EDITOR’S PICK

Civil Monetary Penalties Resulting From Violations of the Emergency Medical Treatment and Labor Act (EMTALA) Involving Psychiatric Emergencies, 2002 to 2018
Sophie Terp, Brandon Wang, Elizabeth Burner et al. 469

SYSTEMATIC REVIEWS (WITH OR WITHOUT META-ANALYSES)

The Yield of Computed Tomography of the Head Among Patients Presenting With Syncope: A Systematic Review
J. Alexander Viau, Hina Chaudry, Ailish Hannigan et al. 479

ORIGINAL CONTRIBUTIONS

Racism Is Not a Factor in Door-to-electrocardiogram Times of Patients With Symptoms of Acute Coronary Syndrome: A Prospective, Observational Study
Martha H. Mackay, Pamela A. Ratner, Gerry Veenstra et al. 491

Patient Uncertainty as a Predictor of 30-day Return Emergency Department Visits: An Observational Study
Kristin L. Rising, Marianna D. LaNoie, Angela M. Gerolamo et al. 501

Multicenter Analysis of Transport Destinations for Pediatric Prehospital Patients
E. Brooke Lerner, Jonathan R. Studnek, Nicole Fumo et al. 510

Feasibility of Emergency Department–initiated, Mobile Health Blood Pressure Intervention: An Exploratory, Randomized Clinical Trial
William J. Meurer, Mackenzie Dome, Devin Brown et al. 517

Contents continued inside.
Do High-sensitivity Troponin and Natriuretic Peptide Predict Death or Serious Cardiac Outcomes After Syncope?
Carol L. Clark, Thomas A. Gibson, Robert E. Weiss et al. 528

Emergency Department Procedural Sedation Practice Limitations: A Statewide California American College of Emergency Physicians Survey
Ellen T. Reibling, Steven M. Green, Tammy Phan et al. 539

RESEARCH LETTERS
Emergency Medical Services Administration of Systemic Corticosteroids for Pediatric Asthma: A Statewide Study of Emergency Department Outcomes
Jennifer N. Fishe, Shiva Gautam, Phyllis Hendry et al. 549

Inter-rater Reliability of the HEART Score
Colin A. Gershon, Annick N. Yagapen, Amber Lin et al. 552

HOT OFF THE PRESS
Hot Off the Press: Comparison of Emergency Medicine Malpractice Cases Involving Residents to Nonresident Cases
Justin Morgenstern, Corey Heitz, Chris Bond et al. 556

THE BIROS SECTION ON RESEARCH ETHICS
Study Enrollment When “Preconsent” Is Utilized for a Randomized Clinical Trial of Two Treatments for Acute Agitation in the Emergency Department
Jon B Cole, Lauren R. Klein, Samuel Z. Mullinax et al. 559

THE BRASS TACKS: CONCISE REVIEWS OF PUBLISHED EVIDENCE
Single Maintenance and Reliever Therapy (SMART) Regimen for Management of Persistent Asthma
Arjun Mohan, Gregory D. Kearney, Andrew C. Miller 567

Prevalence of Pulmonary Embolism in Patients Presenting With Syncope
Brit Long, Alex Koyfman, Michael Gottlieb 571

COMMENTARY—INVITED
Psychiatric EMTALA Enforcement Has Gone Off the Rails: Comments on “Civil Monetary Penalties Resulting From Violations of EMTALA Involving Psychiatric Emergencies, 2002 to 2018”
Robert A. Bitterman 574

Moving Beyond Diagnostic Accuracy With Systematic Reviews and Meta-analyses
Shahriar Zehtabchi, Daniel Michael Fatovich 580

Whose Job Is it Anyway?
Phillip D. Levy 584

REFLECTIONS
The Calm After The Storm
Elizabeth L. Chang 587
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2. Methodology used to develop manuscript and how writing group was identified committee objective, task force work, etc.
3. Unique treatment, analysis, or critique of the current state of knowledge on the topic
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5. References

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CME Information: Civil Monetary Penalties Resulting From Violations of the Emergency Medical Treatment and Labor Act (EMTALA) Involving Psychiatric Emergencies, 2002 to 2018

CME Editor: Corey Heitz, MD

Authors: Sophie Terp, MD, MPH, Brandon Wang, Elizabeth Burner, MD, MPH, MSCI, Denton Connor, Seth A. Seabury, PhD, and Michael Menchine, MD, MPH

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Educational Objectives
After reading the article, participants should be able to discuss financial penalties regarding violation of the Emergency Treatment and Labor Act for psychiatric emergencies.

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Civil Monetary Penalties Resulting From Violations of the Emergency Medical Treatment and Labor Act (EMTALA) Involving Psychiatric Emergencies, 2002 to 2018

Sophie Terp, MD, MPH\(^1,2\), Brandon Wang\(^3\), Elizabeth Burner, MD, MPH, MSCI\(^1\), Denton Connor\(^4\), Seth A. Seabury, PhD\(^1,2\), and Michael Menchine, MD, MPH\(^1,2\)

ABSTRACT

Objective: The objective was to describe characteristics of civil monetary penalties levied by the Office of the Inspector General (OIG) related to violations of the Emergency Medical Treatment and Labor Act (EMTALA) involving psychiatric emergencies.

Methods: Descriptions of EMTALA-related civil monetary penalty settlements from 2002 to 2018 were obtained from the OIG. Cases related to psychiatric emergencies were identified by inclusion of key words in settlement descriptions. Characteristics of settlements involving EMTALA violations related to psychiatric emergencies including date, amount, and nature of the allegation were described and compared with settlements not involving psychiatric emergencies.

Results: Of 230 civil monetary penalty settlements related to EMTALA during the study period, 44 (19%) were related to psychiatric emergencies. The average settlement for psychiatric-related cases was $85,488, compared with $32,004 for non–psychiatric-related cases (\(p < 0.001\)). Five (83%) of the six largest settlements during the study period were related to cases involving psychiatric emergencies. The most commonly cited deficiencies for settlements involving psychiatric patients were failure to provide appropriate medical screening examination (84%) or stabilizing treatment (68%) or arrange appropriate transfer (30%). Failure to provide stabilizing treatment was more common among cases involving psychiatric emergencies (68% vs. 51%, \(p = 0.041\)). Among psychiatric-related settlements, 18 (41%) occurred in CMS Region IV (Southeast) and nine (20%) in Region VII (Central).

Conclusions: Nearly one in five civil monetary penalty settlements related to EMTALA violations involved psychiatric emergencies. Settlements related to psychiatric emergencies were more costly and more often associated with failure to stabilize than for nonpsychiatric emergencies. Administrators should evaluate and strengthen policies and procedures related to psychiatric screening examinations, stabilizing care of psychiatric patients boarding in EDs, and transfer policies. Recent large, notable settlements related to EMTALA violations suggest that there is considerable room to improve access to and quality of care for patients with psychiatric emergencies.
The Emergency Medical Treatment and Labor Act (EMTALA) is a landmark federal law governing emergency care. Passed in 1986 in response to highly publicized incidents of inadequate, delayed, or denied treatment of uninsured patients by emergency departments (EDs), EMTALA requires that patients presenting to a dedicated ED have a timely medical screening evaluation, stabilization of emergency medical conditions, and transfer to another facility for higher level of care if required stabilizing services are unavailable at the original facility. Receiving hospitals have a duty to accept transfer of patients requiring specialty care if the facility has an on-call specialist and capacity to treat the patient. EMTALA applies to all hospitals with Medicare provider agreements, and enforcement is conducted by the Centers for Medicare & Medicaid Services (CMS). In the past decade, CMS has clarified that 1) EMTALA applies to psychiatric emergencies, 2) many psychiatric evaluation areas qualify as dedicated EDs, and 3) psychiatric hospitals participating in Medicare are obligated to accept an appropriate transfer of patients requiring specialized psychiatric care for stabilization whether or not the facility has an area qualifying as a dedicated ED.

Centers for Medicare & Medicaid Services regional offices authorize EMTALA investigations, issue citations for violations, and determine whether a facility has an adequate corrective action plan to ensure future compliance so that a citation can be resolved. The ultimate consequence of failure to resolve an EMTALA citation is termination of the Medicare provider agreement, which almost universally results in hospital closure. This is not a theoretical risk; more than a quarter of U.S. hospitals were cited for EMTALA violations over the past decade, although most resolved citations without Medicare provider agreement termination. Between 2005 and 2014, there were 355 citations for EMTALA violations related to psychiatric emergencies. Among 12 hospitals with Medicare provider agreements terminated for failure to comply with EMTALA, four cases (25%) involved EMTALA violations related to psychiatric emergencies. The Office of the Inspector General (OIG) of the Department of Health and Human Services receives information about EMTALA violations from CMS and may seek civil monetary penalties against hospitals or individual physicians that have violated EMTALA. Civil monetary penalty cases are resolved through settlement agreements, and hospitals and individual physicians can be held liable for penalties not covered by malpractice insurance. The historic maximum civil monetary penalty of $50,000 for an EMTALA violation increased to $103,139 in 2016. Approximately 7.9% of EMTALA violations result in a civil monetary penalty.

Psychiatric complaints comprise a significant and increasing proportion of ED visits. In 2011 there were 2.5 million ED visits for complaints related to mental health disorders, representing a 20% increase from 5 years prior. A concurrent decline in availability of inpatient psychiatric beds has led to an increase in prolonged boarding of psychiatric patients on involuntary commitments in EDs awaiting transfer to available inpatient psychiatric beds. As the number of patients seeking care for emergent psychiatric conditions increases, evaluating EMTALA enforcement for cases related to psychiatric conditions will be crucial to informing and identifying areas in which emergency psychiatric care can be improved. Characteristics of civil monetary penalties related to EMTALA violations involving psychiatric emergencies have not previously been described. The goal of this investigation is to describe characteristics of civil monetary penalty settlements levied by the OIG related to EMTALA violations involving psychiatric emergencies between 2002 and 2018.

METHODS

Study Design and Data Sources

This is a retrospective observational study evaluating EMTALA-related civil monetary penalty settlements from 2002 to 2018. Case descriptions of all civil monetary penalty settlements between 2002 and December 11, 2018, were obtained from the OIG. Civil monetary penalty settlements related to EMTALA violations specifically were identified by inclusion of the terms “EMTALA” or “patient dumping” in the title or text of the settlement description for inclusion, consistent with prior work in this field. OIG civil monetary penalty settlements unrelated to EMTALA (e.g., kickback allegations, fraudulent Medicare claims) were excluded from analysis. Entries included the settlement amount, location, and brief description of the involved patient’s medical and/or psychiatric condition and clinical course. Locations were categorized by CMS region, the level at which EMTALA is enforced. A
Identification of Cases Involving Psychiatric Emergencies

Settlements related to psychiatric conditions were identified by searching the text of the case settlement descriptions with the key words and stems psych-, depress-, suicid-, overdos-, mentally ill, emotional distress, overdose, and Baker Act. The Baker Act is a Florida Mental Health Act allowing for involuntary evaluation of an individual who possibly has a mental illness and is in danger of harm to self or others or of self-neglect. Settlements imposed upon dedicated psychiatric facilities were also included. Each case description was reviewed and coded by two authors (EB, ST), and kappa statistics were calculated to evaluate for inter-reliability for identification of psychiatric cases.

Recording of Case Features

Date, location, and settlement amounts for each case were recorded. Settlement descriptions were reviewed to determine if there was stated 1) failure to provide appropriate medical screening examination, 2) failure to provide stabilizing treatment, 3) failure to arrange appropriate transfer, 4) failure to accept appropriate transfer for specialty services, or 5) failure of an on-call doctor to respond. These categories correspond to EMTALA deficiency tags involving clinical care. A list of deficiency tags and categories is included in Data Supplement S1, Table S1.

Data Analysis

Characteristics of cases resulting in OIG settlements were compared between those involving psychiatric emergencies and nonpsychiatric emergencies with t-tests, chi-square tests, and Fisher’s exact tests as indicated. All statistical analyses were performed using Stata/MP13 (StataCorp, 2013). The institutional review board at the University of Southern California has reviewed and approved the study.

Case Study

The largest OIG settlement related to an EMTALA violation involving a psychiatric emergency was identified and details of the EMTALA investigation are described to provide an illustrative case study. Reports from the EMTALA investigation including the facility’s proposed corrective actions were obtained from CMS via Freedom of Information Act Request. Individual patient-level identifiers were redacted in documents provided. News reports related to this EMTALA violation were examined to provide better understanding of the context in which the hospital operates. Investigation findings and facility corrective actions from this case are summarized to provide a richer example of the EMTALA enforcement process and hospital response to citation for an EMTALA violation.

RESULTS

Characteristics of Civil Monetary Penalties Related to Psychiatric Emergencies

Between 2002 and 2018, a total of 230 civil monetary penalty settlements related to EMTALA were identified. Of these, 222 (97%) were levied against facilities and eight (3%) against individual physicians. We identified 44 (19%) of all civil monetary penalty settlements related to EMTALA involved psychiatric emergencies. The number of annual settlements related to psychiatric and nonpsychiatric emergencies is graphically depicted in Figure 1. We observe a general decline in the number of annual OIG settlements for nonpsychiatric emergencies during the study period, while the number of settlements related to psychiatric emergencies appears relatively stable. Characteristics of OIG settlements related to EMTALA violations involving psychiatric emergencies are included in Table 1.

Average settlements related to psychiatric emergencies have increased in recent years, particularly in comparison to settlements not related to psychiatric conditions (Figure 2). The average psychiatric-related settlement ($85,488) was significantly higher than the mean amount for nonpsychiatric cases ($32,004; p = 0.003). Of six settlements for more than $100,000, five (83%) were related to cases involving psychiatric emergencies. The three largest civil
monetary penalties settlements related to EMTALA violations during the study period all involved psychiatric emergencies and occurred in recent years. The three largest cases were settlements for $360,000 in 2016, $1,295,000 in 2017, and for $200,000 in 2018. Each of these cases involved psychiatric emergencies and occurred in recent years.

