen and creatinine of 37 and 2.32, respectively. Computed tomography (CT) of the neck without contrast showed extensive edema in the oropharynx/hypopharynx, with edema and air within the retropharyngeal and danger space, as well as debris within the piriform sinus (Figures 1 and 2). Given the clinical exam, CT findings highly suspicious for "a gas-forming organism or necrotizing fasciitis," and his laboratory results, blood cultures were drawn and intravenous clindamycin, vancomycin and ceftriaxone were empirically



**Figure 1.** Computed tomography (CT) of the neck demonstrating soft tissue swelling, liquid and air collection within the oropharynx (arrow) near the trachea (labeled T).

started. Otolaryngology was emergently consulted and the decision was made to immediately take the patient to the operating room for incision, drainage and washout.

Following nasotracheal intubation in the operating room (OR), the right neck was explored laterally into the retropharyngeal space. Purulent drainage was found



**Figure 2.** Computed tomography (CT) of the neck showing extensive edema and air within the upper mediastinum (arrow) tracking adjacent to trachea (labeled T).

to track via an overlying necrotic fascial plane into the parapharyngeal spaces as well as inferiorly into the superior mediastinum. Intraoperative gram stain showed gram positive cocci in both chains and clusters, gram negative rods and gram positive rods. The antibiotic regimen was changed to piperacillin/tazobactam and metronidazole (with discontinuation of clindamycin and ceftriaxone). Final wound culture grew Streptococcus anginosus and coagulase negative staphylococcus. The patient remained intubated postoperatively, and a repeat CT was performed on postoperative day 4 due to persistent leukocytosis. A residual phlegmon in the bilateral piriform sinuses was discovered, and the patient was then taken back to the OR for repeat right neck exploration, direct laryngoscopy, and bilateral incision and drainage of the peritonsillar space. Intra-operatively, cardiothoracic surgery was consulted to perform an open lateral thoracotomy to drain a posterior mediastinal phlegmon.

Despite repeat drainage, the patient began to decompensate, requiring multiple vasopressors to maintain adequate perfusion, and he suffered from persistent fevers, acute renal failure and transaminitis (aspartate aminotransferase 4202, alanine aminotransferase 1922). His leukocytosis continued to rise, peaking at 51,600. On postoperative day 7, the patient suffered a cardiac arrest requiring one round of chest compressions and epinephrine before return of spontaneous circulation. On postoperative day 9, his multisystem organ failure began to improve and the patient was slowly weaned off vasopressors, with successful extubation on postoperative day 12. He was discharged to a rehabilitation institution on postoperative day 21 with a peripherally inserted central catheter line to continue vancomycin, clindamycin and metronidazole for a total of four weeks. On recent follow-up with otolaryngology six weeks after his discharge, he was noted to be doing well and has elected to undergo cosmetic revision of right neck scar, the date of which is to be determined.

# DISCUSSION

Cervical necrotizing fasciitis (CNF) is a rare polymicrobial infection of the fascial planes of the neck associated with high morbidity and mortality. With isolated CNF, mortality approaches 20%, and when associated with extension into the mediastinum and sepsis, rates as high as 41% and 64% have been reported respectively.1 Predisposing factors associated with development of CNF include diabetes mellitus, poor dental hygiene, obesity, alcoholism, and immunocompromised states.<sup>2,3</sup> CNF is a destructive and rapidly advancing form of necrotizing fasciitis that most commonly originates from odontogenic or pharyngeal sources, with the signature characteristic of this disease being necrosis of the layers of the fascia underlying the skin and surrounding vasculature.<sup>4,5</sup> Due to a plentiful blood supply, necrotizing fasciitis of the head and neck is rare in comparison to other regions of the body, such as the limbs and perineum.<sup>1</sup> Early death in CNF is often a result of airway compromise, while later mortality is related to sepsis and septic shock. The gas-forming organisms associated with this disease can separate fascial planes and quickly travel to the thorax and mediastinum via the "danger space," an anatomical pathway that connects the base of the skull to the diaphragm. Factors associated with development of mediastinitis include: infection of the pharynx, presence of gas, and use of glucocorticoids prior to hospital admission.7 Mediastinitis has a high rate of mortality, and along with septic shock, is the most dismal prognostic indicator in CNF.<sup>1,7</sup>

Necrotizing fasciitis is well known for its rapid tissue spread and destruction, while having a benign external appearance. Skin evidence of the disease includes grey-patchy discoloration, bullae, or frank necrosis. Despite these characteristic external findings, they typically occur late in the course of the disease. Early signs that should raise awareness for the possibility of necrotizing fasciitis include pain out of proportion to touch or anesthesia/hypoesthesia to the affected area.<sup>5</sup> Diagnosing CNF is largely based on clinical presentation, with findings on CT, such as fat stranding and gas tracking along fascial planes, serving to increase the probability of the diagnosis. The final diagnosis, however, is confirmed by surgical exploration.<sup>6</sup> In the majority of cases, necrotizing fasciitis is a polymicrobial synergistic infection with both aerobic and obligate anaerobic bacteria (streptococci and enterobacteriaceae the most commonly implicated species).<sup>8,9</sup> Treatment includes early incision and drainage, aggressive debridement, broad spectrum intravenous antibiotics, airway management, and close monitoring in an intensive care unit.<sup>1</sup> As with all types of necrotizing fasciitis, drainage and surgical

exploration is the most important part of treatment. Early operative intervention has been shown to improve outcome in CNF, and conversely, a delay in debridement of more than 24 hours is correlated with worsening mortality.<sup>8</sup>

Address for Correspondence: Jeniffer S. Gausepohl, MD, 1000 West Carson St, Box 21, Torrance, CA 90502. Email: jsicalo@ gmail.com.

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# Hemi Orolingual Angioedema after tPA Administration for Acute Ischemic Stroke

Bryan Madden, MD Ralphe B. Chebl, MD Henry Ford Hospital, Department of Emergency Medicine, Detroit, Michigan American University of Beirut, Department of Emergency Medicine, Beirut, Lebanon

Supervising Section Editor: Rick A. McPheeters, DO Submission history: Submitted October 13, 2014; Accepted December 15, 2014 Electronically published January 12, 2015 Full text available through open access at http://escholarship.org/uc/uciem\_westjem DOI: 10.5811/westjem.2014.12.24210 [West J Emerg Med. 2015;16(1):175–177.]

# INTRODUCTION

As studies continue to demonstrate the efficacy of intravenous tissue plasminogen activator (tPA) in acute ischemic stroke, the exclusion criteria continue to narrow, and the time-window continues to increase.<sup>1-3</sup> The most dreaded adverse effect of tPA, hemorrhagic conversion of an ischemic stroke, is well known and well published.<sup>3</sup> However, as an increasing number of patients are receiving tPA worldwide another unusual and potentially life-threatening adverse effect of tPA is becoming more common, angioedema.

# **Case Report**

A 50-year-old man with a history of hypertension, hyperlipidemia, crack-cocaine abuse, and two prior ischemic strokes (2004, 2011) characterized by right-sided weakness with no residual deficits presented to a large urban hospital with left-sided arm weakness, left-sided leg weakness, and mild slurring of speech. Patient had received tPA when he presented with his stroke symptoms in 2011, without any adverse events. He was last seen normal four hours prior to arrival. On presentation he had a National Institute of Health Stroke Scale (NIHSS) of 5, left-sided facial droop, drift and ataxia in both his left arm and left leg. His blood pressure was 175/103mmHg, a pulse of 94beats/minute, a temperature of 37.2°C and a right atrium oxygen saturation of 98%. A computed tomography of the head was negative for any acute hemorrhage. Patient was supposed to be on an angiotensin- converting enzyme (ACE) inhibitor but had been non compliant with his medications for the last three months.

Per protocol he was evaluated by a neurologist and received intravenous (IV) tPA 90mg, 10% as bolus and the remainder as an IV drip over the following hour. His weakness began to improve. As the tPA infusion was ending, the patient started complaining of tongue swelling and his voice was noticed to be altered. He did not have any shortness of breath. On examination the patient had a significant amount of leftsided dorsal and ventral tongue swelling, which abruptly ended at the midline (Figure 1). The posterior pharynx, uvula, soft palate, floor of mouth did not have any swelling. Otolaryngology was consulted and performed a bedside flexible laryngoscopy. He did have some mild interarytenoid, arytenoid, and superior aspect of esophageal inlet swelling. The vallecula and epiglottis were within normal range. He was started on 10mg of dexamethasone IV, 20mg of famotidine IV, and 50mg of diphenhydramine IV. He remained nonintubated and was transferred to the neurologic intensive care unit. Magnetic resonance imaging/angiography demonstrated restricted diffusion in genu and posterior limb of right internal capsule with some extension into the right cerebral peduncle, mild intracranial atherosclerosis of posterior cerebral arteries and a hypoplastic right vertebral artery. His swelling and dysphonia resolved completely within 48 hours (Figure 2). Afterwards, his hospital course was uncomplicated and he was discharged after five days total to acute rehabilitation on aspirin and pravastatin. His NIHSS remained five; however, his left-sided strength had improved. At follow up one month later he was improved, subjectively reporting to be at 60% of his baseline. On examination his speech was fluent with no dysarthria or aphasia, no tongue swelling, strength was 5/5 in all four extremities, although he did have mild dysmetria on the left during finger-to-nose.

# DISCUSSION

TPA is a thrombolytic drug used in the treatment of acute strokes. It hydrolyzes plasminogen to plasmin and results in its fibrinolytic effect. The increase in plasmin may play a role in the development of angioedema by activating the kinin pathway and leading to the formation of the vasodilator bradykinin. Plasmin also activates the complement system and leads to the production of the anaphyloxins C3a, C4a, and C5a, which also cause mast cell degranulation and histamine



**Figure 1**. Hemi orolingual swelling after tissue plasminogen activator infusion.

release.<sup>4</sup> Patient assessment should be done every 15 minutes during tPA infusion for signs of clinical deterioration indicating a possible intracranial hemorrhage, or for signs of angioedema. Angioedema is defined as an acute, transient. well-demarcated swelling that involves the deeper layers of the skin. It usually affects the face, genitalia, as well as the upper respiratory airways and the intestinal epithelial lining.<sup>5</sup> Angioedema could be due to a hereditary deficiency in C1-esterase or it could occur as an allergic reaction to some medications, most commonly ACE inhibitors. The half-life of tPA is approximately seven minutes; therefore, the risk of angioedema can still occur after the infusion has stopped. Hill et al. conducted a prospective study examining 176 patients treated with tPA for acute ischemic stroke and found evidence of orolingual angioedema in nine patients (5.1%). They reported that the typical reaction was mild, transient, and contralateral to the ischemic hemisphere. The lateralization of the edema was hypothesized to be due to the loss of autonomic innervation of that side.<sup>6</sup> Engelter et al. in 2005, published a study about the incidence of life-threatening orolingual angioedema during thrombolysis in acute ischemic stroke. They reported two cases (1.7%) of 120 patients treated with alteplase for acute stroke. Of the two cases, one was mild, and impending asphyxia prompted immediate intubation in the second case. In both studies the risk of angioedema was significantly associated with ACE-inhibitor use.7 The initial goal of therapy is airway management with early intubation if necessary. Due to the extensive airway swelling that can occur in the setting of angioedema and the possibility for an airway disaster, the most skilled person available must handle airway interventions. The tPA infusion should be stopped. Patients who develop angioedema should be treated with histamine antagonists, such as ranitidine and diphenhydramine along with corticosteroids. Patients are admitted to a neurologic intensive care unit for observation.<sup>8,9</sup> This is an interesting



Figure 2. Patient's tongue appearance after treatment.

and unique case because our patient was treated with tPA in 2011, without any side effects. It is possible that he formed antibodies to tPA and had a type I allergic reaction two years later when he was being treated for his third stroke. Having been on an ACE inhibitor increases his chances of having angioedema; however, it is likely that repeated exposure to tPA increases the likelihood of angioedema and emergency physicians should be aware of this risk.

Address for Correspondence: Ralphe B. Chebl, MD, Department of Emergency Medicine, American University of Beirut, Beirut, LBN. Email: rb94@aub.edu.lb.

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# Bedside Echocardiography for Undifferentiated Hypotension: Diagnosis of a Right Heart Thrombus

James F. Kenny, MD\* Xun Zhong, MD<sup>†</sup> Cara Brown, MD<sup>†</sup> Devjani Das, MD<sup>†</sup> Brock Royall, MD<sup>†</sup> Monica Kapoor, MD<sup>†</sup> \*Northwestern University, Emergency Medicine Residency, Chicago, Illinois \*Staten Island University Hospital, Department of Emergency Medicine, Staten Island, New York

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A free-floating right heart thrombus is often a harbinger of a massive pulmonary embolism and must be diagnosed and treated rapidly in order to avoid significant adverse sequelae. We present the case of an 84-year-old female who presented with two days of dyspnea and was hypotensive on arrival. Bedside ultrasound was performed by the emergency physician and showed a large, mobile right heart thrombus leading to immediate administration of a thrombolytic. In this case, bedside ultrasound was utilized to help further delineate clinical care in a progressively worsening patient, leading to a potentially lifesaving treatment. [West J Emerg Med. 2015;16(1):178–180.]

# INTRODUCTION

A right heart thrombus (RHT) can be differentiated into one of two types: Type A or Type B. Type A thrombus, also referred to as a pulmonary embolus (PE)-in-transit, is often the result of a deep venous thrombosis (DVT). As such, it is worm-like in appearance and freely mobile within the heart chambers.<sup>1,2</sup> In contrast, Type B thrombus is considered to have originated within the atrium or ventricle, and tends to be firmly attached to the chamber wall. Type A thrombus is often more clinically significant as its mobility can markedly impede flow through the right heart, predisposing to rapid cardiovascular collapse and shock.<sup>1</sup>

Given the potentially adverse sequelae associated with right heart thrombi, emergent diagnosis and management are necessary. Multiple studies and case reports have shown that thrombolysis has the potential to rapidly lyse a RHT and decrease mortality while improving right ventricular hemodynamics.<sup>1,3-7</sup> In addition, there have been case reports where thrombolytics were not administered, leading to either death or cardiac arrest.<sup>2,8</sup> Thrombolysis, most commonly via tissue-plasminogen activator (t-PA), has the added benefit of rapid administration and availability in institutions where surgery is not feasible.

We present the case of a critically ill patient who continued to deteriorate despite aggressive treatment for

presumed sepsis. Bedside ultrasound can be a valuable tool to use during the assessment of a persistently hypotensive patient who is decompensating despite appropriate therapy both in the intensive care unit (ICU) or the emergency department (ED).<sup>1,9</sup> In such patients, the diagnosis of PE associated with RHT may be a rare etiology of refractory hypotension, but should be in the differential diagnosis. We illustrate how the use of bedside ultrasound can diagnose a RHT and alter the management of a critically ill patient in an emergency department setting. We hope this demonstrates that practicing without point-ofcare ultrasound can limit an emergency physician's ability to adequately care for patients with similar presentations.

# CASE REPORT

An 84 year-old female presented to the ED with shortness of breath for the past two days. She was dyspneic on arrival, with noted use of accessory muscles and difficulty answering questions. Her presenting vitals were blood pressure 76/59, respiratory rate 36, oxygen saturation 75% on a non-rebreather mask, a temperature of 100.2°F, and a pulse of 65. Due to her severe respiratory distress and hypoxemia, she underwent endotracheal intubation as she became progressively unresponsive. The working diagnosis was septic shock, so the patient was started on intravenous antibiotics and underwent aggressive fluid resuscitation. A vasopressor, norepinephrine, was empirically initiated.