Figure 1. Civil monetary penalty settlements related to EMTALA violations, 2002 to 2018. EMTALA = Emergency Medical Treatment and Labor Act.

Table 1
Characteristics of EMTALA-related Civil Monetary Penalty Settlements, 2002 to 2018

<table>
<thead>
<tr>
<th></th>
<th>Psychiatric</th>
<th>Nonpsychiatric</th>
<th>p-value</th>
<th>Statistical test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number</td>
<td>44</td>
<td>186</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Settlement (mean dollars)</td>
<td>$85,488</td>
<td>$32,004</td>
<td>0.003</td>
<td>t-test</td>
</tr>
<tr>
<td>Settlement against physician</td>
<td>0 (0)</td>
<td>8 (4)</td>
<td>0.036</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Minor involved</td>
<td>6 (14)</td>
<td>24 (13)</td>
<td>0.897</td>
<td>Pearson chi-square</td>
</tr>
<tr>
<td>Failure to provide MSE</td>
<td>37 (84)</td>
<td>137 (74)</td>
<td>0.147</td>
<td>Pearson chi-square</td>
</tr>
<tr>
<td>Failure to stabilize</td>
<td>30 (68)</td>
<td>95 (51)</td>
<td>0.041</td>
<td>Pearson chi-square</td>
</tr>
<tr>
<td>Failure to arrange transfer</td>
<td>13 (30)</td>
<td>40 (22)</td>
<td>0.363</td>
<td>Pearson chi-square</td>
</tr>
<tr>
<td>Failure to accept transfer</td>
<td>6 (14)</td>
<td>28 (15)</td>
<td>0.812</td>
<td>Pearson chi-square</td>
</tr>
<tr>
<td>On-call failed to respond</td>
<td>0 (0)</td>
<td>14 (8)</td>
<td>0.078</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>CMS region</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 (2)</td>
<td>5 (3)</td>
<td>0.456</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>2</td>
<td>0 (0)</td>
<td>8 (4)</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>3 (7)</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>15 (34)</td>
<td>80 (43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>4 (9)</td>
<td>20 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>8 (18)</td>
<td>20 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>2 (5)</td>
<td>25 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>0 (0)</td>
<td>6 (3)</td>
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<td>9</td>
<td>5 (11)</td>
<td>27 (15)</td>
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<tr>
<td>10</td>
<td>0 (0)</td>
<td>0 (0)</td>
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</table>

Data are reported as n (%).
CMS = Centers for Medicare & Medicaid Services; EMTALA = Emergency Medical Treatment and Labor Act; MSE = medical screening examination.
several patients and serious violations of the EMTALA law. By comparison, the largest civil monetary penalty settlement related to an EMTALA violation for a nonpsychiatric case was for $170,000. After excluding the top three settlements from analysis, the mean for the remainder of settlements related to psychiatric emergencies ($46,500) was still significantly higher than settlements for nonpsychiatric cases ($p = 0.008).

Failure to provide stabilizing treatment was cited in 30 of 44 (68%) cases involving psychiatric emergencies, compared with only 95 of 186 (51%) nonpsychiatric cases ($p = 0.041). When comparing settlements for psychiatric emergencies to those without psychiatric emergencies, no difference in proportions was found for CMS region, involvement of a minor, failure to provide medical screening examination, failure to arrange appropriate transfer, or failure of an on-call provider to respond. Of the 44 civil monetary penalties related to psychiatric emergencies, 18 (41%) occurred in CMS Region IV, including nine (50%) in Florida and six (33%) in North Carolina. Region VII accounted for nine (20%) settlements related to psychiatric emergencies with seven (78%) imposed upon Missouri hospitals.

**CASE STUDY**

To provide a richer example of the EMTALA enforcement process and hospital response to citation for an EMTALA violation, investigation findings and facility corrective actions from the EMTALA investigation related to the largest OIG civil monetary penalty settlement involving a psychiatric emergency are included in Table 2.

**DISCUSSION**

Emergency Medical Treatment and Labor Act is a landmark federal law governing emergency care, and in the past decade CMS has clarified that the law applies not only to medical emergencies and EDs, but also to psychiatric emergencies, many psychiatric intake areas, and inpatient psychiatric facilities as well. Since 2002, the OIG has reached 44 civil monetary penalty settlements related to EMTALA violations involving psychiatric emergencies. Generally, we found that civil monetary penalties for EMTALA violations related to psychiatric emergencies are associated with higher settlement amounts and are more likely to involve failure to provide stabilization.
compared to cases not involving psychiatric emergencies. Civil monetary penalty settlements involving psychiatric emergencies tend to concentrate in a few CMS regions. Study findings and the case study described highlight a number of key points important for hospital administrators, emergency physicians, and psychiatrists providing emergency and inpatient services to be aware of.

First, civil monetary penalties increased in amount in recent years, especially for cases involving psychiatric emergencies. For the majority of the study period, the maximum OIG civil monetary penalty for an EMTALA violation was set at $50,000, which approximately doubled in 2016.9 Multiple settlements for hundreds of thousands of dollars, with one for over a million dollars, indicate that the OIG has been stacking penalties for multiple violations identified during a single investigation. This is particularly true for cases involving psychiatric emergencies. Of the six settlements during the study period for more than $100,000, five involved psychiatric emergencies. EMTALA-related civil monetary penalties for psychiatric emergencies had a mean settlement amount of $85,488, more than double the average amount for settlements for nonpsychiatric emergencies.

Many evaluation areas at psychiatric facilities where patients are evaluated for emergent conditions on an unscheduled basis qualify as dedicated EDs and are required to comply with EMTALA if located within a hospital with a Medicare provider agreement.6 Among civil monetary penalty settlements involving psychiatric emergencies, failure to provide appropriate medical screening examination was the most commonly cited cause for EMTALA citation preceding the settlement, identified in 84% of cases. While it is commonly known that EMTALA applies for patients presenting to medical EDs, it is important for hospital administrators and psychiatrists to understand that many psychiatric facilities have evaluation or intake areas that qualify as dedicated EDs and are required to comply with screening, stabilization, and transfer requirements of EMTALA.

Reports from the case study provided indicate an expectation by CMS that on-call psychiatrists (when available) be involved in the care of psychiatric patients involuntarily committed in the ED. While it is certainly within the scope of practice for an emergency physician to screen and discharge patients experiencing psychiatric issues but not meeting criteria for involuntary hold, the case study highlights an expectation for
further timely screening by a mental health provider for patients determined to meet hold criteria. Specifically, on-call psychiatrists should participate in psychiatric screening examinations of patients with psychiatric emergencies involuntarily committed in the ED.

Failure to provide appropriate stabilizing treatment was the second most commonly cited cause for EMTALA citation leading to OIG settlement among patients with psychiatric emergencies, identified in more than two-thirds of these cases compared with only half of other cases. The case study described highlights the need for hospitals with the capability of providing stabilizing treatments (on call psychiatrists) to consider implementing and/or reinforcing compliance with policies requiring daily evaluation of psychiatric patients boarding in the ED on involuntary commitments for stabilizing treatment until admission or appropriate transfer can be arranged or until the patient is deemed stable for discharge. This will be particularly important as recent studies have shown that odds of boarding for psychiatric patients were nearly five times higher than for nonpsychiatric patients and that boarding times for psychiatric patients are significantly longer than for nonpsychiatric patients.

Centers for Medicare & Medicaid Services recently issued EMTALA citations for inappropriate transfer for patients with psychiatric emergencies transferred to other facilities when inpatient beds within the sending hospital’s behavioral health unit were available and considered by CMS to represent the same level of care. Nearly one-third of OIG settlements in our study were cited for failure to arrange appropriate transfer. In the case study described, although the hospital’s inpatient psychiatric facility had by policy and practice previously only accepted voluntary admissions, CMS determined that because the hospital had available inpatient beds on a behavioral health unit, it had capacity to provide the psychiatry treatment and milieu needed to help stabilize patients with psychiatric emergencies, although the boarding patients were involuntarily committed. This case highlights the need for hospitals with inpatient behavioral health units to reevaluate exclusions to their admission policies, particularly when they have available beds and affiliated EDs are boarding patients with psychiatric emergency conditions.

In our study, approximately one in seven cases involving psychiatric emergencies referred to failure to accept appropriate transfer for specialized services.

While inpatient psychiatric facilities without areas that qualify as a dedicated ED may not be obligated to adhere to other aspects of EMTALA (e.g., providing medical screening examinations), they are required to accept appropriate transfer of patients from another ED with emergent psychiatric conditions requiring specialized treatment if they have Medicare provider agreements. CMS has also clarified that a recipient hospital’s EMTALA obligation does not extend to patients admitted of another hospital.

Office of the Inspector General settlements related to psychiatric conditions concentrate in two of the 10 CMS regions (IV and VII), with half occurring in three states (Florida, North Carolina, and Missouri). This is consistent with prior published work showing both high rates of EMTALA citations and subsequent OIG settlements in the same regions. Further work is needed to determine if the high rates of civil monetary penalty settlements in these regions reflect inadequate psychiatric emergency care or enhanced enforcement.

In recent years, EMTALA violations for patients with psychiatric emergencies have resulted in several record-breaking civil monetary penalties. Although we did not identify any civil monetary penalties against individual physicians related to psychiatric emergencies in this or prior studies, it is important that both physicians and hospital administrators be diligent to ensure appropriate patient care and that facilities are compliant with the EMTALA statute particularly for patients with psychiatric emergencies.

LIMITATIONS

Our study has some limitations worth noting. First, reported findings rely on administrative data provided by the OIG and may be limited by variability in reporting and enforcement of EMTALA cases related to psychiatric emergencies across regions or over time. However, the information analyzed represents the best available data source to study OIG penalties, and we have no reason to suspect systematic error in recording or reporting of data by the OIG. Second, available data only included EMTALA cases resulting in civil monetary penalty settlement agreements. It is possible that cases for which penalties were recommended, but for which a settlement agreement was not reached, were not reported. Third, as published settlement descriptions varied considerably in length and detail across the study period, it is possible that some
descriptions were sufficiently vague such that settlements related to psychiatric emergencies may not have been identified using our methods. However, in the vast majority of OIG settlement descriptions, the nature of the condition was indicated, and the proportion of settlements related to psychiatric emergencies (19%) was similar to the proportion of overall EMTALA citations involving psychiatric emergencies identified in our prior work (17%).

CONCLUSIONS

Nearly one in five civil monetary penalties related to Emergency Medical Treatment and Labor Act violations involved psychiatric emergencies. Settlements related to psychiatric conditions concentrate in two of the 10 Centers for Medicare & Medicaid Services regions, with half of all settlements occurring in three states (Florida, North Carolina, and Missouri). Average financial penalties related to psychiatric emergencies were over twice as high as penalties for nonpsychiatric complaints. Recent large penalties related to violations of the Emergency Medical Treatment and Labor Act law underscore the importance of improving access to and quality of care for patients with psychiatric emergencies.

The authors thank Adam Gomez for his contribution with data management and review and Raquel Martinez for her assistance with creation of tables and figures.

References


Supporting Information
The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13710/full

Data Supplement S1. Supplemental material.
The Yield of Computed Tomography of the Head Among Patients Presenting With Syncope: A Systematic Review

J. Alexander Viau, MA, BMBS, Hina Chaudry, MBBS, EMBA, Ailish Hannigan, PhD, Mish Boutet, MIS, Muhammad Mukarram, MBBS, MPH, and Venkatesh Thiruganasambandamoorthy, MBBS, MSc

ABSTRACT

Background: Overuse of head computed tomography (CT) for syncope has been reported. However, there is no literature synthesis on this overuse. We undertook a systematic review to determine the use and yield of head CT and risk factors for serious intracranial conditions among syncope patients.

Methods: We searched Embase, Medline, and Cochrane databases from inception until June 2017. Studies including adult syncope patients with part or all of patients undergoing CT head were included. We excluded case reports, reviews, letters, and pediatric studies. Two independent reviewers screened the articles and collected data on CT head use, diagnostic yield (proportion with acute hemorrhage, tumors or infarct), and risk of bias. We report pooled percentages, I^2, and Cochran’s Q-test.

Results: Seventeen articles with 3,361 syncope patients were included. In eight ED studies (n = 1,669), 54.4% (95% confidence interval [CI] = 34.9%–73.2%) received head CT with a 3.8% (95% CI = 2.6%–5.1%) diagnostic yield and considerable heterogeneity. In six in-hospital studies (n = 1,289), 44.8% (95% CI = 26.4%–64.1%) received head CT with a 1.2% (95% CI = 0.5%–2.2%) yield and no heterogeneity. In two articles, all patients had CT (yield 2.3%) and the third enrolled patients ≥ 65 years old (yield 7.7%). Abnormal neurologic findings, age ≥ 65 years, trauma, warfarin use, and seizure/stroke history were identified as risk factors. The quality of all articles referenced was strong.

Conclusion: More than half of patients with syncope underwent CT head with a diagnostic yield of 1.1% to 3.8%. A future large prospective study is needed to develop a robust risk tool.