Despite the vasopressor, the patient continued to deteriorate. A bedside abdominal ultrasound performed by the emergency physician demonstrated a dilated inferior vena cava (IVC) with minimal respiratory variation. Bedside echocardiography showed no evidence of pericardial effusion, however, a free-floating clot was visualized in the right atrium and ventricle (Figure 1). The right ventricle was dilated and the left ventricle displayed wall hypertrophy and poor contractility (Figure 2 and Video). A presumptive diagnosis of massive pulmonary embolism was made based upon these findings.

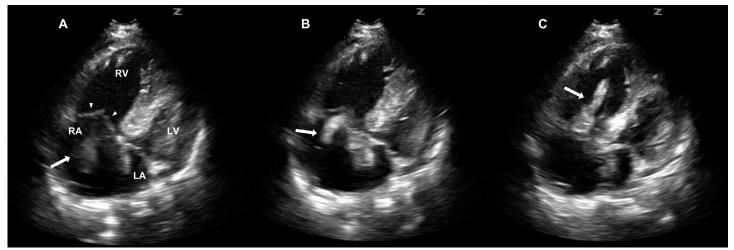
Due to the patient's hemodynamic instability, t-PA was administered after consultation with her family. Subsequent to t-PA administration, the patient's condition began to improve. She was admitted to the ICU, continued on heparin, and bridged to Coumadin. Her post-t-PA echocardiogram showed complete resolution of the clots, however, right ventricular dilation persisted. The patient continued to improve and was discharged to a skilled nursing facility on hospital day 17.

# DISCUSSION

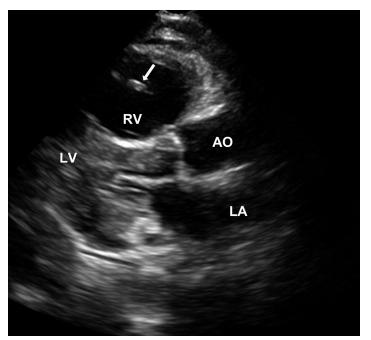
In a patient with undifferentiated shock, bedside ultrasound can provide vital information for both initial resuscitative efforts and also for identifying alternative diagnoses in patients who are decompensating. In particular, bedside echocardiography can diagnose pericardial effusion, assess global cardiac activity, and visualize abnormalities within the cardiac chambers.<sup>10,11</sup> A free floating RHT is a rare condition that is almost always associated with pulmonary embolism.<sup>12</sup> Right heart thrombi have been found to occur in 4-18% of cases of acute PE and convey a poorer prognosis as there is a 16-45% mortality rate in these patients.<sup>2,13,14</sup> Rapid identification and treatment is therefore essential. In our case, the patient arrived to the ED hypotensive, hypoxemic, with an elevated temperature, and was immediately treated for sepsis. The patient, however, continued to deteriorate despite aggressive treatment with intravenous fluids and vasopressors. Without bedside echocardiography, the diagnosis would have been delayed, or possibly never found, which could have drastically changed the patient's outcome.

The utility of bedside focused echocardiography in a patient with hypotension and shock has been embraced by the emergency medicine community, but there remains some concern as to the actual clinical utility of this imaging modality in the emergency department setting.<sup>15</sup> In our case, the use of bedside echocardiography was valuable in diagnosing a free-floating RHT in an undifferentiated hypotensive patient who was rapidly deteriorating. Without the use of bedside ultrasound, t-PA most likely would not have been administered, and the patient would have continued to decompensate. Focused bedside echocardiography proved to be potentially lifesaving for this patient.

Our goal in presenting this case is to continue to put forth evidence supporting the importance of focused bedside ultrasound, including echocardiography, in the care of a critical patient with a substantial change in clinical condition in an emergency department setting. It is our recommendation that all emergency physicians continue to expand their knowledge of point-of-care ultrasound, particularly in the setting of critically ill and hypotensive patients. This case report illustrates the value of using this tool to diagnose potentially overlooked etiologies of such presentations and should remain an essential component of every emergency physician's diagnostic repertoire. It is also our recommendation that education regarding the utility of point-of-care ultrasound as a means to drastically alter management and patient care continue to expand in emergency medicine residency programs. While the



**Figure 1.** Bedside echocardiography in the four chamber view shows a free-floating atrial clot (arrow) as it glides between the right atrium (RA) and moves to the right ventricle (RV) during cardiac diastole and systole. *A*, the clot (arrow) is seen starting in the RA, *B*, moving through tricuspid valve (arrowheads seen in A), *C*, and finally seen in the RV. *LA*, left atrium. *LV*, left ventricle



**Figure 2.** Parasternal long view of the heart with the free-floating clot (arrow) visualized in the dilated right ventricle (RV). *LA*, left atrium; *LV*, left ventricle; *AO*, aortic outflow

major limitation of this case report is that it only demonstrates the utility of point-of-care ultrasound in a single patient with a RHT, increasing awareness of RHT as an uncommon, but emergent, disease process has the potential to alter management in critically ill patients in the future.

Address for Correspondence: James F. Kenny, MD; Staten Island University Hospital Department of Emergency Medicine 475 Seaview Ave. Staten Island, NY 10305. Email: jfkenny12@ gmail.com.

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Video. Video of right heart thrombus.

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# Half-dose Alteplase for Sub-massive Pulmonary Embolism Directed by Emergency Department Point-of-care Ultrasound

Richard Amini, MD\* Ashish R. Panchal, MD, PhD<sup>†</sup> David Bahner, MD<sup>†</sup> Srikar Adhikari, MD, MS\* \*University of Arizona, Department of Emergency Medicine, Tucson, Arizona <sup>†</sup>Ohio State University, Department of Emergency Medicine, Columbus Ohio

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This report describes a patient with sub-massive pulmonary embolism (PE) who was successfully treated with half-dose thrombolytics guided by the use of point-of-care (POC) ultrasound. In this case, POC ultrasound was the only possible imaging since computed tomography was contraindicated. POC ultrasound demonstrated a deep vein thrombosis and evidence of cardiac strain. In situations or locations where definitive imaging is unobtainable, POC ultrasound can help diagnose submassive PE and direct the use of half-dose tissue plasminogen activator. [West J Emerg Med. 2015;16(1):181–183.]

# **INTRODUCTION**

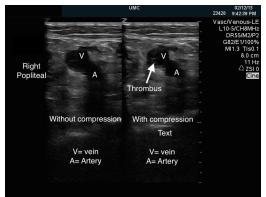
Pulmonary embolus (PE) is a life-threatening condition affecting 250,000 people annually.<sup>1</sup> In the emergency department (ED), computed tomography angiography (CTA) is the method of choice to diagnose PE; however, it may not be feasible to obtain a CTA when patients have abnormal kidney function, hemodynamic instability, or are in resourcelimited areas. In these situations, thrombolytic treatment may be delayed or withheld due to risk benefit concerns. Although thrombolytics decreases clot burden faster than heparin, the complication of intracerebral hemorrhage has led to hesitant physician use. Half-dose tissue plasminogen activator (tPA) research demonstrates decreased complications with similar clot resolution; however, its true influence on morbidity and mortality remains unknown.<sup>2</sup>

# **Case Report**

A patient presented to the ED with a chief complaint of sudden onset diaphoresis, dyspnea and near-syncope with minimal exertion. Aside from recent travel, the patient denied any other medical or surgical history. Triage vital signs were temperature 36.3°C, blood pressure 126/83mm Hg, heart rate 123 beats/min, respiratory rate 34 breaths/ min, SpO2 85% on room air and required a non-rebreather to maintain oxygen saturation above 95%. Initial impression was a dyspneic patient without respiratory distress. Cardiac exam demonstrated tachycardia with irregular rate, and his lung exam was normal. Extremity evaluation demonstrated a slightly enlarged right lower extremity with trace edema. The remainder of the physical examination was normal.

Initial electrocardiogram (ECG) displayed atrial fibrillation with rapid ventricular response (124 beats/min); no evidence of ischemia, infarction or patterns concerning for right ventricle strain. The patient also had an elevated Troponin (1.8ng/ml) and B-type Natriuretic Peptide (888pg/ ml). Chest radiograph was normal, but definitive CTA imaging to diagnose PE could not be pursued due to an elevated creatinine level (1.8mg/dl). Point-of-care (POC) ultrasound of the right lower extremity demonstrated a femoral vein deep vein thrombosis (DVT) extending from the saphenofemoral junction to the popliteal fossa (Figure 1). POC cardiac ultrasound revealed right heart strain (dilatation, hypokinesis, and paradoxical septal motion) and a plethoric inferior vena cava (Figure 2). Given these findings, the patient was diagnosed with a sub-massive PE.

Although this patient was not hemodynamically unstable, it was clear that the patient could decompensate at any moment. The decision was made to start half-dose tPA with heparin infusion.<sup>2</sup> One hour into the infusion, the patient appeared more comfortable, with improved vital signs: blood pressure 123/83mm Hg, heart rate 95 beats/min, respiratory rate 20 breaths/min, and SpO2 of 100% on a nonrebreather. The patient's atrial fibrillation resolved without any dysrhythmic agents. Eight hours later, the patient was



**Figure 1.** Dual image demonstrating right lower extremity popliteal vein clot with and without compression. The popliteal vein does not compress demonstrating active popliteal deep vein thrombosis.

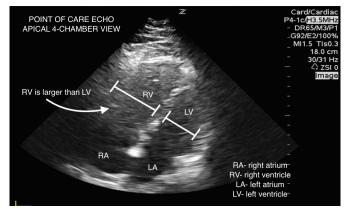
asymptomatic and no longer required oxygen.

After resolution of the patient's acute renal injury, a CTA was performed, which demonstrated extensive PEs in all five pulmonary arteries as well as possible early infarct of the left lower lung. The patient was transitioned to subcutaneous low molecular weight heparin and warfarin and was discharged 72 hours after presentation.

# DISCUSSION

Sub-massive PE is considered in hypoxic and dyspneic patients who are hemodynamically stable but demonstrate signs of heart strain as seen by ECG changes, cardiac biomarkers, or sonographic evidence of right ventricular strain.<sup>3</sup> Treatment with thrombolytics may prevent clinical deterioration and morbidity; however, it is associated with increased risk of intracranial hemorrhage.<sup>4</sup> Some experts choose not to thrombolyse these patients because there is insufficient evidence for reducing mortality.<sup>5</sup> New research demonstrates that treating sub-massive PEs with half-dose tPA may be safer and decrease long-term complications such as pulmonary hypertension.<sup>2</sup> Despite this, emergency physicians must be confident in their diagnosis of PE with POC ultrasound prior to making this decision.

In this case, POC ultrasound was performed by an emergency ultrasound fellowship-trained physician. First, POC ultrasound helped diagnose a lower extremity DVT, which carries concomitant PE in 40-50% of cases.<sup>6,7</sup> When the patient could not undergo definitive imaging secondary to acute renal injury, POC ultrasound demonstrated a dilated right heart, decreased right ventricular contractility, interventricular septal wall motion irregularity, and a plethoric inferior vena cava (Video). Although each of these findings are not sufficient for the diagnosis of PE, a recent study by Nazerian et al. demonstrated a sensitivity of 90% and a specificity of 86.2% when imaging the heart, lung, and veins.<sup>8</sup> In this case, POC ultrasound confirmed the diagnosis of sub-massive PE and directed treatment with half-dose tPA in addition to systemic heparin.



**Figure 2.** Point-of-care echocardiogram in apical 4-chamber view demonstrates significant right ventricle dilation.

While administration of thrombolytic therapy is controversial, and outside the scope of this article, POC ultrasound can assist in the decision making process. Due to the expanded use of POC ultrasound in emergency medicine (EM) and increased emphasis on ultrasound training in EM residency programs, it is reasonable to believe that all graduating EM residents will have the skills necessary to make this diagnosis.<sup>9</sup> POC ultrasound can assist with rapid evaluation and treatment of patients with suspected sub-massive PE, especially in patients with contraindications to CTA.

Address for Correspondence: Richard Amini, MD, University of Arizona, Department of Emergency Medicine, PO Box 245057, Tucson, AZ 85724. Email: richardamini@gmail.com.

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Video. Initial POC ultrasound.

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# **Improving Door-to-balloon Time by Decreasing Door-to-ECG time for Walk-in STEMI Patients**

Christopher J. Coyne, MD\* Nicholas Testa, MD\* Shoma Desai, MD\* Joy Lagrone, MSN, RN<sup>†</sup> Roger Chang, PhD<sup>†</sup> Ling Zheng, PhD<sup>†</sup> Hyung Kim, MD\* \*Los Angeles County/ University of Southern California, Department of Emergency Medicine, Los Angeles, California \*Los Angeles County/ University of Southern California, Los Angeles, California

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**Introduction:** The American Heart Association/American College of Cardiology guidelines recommend rapid door-to-electrocardiography (ECG) times for patients with ST-segment elevation myocardial infarction (STEMI). Previous quality improvement research at our institution revealed that we were not meeting this benchmark for walk-in STEMI patients. The objective is to investigate whether simple, directed changes in the emergency department (ED) triage process for potential cardiac patients could decrease door-to-ECG times and secondarily door-to-balloon times.

**Methods:** We conducted an interventional study at a large, urban, public teaching hospital from April 2010 to June 2012. All patients who walked into the ED with a confirmed STEMI were enrolled in the study. The primary intervention involved creating a chief complaint-based "cardiac triage" designation that streamlined the evaluation of potential cardiac patients. A secondary intervention involved moving our ECG technician and ECG station to our initial triage area. The primary outcome measure was door-to-ECG time and the secondary outcome measure was door-to-balloon time.

**Results:** We enrolled 91 walk-in STEMI patients prior to the intervention period and 141 patients after the invention. We observed statistically significant reductions in door-to-ECG time ( $43\pm93$  to  $30\pm72$  minutes, median 23 to 14 minutes p<0.01), ECG-to-activation time ( $87\pm134$  to  $52\pm82$  minutes, median 43 to 31 minutes p<0.01), and door-to-balloon time ( $134\pm146$  to  $84\pm40$  minutes, median 85 -75 minutes p=0.03).

**Conclusion:** By creating a chief complaint-based cardiac triage protocol and by streamlining ECG completion, walk-in STEMI patients are systematically processed through the ED. This is not only associated with a decrease in door-to-balloon time, but also a decrease in the variability of the time sensitive intervals of door-to-ECG and ECG-to-balloon time. [West J Emerg Med. 2015;16(1):184–189.]

#### INTRODUCTION Background

Expedited treatment of ST-segment elevation myocardial infarction (STEMI) with percutaneous coronary intervention (PCI) has been shown to improve outcomes.<sup>1-4</sup> Multiple strategies may be employed to improve the efficiency with

which STEMI patients are evaluated and treated once they arrive to the emergency department (ED). These include (but are not limited to) early electrocardiography (ECG), prompt ECG interpretation, early catheterization lab activation, an expedited response to activation, and rapid reperfusion.

Previous quality improvement research at our facility was

designed to investigate these intervals and to identify areas of deficiency. It was noted through this investigation that there was a significant difference between door-to-ECG times in those patients that arrived to the ED via ambulance versus those patients who walked in.<sup>5</sup> Previous American Heart Association/American College of Cardiology (AHA/ACC) guidelines have recommended rapid door-to-ECG times (less than 10 minutes) for suspected STEMI patients, and studies have shown that there is an increased risk of poor outcomes if this specific metric is delayed.<sup>6,7</sup> Although our institution met this goal for patients arriving by ambulance (median eight minutes), the door-to-ECG time for walk-in patients (median 23 minutes) was significantly delayed.

Previous data have shown that simple, directed changes to ED triage can significantly affect door-to-ECG time and secondarily door-to-balloon time.<sup>8</sup> These studies have generally focused on smaller, low-to-moderate volume EDs, while our study focuses on a large volume, crowded ED. Patients with chest pain arriving to our ED via ambulance are quickly triaged and an ECG is rapidly obtained. Prior to this study, however, ambulatory patients with chest pain underwent a more lengthy, delayed triage system prior to ECG. In an effort to improve our walk-in door-to-ECG times, our department designed a new pathway for evaluating and treating patients with chief complaints consistent with acute coronary syndrome (ACS).