Syncope is defined as a sudden and brief loss of consciousness (LOC) due to transient global cerebral hypoperfusion, followed by spontaneous and complete recovery.1 It accounts for 1% to 3% of emergency department (ED) visits.1–4 Among ED patients with syncope, 7% to 23% will have serious underlying conditions identified either in the ED or within 30 days of their index visit.5–8 Previous studies have reported 2.3% to 4.4% incidence of serious intracranial conditions (subarachnoid hemorrhage, subdural hematoma, space-occupying lesion, or intraparenchymal infarct or hemorrhage) among underlying conditions identified either in the ED or within 30 days of their index visit.5–8 Previous studies have reported 2.3% to 4.4% incidence of serious intracranial conditions (subarachnoid hemorrhage, subdural hematoma, space-occupying lesion, or intraparenchymal infarct or hemorrhage) among
patients with syncope. However, up to two-thirds of patients with syncope continue to have computed tomography (CT) of the head performed as part of their workup. The Choosing Wisely Campaign in Canada and the United States both recommend against using CT of the head for low-risk ED patients with syncope. Additionally, the Society for Academic Emergency Medicine in the United States, through consensus conferences in 2015 and 2016, aimed to optimize ED diagnostic imaging utilization and reduce unnecessary diagnostic testing to reduce health care costs and unintended consequences.

While clinical decision tools such as the NEXUS-II, Canadian CT Head Rule, and New Orleans Criteria exist for patients with head injury related to the fall during syncope, there is a lack of appropriate synthesis of preexisting literature regarding the usefulness of CT head to identify a serious underlying intracranial conditions potentially related to syncope. With the Choosing Wisely Campaign in mind, the objective of this systematic review is to determine the frequency with which head CT is being performed for patients with syncope, with predominant focus on its yield in identifying serious intracranial conditions. Additionally, we aimed to report any risk factors associated with the serious intracranial conditions identified in studies reviewed.

**METHODS**

**Systematic Review Protocol**

For this review, we adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Guidelines (Data Supplement S1, Appendix S1, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13568/full).

**Search Strategy**

A database search was conducted under the guidance of a research librarians at the University of Ottawa using the following major databases from their inception until June 2016: Medline (via OVID), Embase (via OVID), and Cochrane Database of Systematic Reviews. An updated search was conducted in all three databases between June 2016 and June 2017. Our search strategies used a combination of MeSH headings and keywords and are detailed in Data Supplement S1, Appendixes S2 and S3. Article selection was restricted to English and French articles. A citation search was also conducted on Google Scholar from each of the final articles included in the systematic review to ensure the inclusion of missed articles during the initial database searches. Authors were contacted to obtain unpublished data or further articles that may have been missed by the initial database search.

**Study Selection**

Our search included prospective and retrospective observational cohort studies that met the following inclusion criteria: studies involving adult patients with syncope (or other commonly accepted synonym thereof) as their presenting complaint, of which part, or all received head CT and for whom the head CT results were reported. We excluded studies involving only children, case reports, letters to the editor, narrative reviews, articles in languages other than English or French, and abstracts which had neither sufficient data nor a complete article available. Articles that included patients with obvious non–syncope-related LOC (e.g., head trauma resulting in LOC, seizure, alcohol or drug intoxication, LOC > 5 minutes, or patients with altered mental status from baseline) were also excluded. However, based on literature reports and our prior experience conducting prospective studies sometimes it is difficult to differentiate seizure from syncope. Hence, all studies that enrolled patients with a transient LOC followed by spontaneous complete recovery were included in our review. Duplicates with titles that matched exactly were eliminated using Mendeley, a reference management software program. In Phase I, after removal of duplicates, inclusion and exclusion criteria were applied by two investigators (JAV and HC), each reviewing all articles at the title and abstract level. In Phase II, both reviewers applied the same criteria to the full-text articles selected at the end of Phase I. For included studies, data for literature synthesis was documented in a standardized data collection form (Data Supplement S1, Appendix S4). Disagreements were resolved by consensus.

**Data Abstraction**

The following data were collected: author information, year of publication, study type, specific characteristics of patients included or excluded in the study, whether the cohort was from an ED or inpatient population, number of patients enrolled, number of head CT scans performed, the nature and number of serious
intracranial conditions identified, the risk factors associated with the serious intracranial conditions, and any additional interesting findings.

### Outcome Measures

The outcomes of interest included “acute intracranial conditions” (subarachnoid hemorrhage, subdural hematoma, new or rapidly progressive space occupying lesion, parenchymal hemorrhage, intraventricular hemorrhage, or parenchymal infarct). We defined “yield” as the proportion of patients with the above outcomes identified among those who had CT head performed.

### Risk of Bias Assessment

The Quality Assessment Tool for Quantitative Studies (QATQS), produced by the Effective Public Health Practice Project (EPHPP), was used to determine the quality of each article included in this systematic review.20 The tool assesses for selection bias, study design, confounding variables, blinding, data collection methods, and withdrawal or dropout rate. Subheadings for “integrity” and “analyses” are also included in the design of the QATAS tool but they do not contribute to the numerical global rating. Studies are rated as “1-Strong,” “2-Moderate,” or “3-Weak” for each of the above items, and a similar final rating of strong, moderate, or weak is given for an overall global rating of the article taking into consideration all the above tool items. The performance of EPHPP quality assessment tool was found to have higher and more reliable inter-rater agreement than the Cochrane Collaboration Risk of Bias Tool.21 Risk of bias assessment was independently assessed by two investigators (JAV and HC) and discrepancies were resolved by consensus.

### Data Analysis

For meta-analysis, we pooled the data from studies that included a similar subgroup of patients (e.g., ED patients or patients who were hospitalized). A proportion meta-analysis was carried for each subgroup to calculate the pooled proportion (expressed as a percentage with 95% confidence interval [CI]) of patients who received head CT and the proportion of these patients with serious intracranial conditions. I² was used as a measure of inconsistency across studies, i.e., the percentage of the variability in effect estimates due to heterogeneity rather than sampling error, with I² values of <25% considered low levels of heterogeneity, >75% high, and levels in between moderate. The Cochrane Q-test was used as the statistical test for heterogeneity, with random-effects models used where there was evidence of significant heterogeneity and fixed-effects models used where there was no evidence of significant heterogeneity. Meta-analysis calculations were performed, and graphical plots were created using StatsDirect software.

### RESULTS

Figure 1 depicts the flow diagram describing the number of articles identified and the Phases I and II of the article selection for inclusion in the systematic review. The initial search of the databases Embase, Medline, and Cochrane, from their inception until June 2016 were conducted by JAV under the guidance of the research librarian (MB). This yielded a total of 3,202 articles. The article search was updated in June 2017, with an additional 576 articles identified between June 2016 and June 2017. Hence, a total of 3,778 articles were identified for this review, and after removal of duplicates, 2,951 articles remained. Two investigators (JAV and HC) independently reviewed the title and abstract of these 2,951 articles and found that 2,799 articles did not meet the inclusion criteria and an additional 108 articles met the exclusion criteria leaving 44 articles for Phase II, full review (κ = 0.833 [95% CI = 0.790–0.875]). The reasons for exclusion during Phase I were as follows: 63 case reports, 15 articles in a language other than English or French, 16 educational reviews, one letter to the editor, one audit, and 12 abstracts that did not provide sufficient information for data synthesis and the full article for the same not found. A total of 44 articles were reviewed in full, of which 27 were excluded for the following reasons: 19 articles in which syncope was not the primary focus, six studies that did not report the head CT results, one in which syncope was actively induced in their cohort, and one that was a cost analysis. At the end of Phase II, 17 articles were included in this systematic review (κ = 0.923 [95% CI = 0.856–0.989]).10,22–36

Table 1 shows the characteristics of the 17 studies included in this review involving 3,361 patients with syncope: 15 studies were retrospective chart reviews,10,22,24–36 two were prospective cohort studies,9,25 13 studies were North American,9,10,22,24,25,27,29–35 and four were conducted outside North America.23,26,28,36 Fourteen of the 17 studies enrolled two specific subgroups of
patients with syncope: eight studies included patients who presented to the ED\(^9,10,22–27\) and six studies included hospitalized patients with syncope.\(^{28–33}\) Hence, a meta-analysis was performed for the two subgroups and the data from three remaining articles were not pooled for meta-analysis. Of the three, two studies (Goyal et al.\(^{34}\) and Kaneko et al.\(^{35}\)) enrolled only syncope patients that had head CT performed in their studies, and the third study by Bodhit et al.\(^{36}\) enrolled only syncope patients aged 65 years or older.

Eight studies enrolling a total of 1,669 ED patients with syncope (Table 2) reported the proportion who had CT head performed and the diagnostic yield among these patients. The pooled proportion receiving a head CT across these studies using a random-effects model was 54.4\% (95\% CI = 34.9\%–73.2\%; Figure 2). There was considerable heterogeneity in the proportion receiving head CT across studies (\(I^2 = 98.5\%\); Cochran’s Q p < 0.0001). Of the 870 ED patients with syncope who received a head CT, the pooled proportion using a fixed-effects model for serious underlying intracranial condition was 3.8\% (95\% CI = 2.6\%–5.1\%; Figure 2). There was moderate heterogeneity in the proportion of patients with serious intracranial conditions across studies (\(I^2 = 34.2\%\), Cochran’s Q p = 0.16).

Six studies with a total of 1,289 patients hospitalized with syncope reported the proportion who received a head CT and those with serious underlying intracranial conditions (Table 3). The pooled proportion receiving head CT across these studies using a random-effects model was 44.8\% (95\% CI = 26.4\%–64.1\%; Figure 3). There was high heterogeneity in the proportion receiving head CT across studies (\(I^2 = 97.6\%\); Cochran’s Q p < 0.0001). Of the 607 patients hospitalized for syncope and who received a head CT, the pooled proportion using a fixed-effects model for serious intracranial condition was 1.2\%
### Table 1
Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Type</th>
<th>Patient Population</th>
<th>Patients Enrolled</th>
<th>Head CT Performed</th>
<th>Acute Outcomes Identified</th>
<th>Risk Factors Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ED Patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aggarwal, 2011</td>
<td>Retrospective</td>
<td>ED syncope patients</td>
<td>408</td>
<td>185</td>
<td>5</td>
<td>Nil</td>
</tr>
<tr>
<td>Al-Nsoor, 2010</td>
<td>Prospective</td>
<td>ED (true) syncope patients</td>
<td>254</td>
<td>221</td>
<td>12</td>
<td>Abnormal neurologic findings</td>
</tr>
<tr>
<td>Ansari, 2013</td>
<td>Retrospective</td>
<td>ED syncope patients</td>
<td>108</td>
<td>88</td>
<td>3</td>
<td>Nil</td>
</tr>
<tr>
<td>Day, 1982</td>
<td>Retrospective</td>
<td>ED syncope patients</td>
<td>198</td>
<td>37</td>
<td>4</td>
<td>History of focal seizures or focal deficit on physical examination</td>
</tr>
<tr>
<td>Giglio, 2005</td>
<td>Retrospective</td>
<td>ED syncope patients</td>
<td>128</td>
<td>44</td>
<td>1</td>
<td>Nil</td>
</tr>
<tr>
<td>Grossman, 2007</td>
<td>Prospective</td>
<td>ED syncope patients ≥ 18 years old</td>
<td>293</td>
<td>113</td>
<td>5</td>
<td>Age &gt; 65 Signs/symptoms of neurologic disease including headache, trauma above the clavicles or taking warfarin</td>
</tr>
<tr>
<td>Vanbrabant, 2011</td>
<td>Retrospective</td>
<td>ED syncope patients</td>
<td>117</td>
<td>41</td>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>Velez, 2009</td>
<td>Retrospective</td>
<td>ED syncope patients</td>
<td>163</td>
<td>141</td>
<td>2</td>
<td>Nil</td>
</tr>
<tr>
<td><strong>Hospitalized Patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ben-Chetrit, 1985</td>
<td>Retrospective</td>
<td>Syncope patients &gt; 20 years old</td>
<td>101</td>
<td>16</td>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>Eagle, 1983</td>
<td>Retrospective</td>
<td>Syncope patients &gt; 16 years old</td>
<td>100</td>
<td>24</td>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>Gebreselassie, 2016</td>
<td>Retrospective</td>
<td>Discharge diagnosis of syncope</td>
<td>151</td>
<td>114</td>
<td>1</td>
<td>Nil</td>
</tr>
<tr>
<td>Johnson, 2014</td>
<td>Retrospective</td>
<td>Admit diagnosis of syncope</td>
<td>167</td>
<td>131</td>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>Kapoor, 1982</td>
<td>Retrospective</td>
<td>Admit/discharge diagnosis of syncope</td>
<td>121</td>
<td>39</td>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>Pires, 2001</td>
<td>Retrospective</td>
<td>Patients ≥ 18 years admitted with syncope</td>
<td>649</td>
<td>283</td>
<td>5</td>
<td>History of seizures and/or stroke</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bodhit, 2011</td>
<td>Retrospective</td>
<td>ED syncope patients ≥ 65 years old</td>
<td>189</td>
<td>130</td>
<td>10</td>
<td>Nil</td>
</tr>
<tr>
<td>Goyal, 2006</td>
<td>Retrospective</td>
<td>ED syncope patients ≥ 18 years old + head CT</td>
<td>117</td>
<td>117</td>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>Kaneko, 2012</td>
<td>Retrospective</td>
<td>Syncope patient + GCS 14/15</td>
<td>97</td>
<td>97</td>
<td>5</td>
<td>Diastolic blood pressure &gt; 80 mm Hg</td>
</tr>
</tbody>
</table>

GCS = Glasgow Coma Scale.