# Goals of this study

This study was designed to investigate whether simple, directed changes in the initial evaluation of cardiac patients could significantly affect our door-to-ECG times and secondarily our door-to-balloon times for patients who walked into the ED.

# METHODS

# Study Design and Setting

We conducted this interventional study at a large, urban, public teaching hospital with an annual census of approximately 175,000 patients. It was conducted from April 2010 to June 2012. We included in this study, all walk-in patients with a confirmed ST elevation myocardial infarction. The university institutional review board approved this study.

# **Pre-Intervention Protocol**

From April 2010 through March 2011 we tracked the doorto-ECG times for all walk-in STEMI patients who presented to the ED. The initial intake process during this period consisted primarily of a nurse who designated an urgent or emergent triage category for each patient depending on the severity of the individual's general appearance and chief complaint. Emergent category patients, including all patients with chest pain, were placed in line for an expedited assessment. During this process, the assessment nurse or mid-level provider would receive a brief history and obtain appropriate labs and basic diagnostic studies as part of an early medical screening exam. If an ECG was indicated, the patient was transferred to a separate designated area, where an ECG technician performed this study and requested a physician interpretation. If a STEMI was identified at this time, the cardiology team and catheterization laboratory were alerted. If the physician did not detect STEMI on ECG, the patient was returned to the triage area to await further provider evaluation. Urgent category patients were placed in line for a delayed triage assessment.

# Intervention

From April 2011 through June 2011, we implemented new changes to the ED intake system in an attempt to decrease doorto-ECG times for STEMI patients. These changes included creating a Cardiac Triage designation that was assigned by the ED intake nurse upon arrival based on chief complaint. The Cardiac Triage designation (an addition to our urgent and emergent designations) prioritized the patients in an electronic patient tracking system. Patients were designated as cardiac triage if they had either chest pain, shortness of breath, or if they were thought to have other anginal equivalents based on the triage provider's interpretation. In addition, the ECG technician and machine were moved to the area where the initial triage assessment took place. This was done not only to eliminate the technician transit time, but also to create an increased sense of urgency with regards to the ECG.

# **Post-Intervention Protocol**

From July 2011 through June 2012, we again tracked door-to-ECG times for all STEMI patients. The intake nurse designated all patients as urgent, emergent or cardiac, depending on their chief complaints. Urgent and emergent patients were triaged as noted above. Cardiac patients either receive an immediate ECG in the triage area itself, or if there were mid-level providers available, they received the initial medical screening exam and ECG simultaneously. The ECG was then brought to a physician for interpretation and if indicated, a "code STEMI" was called to notify cardiology and activate the cath lab.

# **Outcomes and Data Collection**

The primary endpoint for this study is the door-to-ECG time. The secondary end points include activation time (ECG to "code STEMI" activation), response time ("code STEMI" activation to arrival of cath team), cath lab arrival time (response to patient arrival to cath lab), attending arrival time (patient in cath lab to attending arrival to cath lab), balloon time (attending in cath lab to balloon time), and overall doorto-balloon time. In addition, we also prospectively collected the demographic characteristics of the walk-in patients. We entered and stored all data in an ACCESS database. All data captured were double-checked by a dedicated research coordinator for accuracy. We performed data quality control on a quarterly basis to identify outliers and fallout cases.

# **Statistical Analysis**

Mean and median time intervals are reported for each

discrete step from ED arrival-to-balloon time. We examined distribution of each variable to determine the appropriate statistical approach used in the analysis. The Wilcoxon Rank-Sum Test was used to compare the mean times between the two groups for each step. We used the Chi-square test or the 2-sided Fisher's exact tests to compare proportions between two groups. A p-value less than or equal to 0.05 was considered statistically significant. We performed all the statistical analyses with the statistical software SAS v9.1.

# RESULTS

## **Characteristics of Study Subjects**

The analysis is based on a dataset of 232 walk-in STEMI patients before and after the intervention period (April 2011 through June 2011) at the Los Angeles County+University of Southern California Medical Center. Ninety-one patients were encountered from April 2010 through March 2011 prior to the intervention, while 141 patients were encountered from July 2011 through June 2012 after the intervention. The data collected during the three-month intervention period were piloted but not included in the analysis.

The demographic characteristics for walk-in STEMI patients before and after the intervention are presented in Table 1. Of note, approximately 10% of overall walk-in patients were placed in the cardiac triage category. We found no statistically significant differences in the median age (p=0.1), gender distribution (p=0.7), ethnicity distribution (p=0.1), or prevalence of chest pain as initial complaint (p=0.1) between the two groups.

# Main Results

The primary and secondary endpoints are compared between the two groups in Table 2. We observed statistically significant reductions in both mean and SD for the following intervals: (1) door-to-ECG time (43±93 to 30±72 minutes, median 23 to 14 minutes, p<0.01), (2) ECG-to-activation time (87±134 to 52±82 minutes, median 43 to 31 minutes p<0.01), and (3) door-to-balloon time (134±146 to 84±40 minutes, median 85 - 75 p=0.03) after the intervention period. Additionally, we observed decreased standard deviation in the time intervals for door-to-ECG, ECG-to-activation, and doorto-balloon after the intervention.

## DISCUSSION

Novel process changes in our ED were associated with a significant reduction in door-to-ECG time, ECG-tocatheterization lab activation time, and door-to-balloon time. Additionally, by streamlining the process for cardiac triage, ECG performance and ECG interpretation, we observed an associated decrease in the variability of these time intervals (Table 2). Much has been published on the topic of quality improvement measures to decrease door-to-balloon times. In 2006, Bradley et al.<sup>9</sup> found that six strategies were associated with faster doorto-balloon times. These included having a single call to a page operator to activate the cath lab, having the ED activate the cath lab, pre-hospital cath lab activation, expecting cath lab staff to arrive within 20 minutes after being paged, having an attending cardiologist always on site and having staff in the ED and cath lab use real-time data feedback. The Door to Balloon Alliance

| Characteristic                         | Pre-intervention<br>(N=91) | Post-intervention<br>(N=141) | p-value <sup>†‡</sup> |
|--|----------------------------|------------------------------|-----------------------|
| Age* (Year)                            | 57.1 ± 11                  | 55 ± 11                      | 0.1                   |
| Gender % (n)                           |                            |                              |                       |
| Male                                   | 70.3% (64)                 | 72.3% (102)                  | 0.7                   |
| Female                                 | 29.7% (27)                 | 27.7% (39)                   |                       |
| Ethnicity % (n)                        |                            |                              |                       |
| White                                  | 9.9% (9)                   | 8.5% (12)                    | 0.1                   |
| African American                       | 5.5% (5)                   | 12.8% (18)                   |                       |
| Asian                                  | 18.7% (17)                 | 12.1% (17)                   |                       |
| Latino                                 | 62.6% (57)                 | 64.5% (91)                   |                       |
| Other                                  | 3.3% (3)                   | 2.1% (3)                     |                       |
| Latino % (n)                           |                            |                              |                       |
| Yes                                    | 62.6% (57)                 | 64.5% (91)                   | 0.8                   |
| No                                     | 37.4% (34)                 | 35.5% (50)                   |                       |
| Chest pain as initial complaint, % (n) | 73.3% (66)                 | 83.7% (118)                  | 0.1                   |

STEMI, ST segment elevation myocardial infarction

<sup>†</sup>Obtained from chi-square test except from Wilcoxon rank-sum test for age.

<sup>‡</sup>P value for ethnicity applies to all subgroups.

<sup>\*</sup>Mean ± SD.

|                                  |    | Pre-intervention Post-intervention                |     |   |               |
|----------------------------------|----|---|-----|---|---------------|
| Time intervals                   | N  | Mean ± SD (minutes)<br>Median (Min,Max) (minutes) | N   | Mean ± SD (minutes)<br>Median (Min,Max) (minutes) | -<br>p-value* |
| Door-to-ECG time                 | 91 | 43.1 ± 93.1<br>23 (0, 636)                        | 141 | 30.3 ± 71.6<br>14 (2, 507)                        | <0.01         |
| ECG-to-activation time           | 90 | 87.1 ± 133.8<br>42.5 (3, 724)                     | 131 | 51.6 ± 81.6<br>31 (5, 539)                        | <0.01         |
| Activation to response time      | 91 | 5 ± 0.2<br>5 (4, 6)                               | 126 | 4.9 ± 0.5<br>5 (0, 6)                             | 0.3           |
| Response to patient in lab time  | 63 | 14.4 ± 5<br>14 (2, 30)                            | 75  | 16.1 ± 15.2<br>13 (1, 127)                        | 0.3           |
| Patient in lab to attending time | 62 | 11.2 ± 7.4<br>9.5 (1, 26)                         | 73  | 9 ± 5.7<br>7 (1, 24)                              | 0.2           |
| Attending to balloon time        | 43 | 22.5 ± 10.9<br>21 (9, 71)                         | 57  | 22 ± 12.1<br>19 (10, 79)                          | 0.4           |
| Door-to-balloon time             | 43 | 134.3 ± 146.3<br>85 (44, 709)                     | 57  | 83.9 ± 39.8<br>75 (44, 243)                       | <0.05         |

STEMI, ST segment elevation myocardial infarction; ECG, electrocardiogram

\*Obtained from Wilcoxon rank-sum test.

subsequently added two additional strategies, including a teambased approach to STEMI and the involvement of senior hospital leadership in the STEMI action plan.<sup>10,11</sup> Although these quality improvement strategies are generally efficacious, supported by interventional studies, they all focus specifically on the period after the diagnosis of STEMI is made.<sup>12,13</sup> This may not be an issue for those patients arriving to the ED by ambulance, where virtually all patients with chest pain are seen immediately. The population of patients walking into the emergency department with chest pain, however, may encounter a significant delay in their diagnosis of STEMI and subsequent treatment, despite having the Bradley et al. best practice measures in place.

Expediting the diagnosis of STEMI and ED cath lab activation (Activation time) is paramount in the effort to decrease door-to-balloon times. Although pre-hospital diagnosis of STEMI has been shown to decrease door-to-activation times for patients arriving via ambulance, there are no best practice measures that address the door-to-activation time for walk-in patients.14 This is despite recent data, which demonstrates that door-to-activation time remains the key determinant of doorto-balloon times.<sup>15</sup> The importance of door-to-activation time on door-to-balloon time was apparent in our own institution, where we noted a significant delay in door-to-balloon times for our ambulatory STEMI patients. This was primarily driven by our lengthy walk-in door-to-activation times. We successfully eliminated this delay by changing our initial triage system for cardiac patients and by moving our electrocardiogram (EKG) technician to the initial triage area.

Although there is a relative lack of research on door-toactivation time, the research that does exist has demonstrated the critical importance of appropriate ED triage. In a study on ED triage of patients with acute myocardial infarction (AMI) in 2011, Atzema et al.<sup>8</sup> found that one-third of all AMI patients were given a low triage score, which was associated with a significant delay in door-to-ECG and door-to-balloon times. Additionally, they found that 26% of STEMI patients were placed in this low-priority triage group, which was associated with increased length of stay and mortality. In an effort to avoid these issues in our ED triage system, we created a new "cardiac" triage category to prioritize patients with chief complaints consistent with acute myocardial infarction. This chief complaint-based, rapid triage for potential AMI patients has been shown to significantly decrease time to definitive therapy.<sup>16</sup> Our new triage system allows cardiac patients to forego the regular triage system and to receive a rapid ECG.

To further expedite our time to ECG, we moved our ECG technician to our preliminary triage area. This allowed for an EKG to rapidly take place, immediately after the patient stated their chief complaint. This is critically important, given that increased time to ECG has been associated with increased mortality in patients with STEMI.<sup>17</sup> Previously, these studies were delayed at our institution, due to the physical distance between the EKG technician and the patient. The location change also introduced a sense of urgency, given that these chest pain patients were placed immediately in front of the EKG tech station. Together, these ED interventions were not only associated with a decrease in our door-to- balloon times, but also a decrease in the variability of the critical intervals of door-to-ECG and ECG-to-cath lab activation.

# LIMITATIONS

One limitation of this study was that we changed our variables simultaneously and therefore cannot state whether it

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ECG time. We propose that both of these interventions likely contributed to our improved intervals and that each change would be efficacious individually at other institutions. A second limitation of our study was that it was done at a single center and therefore may lack external validity. We propose that similar triage protocols are warranted and feasible in all EDs, especially those in which high patient volumes may delay the expedited treatment of potential STEMI patients. Third, although we significantly decreased our door-to-ECG times, we did not meet recommended AHA/ACC guideline for door-to-ECG time (14 minutes vs 10 minute benchmark). Regardless, our interventions were associated with not only a decrease in door-to-ECG times, but also door-to-activations times, which dropped our door-toballoon times below the 90-minute benchmark. Furthermore, with continued efforts within our ED beyond the study period, these intervals anecdotally continued to decrease, though followup studies are necessary to confirm this phenomenon. Finally, it is possible that there are other potential confounders that affected our final interval times. One could argue that the staff knowledge of these interval measurements may have brought down our post-intervention times. That being said, these intervals were tracked long before our intervention period, and there had already been a push for decreased door-to-balloon time prior to the preintervention time period.

was our development of a "cardiac" designation at triage, or the

movement of the ECG technician that decreased our door-to-

# CONCLUSION

Through process changes in the emergency department management of cardiac patients, one can observe an associated decrease in door-to-balloon times for walk-in STEMI patients. With a chief complaint-based "cardiac" triage designation, patients are rapidly triaged, an immediate ECG is obtained, and the catheterization lab is expeditiously activated. With a separate cardiac triage protocol, these patients are systematically processed through the ED, which is associated with decreases in door-to-balloon times, as well as decreased variability in the time sensitive intervals of door-to-ECG and ECG-to-balloon time. Finally, by maintaining a designated ECG technician in the ED triage area, unnecessary delays in the diagnosis and treatment of STEMI patients are eliminated.

Address for Correspondence: Christopher Coyne, MD, 1200 N. State Street, Room 1011, Los Angeles, CA, 90033-1029. Email: coyne.usc@gmail.com.

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# Factors Influencing Rate of Testicular Salvage in Acute Testicular Torsion at a Tertiary Pediatric Center

Puneeta Ramachandra, MD\* Kerrin L. Palazzi, MPH<sup>†</sup> Nicholas M. Holmes, MD<sup>‡</sup> Sarah Marietti, MD<sup>‡</sup>

- \*Valley Children's Hospital, Madera, California
- <sup>†</sup>University of California, San Diego, Moores Cancer Center, Division of Urology, La Jolla, California <sup>‡</sup>Rady Children's Hospital San Diego, Division of Pediatric Urology, San Diego

<sup>‡</sup>Rady Children's Hospital San Diego, Division of Pediatric Urology, San Diego, California

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**Introduction:** Studies have demonstrated that variables other than duration of symptoms can affect outcomes in children with acute testicular torsion. We examined demographic and logistical factors, including inter-hospital transfer, which may affect outcomes at a tertiary pediatric referral center.

**Methods:** We reviewed charts of all pediatric patients with acute testicular torsion during a fiveyear period. Data were collected regarding age, insurance type, socioeconomic status, duration of symptoms prior to presentation, transfer status, time of day, time to surgical exploration, and testicular salvage.

**Results:** Our study included 114 patients. Testicular salvage was possible in 55.3% of patients. Thirty-one percent of patients included in the study were transferred from another facility. Interhospital transfer did not affect testicular salvage rate. Time to surgery and duration of pain were higher among patients who underwent orchiectomy versus orchidopexy. Patients older than eight years of age were more likely to undergo orchidopexy than those younger than eight (61.5% vs. 30.4%, p=0.01). Ethnicity, insurance type, or time of day did not affect the testicular salvage rates. On multivariate analysis, only duration of symptoms less than six hours predicted testicular salvage (OR 22.5, p<0.001).