### Table 2
CT Head Among ED Patients With Syncope

<table>
<thead>
<tr>
<th>Study</th>
<th>Total Sample Size</th>
<th>Patients Who Had Head CT Performed</th>
<th>Patients With Serious Intracranial Conditions Identified on CT</th>
<th>Proportion (% Receiving Head CT (95% CI))</th>
<th>Percentage With Serious Intracranial Conditions (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggarwal 2011</td>
<td>408</td>
<td>185</td>
<td>5</td>
<td>45.3 (40.4–50.3)</td>
<td>2.7 (0.9–6.2)</td>
</tr>
<tr>
<td>Al-Nsoor 2010</td>
<td>254</td>
<td>221</td>
<td>12</td>
<td>87.0 (82.2–90.9)</td>
<td>5.4 (2.8–9.3)</td>
</tr>
<tr>
<td>Ansari 2013</td>
<td>108</td>
<td>88</td>
<td>3</td>
<td>81.5 (72.9–88.3)</td>
<td>3.4 (0.7–9.6)</td>
</tr>
<tr>
<td>Day 1982</td>
<td>198</td>
<td>37</td>
<td>4</td>
<td>18.7 (13.5–24.8)</td>
<td>10.8 (3.0–25.4)</td>
</tr>
<tr>
<td>Giglio 2005</td>
<td>128</td>
<td>44</td>
<td>1</td>
<td>34.4 (26.2–43.3)</td>
<td>2.3 (0.06–12.0)</td>
</tr>
<tr>
<td>Grossman 2007</td>
<td>293</td>
<td>113</td>
<td>5</td>
<td>38.6 (33.0–44.4)</td>
<td>4.4 (1.5–10.0)</td>
</tr>
<tr>
<td>Vanbrabant 2011</td>
<td>117</td>
<td>41</td>
<td>0</td>
<td>35.0 (26.5–44.4)</td>
<td>0 (0–8.6)</td>
</tr>
<tr>
<td>Velez 2009</td>
<td>163</td>
<td>141</td>
<td>2</td>
<td>86.5 (80.3–91.3)</td>
<td>1.4 (0.2–5.0)</td>
</tr>
<tr>
<td>Total</td>
<td>1,669</td>
<td>870</td>
<td>32</td>
<td>54.4 (34.9–73.2)</td>
<td>3.8 (2.6–5.1)</td>
</tr>
</tbody>
</table>
Figure 2. Forest plots for the proportion of ED patients with syncope who received a head CT (top) and its diagnostic yield (bottom).

Table 3
CT Head Among Patients Hospitalized for Syncope

<table>
<thead>
<tr>
<th>Study</th>
<th>Total Sample Size</th>
<th>Patients Who Had Head CT Performed</th>
<th>Patients With Serious Intracranial Conditions Identified on CT</th>
<th>Percentage Receiving Head CT (95% CI)</th>
<th>Percentage With Serious Intracranial Conditions (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ben-Chetrit 1985</td>
<td>101</td>
<td>16</td>
<td>0</td>
<td>15.8 (9.3–24.4)</td>
<td>0 (0–20.6)</td>
</tr>
<tr>
<td>Eagle 1983</td>
<td>100</td>
<td>24</td>
<td>0</td>
<td>24.0 (16.0–33.6)</td>
<td>0 (0–14.2)</td>
</tr>
<tr>
<td>Gebreselassie 2016</td>
<td>151</td>
<td>114</td>
<td>1</td>
<td>75.5 (67.8–82.1)</td>
<td>0.9 (0.02–4.8)</td>
</tr>
<tr>
<td>Johnson 2014</td>
<td>167</td>
<td>131</td>
<td>0</td>
<td>78.4 (71.4–84.4)</td>
<td>0 (0–2.8)</td>
</tr>
<tr>
<td>Kapoor 1982</td>
<td>121</td>
<td>39</td>
<td>0</td>
<td>32.2 (24.0–41.3)</td>
<td>0 (0–9.0)</td>
</tr>
<tr>
<td>Pires 2001</td>
<td>649</td>
<td>283</td>
<td>5</td>
<td>43.6 (39.7–47.5)</td>
<td>1.8 (0.6–4.1)</td>
</tr>
<tr>
<td>Total</td>
<td>1,289</td>
<td>607</td>
<td>6</td>
<td>44.8 (26.4–64.1)</td>
<td>1.2 (0.5–2.2)</td>
</tr>
</tbody>
</table>
There was no heterogeneity in the proportion with serious intracranial condition across studies ($I^2 = 0\%$, Cochran’s $Q = 0.63$; Figure 3).

Of the three studies not included in the meta-analysis, two studies, Goyal et al.\textsuperscript{35} and Kaneko et al.\textsuperscript{36} only enrolled patients who had CT head performed. Of the 214 patients in these two studies, five (2.3%) patients

---

**Table 4**

Types of Serious Intracranial Conditions Identified Among Patients With Syncope in the Included Studies

<table>
<thead>
<tr>
<th></th>
<th>Subarachnoid Hemorrhage</th>
<th>Subdural Hematoma</th>
<th>Space Occupying Lesion</th>
<th>Intraparenchymal Hemorrhage</th>
<th>Intraparenchymal Ischemia/Infarct</th>
<th>Unspecified</th>
<th>Group Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED</td>
<td>4</td>
<td>3</td>
<td>9</td>
<td>6</td>
<td>8</td>
<td>2†</td>
<td>32</td>
</tr>
<tr>
<td>Hospitalized</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Others*</td>
<td>4</td>
<td>0</td>
<td>7</td>
<td>8</td>
<td>3</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>Totals</td>
<td>9</td>
<td>3</td>
<td>16</td>
<td>14</td>
<td>16</td>
<td>4</td>
<td>53</td>
</tr>
</tbody>
</table>

*Others includes articles by Goyal et al.\textsuperscript{35} Kaneko et al.\textsuperscript{36} and Bodhit et al.\textsuperscript{34}

†Velez et al.\textsuperscript{27} report two patients with serious intracranial conditions as listed in the above, but the specific abnormality was not reported.
had a serious intracranial condition identified. The study by Bodhit et al.\textsuperscript{34} included only ED patients 65 years or older with syncope. Of the 189 patients in this study, 130 (68.8%) received a head CT and 10 (7.7%) patients had a serious intracranial condition identified.

Of the 3,361 patients from the 17 studies included in this review, a total of 1,821 patients (54.2%) underwent CT head, of whom 53 patients (2.9% [95% CI = 2.2%–3.8%]) had serious intracranial conditions identified. Of the eight articles that enrolled ED patients, seven studies (except Vanbrabant et al.\textsuperscript{26}) found patients with serious underlying conditions; among the five that enrolled hospitalized patients with syncope, one (Pires et al.\textsuperscript{33}) included patients with serious intracranial conditions. The serious underlying conditions among syncope patients identified in this review include subarachnoid hemorrhage, subdural hematoma, space occupying lesions, parenchymal ischemia or infarction, and intraparenchymal hemorrhage (Table 4). Meta-analysis of data from the articles included in this study showed that 54.4% of ED patients with syncope had CT head performed with a yield of 3.8%, and 44.8% of hospitalized patients with syncope had CT head performed with a diagnostic yield of 1.2%.

Five articles identified risk factors (see Table 1) that were associated with serious underlying intracranial serious condition on CT head among patients with syncope. Three studies (Al-Nsoor and Mhearat,\textsuperscript{23} Day et al.,\textsuperscript{25} and Grossman et al.\textsuperscript{9}) observed that these serious intracranial conditions were more likely to be found among patients that presented with neurologic deficit or headache in their history or examination. Of these three studies, Day et al.\textsuperscript{25} was the only one that reported statistical significance ($p < 0.0001$) for neurologic deficits. Grossman et al.\textsuperscript{9} also found that patients taking warfarin and those with concomitant signs of trauma above the clavicles are more likely to have serious underlying intracranial conditions.\textsuperscript{9} Day et al.\textsuperscript{25} observed that focal seizure activity or focal neurologic findings among patients with syncope were associated with space-occupying lesions found on head CT, while Pires et al.\textsuperscript{33} observed that history of stroke was associated with a higher likelihood of serious underlying intracranial conditions among patients with syncope. Kaneko et al.\textsuperscript{36} identified serious intracranial outcomes among patients with a diastolic blood pressure $> 85$ mm Hg. However, this finding was not statistically significant ($p = 0.010$).\textsuperscript{36} The cohort in Gebreselassie et al.\textsuperscript{30} was composed of approximately 85% black patients but there was no increased risk for intracranial event found to be associated with this population. Except for the specific studies indicated above, none of the other studies reported statistical significance for the identified risk factors. The above-listed risk factors were the only ones evaluated in the included studies. Bodhit et al.\textsuperscript{34} in their study found that warfarin was not significantly associated with intracranial hemorrhage in patients 65 years or older with syncope. However, warfarin was identified as a risk factor by Grossman et al.\textsuperscript{9}.

**Risk of Bias Within Studies**

For the six distinct items in the QATQS tool, the quality of all the included studies were rated as strong or moderate (Table 5). There was an initial disagreement on only one item in two studies with the rest of the 100 independent evaluations being identical between the two investigators (JAV and HC). The kappa was 0.96 (95% CI = 83.4–99.7). The disagreement on these two items was resolved by consensus. For the global rating, all included studies were rated strong by the two investigators with 100% agreement.

**DISCUSSION**

In our review, we found that a high proportion of all patients with syncope have a CT head performed with a diagnostic yield of 1.2% for hospitalized patients and 3.8% for ED patients. We believe that the results of our review will aid in choosing wisely and facilitate shared decision making for performing CT head in the management of patients with syncope.

One previous review by Pournazari et al.\textsuperscript{37} reported the diagnostic value of neurologic studies among patients with syncope and reported that 57.3% of patients had CT head performed with a diagnostic yield of 1.2%. However, this review did not clearly report the conditions that constituted a positive diagnostic yield. A previous study by our team observed that a very low proportion (0.4%) have serious neurologic conditions identified during the syncope evaluation.\textsuperscript{38}

The six intracranial outcomes included in the study were selected based on clinical relevance, previous literature, and consensus among the coauthors. With respect to the risk factors associated with serious intracranial conditions among patients with syncope, we found only one common theme: the presence of neurologic deficits. The included studies found it challenging to identify risk factor associations for all the serious
intracranial conditions: subarachnoid hemorrhage, subdural hematoma, or brain tumors due to diversity in their pathophysiology. Five articles identified potential risk factors indicating a need for head CT; however, there is little agreement among them. A higher proportion of patients with a diastolic blood pressure of $>85$ mm Hg and those taking warfarin were observed to have subarachnoid hemorrhage, intraparenchymal hemorrhage, or subdural hematoma but these factors have no known impact on the incidence of brain tumors. Three articles identified some degree of neurologic deficit as being a strong indicator for head CT; however, such would be the case even in the absence of a syncopal event. Two studies in our review reported underlying parenchymal or intraparenchymal infarct, which likely is the cause of neurologic deficits among patients enrolled in these studies. It is also very likely that these patients suffered an acute cerebrovascular accident rather than true syncope, which is caused by transient global hypoperfusion. Day et al. recognized that patients with focal seizure or focal neurologic deficits on presentation were much more likely to have an underlying serious intracranial condition as the cause for their syncope. It is, however, sometimes difficult to distinguish seizure from syncope on initial ED presentation. A thorough yet focused history and examination is invaluable in identifying patients with true syncope and those who will likely benefit from CT of the head based on the above risk factors reported. Additionally, among patients who sustain head trauma after syncope can be assessed using the published risk tools (NEXUS-II, Canadian CT Head Rule, or the New Orleans Rule) to identify those who will benefit from a CT head.

In our review we included only articles that enrolled patients with syncope and assessed the role of CT head. One article by Mitsunaga et al. reported the role of CT head among both syncope and presyncope patients. We excluded this article as we were unable to extract the results for the syncope subgroup. In each of the 17 included studies, a high proportion of enrolled patients had CT head performed with the clear majority being negative. For every 26 scans carried out on ED patients and for every 83 scans among patients hospitalized for syncope, an estimated one scan reported positive findings. None of the studies succeeded in establishing a common set of characteristics for identifying patients with serious underlying intracranial conditions when presenting with syncope.

Injudicious use of head CT to investigate syncope is not only costly but also exposes patients to high levels of
radiation (2 mSv; 8-month background dose accumulation). It is therefore imperative to establish a robust set of guidelines that aids in the identification of patients that are likely to be at high risk for a serious intracranial condition. A prospective study involving a larger cohort of patients with syncope is needed to develop such a risk tool. Our review results support the recommendations of the Choosing Wisely Campaign that advocate against overuse of CT head among low-risk patients with syncope.\textsuperscript{12,13} The 2015 Academic Emergency Medicine (AEM) Consensus Conference, with input from multidisciplinary experts, aimed to develop a research agenda for optimize ED diagnostic imaging by identifying opportunities, knowledge gaps, and develop priorities.\textsuperscript{14} The content areas identified by this expert panel were clinical decision rules and comparative research for alternatives to CT use. The results of our review identify that a knowledge gap exists, and future research for appropriate use of CT head in syncope is needed. The results of our review also indicate that the choice of CT head among patients with syncope will be amenable to shared decision making (SDM), as usually a worst-case scenario approach is taken rather than the most likely scenario. The issue of CT head in syncope also fulfills the SDM appropriateness criteria (e.g., pretest probability can be estimated, testing equipoise exists, test performance data are emerging about risks, and benefits are available) identified at the 2016 AEM consensus conference on SDM in the ED on diagnostic testing.\textsuperscript{15}

We believe that the results of our review can be used in clinical practice in the following manner: The probability of finding any important abnormalities in CT head among patients with syncope is 3.8\% during ED evaluation and 1.2\% when hospitalized after ED evaluation. This probability is higher if any of the risk factors identified in our review are present and lower if absent. Pretest probabilities estimated from the above results can be shared with the patient in addition to the fact that no clear-cut evidence for optimal approach exists. A potential alternate approach to defer CT head and watch for development of any of the above risk factors can be offered to patients who have none of the risk factors identified.

Based on the results of our review, we are unable to qualify the yield of CT head among patients with syncope as low or modest. Decisions regarding testing threshold are beyond the scope of this review. Future studies should provide more reliable estimates of diagnostic yield and derive testing threshold for CT head among patient with syncope by addressing pretest probability, risks, and benefits of CT head. Furthermore, guidelines for CT head in syncope can be developed based on the testing threshold and input from an expert consensus panel.\textsuperscript{43}

**LIMITATIONS**

The limitations of our study are consistent with the design of a systematic review. In our review, the majority of the studies were retrospective in nature, and several studies enrolled a small number of patients. The studies were conducted on different populations and settings, with substantial heterogeneity on several aspects included the types of serious intracranial conditions listed as outcomes. Further, some of the earlier studies (Day et al.,\textsuperscript{25} Kapoor et al.,\textsuperscript{32} and Eagle and Black\textsuperscript{29}) had relatively small patient cohorts, which may not have fully represented the use and yield of head CT accurately for this time period. Despite this, we believe that the studies we have included are, collectively, an accurate representation of the frequency of CT head use among adult syncope patients. Furthermore, the results that half of all patients with syncope have CT head performed and the yield is 1\% to 3\% is consistent. We considered the risk of spectrum bias as not all patients in several included studies had CT head performed. The studies, however, represent the spectrum of patients with syncope that present to the ED and it is also not ethical to subject all patients to CT head. The aim of our systematic review is to provide an overview of the use of CT head among adult patients with syncope and the proportion that were positive for the outcomes listed in the study. We stratified our results by setting, but the reporting of the studies limited further stratification or meta-regression. It could be argued that patients found to have intraparenchymal ischemia on head CT likely did not suffer true syncope. Hence, our study results likely overestimate the diagnostic yield for CT head as approximately one-third of intracranial conditions identified in our review were intraparenchymal ischemia or infarction. Grossman et al.\textsuperscript{9} reported trauma above the clavicles as a risk factor associated with a positive finding on CT head. It is possible that these patients who sustained trauma would have a received a head CT regardless of their syncope. The risk factors identified are very varied and based on very small number of patients with serious outcomes. Our review was limited to the use of CT head among adult patients with syncope and excluded pediatric patients. All organizations, including Choosing Wisely and the American College of
Emergency Physicians, highlight the overuse of CT head among adult syncope patients. Hence, we focused our review on adult patients. Due to resource limitations, for this review we focused solely on articles in English and French. It could be argued that including articles from the 1980s might not be in line with the current ethos for diagnosing and treating syncope, but we deemed it necessary to include these studies for completeness. However, our synthesis of the literature on the use and yield of CT head among patients with syncope is one of the very few to date on this topic.

CONCLUSION

Our systematic review found that half of all patients with syncope have computed tomography head performed with a yield of 1.2% to 3.8%. Caution should be exercised against indiscriminate use of computed tomography head in the evaluation of patients with syncope. A few studies identified presence of neurologic deficits as a risk factor for underlying serious intracranial conditions. Future large-scale studies are needed to provide more reliable estimates for diagnostic yield for computed tomography of the head among patients with syncope, develop a robust prediction tool to guide physicians for optimal use of computed tomography of the head, and expert clinical consensus regarding acceptable miss rate.

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References


Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13568/full

Data Supplement S1. Supplemental material.
Racism Is Not a Factor in Door-to-electrocardiogram Times of Patients With Symptoms of Acute Coronary Syndrome: A Prospective, Observational Study

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ABSTRACT

Background: Investigators have identified important racial identity/ethnicity-based differences in some aspects of acute coronary syndrome (ACS) care and outcomes (time to presentation, symptoms, receipt of coronary angiography/revascularization, repeat revascularization, mortality). Patient-based differences such as pathophysiology and treatment-seeking behavior account only partly for these outcome differences. We sought to investigate whether there are racial identity/ethnicity-based variations in the initial emergency department (ED) triage and care of patients with suspected ACS in Canadian hospitals.

Methods: We prospectively enrolled ED patients with suspected ACS from one university-affiliated and two community hospitals. Trained research assistants administered a standardized interview to gather data on symptoms, treatment-seeking patterns, and self-reported racial/ethnic identity: “white,” “South Asian” (SA), “Asian,” or “Other.” Clinical parameters were obtained through chart review. The primary outcome was door-to-electrocardiogram (D2ECG) time. ECG times were log-transformed and two linear regression models, controlling for important demographic, system, and clinical factors, were fit.

Results: Of 448 participants, 214 (48%) reported white identity, 115 (26%) SA, 83 (19%) Asian, and 36 (8%) “Other.” Asian respondents were younger and more likely to report initial discomfort as “low” and be accompanied by family; respondents identifying as “Other” were more likely to report initial discomfort as “high.” There was no difference in D2ECG time between white participants and all other groups, but there were statistically significant differences by sex: women had longer D2ECG times than men. Exploring more specific racial identities revealed similar findings: no significant differences between the white, SA, Asian, and other
groups, while sex (women had 13.4% [95% confidence interval, 0.81%–27.57%] longer D2ECG times) remained statistically significantly different in the adjusted models.

**Conclusion:** Although racial/ethnicity-based differences in aspects of ACS care have been previously identified, we found no differences in the current study of early ED care in a Canadian urban setting. However, female patients experience longer D2ECG times, and this may be a target for process improvements.

Ethnicity has been defined as “a self-chosen category that reflects distinctness based on ancestry, culture, language, religion, and geographic location.” Race, or racial identity, by contrast, generally refers to a conferred identity based on an concocted hierarchy of human value related to phenotypes, skin color, and other putative biologic features of inferiority, often associated with exclusion and unequal power between groups. Therefore, we use the term ethnicity to refer to a self-chosen category, racial identity to refer to one that has been conferred by others, and racial identity/ethnicity when the source of the designation is unclear.

Rates of receiving guideline-directed treatments, and outcomes, have differed by ethnicity or racial identity, apparent in symptoms and treatments-seeking among patients with acute coronary syndrome (ACS). However, these patient-based differences only partly explain the observed differences in access to appropriate treatment and in outcomes. Given the global burden of ACS as well as the spectrum of ethnic diversity, a fuller understanding of the factors contributing to these differences is important, but lacking.

Some researchers have invoked the concept of implicit (unconscious) bias to explain some ethnicity/racial identity–based health care disparities. U.S. physicians have been found to exhibit a strong implicit preference for white over black patients, which was more predictive of their behavior than explicit attitudes, including in care of myocardial infarction patients. Similar bias has also been found among pharmacy, nursing, and medical students. However, little research has examined whether there are ethnicity/racial identity–based differences in “upstream” processes (e.g., patient–provider interactions or health professionals’ assessment and clinical decision making) in the critical moments after presentation to an emergency department (ED) with symptoms of ACS—processes that shape the eventual clinical trajectory on which ACS patients travel. Indeed, experts have recently urged that the implicit attitudes and behaviors of health professionals be targeted for study.

We conducted a multisite, observational study to investigate whether there are differences, based on racial identity, in the initial care received (as measured by door-to-ECG [D2ECG] time) among patients presenting to EDs with symptoms of ACS. Both ethnicity and racial identity may affect the quality of health care received, but because our aim was to examine the behaviors of health professionals, we focused on racial identity as a potential predictor of D2ECG.

**METHODS**

**Setting and Sample**

This was a multicenter, prospective, observational study, conducted in Vancouver, British Columbia, a metropolis of approximately 3 million people. Those identifying as being of Asian and South Asian (SA) ethnicity make up the second and third largest ethnic minorities, respectively, after those of European origin. For this multicenter, prospective, observational study, we identified potential participants in the EDs of three sites: an innercity, university-affiliated hospital referral center with a 24-hour cardiac catheterization laboratory and two community hospitals. The annual volumes of patients with possible ACS seen at these sites were 2,800, 6,500, and 1,300, respectively. All EDs have established minimum levels for nurse and physician staffing; in particular, the triage positions are always preferentially filled.

Research staff approached patients, either in the ED or, if they could not be approached in the ED for clinical reasons, on an inpatient unit within 48 hours of ED presentation, if they met all of the following inclusion criteria: 1) 20 years of age or older; 2) presented to the ED and triaged with codes related to a possible ACS (see below); 3) suspected to be having ACS, as evidenced by the emergency physician ordering either immediate cardiology consultation or management with a standardized protocol for continued observation (ultimately admitted or not); 4) hemodynamically stable and free of their initial presenting complaint for at least 1 hour; 5) English, Mandarin, Cantonese, or Punjabi speaking; and 5) able to provide informed consent. We excluded patients being cared for by a coinvestigator. We recruited participants 6 days per week, generally between the hours of 0800 and 1800.
The research ethics board at each site approved the study and all participants gave written, informed consent.

The sites had similar protocols for managing patients with potential ischemic symptoms. All Canadian EDs use the Canadian Triage and Acuity Scale (CTAS), which defines the urgency of the presentation (the maximum interval until a patient should be seen by a physician). Nurses also use the Canadian Emergency Department Information System to classify the presenting complaint (participants included in this study had triage codes of chest pain, cardiac features; chest pain, moderate-severe respiratory distress; chest pain, moderate-severe hemodynamic compromise; chest pain resolved, significant cardiac history), which then generates a corresponding CTAS score. All study sites had protocols in place that triggered a nurse-initiated call for technician to perform an immediate 12-lead ECG for patients triaged with any of the above codes related to suspected ischemia. Depending on clinical status and bed availability, patients were triaged to 1) the resuscitation room, 2) a nurse-staffed stretcher with cardiac monitoring, or 3) a chair in the waiting room. This initial location would quickly change, depending on ECG or laboratory findings, change in clinical status, or increased bed availability.

**Procedures**

After obtaining informed consent, trained research assistants administered a standardized questionnaire in one of the four languages of the patient’s choosing. The questionnaire included items about sociodemographic attributes, symptoms (onset, quality, duration), treatment-seeking behavior, their ethnic and racial identity, and satisfaction with the care received in the ED. Following the interview, data regarding delivery of guideline-based and other aspects of care in the ED (e.g., D2ECG time, time to first MD assessment, medications administered) and other processes (e.g., occurrence and timing of cardiology consultation, transfer from ED to an inpatient area) were collected from the clinical record. Data regarding several patient-, environment-, and system-related potential confounders were also collected (e.g., mode of arrival at ED, language spoken, whether accompanied by family/friend, language ability of family/friend, symptoms reported, and ED staffing levels).

**Measures**

The main outcome, D2ECG, which is a widely accepted measure of ED performance in ACS care, was defined as the time from registration with ED triage to the time of the initial 12-lead ECG, both of which were available as electronic time stamps. For our analysis, in which our focus was on health professionals’ responses to patients, it would have been ideal to ask the staff caring for the participants what they perceived the patient’s racial identity to be. However, we felt this would have led to the staff changing their behavior, thus threatening the validity of our findings. Therefore, we relied on participants’ reports of how others perceived them (“reflected racial identity”) using the question: “What about people you meet, what racial background do they tend to think you are? Do they think you’re white, Asian, South Asian, black, or Aboriginal or perhaps some combination of these or maybe something else?” Trained research assistants recorded participants’ responses verbatim. However, although participants responded freely to the racial identity question, to achieve statistical power we then categorized responses into one of four categories: “white,” “Asian,” “South Asian” (SA), or “other/unknown”). These racial identity categories were chosen based on the most common identities in the Canadian population. Two investigators categorized the responses independently and then reviewed the resulting categorizations for agreement.

**Data Analysis**

Sample sizes were estimated using 80% power, 5% family-wise significance testing, and a 10-minute difference in D2ECG as clinically significant, assuming a normal distribution for log10-transformed mean (±SD) of 1.21 (±0.42) for the white group, using PASS 2008, version 08.0.5. This demonstrated that a total sample size of 402 participants (67 Asian, 134 South Asian, and 201 white) was required. Categorical baseline characteristics were summarized as frequencies and percentages. To test for differences across racial identities, the chi-square test was conducted. Continuous baseline variables were summarized either using the mean and standard deviation or median and first and third quartiles. Racial identity differences were tested using either ANOVA or the Kruskal-Wallis test. Two linear regression models were constructed to assess if there were racial identity–based differences in the primary outcome. In model 1, we adjusted for age, sex, and site. To further examine the D2ECG times by racial identity, in model 2 we adjusted for clinically important potential mediators: education, mode of arrival (ambulance or not), severity of discomfort, CTAS score, whether the patient was accompanied by family/friend/coworker, and whether English was the...
primary language spoken at home, in addition to the variables in model 1. As D2ECG is a naturally right-skewed variable, a log transformation was applied. The beta coefficients and the corresponding 95% confidence intervals (CIs) from the linear regression models were transformed using $100\% (e^\beta - 1)$; thus, they can be interpreted as a percent increase or decrease relative to the reference level. Age was categorized as ≤55, 56 to 70, and >70 years, since the linearity assumption was not satisfied. Model 2 was used to assess the two-way interactions between racial identity and site, sex, and age. If the interaction term was not statistically significant ($p > 0.05$), the interaction term was removed from the model. Statistical analyses were performed using SAS software, version 9.4.

**RESULTS**

Of 970 eligible patients, 448 participants were recruited between October 2013 and January 2017. Figure 1 outlines the study recruitment flow. The demographic and clinical characteristics of the final sample are summarized in Table 1. A total of 214 (47.8%) reported white racial identity, 115 (25.7%) SA, 83 (18.5%) Asian, and 36 (8.0%) other. There were no significant differences in ages across the groups.