**Conclusion:** Even though inter-hospital transfer delays definitive surgical management, it may not affect testicular salvage rates. Time to presentation is the most important factor in predicting outcomes in children with acute testicular torsion. [West J Emerg Med. 2015;16(1):190–194.]

# **INTRODUCTION**

The management of the acute scrotum in pediatric patients can be challenging. In a patient with acute testicular torsion, a delay in presentation, diagnosis, or definitive management may result in poor outcomes such as loss of the affected testis. Previous studies have demonstrated that a number of variables can affect testicular salvage, including symptom duration, insurance type, and race.<sup>1-3</sup> Age has been shown to negatively impact testicular salvage in some studies,<sup>4</sup> while other series show a positive correlation with age and testicular salvage.<sup>1-3</sup>

In geographic areas where pediatric specialty care is

unavailable, children may be transferred to tertiary care centers for emergent conditions. Reasons for transferring a pediatric patient for acute scrotum may include lack of availability of pediatric urologists or anesthesiologists, lack of appropriate diagnostic modalities, patient preference, insurance status, or other explanations. Transfer from one hospital to another inherently delays definitive management and may ultimately affect outcome.

The aim of this study was to examine the cohort of patients seen at a tertiary pediatric referral center, comparing patients who presented primarily to our facility to those who

# METHODS

Following approval from the local institutional review board, we retrospectively reviewed charts of all patients with a diagnosis of acute testicular torsion presenting between 2005 and 2011. Charts to be abstracted were identified based on having an ICD-9 code for testicular torsion (608.2, 608.20, 608.21, 608.22). All charts were electronic. We included all patients seen in the emergency department (ED) who underwent surgical exploration at our institution. Our referral center is the main pediatric treatment facility for a large geographic area, routinely caring for patients who live more than two hours away. Patients who were transferred were sent from the outside facilities' EDs to the ED at our facility, where they were reevaluated prior to surgery. A diagnosis of testicular torsion was made prior to surgical exploration and confirmed at the time of surgery. All patients underwent Doppler ultrasonography either at their presenting hospitals or at our institution prior to surgical exploration. We excluded from the analysis patients with neonatal torsion and suspected intermittent torsion who were treated in a nonemergent fashion.

All charts were reviewed and data extracted by a single reviewer (the lead author). Data were extracted from hospital charts regarding age, insurance type, ethnicity, whether or not the patient was transferred, presentation before 5pm vs. after 5pm, duration of symptoms prior to presentation in any ED, time from first presentation in any ED to surgical exploration, and results of scrotal exploration (orchiectomy vs. orchidopexy). We decided to use a cutoff time of 5pm to analyze patients, hypothesizing that the time the patient presented could influence the decision to transfer a patient to our facility. The decision to proceed with orchiectomy or orchidopexy was made by each individual surgeon based on the appearance of the testicle during exploration. Insurance type was categorized as Medicaid, private (PPO/HMO), or managed Medicaid (Medi-cal HMO). We excluded from the analysis seven patients with a particular type of insurance (CPCMG) as these patients are contractually obligated to be treated at our facility. Symptom duration was recorded as the longest duration of symptoms prior to initial presentation reported by the patient or caregiver to any provider during the evaluation. We characterized ethnicity as Hispanic or non-Hispanic. Records from transferring facilities were not available for review in all cases; therefore, we could not record the reason for transfer or whether or not a local urologist was contacted before initiating transfer. We calculated the time to surgical exploration as time from first presentation in any ED to the operating room start time

recorded on the anesthesia record at our facility.

Univariate comparative statistics including Mann-Whitney u-test and Spearman Rank correlation for continuous, non-normally distributed variables, and Chi<sup>2</sup> test and Fisher's exact test for categorical variables, were used to examine associations between our variables of interest and testicular salvage. Age was found to have a bimodal distribution and was examined as both a continuous measure and grouped into younger than eight years vs.  $\geq$  eight years-old. We used binary logistic regression models (multivariate) to determine significant predictors of testicular salvage in the overall cohort, as well as separately in the younger than eight and older than eight-year-old age groups. Variables at or approaching significance on univariate analysis (p<0.2) and clinically relevant variables were entered in the models. We included in the final models only variables that remained significant. All tests were performed using SPSS v 17.0 (Chicago, IL, USA) with statistical significance set a priori at  $\alpha < 0.05$ .

# RESULTS

We included 114 patients in the final analysis. Testicular salvage was possible in 63 patients (55.3%), and orchiectomy was performed in 51 patients. The mean age of the cohort was  $11.3 \pm 4.7$  years. Thirty-five (31%) patients were transferred to the pediatric hospital after presenting in another ED, compared with 79 (69%) who presented primarily. In the entire cohort, median duration of symptoms prior to ED presentation was seven hours, and median time to operating room from first presentation was 3.33 hours. Testicular salvage rate was not different between patients who were transferred to our facility vs. those who presented primarily (60% vs. 53.2%, p=0.55). On univariate analysis, age, time to the operating room and duration of pain, was significantly different amongst patients who underwent orchiectomy vs. orchidopexy. Patient characteristics and results of the univariate analysis are listed in Table 1. Patients older than eight years of age were more likely to undergo orchidopexy than those younger than eight years (61.5% vs. 30.4%, p=0.01). Median duration of pain prior to presentation was higher in the orchiectomy vs. orchidopexy groups (42 vs. 4 hours, p<0.001). Patients who had symptoms for less than six hours were much more likely to undergo orchidopexy than those with symptoms for six hours or more (90% vs. 28.6%, p<0.001). Median time to the operating room from first presentation was higher in the orchiectomy group compared to the orchidopexy group (240 vs. 180 minutes, p=0.02). Ethnicity, insurance type, and laterality did not affect the testicular salvage rates.

Table 2 compares patients who were transferred to those who presented primarily. Transferred patients had longer median times to the operating room than primary patients (260 vs. 177 min, p<0.001). In regards to insurance status, transferred patients more likely to have Medicaid than those who presented primarily (40% vs. 19%, p=0.05); however,

| Table 1. Patient characteristics, un | ivariate analysis | comparing testicular | salvage. |
|--------------------------------------|-------------------|----------------------|----------|
|--------------------------------------|-------------------|----------------------|----------|

|  | Orchiectomy   | Orchidopexy   |         |
|--|---------------|---------------|---------|
|  | n=51          | n=63          | p-value |
| Median age (IQR), years                                      | 12 (4-14)     | 13 (12-14)    | 0.17    |
| Age group  |               |               | 0.01    |
| <8 years (n=23)  | 16 (69.6%)    | 7 (30.4%)     |         |
| ≥8 years (n=91)  | 35 (38.5%)    | 56 (61.5%)    |         |
| Race   |               |               | 0.85    |
| Hispanic (n=53)  | 24 (47.4%)    | 29 (52.6%)    |         |
| Other (n=57)   | 27 (45.3%)    | 30 (54.7%)    |         |
| Side   |               |               | 0.56    |
| Left (n=69)  | 33 (47.8%)    | 36 (52.2%)    |         |
| Right (n=44)   | 18 (40.9%)    | 26 (59.1%)    |         |
| Insurance  |               |               | 0.09    |
| Private (PPO/HMO) (n=48)                                     | 18 (37.5%)    | 30 (62.5%)    |         |
| Medi-cal HMO (n=37)  | 15 (40.5%)    | 22 (59.5%)    |         |
| Medicaid (n=29)  | 18 (62.1%)    | 11 (37.9%)    |         |
| Admission  |               |               | 0.55    |
| Primary (n=79)   | 37 (46.8%)    | 42 (53.2%)    |         |
| Transfer (n=35)  | 14 (40%)      | 21 (60%)      |         |
| Median time to operating room (IQR), minutes                 | 240 (163-320) | 180 (140-240) | 0.02    |
| Median duration of pain prior to operating room (IQR), hours | 42 (18-72)    | 4 (2-6)       | <0.001  |
| Duration of pain   |               |               | <0.001  |
| <6 hours (n=50)  | 5 (10%)       | 45 (90%)      |         |
| ≥6 hours (n=63)  | 45 (71.4%)    | 18 (28.6%)    |         |

PPO, preferred provider organization; HMO, health maintenance organization

this was not statistically significant. Time of day, ethnicity, and age group did not affect transfer status.

On multivariate analysis of factors associated with testicular salvage, only duration of symptoms prior to presentation of less than six hours remained a significant predictor of testicular salvage (OR 22.5, p<0.001) (Table 3). Transfer status, age, time to operating room from first presentation, race, and insurance status were not significant predictors of testicular salvage. In a subgroup analysis of the patients  $\geq$  eight years old, duration of symptoms was again the only predictor of testicular salvage (OR 22.5, p<0.001). In subgroup analysis of patients < eight years of age (n=23), no variables examined were predictive of testicular salvage.

# DISCUSSION

Our study showed that duration of symptoms prior to presentation was the most significant factor in testicular salvage overshadowing other factors such as age and transfer status. This was especially the case in older patients. Neither transfer status nor time to surgical exploration independently predicted testicular salvage. While transfer status did delay surgical exploration in our patient cohort, transferring a patient did not change overall outcome in our series. Nevertheless, delaying definitive surgical exploration may have resulted in orchiectomy in a small number of patients. In other words, transferring patients who already have relatively long duration of symptoms prior to presentation may result in orchiectomy. It is impossible to truly know whether transferred patients could have been salvaged had they not been transferred.

Children from surrounding areas are frequently transferred to our center, not only for treatment of urologic emergencies, but also for diagnostic tests. Lack of pediatric expertise at community treatment facilities, such as pediatric anesthesiology or pediatric radiology, may also necessitate transfer of pediatric patients. While such inter-hospital transfer is appropriate and essential in many cases, there is concern that it results in delay of care for time-dependent conditions such as testicular torsion.

Bayne et al.<sup>1</sup> reported a series of 97 testicular torsion patients. Those investigators found that transfer delay in patients with potentially salvageable testes (i.e. those with symptoms less than 24 hours duration) puts those children at risk for orchiectomy. Patients who underwent orchiectomy also had longer pain duration and lived farther away from the Table 2. Comparison of primary and transferred patients.

|  | Primary        | Transfer      | p-value |
|--|----------------|---------------|---------|
| Salvage  |                |               | 0.546   |
| Orchiectomy (n=51)   | 37 (46.8%)     | 14 (40%)      |         |
| Orchidopexy (n=63)   | 42 (53.2%)     | 21 (60%)      |         |
| Age group  |                |               | 1.00    |
| <8 (n=23)  | 16 (20.3%)     | 7 (20%)       |         |
| ≥8 (n=92)  | 63 (79.7%)     | 28 (80%)      |         |
| Ethnicity  |                |               | 0.68    |
| Hispanic (n=53)  | 36 (46.8%)     | 17 (51.5%)    |         |
| Other (n=59)   | 43 (41 (53.2%) | 16 (48.5%)    |         |
| Time of day  |                |               | 0.42    |
| Day (n=62)   | 45 (57%)       | 17 (48.6%)    |         |
| Night (n=52)   | 34 (43%)       | 18 (51.4%)    |         |
| Insurance  |                |               | 0.05    |
| Private insurance (PPO/HMO) (n=48)                           | 35 (44.3 %)    | 13 (37.1%)    |         |
| Medi-cal HMO (n=37)  | 29 (36.7%)     | 8 (22.9%)     |         |
| Medicaid (n=29)  | 15 (19%)       | 14 (40%)      |         |
| Median time to operating room (IQR), minutes                 | 177 (140-229)  | 260 (220-360) | <0.001  |
| Median duration of pain prior to operating room (IQR), hours | 8.5 (3.8-48)   | 6 (2-24)      | 0.11    |

PPO, preferred provider organization; HMO, health maintenance organization

**Table 3.** Multivariate analysis predicting orchidopexy in the overall cohort and in patients  $\ge 8$  years old.

| 3 <0.001   |
|------------|
| 5 <0.001   |
| 5.8<br>5.1 |

ED, emergency department

hospital. Similar to our findings, the investigators reported that age was not an independent risk factor predicting orchiectomy, even though patients who received orchiectomy were younger than those who avoided orchiectomy.<sup>1</sup>

The clinical presentation of testicular torsion, especially in younger children may overlap other nonsurgically managed processes, such as torsion of an appendix epididymis or appendix testis. While most adult men would be able to describe symptoms, such as sudden onset of pain, quality of pain, and duration of pain, pediatric patients are much less reliable historians. Because obtaining an accurate history is difficult, we have found that exploration for all acute scrotums may lead to many negative explorations. This has described by Lam et al.<sup>5</sup> Therefore, most patients with the acute scrotum that present to our ED go immediately to ultrasound, a practice that has been endorsed by the American College of Radiology in their recommendations regarding imaging for acute onset scrotal pain.<sup>6</sup>

The current series failed to identify any predictors of testicular salvage in patients younger than eight years. Younger children may have difficulty communicating

their symptoms to caregivers and may not have noticeable physical findings such as scrotal swelling or firmness until later in the course of their disease. Children who do not require as much assistance for bathing or using a toilet may not have close monitoring of their genitalia by their caregivers. Therefore, these young children may be the most vulnerable group, as they may not express their symptoms clearly. The duration of symptoms in this group may be even longer than what caregivers communicated in the patient's history in the current series. In several studies, children with acute testicular torsion have symptoms other than scrotal pain and swelling, such as abdominal pain, nausea, and vomiting.<sup>7-9</sup> It is crucial for providers to perform a focused genital examination for boys who present with abdominal pain, especially when patients may not be able to accurately describe their symptomatology.

Other researchers have shown that despite disease severity, children who are uninsured or have Medicaid insurance are more likely to undergo hospital transfer.<sup>10,11</sup> We initially hypothesized that insurance status or socioeconomic factors may affect the rate of testicular salvage or transfer rates in our cohort. While insurance status did not impact the rate of testicular salvage, there was an alarming trend toward increasing transfer rates in patients with Medicaid compared to private insurance. While our study was not able to truly demonstrate statistical significance, this trend may very well be clinically relevant. Larger studies are needed to further characterize the effects of insurance on patient outcomes.

# LIMITATIONS

Our study has several important limitations, including the retrospective nature of the data. Chart reviews and historical accounts may have significant inaccuracies in regards to subjective information such as duration of symptoms. Charts and data from transferring institutions were not always available for review, making it difficult to know why patients were transferred. For the transferred patients, we could not determine if there was a local urologist available or if a local urologist had been contacted prior to initiating a transfer to our facility. We were also not consistently able to calculate distances from patients' homes to the ED where they presented or if there was any correlation between home zip code and insurance type. Outcomes for those patients who were surgically treated at outside facilities instead of being transferred are also not known. We also may have had an inadequate sample size to detect significant differences resulting from insurance type. Specifically, the number of transferred patients was small compared to the number of patients who presented primarily, and the number of patients younger than eight years was small compared to patients older than eight years. Finally, we do not have long-term followup data for most of our patients, especially in terms of postoperative testicular viability in patients who underwent testicular salvage. Despite these important limitations, the current data reinforces conclusions in prior studies<sup>1,4,14</sup> that delays in presentation and treatment are more likely to be associated with the need for orchiectomy.

# CONCLUSION

Time to presentation to the ED is the most important factor in predicting testicular salvage in patients with acute testicular torsion. Boys with acute scrotum should be referred quickly for emergency care to increase their chances of testicular salvage. Evaluation of abdominal pain should include a brief genital exam, especially in younger patients who may not be able to accurately describe their symptoms. Children and families should be educated on the seriousness of severe testicular pain and its consequences.