The unadjusted D2ECG times, stratified by racial identity, are presented in Table 2. This unadjusted analysis indicated that SA participants had the shortest time, but after adjustment for baseline differences...
Table 1
Sample Characteristics, by Racial Identity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>White (n = 214)</th>
<th>Asian (n = 83)</th>
<th>South Asian (n = 115)</th>
<th>Other/Unknown (n = 36)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>85 (39.7)</td>
<td>33 (39.8)</td>
<td>42 (36.5)</td>
<td>13 (36.1)</td>
<td>0.927</td>
</tr>
<tr>
<td>Age (years)†</td>
<td>62.1 ± 13.7</td>
<td>57.3 ± 14.2</td>
<td>61.0 ± 14.5</td>
<td>59.9 ± 14.3</td>
<td>0.067‡</td>
</tr>
<tr>
<td>Age groups (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤55</td>
<td>70 (32.7)</td>
<td>36 (43.4)</td>
<td>35 (30.4)</td>
<td>12 (33.3)</td>
<td>0.460</td>
</tr>
<tr>
<td>≤56 and ≤70</td>
<td>84 (39.3)</td>
<td>32 (38.6)</td>
<td>49 (42.6)</td>
<td>16 (44.4)</td>
<td></td>
</tr>
<tr>
<td>&gt; 70</td>
<td>60 (28.0)</td>
<td>15 (18.1)</td>
<td>31 (27.0)</td>
<td>8 (22.2)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or less</td>
<td>85 (39.7)</td>
<td>40 (48.2)</td>
<td>64 (55.7)</td>
<td>14 (38.9)</td>
<td>0.036</td>
</tr>
<tr>
<td>More than high school</td>
<td>129 (60.3)</td>
<td>43 (51.8)</td>
<td>51 (44.3)</td>
<td>22 (61.1)</td>
<td></td>
</tr>
<tr>
<td>Canadian residency status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Born in Canada</td>
<td>156 (72.9)</td>
<td>13 (15.7)</td>
<td>14 (12.2)</td>
<td>13 (36.1)</td>
<td></td>
</tr>
<tr>
<td>Not born in Canada</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lived ≤ 10 years</td>
<td>6 (2.8)</td>
<td>14 (16.9)</td>
<td>23 (20.0)</td>
<td>5 (13.9)</td>
<td></td>
</tr>
<tr>
<td>Lived &gt; 10 years</td>
<td>52 (24.3)</td>
<td>56 (67.5)</td>
<td>78 (67.8)</td>
<td>18 (50.0)</td>
<td></td>
</tr>
<tr>
<td>English spoken at home§</td>
<td>195 (91.1)</td>
<td>20 (24.1)</td>
<td>19 (16.7)</td>
<td>23 (63.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Main symptom chest pain</td>
<td>156 (72.9)</td>
<td>67 (80.7)</td>
<td>93 (80.9)</td>
<td>31 (86.1)</td>
<td>0.147</td>
</tr>
<tr>
<td>Chest pain on arrival</td>
<td>197 (92.1)</td>
<td>76 (91.6)</td>
<td>110 (95.7)</td>
<td>35 (97.2)</td>
<td>0.418</td>
</tr>
<tr>
<td>Discomfort on arrival</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/low (1–3)</td>
<td>67 (31.3)</td>
<td>28 (33.7)</td>
<td>23 (20.0)</td>
<td>8 (22.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medium (4–7)</td>
<td>86 (40.2)</td>
<td>30 (36.1)</td>
<td>33 (28.7)</td>
<td>19 (52.8)</td>
<td></td>
</tr>
<tr>
<td>High (8–10)</td>
<td>20 (9.3)</td>
<td>10 (12.0)</td>
<td>16 (13.9)</td>
<td>7 (19.4)</td>
<td></td>
</tr>
<tr>
<td>Not available</td>
<td>41 (19.2)</td>
<td>15 (18.1)</td>
<td>43 (37.4)</td>
<td>2 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Arrival by ambulance</td>
<td>55 (25.7)</td>
<td>22 (26.5)</td>
<td>35 (30.4)</td>
<td>16 (44.4)</td>
<td>0.128</td>
</tr>
<tr>
<td>Accompanied by family/friend/coworker</td>
<td>77 (36.0)</td>
<td>42 (50.6)</td>
<td>48 (41.7)</td>
<td>11 (30.6)</td>
<td>0.078</td>
</tr>
<tr>
<td>Triage code¶</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP, cardiac features</td>
<td>179 (84.0)</td>
<td>68 (81.9)</td>
<td>108 (93.9)</td>
<td>32 (88.9)</td>
<td></td>
</tr>
<tr>
<td>CP, severe respiratory distress</td>
<td>6 (2.8)</td>
<td>3 (3.6)</td>
<td>2 (1.7)</td>
<td>1 (2.8)</td>
<td></td>
</tr>
<tr>
<td>CP, respiratory distress (&lt;severe)</td>
<td>14 (6.5)</td>
<td>5 (6.0)</td>
<td>1 (0.9)</td>
<td>1 (2.8)</td>
<td></td>
</tr>
<tr>
<td>CP resolved, signif card hx</td>
<td>14 (6.6)</td>
<td>6 (7.2)</td>
<td>1 (0.9)</td>
<td>2 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Syncpe/presyncpe</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0 (0.0)</td>
<td>0 (1.2)</td>
<td>2 (1.7)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>CTAS§</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 1 or 2</td>
<td>185 (86.9)</td>
<td>65 (78.3)</td>
<td>94 (81.7)</td>
<td>30 (83.3)</td>
<td>0.303</td>
</tr>
<tr>
<td>Level 3 or 4</td>
<td>28 (13.1)</td>
<td>18 (21.7)</td>
<td>21 (18.3)</td>
<td>6 (16.7)</td>
<td></td>
</tr>
<tr>
<td>Hospital site</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (tertiary)</td>
<td>119 (55.6)</td>
<td>48 (57.8)</td>
<td>17 (14.8)</td>
<td>21 (58.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2 (community)</td>
<td>20 (9.3)</td>
<td>11 (13.3)</td>
<td>3 (2.6)</td>
<td>1 (2.8)</td>
<td></td>
</tr>
<tr>
<td>3 (community)</td>
<td>75 (35.0)</td>
<td>24 (28.9)</td>
<td>95 (82.6)</td>
<td>14 (38.9)</td>
<td></td>
</tr>
<tr>
<td>Treatment-seeking delay¶** hours</td>
<td>3.5 (0.5, 24.5)</td>
<td>2.0 (0.5, 20.0)</td>
<td>2.1 (0.3, 11.3)</td>
<td>8.5 (1.0, 66.5)</td>
<td>0.078‡‡</td>
</tr>
</tbody>
</table>

Data are reported as n (%).

CP = chest pain; CTAS = Canadian Triage and Acuity Scale; signif card hx = significant cardiac history.

*All testing based on chi-square test unless otherwise noted.
†Mean ± SD.
‡ANOVA.
§One missing.
¶Two missing.
||Twenty-five missing (14 White, seven Asian, two South Asian, two other/unknown).
**Median (Q1, Q3).
††Kruskal-Wallis test.
this was no longer apparent. Our initial model, which adjusted for age, sex, and site, showed no differences by racial identity. However, further examination of white racial identity versus the other groups, with adjustment for additional relevant sociodemographic and clinical variables, revealed statistically significant differences in D2ECG time by 1) sex (women’s times were 13.41% [95% CI = 0.81% to 27.57%] longer) and 2) language spoken at home (those not speaking English at home had 15.90% [95% CI = –28.56 to 0.98%] shorter D2ECG times) while racial identity remained nonsignificant (see Table 3 and Figure 2). However, the interaction terms for racial identity by age, sex, and language spoken were not statistically significant. Exploring factors known to vary by sex demonstrated that chest pain was reported less frequently as the main symptom by women (72.5% vs. 81.5% for men, \( p = 0.04 \)).

### DISCUSSION

We prospectively investigated 448 patients with symptoms of ACS at three Canadian EDs and found no statistically significant differences in D2ECG time, based on racial identity. However, women and those who spoke English at home had significantly longer D2ECG times.

Previous research has found differences based on racial identity in the early phases of ACS care: Diercks et al.\(^ {25} \) demonstrated that the 10-minute D2ECG benchmark was significantly less likely to be achieved for nonwhite patients than for white patients and King et al.\(^ {11} \) reported that early coronary angiography and percutaneous coronary intervention were performed significantly less often among SA, South-East Asian, and Chinese patients than those of European background. Further, research regarding general health care inequities among Canadian ethnic/racial

### Table 2

Unadjusted D2ECG Times, by Racial Identity

<table>
<thead>
<tr>
<th>Outcome</th>
<th>White (n = 214)</th>
<th>Asian (n = 83)</th>
<th>South Asian (n = 115)</th>
<th>Other/Unknown (n = 36)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Door to ECG (mins)</td>
<td>15.0 (10.5, 23.0)*</td>
<td>16.0 (10.0, 23.0)</td>
<td>12.0 (7.0, 17.0)†</td>
<td>16.0 (9.5, 27.0)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Data are reported as median (Q1, Q3).

D2ECG = door-to-ECG.

*Two missing.

†One missing

### Table 3

Percent Difference in Adjusted D2ECG Estimates, with 95% CIs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>((e^b - 1))*100%</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian vs. white</td>
<td>10.65</td>
<td>–8.78 to 34.20</td>
<td>0.304</td>
</tr>
<tr>
<td>South Asian vs. white</td>
<td>5.44</td>
<td>–12.59 to 27.20</td>
<td>0.579</td>
</tr>
<tr>
<td>Other/unknown vs. white</td>
<td>24.06</td>
<td>–0.57 to 54.78</td>
<td>0.056</td>
</tr>
<tr>
<td>Age ≥ 56 and ≤ 70 vs. &lt; 55 years</td>
<td>2.14</td>
<td>–10.86 to 17.02</td>
<td>0.760</td>
</tr>
<tr>
<td>Age &gt; 70 vs. &lt; 55</td>
<td>17.15</td>
<td>–0.12 to 37.39</td>
<td>0.052</td>
</tr>
<tr>
<td>Female vs. male</td>
<td>13.41</td>
<td>0.81 to 27.57</td>
<td>0.036</td>
</tr>
</tbody>
</table>

**Education**

| More than high school vs. high school or less education | –6.26 | –16.74 to 5.53 | 0.284 |
| CTAS level 1 or 2 vs. 3 or 4                       | –1.01 | –15.78 to 16.35 | 0.902 |
| Accompanied by family/friend/coworker vs. no one   | 6.94  | –5.83 to 21.44   | 0.300 |
| Language spoken at home: other vs. English         | –15.90| –28.56 to –0.98  | 0.038 |
| Mode of arrival: not ambulance vs. ambulance       | 1.33  | –11.55 to 16.09  | 0.849 |

**Severity of discomfort**

| High vs. none/low                                | –13.60| –30.02 to 6.67  | 0.167 |
| Medium vs. none/low                              | –16.71| –27.94 to –3.73 | 0.014 |
| Missing vs. none/low                             | –14.45| –28.92 to 2.97  | 0.099 |

CTAS = Canadian Triage and Acuity Scale; D2ECG = door-to-ECG.
minority groups has shown that, even in a universal-access system, disparities exist, such as access to renal transplantation or dialysis.\(^{26,27}\) Researchers have suggested that racial identity–based differences in self-reported health status, which remain largely unexplained after adjustment for relevant demographic factors\(^ {28}\) and the deteriorating health of immigrants following immigration\(^ {29,30}\) may be due to the cumulative stress of frequent encounters with racism and discrimination in societal institutions\(^ {28}\) and ethnic/racial bias or stereotyping in clinical encounters and decision making.\(^ {31,32}\) Although we acknowledge that this observational study cannot determine causality, we are encouraged by finding no racial identity–based differences in this aspect of ACS care, particularly so in spite of a high proportion of non–English-speaking participants in the Asian and SA groups, which might impede the triage process. Whereas other investigators have found differences in early ACS care\(^ {11,25}\) we speculate that our findings may be related to the fact that, although 46% of our participants were not born in Canada, a high proportion (81%) had lived in Canada more than 10 years and thus would likely have been familiar with the Canadian health care system. Such familiarity might have increased these participants’ confidence during the clinical encounter, and perhaps clinicians’ perceptions of them as “good patients,”\(^ {33}\) both of which could have led to equitable care. As well, there was a generally high level of education across all groups that may have improved communication and health literacy.

Although racial biases were not evident in our findings, unfortunately there were significantly longer D2ECG times among women (p = 0.036) and those who spoke English at home, in our adjusted model. Women are more likely to present later and to have vague symptoms,\(^ {34,35}\) both of which could lead to a prolonged triage process. Reinforcing this notion, women experience a longer diagnostic phase after presenting with symptoms of ACS.\(^ {36,37}\) Indeed, in our study, a smaller proportion of women reported chest pain the main symptom, which may at least partially explain their observed longer D2ECG times.

Those who reported speaking a language other than English at home had shorter D2ECG times, which was initially surprising. However, a possible explanation for this is that, because verbal communication would likely have been difficult in this English-speaking clinical environment, this may have paradoxically sped up acquisition of the ECG by cutting short the assessment phase. The triage nurse may simply have erred on the side of caution if there were any suggestion of serious symptoms.\(^ {38}\)

**Figure 2.** Percent difference in D2ECG time estimates, with 95% CIs. *Model also adjusted for hospital site. CTAS = Canadian Triage and Acuity Scale; D2ECG = door-to-ECG; ECG = electrocardiogram.
Finally, in all groups, the D2ECG times exceeded the recommended time of 10 minutes. Quality improvement approaches and vigilance are required to achieve and sustain these targets.