Address for Correspondence: Puneeta Ramachandra, MD, Valley Children's Hospital, 9300 Valley Children's Place, Madera, CA 93636. Email: puneeta.ramachandra@gmail.com. *Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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# Validation of a Decision Rule for Selective TSH Screening in Atrial Fibrillation

Shawna D. Bellew, MD\* Rajat Moman, MA<sup>†</sup> Christine M. Lohse, MS<sup>‡</sup> Erik P. Hess, MD, MSc\*<sup>§</sup> M. Fernanda Bellolio, MD, MS\*<sup>§</sup> \*Mayo Clinic, Department of Emergency Medicine, Rochester, Minnesota
<sup>†</sup>Mayo Medical School, Rochester, Minnesota
<sup>‡</sup>Mayo Clinic, Department of Health Sciences Research, Division of Biostatistics, Rochester, Minnesota
<sup>§</sup>Mayo Clinic, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Rochester, Minnesota

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**Introduction**: Atrial fibrillation (AF) is the most common cardiac dysrhythmia. Current guidelines recommend obtaining thyroid-stimulating hormone (TSH) levels in all patients presenting with AF. Our aim was to investigate the utility of TSH levels for emergency department (ED) patients with a final diagnosis of AF while externally validating and potentially refining a clinical decision rule that recommends obtaining TSH levels only in patients with previous stroke, hypertension, or thyroid disease.

**Methods**: We conducted a retrospective, cross-sectional study of consecutive patients who presented to an ED from January 2011 to March 2014 with a final ED diagnosis of AF. Charts were reviewed for historical features and TSH level. We assessed the sensitivity and specificity of the previously derived clinical decision rule.

**Results**: Of the 1,964 patients who were eligible, 1,458 (74%) had a TSH level available for analysis. The overall prevalence of a low TSH (<0.3µIU/mL) was 2% (n=36). Elevated TSH levels (>5µIU/mL) were identified in 11% (n=159). The clinical decision rule had a sensitivity of 88.9% (95% CI [73.0-96.4]) and a specificity of 27.5% (95% CI [25.2-29.9]) for identifying a low TSH. When analyzed for its ability to identify any abnormal TSH values (high or low TSH), the sensitivity and specificity were 74.4% (95% CI [67.5-80.2]) and 27.3% (95% CI [24.9-29.9]), respectively.

**Conclusion**: Low TSH in patients presenting to the ED with a final diagnosis of AF is rare (2%). The sensitivity of a clinical decision rule including a history of thyroid disease, hypertension, or stroke for identifying low TSH levels in patients presenting to the ED with a final diagnosis of atrial fibrillation was lower than originally reported (88.9% vs. 93%). When elevated TSH levels were included as an outcome, the sensitivity was reduced to 74.4%. We recommend that emergency medicine providers not routinely order TSH levels for all patients with a primary diagnosis of AF. Instead, these investigations can be limited to patients with new onset AF or those with a history of thyroid disease with no known TSH level within three months . [West J Emerg Med. 2015;16(1):195–202.]

# **INTRODUCTION**

Atrial fibrillation (AF) is the most common cardiac dysrhythmia, affecting an estimated three million persons in the United States, a number that is expected to increase to 7.5 million by the year 2050.<sup>1,2</sup> Associated with heart failure and

stroke, AF represents a significant contributor to mortality, morbidity, and healthcare expenditures.<sup>3,4</sup> AF accounts for 0.5% of all emergency department (ED) visits, a setting in which initial diagnosis and management often occurs.<sup>5,6</sup> Initial management of AF includes ruling out reversible

Volume XVI, NO. 1 : January 2015

causes and contributors to the condition, including thyroid dysfunction.<sup>7-9</sup> Atrial fibrillation has long been observed to be a sequela of hyperthyroidism. This relationship has been described in both clinical and subclinical hyperthyroidism, with overt hyperthyroidism conferring up to a five-fold increase in the relative risk of developing AF.<sup>10-12</sup> Patients with subclinical hyperthyroidism or even high normal thyroid function have been shown to be significantly more likely to develop AF, with as much as a three-fold increase in risk.<sup>13,14</sup> More controversial is the relationship of hypothyroidism and AF. While early studies suggested an association between the two conditions,<sup>15-17</sup> others have indicated that hypothyroidism might actually be protective against developing AF.<sup>18</sup>

Although many studies have reported an increased incidence of AF in patients with thyroid disease, particularly hyperthyroidism, far fewer studies have focused on the incidence of thyroid disease in those with AF. Published studies indicate that while abnormal thyroid stimulating hormone (TSH) levels are present in as many as 16.6% of patients with atrial fibrillation,<sup>19</sup> the incidence of clinically significant thyroid disease is likely closer to 2%.<sup>20</sup> Therefore, the utility of routine testing has been called into question.

In 2010, Bruccelletti et al. published the results of a cross-sectional observational study of 433 patients admitted to an ED observation unit for new-onset atrial fibrillation who underwent thyroid function tests.<sup>21</sup> Recursive partitioning was performed in an effort to identify clinical characteristics associated with a TSH <0.35 $\mu$ IU/mL. From this analysis, a model was proposed that recommended obtaining TSH levels only in patients with any one of the following: previous cerebrovascular disease, hypertension, or thyroid disease. When applied to the derivation patient population, this model had a sensitivity of 93% and a specificity of 31%. Application of the model could potentially have avoided 30% of TSH evaluations in the study population.

Given the expanding prevalence of AF, limiting the acquisition of TSH levels could be a small but substantial step towards decreasing the cost of care for this patient population. With this end objective in mind, we aimed to externally validate this clinical decision rule with a secondary goal of identifying any further predictors of an abnormal TSH in our population for further refinement of the model. Finally, we set out to describe the incidence of TSH abnormalities in a large sample of ED patients with a diagnosis of AF, therefore exploring the yield of this commonly ordered laboratory investigation.

# METHODS

# **Study Design and Setting**

We performed a retrospective, cross-sectional study of all the patients who presented to an academic tertiary care emergency department (ED) with 73,000 annual patient visits with an ED diagnosis of atrial fibrillation. Consecutive patients presenting from January 3, 2011 to March 16, 2014 with a final diagnosis of atrial fibrillation were included. Patients were excluded if they did not consent to having their medical records reviewed for research purposes. The institutional review board approved the research protocol.

# **Data Processing**

Electronic medical records (EMR) with a final diagnosis of atrial fibrillation after the ED visit were extracted by a data quality analyst. For each patient, the following data were extracted from the EMR: date, time of visit, patient age, gender, diagnosis, disposition, vital signs, and medications administered. Then, a focused chart review was performed by a resident physician and a medical student. The following data were extracted into a Microsoft Excel (Microsoft Corporation, Redmond, WA) spreadsheet: history of hypertension, heart failure, diabetes mellitus, cerebrovascular accident or transient ischemic attack, thyroid disease, and TSH level (µIU/mL) within 24 hours of ED presentation or within 30 days of ED presentation. For each patient, the presence or absence of historical features was abstracted from the additive problem list feature of the EMR, which often contains prior primary care visits as well as the identified ED visit. Reviewers agreed upon a predetermined definition of the historical features abstracted, in which heart failure was considered present regardless of preserved systolic function if a diagnosis was made by a cardiologist, hypertension was considered present if the patient carried a previous diagnosis of hypertension, cerebrovascular disease included a diagnosis of stroke, cerebrovascular accident, or transient ischemic attack, and thyroid disease included hypothyroidism or hyperthyroidism. We used these historical features to calculate the Congestive heart failure, Hypertension, Age >75, Diabetes mellitus, Prior Stroke or Transient ischemic attack or Thrombeombolism (CHADS2) score for each patient. The CHADS2 score is a clinical prediction rule that generates an estimated yearly risk of stroke in patients with AF. Patients with higher scores are more likely to experience stroke. Statistical analyses were performed by a biostatistician using the SAS software package (SAS Institute, Cary, NC).

# Data Analysis

The main outcome measures were the test characteristics of the clinical decision rule including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (+LR) and negative likelihood ratio (-LR) for identifying an abnormal TSH level. Analysis of these characteristics was performed separately to assess the performance of the rule to identify a low TSH level or any abnormal TSH level. In addition to determining the performance characteristic of the decision rule, we further analyzed each feature separately for its independent correlation to low or abnormal TSH levels.

We summarized continuous data were summarized with means, medians, and IQRs, while categorical data

were summarized with frequency counts and percentages. Comparisons of characteristics of patients with and without a TSH available for analysis were evaluated using Wilcoxon rank sum and chi-square tests. Only patients who had a TSH available on chart abstraction were included in the estimation of the sensitivity, specificity, +LR, -LR, PPV, and NPV of the clinical decision rule. Comparisons of features by TSH level ( $\geq 0.3 \mu$ IU/mL versus <0.3 \muIU/mL and normal versus abnormal) were evaluated using Wilcoxon rank sum, chi-square, and Fisher exact tests. We defined an abnormal TSH level as being either <0.3 or >5 \muIU/mL. These cutoffs were based on the institution's laboratory definitions of normal. All tests were two-sided and we considered p-values <0.05 statistically significant.

# RESULTS

From January 2011 to March 2014, 2,071 patients presented to the ED with a final diagnosis of atrial fibrillation. One hundred and seven patients declined consent for charts review. Therefore, 1,964 patients were included. The features of these patients are summarized in Table 1.

A TSH level was available for 1,458 (74%) of these patients, who were therefore included in the analysis of the diagnostic performance of the clinical decision rule. Seventy-one percent (n=1032) of these values were obtained within 24 hours of ED presentation and the remaining within 30 days of presentation. Patients with a TSH level available were more likely to be female (47%) vs. 41%; p=0.036), more likely to have a history of thyroid disease (20% vs. 9%; p < 0.001), and had higher heart rates (median 120 vs. 115; p < 0.001) compared to patients without a TSH level measured. Seventy-three percent (n=1063) of the patients with a TSH level available for analysis met at least one of the criteria for the clinical decision rule (presence of cerebrovascular disease, hypertension, or thyroid disease). Seventy percent (n=353) of the 506 patients without a TSH level available met the criteria (p=0.17).

Of the 1,458 patients with a TSH available for analysis, 36 (2%) had a low TSH level ( $<0.3\mu$ IU/mL), 1263 (87%) a normal TSH level (between 0.3 and 5.0 $\mu$ IU/mL), and 159 (11%) a high TSH level (>5.0 $\mu$ IU/mL). Table 2 shows the association between clinical features and low TSH levels. There was no significant association between temperature, heart rate, blood pressure, or CHADS2 score and a low TSH level. Female sex and a history of thyroid disease were significantly associated with a low TSH level. When these features were analyzed for their association with any TSH abnormality, the findings were largely the same (illustrated in Table 3).

Applying the rule, 1063 (72.9%) of the 1,458 patients met criteria for having a TSH level drawn, which identified 32 (88.9%) of the 36 patients with an abnormally low TSH level. This resulted in the following performance **Table 1.** Features of all eligible patients, N=1,964, in a study of the utility of TSH levels for emergency department patients with a final diagnosis of atrial fibrillation.

| inal diagnosis of atrial libriliation. |                    |
|--|--------------------|
| Feature                                | Mean (Median; IQR) |
| Age in years                           | 68.9 (70;61-79)    |
| Gender                                 | N (%)              |
| Female                                 | 886 (45)           |
| Male                                   | 1078 (55)          |
| Congestive heart failure               | 494 (25)           |
| Diabetes mellitus                      | 375 (19)           |
| Cerebrovascular disease                | 198 (10)           |
| Hypertension                           | 1291 (66)          |
| Thyroid disease                        | 345 (18)           |
| CHADS2 score                           |                    |
| 0                                      | 385 (20)           |
| 1                                      | 585 (30)           |
| 2                                      | 536 (27)           |
| 3                                      | 277 (14)           |
| 4                                      | 125 (6)            |
| 5                                      | 46 (2)             |
| 6                                      | 10 (1)             |
| TSH μIU/mL (N=1458)                    |                    |
| <0.1                                   | 24 (2)             |
| <0.3                                   | 36 (2)             |
| 0.3-5.0                                | 1263 (87)          |
| >5.0                                   | 159 (11)           |
| >20.0                                  | 3 (<1)             |

*CHADS2*, Congestive heart failure, Hypertension, Age  $\geq$ 75, Diabetes mellitus, Prior Stroke or Transient ischemic attack or Thrombeombolism; *TSH*, thyroid-stimulating hormone

characteristics: sensitivity 88.9% (95% CI [73.0-96.4]), specificity 27.5% (95% CI [25.2-29.9]), positive LR 1.23 (95% CI [1.09-1.38]), negative LR 0.40 (95% CI [0.16-1.02]), PPV 3.0% (95% CI [2.1-4.3]), and NPV 99.0% (95% CI [97.2-99.7]) (Figure, Table 4). When both abnormally low and high TSH levels were analyzed as the outcome, the criteria identified 145 of the 195 patients with abnormal levels. The clinical decision rule had the following diagnostic performance for detecting any TSH abnormality: sensitivity 74.4% (95% CI [67.5-80.2]), specificity 27.3% (95% CI [24.9-29.9]), positive LR 1.02 (95% CI [0.94-1.12]), negative LR 0.94 (95% CI [0.74-1.20]), PPV 13.6% (95% CI [11.7-15.9]), and NPV 87.3% (95% CI [83.6-90.4]) (Figure, Table 4).

#### DISCUSSION

Atrial fibrillation (AF) affects up to 8% of the U.S. population by the age of 80 and costs an estimated 26 billion dollars per year.<sup>22,23</sup> AF is associated with hypertension, diabetes mellitus, heart failure, obstructive sleep apnea,

Table 2. The predictive value of features for a low TSH level (≥0.3 versus <0.3µIU), N=1,458.

| TSH level [N (%)]          |                   | LR (9          | (95% CI) |                  |                  |
|----------------------------|-------------------|----------------|----------|------------------|------------------|
| Feature                    | ≥0.3µIU (n=1,422) | <0.3µIU (n=36) | p-value  | +LR*             | -LR*             |
| Age <sup>†</sup>           |                   |                |          |                  |                  |
| <75                        | 909 (64)          | 19 (53)        | 0.17     | 0.83 (0.60-1.13) | 1.31 (0.92-1.85) |
| ≥ 75                       | 513 (36)          | 17 (47)        | 0.17     | 0.83 (0.60-1.13) | 1.31 (0.92-1.85) |
| Sex                        |                   |                |          |                  |                  |
| Female                     | 654 (46)          | 24 (67)        | 0.14     | 1.45 (1.13-1.84) | 1.45 (1.13-1.84) |
| Male                       | 768 (54)          | 12 (33)        | 0.14     | 1.45 (1.13-1.84) | 1.45 (1.13-1.84) |
| Congestive heart failure   | 363 (26)          | 8 (22)         | 0.65     | 0.87 (0.47-1.61) | 1.04 (0.88-1.24) |
| Diabetes mellitus          | 274 (19)          | 6 (17)         | 0.70     | 0.85 (0.41-1.81) | 1.03 (0.89-1.19) |
| Cerebrovascular<br>disease | 134 (9)           | 2 (6)          | 0.57     | 0.59 (0.15-2.29) | 1.04 (0.96-1.13) |
| Hypertension               | 932 (66)          | 21 (58)        | 0.37     | 0.89 (0.67-1.18) | 1.21 (0.82-1.78) |
| Thyroid disease            | 275 (19)          | 23 (64)        | <0.001   | 3.30 (2.53-4.32) | 0.45 (0.29-0.69) |
| CHADS2 score               |                   |                |          |                  |                  |
| 0                          | 277 (19)          | 10 (28)        | 0.55     |                  |                  |
| 1                          | 435 (31)          | 8 (22)         | 0.55     |                  |                  |
| 2                          | 380 (27)          | 11 (31)        | 0.55     |                  |                  |
| 3                          | 208 (15)          | 4 (11)         | 0.55     |                  |                  |
| 4                          | 85 (6)            | 2 (6)          | 0.55     |                  |                  |
| 5                          | 31 (2)            | 0              | 0.55     |                  |                  |
| 6                          | 6 (<1)            | 1 (3)          | 0.55     |                  |                  |

\*Positive and negative likelihood ratios for predicting a low TSH level (<3µIU).

<sup>†</sup>Mean age for  $\ge 0.3\mu$ IU was 68.7; median 70, IQR 60-79. Mean age for  $< 0.3\mu$ IU was 68.8; median 69; IQR 60-81. p-value 0.96. *TSH*, thyroid-stimulating hormone; +*LR*, positive likelihood ratio; -*LR*, negative likelihood ratio; *CHADS2*, Congestive heart failure, Hypertension, Age  $\ge$ 75, Diabetes mellitus, Prior Stroke or Transient ischemic attack or Thrombeombolism

and obesity. Most commonly, AF is thought to result from histopathologic changes of the atrial walls, resulting in aberrant conduction. In animal studies, both hyperthyroidism and hypothyroidism result in interstitial fibrosis of the atrial walls and therefore AF.<sup>24,25</sup>

Hypothyroidism occurs in approximately 4% of the population, becoming increasingly common with advanced age.<sup>26</sup> Hyperthyroidism is less common, affecting less than 0.5%. Thus, despite the increased risk of developing AF conferred by hyperthyroidism, the incidence of hyperthyroidism in AF remains small, reported from 0.7% to 5.2%.<sup>27-29</sup> Meanwhile, hypothyroidism is found in 8-15% patients with AF.<sup>16,17,28,29</sup> There is some controversy as to whether hypothyroidism plays a contributory role in the development of AF versus simply tending to occur in the same patient population, namely the elderly.<sup>30</sup> A recent cohort study of Framingham heart study participants found no significant association with hypothyroidism and increased risk of AF over 10-years.<sup>31</sup> However, there is a plausible mechanism for hypothyroidism contributing to AF, given that it does seem to contribute to associated conditions, namely hypertension, atherosclerosis, and heart failure.<sup>7</sup>

In our study, 74% of patients had a TSH level available

for analysis (52% drawn within 24 hours of ED presentation and another 22% with levels drawn within 30 days of presentation). These patients were more likely to be female (47% vs. 41%; p=0.036) and were more likely to have a history of thyroid disease (20% vs. 9%; p<0.001) than patients who had no available level. It is not surprising that many patients did not have a TSH ordered, given that our institution possesses a highly integrated EMR that captures much of the surrounding primary care, and therefore many patients likely already had an available recent TSH level.

The incidence of abnormal TSH levels in our study was 13%. Two percent of patients had low TSH levels ( $<0.3\mu$ IU/mL) and 11% had high TSH levels ( $>5\mu$ IU/mL). Therefore, a provider would have to screen 50 patients presenting with AF to identify one patient with hyperthyroidism. These incidences are similar to those previously reported, though the prevalence of hyperthyroidism in our study population was markedly less than the 10.8% reported by Bruccelleti et al.<sup>21</sup> Prior to this study, there were few published studies reporting the prevalence of these findings specific to the ED setting or patient population.<sup>19</sup>

We found a high incidence of patients with a history of thyroid disease (18%). This was likely due to our broad

|                             | TSH leve         | el [N (%)]       | LR (95% CI) |                  | % CI)            |
|-----------------------------|------------------|------------------|-------------|------------------|------------------|
| Feature                     | Normal (n=1,263) | Abnormal (n=195) | p-value     | +LR*             | -LR*             |
| Age                         |                  |                  |             |                  |                  |
| <75                         | 797              | 131              | 0.27        | 1.06 (0.96-1.18) | 0.89 (0.73-1.09) |
| ≥ 75                        | 466              | 64               | 0.27        | 1.06 (0.96-1.18) | 0.89 (0.73-1.09) |
| Sex                         |                  |                  |             |                  |                  |
| Female                      | 572 (45)         | 106 (54)         | 0.18        | 1.20 (1.04-1.38) | 0.83 (0.71-0.97) |
| Male                        | 691 (55)         | 89 (46)          | 0.18        | 1.20 (1.04-1.38) | 0.83 (0.71-0.97) |
| Congestive heart<br>failure | 324 (26)         | 47 (24)          | 0.64        | 0.94 (0.72-1.23) | 1.02 (0.94-1.11) |
| Diabetes mellitus           | 249 (20)         | 31 (16)          | 0.21        | 0.81 (0.57-1.13) | 1.04 (0.99-1.11) |
| Cerebrovascular<br>disease  | 123 (10)         | 13 (7)           | 0.17        | 0.68 (0.39-1.19) | 1.03 (1.00-1.07) |
| Hypertension                | 846 (67)         | 107 (55)         | <0.001      | 0.82 (0.72-0.94) | 1.37 (1.17-1.60) |
| Thyroid disease             | 221 (18)         | 77 (39)          | <0.001      | 2.25 (1.83-2.79) | 0.73 (0.65-0.82) |
| CHADS2 score                |                  |                  |             |                  |                  |
| 0                           | 231 (18)         | 56 (29)          | 0.002       |                  |                  |
| 1                           | 386 (31)         | 57 (29)          | 0.002       |                  |                  |
| 2                           | 344 (27)         | 23 (12)          | 0.002       |                  |                  |
| 3                           | 189 (15)         | 23 (12)          | 0.002       |                  |                  |
| 4                           | 80 (6)           | 7 (4)            | 0.002       |                  |                  |
| 5                           | 28 (2)           | 3 (2)            | 0.002       |                  |                  |
| 6                           | 5 (<1)           | 2 (3)            | 0.002       |                  |                  |

Table 3. The predictive value of features for an abnormal TSH level (<0.3 or >5µIU/mL), N=1,458.

\*Positive and negative likelihood ratios for predicting an abnormal TSH level (<0.3 or >5µIU/mL).

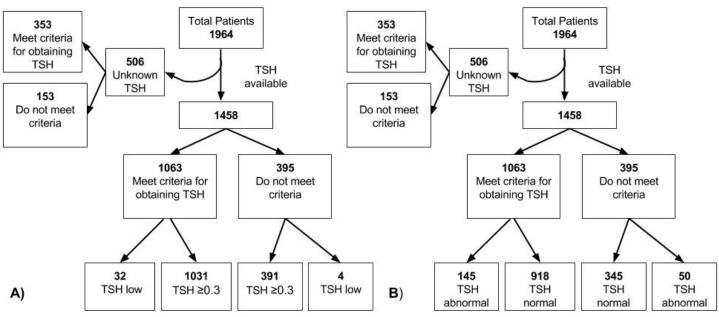
<sup>†</sup>Mean age for  $\ge 0.3\mu$ IU was 68.9; median 70, IQR 60-79. Mean age for  $< 0.3\mu$ IU was 67.4; median 68; IQR 59-78. p-value 0.13. *TSH*, thyroid-stimulating hormone; +*LR*, positive likelihood ratio; *-LR*, negative likelihood ratio; *CHADS2*, Congestive heart failure, Hypertension, Age  $\ge$ 75, Diabetes mellitus, Prior Stroke or Transient ischemic attack or Thrombeombolism

definition of thyroid disease, as we included any past diagnosis available in the EMR of thyroid abnormality including subclinical hyperthyroidism or hypothyroidism. However, our measured incidences of TSH abnormalities were consistent with that previously reported. Therefore, our study population is likely representative of the general population.

When externally validating the previously derived rule proposed by Bruccelleti et al in 2010, we found a mildly lower sensitivity and specificity for hyperthyroidism (89.9%; 27.5%) when compared that originally reported (93%; 31%). Given the low incidence of hyperthyroidism, the negative predictive value remained high (99%). Though the existence of any causal relationship between hypothyroidism and AF remains questionable, detecting underlying hypothyroidism could have implications for downstream care. Therefore, we also analyzed the ability of the rule to detect any TSH abnormality. Under these constraints, the rule was predictably less sensitive (74.4%), with a lower negative predictive value (87.3%) than for predicting hyperthyroidism alone.

Notably, we did not limit our study population to new onset atrial fibrillation, as was done by Bruccelleti et al. Based on provider final diagnosis, approximately 13% of our sample was new onset atrial fibrillation. As supported by our data, TSH levels are ordered in patients with a primary ED diagnosis of AF regardless of whether the impetus for the visit is chronic AF with a rapid ventricular rate, paroxysmal symptomatic AF, or newly discovered AF. Therefore, for the rule to have maximal economic impact, it would have to be sufficiently sensitive in all comers with a primary diagnosis of AF. Perhaps, patients with new onset AF are more likely to have a secondary cause, thus increasing the positive predictive value of the decision rule for that specific subset of patients. However, the sensitivity of the rule, which is the overriding concern of a screening tool, should not be altered.

In order to refine the clinical decision rule, we extracted additional data from the EMR, including vital signs, CHADS2 features (a history of heart failure, age, diabetes mellitus, hypertension and stroke or TIA). We then looked for a correlation between any of these features and TSH abnormalities. Though we originally hypothesized that younger patients, perhaps with a particular pattern of vital sign abnormalities, would be more likely to have underlying thyroid dysfunction as a contributing factor to AF, we did



**Figure.** Flow diagram illustrating validation of a clinical decision rule including a history of thyroid disease, cerebrovascular disease, or hypertension for identifying (A) low TSH (<3µIU) or (B) any TSH abnormality (<0.3 or >5µIU/mL). *TSH*, thyroid-stimulating hormone

| Table 4. Performance characteristics of a clinical decision rule for predicting low TSH (<3µIU) or any TSH abnormality (<0.3 or >5µIU/mL) |
|---|
| in 1,984 patients presenting to the emergency department with atrial fibrillation.  |

| Low TSH       |                |                |               | Low or elevated TSH |            |  |
|---------------|----------------|----------------|---------------|---------------------|------------|--|
| Decision rule | TSH <0.3µIU/mL | TSH ≥0.3µIU/mL | Decision rule | TSH abnormal        | TSH normal |  |
| Yes           | 32             | 1031           | Yes           | 145                 | 918        |  |
| No            | 4              | 391            | No            | 50                  | 345        |  |

\*Sensitivity 88.9% (95% CI [73.0-96.4]), specificity 27.5% (95% CI [25.2-29.9]), PPV 3.0% (95% CI [2.1-4.3]), and NPV 99.0% (95% CI [97.2-99.7]). +LR 1.23 (95% CI [1.09-1.38]). -LR 0.40 (95% CI [0.16-1.02]).

<sup>†</sup>Sensitivity 74.4% (95% CI [67.5-80.2]), specificity 27.3% (95% CI [24.9-29.9]), PPV 13.6% (95% CI [11.7-15.9]), and NPV 87.3% (95% CI [83.6-90.4]). +LR 1.02 (95% CI [0.94-1.12]). -LR 0.94 (95% CI [0.74-1.20]).

*TSH*, thyroid-stimulating hormone; +*LR*, positive likelihood ratio; *-LR*, negative likelihood ratio; *PPV*, positive predictive value; *NPV*, negative predictive value

not identify any further features suggestive of possible refinements for previously derived rule.

# LIMITATIONS

There are several limitations to this validation study. Foremost among these is the retrospective nature of our investigation, which made it impossible to ensure universal TSH sampling. For this reason, we have no way of knowing what factors led providers to order or forgo ordering TSH levels. Further, the retrospective nature of the study necessitated use of the cumulative EMR past medical history, which may have been incomplete. However, given the highly integrated nature of our healthcare system, it is also likely that we had more information than would typically be available by interview alone. We did not isolate our analysis to new-onset or recent onset AF. Instead, we chose to include all patients presenting with AF in order to maximize clinical applicability. This is a single center study, which is potentially problematic as the incidence of thyroid disease varies geographically. Lastly, we were unable to capture the clinical significance of the identified TSH abnormalities, since we do not know whether these led to alterations in management.

Previous studies investigating the value of TSH screening in AF have used various cutoffs to help delineate the difference between technical and clinically important TSH abnormalities. Typically, the threshold for defining clinically significant hyperthyroidism has ranged from  $0.1 \mu IU/mL$  to as high as  $0.3 \mu IU/mL$  in later studies following the publication of evidence of a relationship between subclinical hyperthyroidism in AF.

For hypothyroidism, a threshold of as high as  $20\mu$ IU/mL has been used.<sup>29</sup> When these more specific, less sensitive cutoffs were used on our data, the clinical performance metrics of the rule were largely unchanged. The resulting sensitivity, specificity, positive predictive value, and negative predictive value for TSH <0.1 or >20µIU/mL was calculated to be 88.9% (95% CI [69.7-97.1]), 27.4% (25.1-29.8), 2.3% (1.5-3.4), and 99.2% (97.6-

99.8), respectively. The lack of universally accepted cutoffs for defining clinically significant TSH abnormalities complicates the interpretation of the literature in this field and the management of TSH abnormalities in clinical practice.

The utility of obtaining routine TSH levels and moreover applying the Bruccelleti rule is dependent on the degree of importance clinicians place on identifying abnormalities in thyroid function. Presumably, the primary objective in identifying abnormal thyroid function is to diagnose underlying hyperthyroidism. Hyperthyroidism has a specific management implication in AF. About two-thirds of patients will spontaneously convert to sinus rhythm upon thyroid normalization, and current guidelines suggest that a euthyroid state should be reached prior to cardioversion.<sup>7,32,33</sup> There are no specific guidelines addressing management of AF in the setting of hypothyroidism.

# CONCLUSION

While TSH abnormalities in emergency department patients with a primary diagnosis of AF are common (13%), low TSH is rare (2%). Only hyperthyroidism has a direct management implication in the acute management of AF. We externally validated a clinical decision rule which included criteria of history of thyroid disease, hypertension, or cerebrovascular disease for its ability to predict TSH abnormalities in patients presenting to the emergency department with atrial fibrillation. We found a slightly lower sensitivity and specificity for hyperthyroidism (89.9%; 27.5%) compared to that originally reported by Bruccelleti et al. (93%; 31%).<sup>21</sup> We recommend that emergency medicine providers not routinely order TSH levels for all patients presenting with a primary diagnosis of AF. Instead, these investigations can be limited to patients with new onset AF or those with a history of thyroid disease with no known TSH level within three months.

Address for Correspondence: M. Fernanda Bellolio, MD, MS, Department of Emergency Medicine, Mayo Clinic. Email: Bellolio. fernanda@mayo.edu.

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# Lack of Gender Disparities in Emergency Department Triage of Acute Stroke Patients

Tracy E. Madsen, MD, ScM\* Esther K. Choo, MD, MPH\* Todd A. Seigel, MD<sup>†</sup> Danielle Palms<sup>‡</sup> Brian Silver, MD<sup>§</sup> \*Alpert Medical School of Brown University/Rhode Island Hospital, Department of Emergency Medicine, Providence, Rhode Island
<sup>†</sup>Kaiser Permanente East Bay, Department of Criticial Care Medicine, Department of Emergency Medicine, Oakland, California
<sup>‡</sup>Emory University, Department of Epidemiology, Rollins School of Public Health Atlanta, Georgia
<sup>§</sup>Alpert Medical School of Brown University/Rhode Island Hospital, Department of Neurology, Providence, Rhode Island

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**Introduction:** Previous literature has shown gender disparities in the care of acute ischemic stroke. Compared to men, women wait longer for brain imaging and are less likely to receive intravenous (IV) tissue plasminogen activator (tPA). Emergency department (ED) triage is an important step in the rapid assessment of stroke patients and is a possible contributor to disparities. It is unknown whether gender differences exist in ED triage of acute stroke patients. Our primary objective was to determine whether gender disparities exist in the triage of acute stroke patients as defined by Emergency Severity Index (ESI) levels and use of ED critical care beds.