**LIMITATIONS**

We recruited daytime patients with potential ischemic chest pain (not ACS) and most patients were deemed lower acuity, so our findings cannot be generalized to critically ill patients or those attending at night. To mitigate the Hawthorne effect, the study sites’ ED staff and physicians were blinded to the true purpose of our study. Therefore, we could not collect information about staff racial identity/ethnicity, their perception of patients’ racial identity, or their years of experience, all of which could have influenced any care processes. Instead, we asked participants what racial background other people tend to think they are, as a proxy for the staff’s perceptions. Although participants self-reported their racial identity, we then recategorized their responses into four groups, to achieve sufficient statistical power, and this may have obscured some racial variation in our sample. To mitigate this, we also collected data on “immigration status” (i.e., whether born in Canada and length of residency), to further characterize our sample. Based on census data, we are confident that the majority of those not belonging to the Asian or South Asian group were of European background.

We were only able to recruit participants who were fluent in English, Mandarin/Cantonese, and Punjabi. As a result, the diversity of the sample may have been compromised. Because we could not collect racial identity or other clinical or demographic information from those who did not consent to participate, we have only age and sex data about those who were initially eligible but not recruited, which were similar to those who were recruited. However, noting that a significant proportion of immigrants in our sample had been in Canada more than 10 years, our findings cannot be generalized to recent immigrants. While EDs can have variable levels of crowding, all sites declared that triage nurse positions are always filled and electrocardiographic technicians are always available, so the provision of ECGs should be reasonably independent of any crowding metrics. The interview tool has not been validated; however, some items have been used and validated by Statistics Canada, as described.

**CONCLUSION**

We are cautiously encouraged that no racial identity–based differences in initial ED care were found in this sample of patients presenting with possible acute coronary syndrome, which may be partially explained by the high proportion of participants who had lived in Canada for more than 10 years. This fact may have increased their knowledge and confidence in using the health system, which, in turn, could have tempered potential unconscious bias among health professionals. However, we acknowledge that this does not mean that such bias among health professionals, based on patients’ racial identity, does not exist in the initial care of acute coronary syndrome patients—only that it was not found here, as measured by door-to-electrocardiogram. The poorer door-to-electrocardiogram performance afforded to female patients remains a concern.

We acknowledge the assistance of the emergency department nursing staff in all study sites in the conduct of this study. We also acknowledge the high-quality work of Diana Kao and Mary O’Sullivan and numerous research staff during the course of this study. Finally, we thank the patient participants for giving generously of their time.

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Patient Uncertainty as a Predictor of 30-day Return Emergency Department Visits: An Observational Study

Kristin L. Rising, MD, MSHP, Marianna D. LaNoue, PhD, MS, Angela M. Gerolamo, PhD, Amanda M.B. Doty, MS, Alexzandra T. Gentsch, and Rhea E. Powell, MD, MPH

ABSTRACT

Objective: The objective was to examine the relationship between patient uncertainty at the time of emergency department (ED) discharge as measured by the “Uncertainty Scale” (U-Scale) and 30-day return ED visits. We hypothesized that a higher score on the U-Scale predicts a higher likelihood of a 30-day return ED visit.

Methods: This was a cross-sectional single-site pilot study performed with adult patients discharged from an urban academic ED to assess the relationship of U-Scale total and subscale scores with 30-day return ED visits. We collected demographic and U-Scale scores at the time of ED discharge and subsequent 30-day ED utilization data by follow-up telephone call.

Results: No association was found between the total U-Scale score and subsequent ED utilization. Patients with higher uncertainty on the Treatment Quality subscale of the U-Scale had higher odds of a 30-day return ED visit (adjusted odds ratio [AOR] = 1.16), while patients with lower uncertainty on the Decision to Seek Care subscale had higher odds of a 30-day return ED visit (AOR = 0.68).

Conclusion: Patient uncertainty as measured by the U-Scale total score was not predictive of subsequent ED utilization. However, uncertainty related to treatment quality and the decision to seek care as measured by the U-Scale subscales may be important in predicting repeat ED utilization. Unlike individual patient factors such as age and race that have been associated with frequent ED visits in prior studies, these domains of uncertainty are potentially modifiable. Providers and health systems may successfully prevent recurrent acute care encounters through implementation of interventions designed to address patient uncertainty. Further work is needed to refine the U-Scale and test its predictive utility among a larger patient cohort.

Background

As health care reimbursement shifts toward value over volume, it is critical for health systems to anticipate the needs of patients and facilitate care delivery in a patient-centered, high-value, and lower-cost manner. Much attention has been dedicated to efforts...
to reduce acute care utilization, a commonly cited driver of high cost care.\textsuperscript{1} Prior research focused on identifying factors that predict frequent emergency department (ED) use has found numerous patient-level factors associated with higher frequency of ED visits including sex, race, mental health status, employment status, Medicaid and insurance status, arrival mode to the ED, and prior ED utilization.\textsuperscript{2–4} Illness severity and comorbidity indices have also been shown to predict risk of ED use and hospital readmissions.\textsuperscript{5–8} Yet these factors provide an incomplete picture of patients at high-risk of ED utilization. Studies that measure individual-level predictors easily available in administrative data such as sex or race tend to capture only a small amount of the variability in ED usage or to not report total variability explained.\textsuperscript{2,9–11} Further, there is evidence that stable personality traits account for a large proportion of variability.\textsuperscript{12} Patient-level factors that could be addressed through provider and system interventions are needed.

\textbf{Importance}

Our prior work suggests that patients’ decisions regarding when and where to seek care are influenced by potentially modifiable factors, such as emotional state, health system trust, and satisfaction. Patients report that they seek care in the ED because they are afraid and uncertain about various aspects of their symptoms\textsuperscript{13–15} and that they return to the ED because of ongoing uncertainty related to their symptoms.\textsuperscript{16} Uncertainty is defined as “the inability to determine the meaning of illness-related events.”\textsuperscript{17} Mishel\textsuperscript{18} developed the Uncertainty in Illness Scale to measure the level of uncertainty in hospitalized patients with chronic conditions. The uncertainty stress scale was then developed to measure uncertainty during illness as well as the stress, threat, and positive feelings associated with the state of uncertainty.\textsuperscript{19} These scales do not address the unique aspects of unscheduled acute care pointing to the need to develop a scale to measure uncertainty during an episode of acute care. Understanding the relationship between patient uncertainty and acute care utilization is essential so that health systems can better predict risk of acute care utilization, design interventions to meet patient needs, and more precisely deploy resources to improve health care outcomes.

\textbf{Goals of This Investigation}

Our team developed a scale to measure patient uncertainty related to symptoms, the “Uncertainty Scale” (U-Scale), which demonstrated evidence of content validity, internal consistency, reliability, and concurrent validity in initial testing.\textsuperscript{20} Exploratory factor analysis during scale testing and validation suggested the U-Scale is composed of seven subscales. The goal of this pilot study is to assess the relationship between patient uncertainty at the time of ED discharge as captured by the U-Scale total and subscale scores and subsequent ED utilization. We hypothesized that a higher total score on the U-Scale predicts a higher likelihood of a 30-day return ED visit. Analyses conducted with the subscale scores were exploratory models to investigate whether certain domains of uncertainty are individually related to subsequent ED utilization.

\textbf{METHODS}

\textbf{Study Design and Setting}

This cross-sectional, single-site pilot study was conducted to assess whether higher patient uncertainty at the end of an ED visit as measured by the U-Scale is predictive of subsequent ED use. Data for this study were collected at the same time as data for scale reliability and validity testing of the U-Scale.\textsuperscript{20} Participants were recruited from a single ED at Thomas Jefferson University Hospital, a large academic hospital located in an urban center. This observational study is compliant with STROBE guidelines.

\textbf{Selection of Participants}

Trained research assistants screened the electronic medical record to identify potentially eligible patients and then approached patients to complete an eligibility assessment. English-speaking adult (18 years and older) patients who were being discharged from the ED were recruited at the end of their ED visit. Patients with communication barriers (including hearing and visual impairments) or severe medical acuity were excluded from the study. Patients who were unable to provide consent due to intoxication, mental impairment, or altered mental status; who were undergoing medical clearance or in police custody; or who had already been enrolled in the study during a previous ED visit were also excluded from the study. Finally, pregnant women were excluded since their health status gives them a unique profile of needs and perspectives on their symptoms that are potentially not generalizable across the broader population of ED patients. The study received institutional review board approval, and written informed consent was collected from all patients at the time of enrollment.
Measurements
Trained research assistants recorded and stored all study measurements using a REDCap database. Participant characteristics and U-Scale scores were obtained during the enrollment ED visit. Participants were contacted by telephone 30 days after study enrollment to provide self-report data of the number of times they visited an ED in the 30 days after their initial enrollment ED visit.

Participant Characteristics. Participant information was collected via self-report at enrollment and included age, sex, household income category, level of education, race/ethnicity, insurance status, whether they had a primary care provider, presence of a chronic condition (cardiovascular disease, cancer, pulmonary disease, endocrine disorder, kidney disease, mental health disorder, nervous system disease, chronic infectious disease, gastrointestinal disease, and chronic pain), and whether they had an ED visit in the 30 days prior to study enrollment. We collapsed the conditions into five categories (cardiovascular, pulmonary, endocrine, mental health, and gastrointestinal) and then created a categorical variable for chronic disease categories: 0, 1–2, and 3 or more. These variables were used to characterize the overall sample and to identify potential covariates for the primary analyses.

U-Scale. The U-Scale is a 30-item scale that captures domains of patient uncertainty related to the experience of symptoms. Individual items are responded to on a 1 to 5 Likert scale; thus, the nominal range for the total U-Scale score is 30 to 150, with higher scores indicating higher uncertainty. The scale demonstrated evidence of content validity, internal consistency, reliability, and concurrent validity in initial psychometric testing. Exploratory factor analysis suggested seven nonoverlapping subscales capturing subdomains of patient uncertainty: Treatment Quality, Self-management, Diagnosis, Worries and Concerns, Decision to Seek Care, Self-efficacy, and Psychosocial Concerns. Descriptions, example items, and reliability for the subscales are shown in Table 1.

30-day ED Utilization. The primary outcome was coded dichotomously as presence/absence of at least one return ED visit. As this study was conducted in an urban metropolitan area where patients have access to a number of different ED and health systems, 30-day ED utilization was collected by patient self-report to capture ED use at any health system.

Data Analysis
Our analysis approach was designed to assess the relationship between uncertainty, including subdomains of uncertainty, as measured by the U-Scale total and subscale scores and the occurrence of at least one 30-day return ED visit. We first calculated descriptive statistics for the sample, including patient descriptive variables, U-Scale total score, and the seven U-Scale subscale scores. The U-Scale total score and subscale scores

<table>
<thead>
<tr>
<th>Subscale Name</th>
<th>Subscale Description</th>
<th>Item Example</th>
<th>Number of Items</th>
<th>Internal Consistency Reliability*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Quality</td>
<td>Perceived quality of care received</td>
<td>I often feel like my doctors don’t give me enough information about my test results</td>
<td>9</td>
<td>0.86</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Desire for explanation about cause and treatment for symptoms</td>
<td>I don’t have an explanation for what is causing my symptoms</td>
<td>8</td>
<td>0.82</td>
</tr>
<tr>
<td>Self-management</td>
<td>Knowledge and ability to manage one’s own symptoms</td>
<td>I have the knowledge and ability to treat my symptoms</td>
<td>4</td>
<td>0.71</td>
</tr>
<tr>
<td>Worries &amp; Concern</td>
<td>Emotional distress related to symptoms</td>
<td>Feeling nervous about my symptoms is causing emotional distress</td>
<td>3</td>
<td>0.66</td>
</tr>
<tr>
<td>Decision to Seek Care</td>
<td>Ability to determine when to seek care</td>
<td>I don’t know which symptoms I should go see a medical professional about</td>
<td>2</td>
<td>0.76</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>Ability to identify how and where to get help when needed</td>
<td>I don’t know where to go for help when experiencing different kinds of symptoms</td>
<td>2</td>
<td>0.61</td>
</tr>
<tr>
<td>Psychosocial Issues</td>
<td>Concern about how medical needs will impact life</td>
<td>I worry that seeking medical care will get in the way of my commitments at home or work</td>
<td>2</td>
<td>0.60</td>
</tr>
</tbody>
</table>

U-Scale = Uncertainty Scale.
*Cronbach’s alpha
were screened for distributional assumptions through visual inspection and calculation of the ratio of the skew and kurtosis values to their standard errors. We then screened the variables at this step for the presence of outliers and influential cases relative to the logistic regression analysis by obtaining the Pearson residuals and leverage values for the U-Scale total and each subscale predictor individually with respect to each case’s standing on the outcome. One case was removed based on its standing on the Self-efficacy subscale and its leverage values. The predictor variables with this case removed were all normally distributed, and no more influential cases were identified. Sample sizes for the first and second logistic regression models were 156 and 155, respectively.

We compared these variables between the groups with and without a repeat ED visit within 30 days using chi-square for categorical variables and t-tests for continuous variables. We used an entry criterion of \( p < 0.10 \) for variable inclusion in the logistic regression models. With the exception of self-reported prior ED usage in the 30 days before study enrollment, none of the measured patient variables were related to the outcome of 30-day return ED visit at the \( p < 0.10 \) threshold. Because participants’ ED usage in the 30 days prior to enrollment was significantly related to the outcome and was also associated with the U-Scale total score and with two of the seven subscale scores, it was included as a covariate in the logistic regression models.