**Methods:** This was a retrospective, observational study of both ischemic and hemorrhagic stroke patients age ≥18 years presenting to a large, urban, academic ED within six hours of symptom onset between January 2010, and December 2012. Primary outcomes were triage to a non-critical ED bed and Emergency Severity Index (ESI) level. Primary outcome data were extracted from electronic medical records by a blinded data manager; secondary outcome data and covariates were abstracted by trained research assistants. We performed bivariate and multivariate analyses. Logistic regression was performed using age, race, insurance status, mode of and time to arrival, National Institutes of Health Stroke Scale, and presence of atypical symptoms as covariates.

**Results:** There were 537 patients included in this study. Women were older (75.6 vs. 69.5, p<0.001), and more women had a history of atrial fibrillation (39.8% vs. 25.3%, p<0.001). Compared to 9.5% of men, 10.3% of women were triaged to a non-critical care ED bed (p=0.77); 92.1% of women were triaged as ESI 1 or 2 vs. 93.6% of men (p=0.53). After adjustment, gender was not associated with triage location or ESI level, though atypical symptoms were associated with higher odds of being triaged to a non-critical care bed (aOR 1.98, 95%CI [1.03 – 3.81]) and 3.04 times higher odds of being triaged as ESI 3 vs. ESI 1 or 2 (95% CI [1.36 – 6.82]).

**Conclusion:** In a large, urban, academic ED at a primary stroke center, there were no gender differences in triage to critical care beds or ESI levels among acute stroke patients arriving within six hours of symptom onset. These findings suggest that ED triage protocols for stroke patients may be effective in minimizing gender disparities in care. [West J Emerg Med. 2015;16(1):203–209.]

# INTRODUCTION

Gender disparities have been observed in the use of intravenous (IV) tissue plasminogen activator (tPA) for acute ischemic stroke, one of the few known treatments to improve long-term outcomes in this condition.<sup>1-5</sup> In addition, women are less likely to meet quality markers for stroke: they are less likely to have non-contrast computed tomography (CT) within 25 minutes and to receive IV tPA within one hour.<sup>3,6</sup>

Factors leading to these disparities have never been identified, though provider bias may be a contributor. Specifically, emergency department (ED) triage, a critical decision point, provides an opportunity for unintentional provider bias because of its inherent subjectivity.<sup>7,8</sup> In addition, ED triage affects time to provider evaluation in stroke patients<sup>9</sup> and influences time to provider, ED length of stay, and mortality in other patient populations.<sup>10,11</sup> Furthermore, ED triage level and location could serve as targets for interventions to improve ED care and decrease potential disparities.

During ED triage of a potential stroke patient, triage nurses assign both an acuity level and an ED bed. Though there is no uniformly adopted ED triage tool in the United States, the most commonly used system is the Emergency Severity Index (ESI), a 5-level scale used to triage ED patients from least acute (ESI 5) to most acute (ESI level 1).<sup>7,8,12,13</sup> The ESI tool has been externally validated multiple times, but may be less accurate in certain demographics of patients, including the elderly.<sup>7,13,14</sup> Bed assignment is the second decision of the triage process, as patients perceived as needing critical interventions may be transferred immediately to a resuscitation area. Placement in an ED critical care bed could be considered a surrogate measure of aggressiveness of care and affects time to provider in the study hospital's ED.

ESI level is a predictor of wait times for patients and thus may contribute to delays in time to provider assessment of stroke patients, though ESI level has not yet been studied as a possible contributor to ED delays in women with stroke.<sup>9,10</sup> The guidelines for use of the ESI tool suggest that patients with acute neurologic deficits be triaged as an ESI 1 or 2. Patients who require immediate intervention or resuscitation meet criteria for level 1, while those with a "high risk situation" or abnormal vital signs should be assigned an ESI level of 2. If patients do not meet the criteria to be an ESI 1 or 2, the number of anticipated resources is used to assign patients into ESI categories 3, 4, or 5.<sup>7,8,13</sup> Of note, lack of recognition of "high risk situations" has been shown to be a common reason for ESI 2 patients being misclassified as ESI 3.<sup>14</sup>

Previous studies have not investigated ED triage level or triage location by gender in stroke patients, despite the potential to use these factors as a method to reduce disparities in stroke care. Using ESI level and assignment to ED critical care beds, the objective of our study was to investigate ED triage of stroke patients by gender as a potential contributor to disparities in care, as those triaged as less acute may be subsequently treated less aggressively. Our study hypotheses were that women would be triaged to lower acuity ESI levels and to non-critical care beds more often than men. Secondary objectives included performance of non-contrast CT within 25 minutes of arrival, IV tPA given within 60 minutes of arrival, survival to hospital discharge, and discharge destination in women compared to men.

# **METHODS**

# **Study Design/ Patient Population**

This study was a retrospective cohort study of ischemic and hemorrhagic stroke patients at least 18 years old admitted to a large, urban, academic ED between January 2010, and December 2012. We included in the study patients with a discharge diagnosis of acute ischemic stroke or intracerebral hemorrhage if they arrived at the ED within six hours of symptom onset. This time window was chosen in order to select patients who were potentially eligible for intervention at our institution. We excluded patients if they met the following criteria: 1) if they were transferred from an outside hospital or 2) if the discharge diagnosis was subarachnoid hemorrhage. The study was approved by the hospital's institutional review board.

Given the lack of prior literature on specific triage outcomes in stroke patients, this was designed as a hypothesis-generating study. We chose the study period to incorporate a time period during which stroke triage protocols were introduced into the study hospital's ED. Specifically, code stroke activations were introduced during early 2010; these activations consist of blast pages to ED physicians and on-call neurologists upon the arrival of a potentially tPA eligible stroke patient. An additional type of activation, "neurology team," was introduced in early 2012. The "neurology team" activation by triage nurses alerts ED physicians that a potential stroke patient has been placed into a room.

# **Primary and Secondary Outcomes**

The primary outcomes were the following: 1) ESI score, assigned by the ED triage nurse, and 2) ED triage assignment to either a critical care or urgent area bed. The study hospital's ED consists of three sections designated as "urgent" pods and a 12-bed section designated as the "critical care" pod. Triage personnel assign patients that warrant immediate evaluation to critical care beds rather than urgent area beds; for example, stroke patients arriving within the tPA time window as determined by the triage nurse are assigned to critical care beds. The two primary triage outcomes were not combined because of the concern that predictors of ESI may not be the same as predictors of triage to a critical care bed.

Secondary outcome variables were the following: 1) performance of non-contrast CT within 25 minutes of arrival, 2) IV tPA given within 60 minutes, 3) survival to hospital discharge, and 4) discharge destination.

# **Data Collection**

We collected data in two ways. First, data on primary outcomes (ESI level, assigned bed) as well as demographic

variables (gender, age, race, and ethnicity) were extracted from ED electronic medical records by a data manager blinded to the study hypothesis. Approximately 15% of these data were validated by research assistants (RAs) to ensure accuracy.

Second, data pertaining to secondary outcomes and study covariates were abstracted from patients' ED and inpatient electronic medical records by three trained RAs using standardized data abstraction forms. These data included initial vital signs, National Institutes of Health Stroke Scale (NIHSS), mode of arrival, medical comorbidities, initial presenting complaint as documented by the triage nurse, time to CT, survival to discharge, and discharge destination. Presenting complaints were categorized as atypical as defined in previous studies and included non-neurologic symptoms (chest pain, shortness of breath, nausea, vomiting), change in level of consciousness, and "generalized" weakness when not associated with other typical symptoms.<sup>15-17</sup> Symptoms including unilateral weakness, sensory changes, visual changes, headache, dizziness/vertigo, and ataxia/gait difficulty were considered typical. Multiple RAs reviewed approximately 10% of charts, and inter-rater reliability for secondary outcomes and covariates was calculated using Cohen's kappa; kappa values ranged from 0.80 to 1.00. Missing NIHSS scores were estimated retrospectively by two study investigators (TM and BS) using the documented physical exam on admission, a previously validated method.18,19 The weighted kappa value for missing NIHSS scores was 0.87.

# **Data Analysis**

We used means, medians, and proportions to describe the sample as appropriate. For bivariate analyses, Pearson's chisquare tests, Student's t-tests, or Wilcoxon rank-sum tests were performed as appropriate. Primary outcomes were the two triage measures: 1) ESI level and 2) triage location (critical care vs. urgent area bed); gender was the independent variable. ESI level was recoded into a binary variable (ESI 1 or 2 vs. ESI 3) after analyzing the distribution of the variable: only 4.84% (n=26) were triaged as ESI 1 so those patients were combined with ESI 2 patients. No patients were assigned ESI 4 or 5.

We performed multivariate regression with each of our two primary outcomes (ESI and triage location). With regard to missing outcome data, 76 patients had missing ESI scores and were excluded from the ESI regression model while only one patient had a missing triage location. Potential covariates were chosen a priori based on prior studies of ED triage, time to CT, and time to provider evaluation in stroke patients.<sup>6,8,9,15,20</sup> Because literature on ED triage of stroke patients was limited, studies of time to CT and time to provider evaluation were also used to guide covariate choice; this method was felt to be plausible because ED triage is an important contributor to both time to CT and provider evaluation.

For each model, the potential covariates were gender, age, race, ethnicity, insurance status, initial systolic blood pressure, mode of arrival, presence of atypical symptoms, time to hospital arrival, and NIHSS. We initially included all potential covariates; covariates with significant multicollinearity (ethnicity and systolic blood pressure) were then removed. Time to arrival in minutes, initially a continuous variable (range: 3 - 360, IQR: 43 - 160, mean: 115, median: 80), was transformed into a binary variable because of its non-normal distribution. We also transformed NIHSS because of a non-normal distribution (range: 0 -38, IQR: 3 - 17, mean: 10, median: 7). The final model for both triage location and ESI included gender, age, race, insurance status, presence of atypical symptoms, NIHSS (transformed using square root), arrival within three hours, and mode of arrival. We tested model fit using Hosmer-Lemeshow goodness-of-fit testing.

The gender-stratified models for triage location had adequate model fit. Gender-stratified results for ESI, however, were not reported due to potential model instability; this instability may be a result of missing data or unmeasured predictors of ESI.

Models were checked for potential bias introduced by the relatively rare outcomes of ESI 3 and triage to non-critical care beds using the Firth method of logistic regression.<sup>21</sup> By using an alternate estimating method to maximum likelihood estimation, the Firth approach reduces potential bias resulting from using small samples or rare events.<sup>21,22</sup> This method did not significantly change model coefficients or p-values. For logistic regression models, adjusted odds ratios (aOR) with 95% confidence intervals were reported. Stata version 12.1 was used for all analyses.

# RESULTS

We included 537 patients in our analysis; 264 (49.2%) were women, 91 (17.0%) were non-white, and 42 (7.8%) were Hispanic (Table 1). Women were about six years older than men on average (75.6 vs. 69.5, p<0.001) and were more likely to have a history of atrial fibrillation (39.8% vs. 25.3%, p=0.002). Otherwise, baseline characteristics including NIHSS scores were similar between men and women. A slightly greater proportion of women had atypical symptoms; however, this was not statistically significant (47.2% vs. 42.8%, p=0.31).

# **Triage Location**

The majority of our sample was triaged to ED critical care beds (90.1%, n=483). Using bivariate analysis, there was no gender difference in the proportion of patients triaged to non-critical care beds (10.3%, women vs. 9.5%, men, p=0.77). In our multivariate model, after adjusting for age, race, insurance status, mode of arrival, atypical symptoms, NIHSS, and arrival within three hours, gender remained unassociated with triage to a

Table 1. Selected characteristics of participants, by gender.

| Characteristic           | Women (n= 264)   | Men (n=273)      | p-value |  |
|--------------------------|------------------|------------------|---------|--|
| Age (mean)               | 75.6 (73.9–77.4) | 69.5 (67.7–71.4) | p<0.001 |  |
| Non-white race           | 16.3% (43)       | 17.7% (48)       | p=0.66  |  |
| Hispanic ethnicity       | 8.3% (22)        | 7.3% (20)        | p=0.66  |  |
| Uninsured                | 12.6% (33)       | 16.1% (44)       | p=0.25  |  |
| NIHSS (median, IQR)      | 8.0 (3–18)       | 7.0 (3–15)       | p=0.23  |  |
| Arrival within 3 hours   | 76.5% (202)      | 81.3% (222)      | p=0.17  |  |
| Discharge diagnosis      |                  |                  |         |  |
| Ischemic stroke          | 88.3% (233)      | 83.9% (220)      | -0.14   |  |
| Intracerebral hemorrhage | 11.7% (31)       | 16.1% (44)       | p=0.14  |  |
| Mode of arrival          |                  |                  |         |  |
| EMS                      | 92.1% (233)      | 88.5 (239)       | n-0 17  |  |
| Walk-in                  | 7.9% (20)        | 11.5% (31)       | p=0.17  |  |
| Hypertension             | 80.3% (212)      | 83.9% (229)      | p=0.28  |  |
| Diabetes mellitus        | 28.0% (74)       | 28.9% (79)       | p=0.82  |  |
| Atrial fibrillation      | 39.8% (97)       | 25.3% (64)       | p<0.001 |  |
| CT within 25 minutes     | 45.8% (107)      | 46.9% (105)      | p=0.81  |  |
| Discharge destination    |                  |                  |         |  |
| Home                     | 33.5 (88)        | 47.0 (126)       |         |  |
| Other                    | 55.1 (145)       | 41.4 (111)       | p=0.004 |  |
| Died prior to discharge  | 11.4 (30)        | 11.6 (31)        |         |  |

NIHSS, National Institute of Health Stroke Scale; EMS, emergency medical services; CT, computed tomography

non-critical care bed (aOR 0.94, 95% CI [0.50 to 1.78]) (Figure 1). Those with higher NIHSS were less likely to be triaged to non-critical care beds (aOR 0.33, 95% CI [0.23 - 0.48]), and those with any atypical symptoms were more likely to go to non-critical care beds (aOR 1.98, (95% CI [1.03 - 3.81]). Age was not significantly associated with triage location (aOR 0.99, 95% CI [0.97 - 1.02]).

After stratifying the sample by gender, non-white race was associated with triage to non-critical care beds in women but not men (aOR 4.80, 95% CI [1.63 -14.11], vs. aOR 0.44, 95% CI [0.10 – 1.89]). In addition, arrival within three hours was associated with triage to a non-critical care bed in women but not men (women, aOR 0.22, 95% CI [0.08 – 0.61] vs. men, aOR 0.56, 95% CI [0.19 – 1.68]), while presence of atypical symptoms was more strongly associated with triage location in men compared to women (men, aOR 2.82, 95% CI [1.08 – 7.43] vs. women, aOR 1.38, 95% CI [0.53 – 3.6]). For gender-stratified models, model fit was adequate for both women ( $\chi^{2}$ = 10.98, p=0.20) and men ( $\chi^{2}$ = 10.35, p=0.24). Lower NIHSS scores were associated with triage to non-critical care beds in both genders.

# ESI Level

Most of the sample was assigned as ESI 2 upon triage (74.9%, n=402). Using bivariate analyses, there were no significant gender differences in the distribution of ESI levels between women and men (ESI 1: 4.6% women vs. 5.1% men,

ESI 2: 74.6% women vs. 75.1% men, ESI 3: 6.8% women vs. 5.5% men, missing ESI: 14.0% women vs. 14.3% men, p=0.92). No patients were assigned triage levels of ESI 4 or 5. After adjusting for age, race, insurance status, presence of atypical symptoms, NIHSS, mode of arrival, and arrival within three hours, gender was not significantly associated with triage as ESI 3 versus ESI 1 or 2 (aOR 0.61, 95% CI [0.29 – 1.31]) (Figure 2). Of note, those categorized as having atypical symptoms were 3.04 times more likely to be triaged as ESI 3 versus ESI 1 or 2 (95% CI [1.36 – 6.82]). Age was not significantly associated with ESI level (aOR 0.98, 95% CI [0.95 – 1.00], p = 0.08). Model fit was adequate but had a borderline p-value ( $\chi^2$ = 15.7, p=0.05).

# **Secondary Outcomes**

Women and men were equally like to have non-contrast CTs within 25 minutes (45.8% vs. 46.9%, p=0.81). Similarly, of those with ischemic stroke who arrived within three hours of symptom onset, 39.2% of women compared to 40.8% of men received IV tPA within 60 minutes (p=0.84). At discharge, mortality between women and men was similar (11.4% vs. 11.4%, p=0.99). Women were, however, less likely to be discharged home from the hospital (33.5% vs. 47.0%, p=0.004).

# DISCUSSION

In our novel, exploratory study of potential triage disparities in acute stroke patients, there were no gender

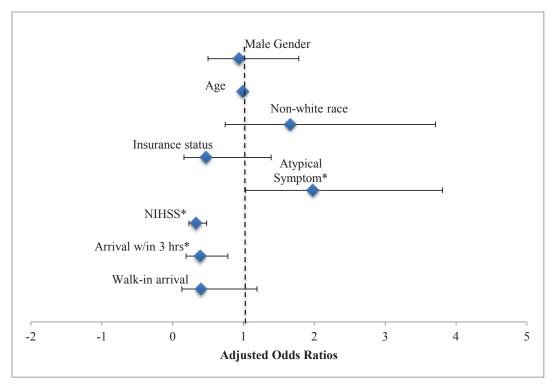
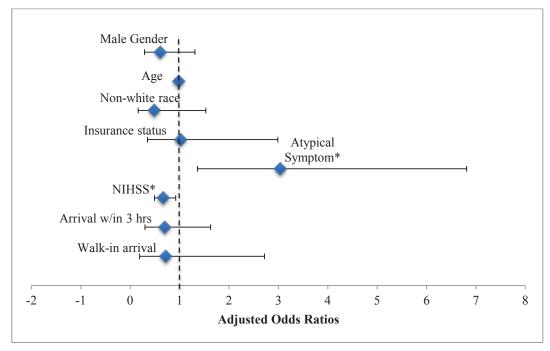


Figure 1. Adjusted odds of triage to non-critical care beds are displayed.

NIHSS, National Institute of Health Stroke Scale

Predictors are male gender, age, non-white race, insurance status, presence of atypical symptom (\*p=0.04), NIHSS score as a continuous variable transformed using square root (\*p<0.001), walk-in arrival compared to ambulance arrival, and arrival within 3 hours of symptom onset (\*p=0.008). Model fit was tested using Hosmer–Lemeshow goodness-of-fit test, ( $\chi^2$ =7.87, p=0.45).



# Figure 2. Adjusted odds of triage as ESI 3 compared to ESI 1 or 2 are displayed.

*NIHSS*, National Institute of Health Stroke Scale

Predictors are male gender, age, non-white race, insurance status, presence of atypical symptom (\*p=0.007), NIHSS score as a continuous variable transformed using square root (\*p=0.013), walk-in arrival compared to ambulance arrival, and arrival within 3 hours of symptom onset. Model fit was tested using Hosmer–Lemeshow goodness-of-fit test, ( $\chi$ 2= 15.7, p=0.05).

disparities in triage acuity levels or ED triage location. Though previous studies have reported gender differences in time to initial CT and time to provider evaluation,<sup>6,20</sup> our study is the first to investigate ED triage as a potential contributor to these gender disparities. We found that overall, triage to noncritical care ED beds and assignment to less acute ESI levels were relatively rare events. Significant predictors of triage to non-critical care beds or less acute ESI levels included lower NIHSS scores and atypical symptoms. We found no significant association between age and triage status, and there did not appear to be gender-specific effects of age in our stratified models, despite the fact that women in our sample were, on average, older. Finally, we found a potential interaction between gender and race, with non-white women experiencing triage disparities in comparison to white women.

Our results are notable for several reasons. First, triage of acute stroke patients by gender has not previously been characterized. In our study, triage assignments did not differ significantly by gender among ED stroke patients. Given the lack of understanding around the contributors to gender disparities in treatment of acute stroke, this is an important finding. If this negative finding is confirmed in other hospital settings and in larger patient samples, attention should be shifted to other potential contributors to gender disparities in stroke treatment such as differences in tPA eligibility or subconscious physician bias.

Second, in contrast to prior studies, we did not find any gender differences with regard to time to CT or administration of IV tPA within 60 minutes.<sup>6</sup> For example, in an analysis of a national stroke registry by Kelly et al.,<sup>6</sup> women were less likely to have an initial CT performed within 25 minutes. Other literature has shown a gender disparity in time to physician evaluation.<sup>20</sup> The differences between our findings and previous studies may be a result of different study populations; our sample was from a single academic stroke center, while the Kelly et al.<sup>6</sup> study was a large, multi-center study including many community hospital EDs. We also must consider the possibility that the lack of gender differences in CT within 25 minutes and/or IV tPA within 60 minutes are the result of prompt and appropriate ED triage for both women and men, though this would require further investigation in a future study.

There are several potential explanations for the lack of gender disparities in our study. First, gender disparities in the care of acute stroke may be decreasing over time as the importance of time to treatment becomes more evident, and our data may reflect this.<sup>23</sup> In addition, our findings suggest that the use of stroke triage protocols including nursing notifications of the arrival of acute stroke patients and a blast page system to indicate the arrival of tPAeligible patients may decrease gender disparities in stroke care, though this will require investigation in future studies comparing EDs with stroke protocols to those without stroke protocols. Similarly, designated stroke centers could

be compared to centers without such certifications with respect to potential gender differences in triage and/or stroke treatments. Previous literature regarding the effect of stroke center designation on treatment disparities is lacking. Though some preliminary data suggest that gender disparities in the use of IV tPA use are not eliminated at primary stroke centers (PSC),<sup>24</sup> these particular data are limited by a very small absolute difference in tPA use between women and men (6.7% vs. 7.5%) as well as lack of adjustment for tPA eligibility, NIHSS, and changes in tPA use over time. Other previous literature suggests that gender and racial disparities in tPA use are decreasing over time, though these studies lack the ability to control for stroke center designation.23,25 Finally, EMS protocols could have affected our results. The vast majority of our sample arrived via EMS; if pre-hospital providers had already identified these patients as potential strokes, this could have significantly affected ED triage.

Our findings of the other predictors of less acute triage assignments suggest additional directions for future research in ED stroke care. For example, the gender-specific effects of atypical symptoms and arrival times on ED triage we describe need to be confirmed and explored in future studies. In addition, our concerning finding that non-white women are more often triaged to non-critical care beds will need to be re-examined in further investigations of the interaction of race and gender in treatment disparities. Previous literature has demonstrated that non-white women experience more treatment disparities than other demographic subgroups,<sup>26</sup> but the differences in triage will require confirmation. We also found that patients with lower NIHSS scores or atypical symptoms of stroke were more likely to go to non-critical ED beds or have less acute ESI assignments. Because less acute ESI assignments and placement in non-critical care beds likely lead to delayed diagnostic assessments, these findings should be confirmed in future studies. Additionally, triage protocols should be modified to ensure that patients with minor strokes and atypical symptoms are triaged so that they receive immediate assessment

# LIMITATIONS

Our study has several limitations. It is a retrospective, single-center study; because of this, generalizability may be limited. Our outcomes of triage to non-critical care beds and less acute ESI levels were also relatively rare. Because of the low outcome rates, results taken from our gender-stratified models must be interpreted with caution. We anticipated these limitations, however, and intended our study to be exploratory in nature. In addition, our ED is part of a large, academic, high stroke volume hospital certified as a PSC: Code stroke protocols may reduce triage disparities and make the results less generalizable to EDs without these protocols in place. Data on other factors that may influence the triage of stroke patients including the gender of the triage nurse were not collected. Finally, data regarding time between arrival and triage assessment as well as time to physician assessment were not available; we used time to initial CT as a surrogate measure of physician assessment.

# CONCLUSION

In a sample of acute stroke patients seen in a large, urban, academic ED within a primary stroke center, we observed no gender differences in ED triage level or ED triage location. In academic designated stroke centers, triage is not likely to be a major source of delays for stroke care in women. In future research, stroke triage in EDs with organized stroke care and/ or designated as stroke centers should be compared to other EDs to evaluate the effectiveness of organized stroke care in reducing gender disparities.

Address for Correspondence: Tracy E. Madsen, MD, Alpert Medical School of Brown University/Rhode Island Hospital, 55 Claverick Street, 2nd floor, Providence, RI. Email: Tracy\_ Madsen@brown.edu.

*Conflicts of Interest*: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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# In Response to: "Using Lean-Based Systems Engineering to Increase Capacity in the Emergency Department

#### DOI: 10.5811/westjem.2014.11.24355

White BA, Chang Y, Grabowski B G. Using Lean-Based Systems Engineering to Increase Capacity in the Emergency Department. *West J Emerg Med.* 2014;15(7):770-776.

#### To the editor:

We read with interest the article by White et al., "Using Lean-Based Systems Engineering to Increase Capacity in the Emergency Department," in which the authors conclude that Lean could improve emergency department (ED) throughput and capacity.

A number of other studies have also suggested that Lean is beneficial in addressing the problem of ED wait times. As in White et al., the vast majority of these studies have been conducted in single centers and/or as before-after evaluations.<sup>1-6</sup> Moreover, publication bias likely also plays a role in the consistency of these findings since positive evaluations are more likely to be published.<sup>7</sup> Although White et al. compared changes in ED length of stay with a concurrent population in their own center, it is not possible to generalize beyond this particular ED.

We recently published a large multi-center controlled study of Lean in Ontario, Canada, (http://www.annemergmed.com/ article/S0196-0644%2814%2900516-2/fulltext) and found that while there were reductions in ED length of stay among the 36 hospitals that participated in the Lean program, similar reductions were observed among the 63 matched control hospitals over the same period. In our study, context was also important. Because Lean was part of a broader ED wait time strategy, including wait time targets, public reporting, and targeted financial incentives, it was clear that a wide array of incentives had an effect on wait times in all EDs across the region.

Our conclusion is that single-center and before-after studies do not provide rigorous or generalizable evidence that Lean is effective in reducing ED length of stay. Decisions to implement should be based on solid evidence, since Lean initiatives typically require the engagement of external consultants and/or the dedication of significant internal resources for their development and implementation.

Marian J. Vermeulen, MHSc Michael J Schull, MD, MSc

# Institute for Clinical Evaluative Sciences, Canada

*Address for Correspondence*: AMarian J. Vermeulen, MHSc, G1 06, 2075 Bayview Avenue, Toronto, Ontario, Canada, M4N 3M5. Email: marian.vermeulen@ices.on.ca.

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# In Reply:

We very much appreciate the interest of our colleagues in this important topic, one that has yet to fully mature in the pantheon of emergency medicine literature. We also recognize and noted in our manuscript that the single-site nature of our work is a limitation. However, we disagree that this limitation makes scientific exploration and publication of this nature a fruitless endeavor as implied.

Publication bias aside, the central tenet of Lean methodologies is the elimination of waste in all forms, and thus it is an inherently generalizable tool to improve any process in which waste exists. However, by definition the specific details relating to the underlying process and the implementation of Lean are of key importance, and its potential utility needs to be weighed in each individual setting.

In addition, partly for this reason, we suggest that local processes not affected by the intervention may serve as reliable controls. We specifically used another area of our ED as a control group to avoid the recognized limitations of an analysis that was purely based on data that were obtained "before and after" the changes were implemented. Finally, Lean methodologies do not always have to be resource intensive as our colleagues suggest. For example, no external consultants or significant internal resources were utilized for this work, and in addition we were in fact able to decrease resource utilization as is common with successful Lean interventions. We respectfully suggest that it is often in this simplicity and focus that Lean interventions, and robust scientific studies describing them, have the potential to be so powerful.

Benjamin A. White, MD Yuchiao Chang, PhD Beth G. Grabowski, MBA David F.M. Brown, MD Massachusetts General Hospital, Department of Emergency Medicine, Boston, Massachusetts

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Address for Correspondence: Benjamin A. White, MD, Department of Emergency Medicine, Massachusetts General Hospital, Zero Emerson Place-3b, Boston, MA 02114. Email: bwhite3@partners.org.

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GREAT NETWORK CONGRESS

FOCUS ON INNOVATIONS AND TRANSLATIONAL RESEARCH IN EMERGENCY MEDICINE

# SEPTEMBER 4-9, 2015 ROME, ITALY

The VIII<sup>th</sup> MEMC is jointly organized by the American Academy of Emergency Medicine (AAEM), the Global Research on Acute Conditions Team (GREAT) Network & the Mediterranean Academy of Emergency Medicine (MAEM). In conjuction with the GREAT 2015 Annual Conference — organized by the GREAT Network.



Call for Papers 2015 Academic Emergency Medicine Consensus Conference

## Diagnostic Imaging in the Emergency Department: A Research Agenda to Optimize Utilization

The 2015 Academic Emergency Medicine (AEM) consensus conference, **Diagnostic imaging in the emergency department: A research agenda to optimize utilization** will be held on May 12, 2015, immediately preceding the SAEM Annual Meeting in San Diego, CA. Original papers on this topic, if accepted, will be published together with the conference proceedings in the December 2015 issue of *AEM*.

Diagnostic imaging is integral and beneficial to the practice of emergency medicine. Over the last several decades, emergency department (ED) diagnostic imaging has increased without a commensurate rise in identified pathology or improvement in patient-centered outcomes. Unnecessary imaging results in increased resource use and significant exposure risks. ED diagnostic imaging has become the focus of many stakeholders, including patients and various regulatory agencies. This multidisciplinary consensus conference represents the first coordinated effort to further our evidence-based knowledge of ED diagnostic imaging, initiate a collaborative dialogue between stakeholders, and align this research agenda with that of federal funding agencies.

#### Consensus Goal:

The overall mission of the 2015 *AEM* consensus conference will be to create a prioritized research agenda in emergency diagnostic imaging for the next decade and beyond. The consensus conference will feature expert keynote speakers, panel discussions including nationally recognized experts, and facilitated breakout group sessions to develop consensus on research agendas by topic. Optimizing diagnostic imaging in the ED is a timely topic that is relevant to all who practice emergency medicine. Furthermore, the conference content spans many other specialties (e.g. radiology, pediatrics, cardiology, surgery, internal medicine), all of which will be invited to participate in the conference to optimize the agenda and for future collaboration in order to improve emergency diagnostic imaging use.

#### Consensus Objectives:

1. Understand the current state of evidence regarding diagnostic imaging utilization in the ED and identify opportunities, limitations, and gaps in knowledge of previous study designs and methodology

2. Develop a consensus statement that emphasizes the priorities and opportunities for research in emergency diagnostic imaging that will result in practice changes, and the most effective methodologic approaches to emergency diagnostic imaging research

3. Explore and improve knowledge of specific funding mechanisms available to perform research in emergency diagnostic imaging

Accepted manuscripts will present original, high-quality research in emergency diagnostic imaging in areas such as clinical decision rules, shared decision making, knowledge translation, comparative effectiveness research, and multidisciplinary collaboration. They may include work in clinical/translational, health systems, policy, or basic sciences research. Papers will be considered for publication in the December 2015 issue of *AEM* if received by April 17, 2015. All submissions will undergo peer review and publication cannot be guaranteed.

For queries, please contact Jennifer R. Marin, MD, MSc (jennifer.marin@chp.edu) or Angela M. Mills, MD (millsa@uphs.upenn.edu) the 2015 consensus conference co-chairs. Information and updates will be regularly posted in *AEM*, the SAEM Newsletter, and the journal and SAEM websites.

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# **2015 Conferences**

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JUNE 12, 2015 ANNUAL ASSEMBLY // Los Angeles/Universal City