We then estimated two logistic regression models to explore associations between the binary outcome of 30-day return ED visit and the uncertainty variables. Both models used a direct entry method, with the identified covariate of any prior 30-day ED visit entered in the first block. Model 1 used the U-Scale total score in the second block, and model 2 used the seven U-Scale subscale scores in the second block. These models assess the independent contribution of the uncertainty variables, controlling for the identified covariate. The model with the seven U-Scale subscales entered together assesses the association between each subscale and the outcome, controlling for the other subscales, and therefore estimates the effect of each domain of uncertainty allowing for uncertainty in the other domains. We report model fit statistics using the significance of the Hosmer-Lemeshow test\(^{21}\) and percent of correct classifications; Nagelkerke \( R^2 \) for proportion of variability in the outcome explained by the model; and adjusted odds ratios (AORs), their significance values and confidence intervals (CIs) for regression coefficients. We set an alpha of 0.05 for this study.

As this was pilot work, we did not have any a priori expectations about the magnitude of potential effects of covariates; additionally, the available sample size was constrained as these data were collected for another purpose. Therefore, no a priori power analysis was conducted. For the effects that were significant, we evaluated effect size using a general linear model approach to obtain covariate-adjusted estimates of the between-group differences (for those with and without a 30-day return ED visit) for the U-Scale total and for both subscales that were significantly related to the binary outcome in the second logistic regression model. These analyses controlled for the presence of a prior 30-day ED visit, and the estimates for the subscales also controlled for each of the other subscales. The adjusted between-group difference in each case was divided by the pooled standard deviation (SD) to obtain Cohen’s ‘\( d \)’—the standardized between-group difference—as an effect size. This effect size reflects the distance between group means in SD units and thus is a scale-free measure of effect for continuous variables.

**RESULTS**

**Characteristics of Study Subjects**

We enrolled 200 patients at the time of ED discharge between February 2017 and April 2017 and successfully contacted 156 of the 200 enrolled patients (78%) by telephone for a 30-day follow-up assessment within a mean of 32 days (range, 29–85 days) of their enrollment ED visit. Patients unable to be contacted at follow-up did not differ significantly from initial study sample on any of the demographic characteristics collected including age, sex, income, race, ethnicity, education, insurance status, presence of a primary care provider, or number of chronic conditions, nor did the patients lost to follow up differ on the U-Scale total or subscale scores (results not shown). Descriptive variables and between-group differences for the study population are shown in Tables 2 and 3.

**Main Results**

**Model 1 Result.** Model 1 tested prediction of 30-day return ED utilization using prior 30-day ED visit as a covariate in step 1 and with the U-Scale total score entered in step 2. The model chi-square was
non-significant ($\chi^2(2) = 14.64$, $p > 0.10$). In this model, only the self-reported prior 30-day ED use was a significant predictor (AOR $= 2.6$ [95% CI = 1.04–6.70], $p < 0.05$), indicating a 2.6-times increase in the odds of having a 30-day return ED visit for those who reported a prior 30-day ED visit. The U-Scale total score was not significant (AOR $= 1.01$ [95% CI = 0.98–1.03], $p > 0.10$). The nonsignificant Hosmer-Lemeshow test indicated acceptable model fit ($p = 0.47$).

### Model 2 Result

Model 2 tested prediction of 30-day return ED utilization using prior 30-day ED visit as a covariate in step 1 and with the seven U-Scale subscales entered in step 2. The model chi-square was not significant ($\chi^2(8) = 15.38$, $p = 0.052$). Nagelkerke $R^2$ indicated that 17.2% of the variability in the outcome was captured by the model, with 87.1% correct classifications. Hosmer-Lemeshow test indicated acceptable model fit ($p = 0.75$). In addition to the covariate of previous 30-day ED use, the (Uncertainty about ...)

- Treatment Quality and Decision to Seek Care subscales were significant predictors in the model. Higher uncertainty on the Treatment Quality subscale was associated with increased odds of having a 30-day return ED visit (AOR $= 1.16$ [95% CI = 1.02–1.32], $p < 0.05$). Specifically, each one-point increase in the Treatment Quality subscale was associated with a 16% increase in the odds of a return visit. In contrast, higher scores on the Decision to Seek Care subscale were associated with lower odds of having a return ED visit (AOR $= 0.68$ [95% CI = 0.47–0.98], $p < 0.05$). Specifically, every one-point increase in the Decisions to Seek Care subscale was associated with a 32% decrease in the odds of a return visit.

### Effect Size

For the significant subscales, the Cohen’s ‘d’ values were 0.46 for the Treatment Quality subscale and 0.41 for the Decision to Seek Care subscale. These standardized differences are considered medium effects and are consistent with the proportion of variance explained in the models; in the logistic regression model containing all the subscales simultaneously, over 17% of the variability in the outcome was explained.

### DISCUSSION

Our analyses demonstrated that patient uncertainty as measured by the U-Scale total score was not predictive
of recurrent 30-day ED visits; however, exploratory analyses suggested that uncertainty as measured by two of the subscales is predictive of ED return visits. Specifically, patients with higher uncertainty measured on the Treatment Quality (perceived quality of care received) subscale of the U-Scale had higher odds of a 30-day return ED visit, while patients with higher uncertainty on the Decision to Seek Care (ability to determine when to seek care) had lower odds of a 30-day return ED visit. Analysis of effect size for these subscales along with amount of variance explained in these domains of uncertainty and self-reported ED utilization. There was no association between uncertainty as captured in the other five subscales: Diagnosis (desire for explanation about cause and treatment for symptoms), Worries and Concerns (emotional distress related to symptoms), Self-management (knowledge and ability to manage one’s symptoms), Self-efficacy (ability to identify how and where to get help when needed), and Psychosocial Concerns (concern about how medical needs will impact life).

While we did not find a significant relationship between the overall U-Scale score and subsequent ED visits, the relationship between two specific subscales suggest that the relationship between patient uncertainty and ED utilization may be more nuanced than the total scale score captures and that uncertainty related to specific aspects of symptom management—particularly treatment quality and decision making—may be more impactful than other aspects of uncertainty. Prior work has demonstrated that patient perceptions of treatment quality impact a number of important outcomes including patient satisfaction, choice of provider, and adherence to medical advice. In addition, trust in medical provider and health care institution impacts patient adherence to recommendations, self-rated health, clinical outcomes, and overall satisfaction with care. Our finding that higher uncertainty regarding treatment quality is associated with higher odds of a 30-day return ED visits adds to the literature by suggesting a direct link between perceived quality of care received during health care encounters and subsequent ED utilization. This suggests that understanding and intervening on factors that influence patient perceptions of treatment quality may reduce subsequent resource utilization. A model developed by Sofaer and Firminger suggests that patient perceptions of quality of care are influenced by patient expectations and prior experiences. Sofaer and Firminger also note that patients have distinct criteria for quality of care, and these criteria are often implicit. Providers and health care organizations wishing to impact patient utilization may benefit from establishing shared criteria for quality of care that incorporates patient perspectives and is explicitly articulated during the acute care encounter.

A notable and unexpected finding is that patients who scored higher on the Decision to Seek Care uncertainty subscale were less likely to return to the ED—that is, patients who were more uncertain about whether their symptoms required evaluation in the ED were less likely to return to the ED for a subsequent visit within 30 days. These findings may be explained in a few ways. First, patients who are not confident in deciding when to go to the ED are likely to make a different decision regarding whether and when to seek care in the future for ongoing or new symptoms.

### Table 3

<table>
<thead>
<tr>
<th>Measure (Range)</th>
<th>With Return ED Visit (n = 22 for Total Score, n = 21 for Subscales)</th>
<th>Without Return ED Visit (n = 134)</th>
<th>Mean Difference (95% CI) (covariate adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U-Scale (34–118)</td>
<td>74.9 (±17.3)</td>
<td>72.2 (±18.4)</td>
<td>2.7 (0.0 to 6.9)</td>
</tr>
<tr>
<td>Treatment Quality subscale (13–37)</td>
<td>23.9 (±5.7)</td>
<td>21.7 (±4.9)</td>
<td>2.2 (0.36 to 4.1), d = 0.41</td>
</tr>
<tr>
<td>Diagnosis subscale (8–38)</td>
<td>19.7 (±6.4)</td>
<td>20.3 (±5.9)</td>
<td>0.6 (1.5 to 2.7)</td>
</tr>
<tr>
<td>Self-management subscale (4–17)</td>
<td>8.8 (±3.1)</td>
<td>8.5 (±3.2)</td>
<td>0.3 (-0.78 to 1.6)</td>
</tr>
<tr>
<td>Worries &amp; Concerns subscale (3–15)</td>
<td>8.4 (±3.0)</td>
<td>8.2 (±2.8)</td>
<td>0.2 (-0.96 to 1.4)</td>
</tr>
<tr>
<td>Psychosocial subscale (2–10)</td>
<td>4.1 (±2.0)</td>
<td>4.7 (±1.4)</td>
<td>0.5 (-0.2 to 1.4)</td>
</tr>
<tr>
<td>Decision to Seek Care subscale (2–10)</td>
<td>4.2 (±2.0)</td>
<td>5.1 (±1.9)</td>
<td>0.9 (0.10 to 1.6), d = 0.46</td>
</tr>
<tr>
<td>Self-efficacy subscale (2–10)</td>
<td>4.0 (±1.5)</td>
<td>3.5 (±1.8)</td>
<td>0.5 (-1.0 to 0.08)</td>
</tr>
</tbody>
</table>

Data are reported as mean (±SD). U-Scale = Uncertainty Scale.

*All estimates are adjusted by self-reported ED visit in previous 30 days. Each subscale also adjusted by the other subscales. For subscales that were significant predictors of the outcome, Cohen’s d is also given.
because they do not have routine health care use patterns. Alternatively, patients may have been uncertain only about their most recent decision to seek care, and their ED visit itself may have resulted in them not deciding to seek ED care again in the future. Finally, patients who were unsure about their decision to seek care may have had symptoms that resolved more quickly than those with higher certainty, thus not requiring a return ED visit.

Our finding of the lack of association between the total U-Scale score and recurrent 30-day ED visits, yet a significant association with two of the U-Scale subscale scores and subsequent utilization suggests that uncertainty is not a unitary phenomenon and that only some aspects of uncertainty are predictive of future utilization. The obtained effect sizes for the Treatment Quality and Decision to Seek Care subscales (0.41 and 0.46, respectively) are medium effects that will inform future scale development work determining cutoff values that might be used in clinical screening or intervention.

LIMITATIONS

This study has several limitations. We enrolled a convenience sample from a single ED located within a large urban academic hospital to recruit respondents who sought care in the ED and did not get hospitalized. More than half of the sample was black, female, and earned less than $49,999 annually, so findings may not be generalizable to other populations, although our sampling frame likely resulted in a relatively representative sample from our population.

We assessed utilization by patient self-report. Data available to our team did not include administrative claims related to ED use at health systems outside the index institution where this study was performed. Given that acute care utilization patterns are often independent of health system boundaries, especially in the geographic region where this study was performed, which has multiple health systems in one urban region, single-site administrative data would like underestimate repeat visits. As such, the team decided that patient self-report was preferable to the alternative of chart review, in which we would miss visits occurring outside the health system. With patient self-report, we acknowledge that there is potential for bias due to both recall bias and patient preferences to either under- or overreport their utilization. Recall bias in self-report of health care utilization may be influenced by factors such as patient cognitive abilities, recall time frame, type and frequency of utilization, questionable design, and mode of data collection.

Prior studies of concordance between self-report and insurance claims specifically for ED visits suggest good to very good concordance recall within a year, and the impact of memory decay on recall in our study may be mitigated by the relatively short recall time (30 days).

Our sample size was relatively small, with a ratio of cases to predictors of approximately 15:1. Despite this, we did find two significant effects, both of medium magnitude. It is possible that other effects were missed owing to low power and we plan to address this in follow-up work. Our sample size was reduced by the fact that close to one-quarter of the enrolled sample were unable to be contacted for follow-up. Although our analyses indicate that those lost to follow-up were not demographically different from those we were able to follow-up in any of the characteristics we identified, it remains possible that this group could have different in factors not captured by these variables. We are working with the regional healthshare data exchange for future work to facilitate more accurate collection of subsequent utilization data.

In addition, these data were collected as part of initial scale refinement and validation work, and the factor analysis resulted in subscales/subdomains of patient uncertainty measured with as few as two items. Our subsequent work is focused on scale refinement including the potential addition of items within subdomains. This will be followed by further exploratory and confirmatory factor analyses as well as predictive modeling to establish validity of the subscales. Although some subscales consisted of only a few items they demonstrated reasonable internal consistency and showed strong associations with the outcome. Despite these limitations, to our knowledge, this is the first study to assess patient uncertainty as a predictor of return ED visits. Findings suggest that uncertainty may be a predictor of ED returns and that this association warrants further study with a larger sample.

CONCLUSION

In summary, our findings suggest that patient uncertainty during an ED visit related to treatment quality and the decision to seek care may be important in predicting future ED utilization. Importantly, unlike many patient factors that have been identified as associated
with frequent ED visits, such as age and insurance status, these patient domains of uncertainty are potentially modifiable. Through application of interventions designed to specifically address these unmet patient needs, providers and health systems may successfully prevent recurrent care cycles. As such, the next steps include continued refinement of the scale by testing in different geographic locations and using a larger sample. Our developmental work with the U-Scale is ongoing, and the finding of predictive utility of two elements of uncertainty as measured by the U-Scale provides evidence that the concept of uncertainty is viable and that patient uncertainty contributes to the decision to seek care.

References

Multicenter Analysis of Transport Destinations for Pediatric Prehospital Patients

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ABSTRACT

Background: Although all emergency departments (EDs) should be ready to treat children, some may have illnesses or injuries that require higher-level pediatric resources that are not available at all hospitals. There are no national guidelines for emergency medical services (EMS) providers about when to directly transport children to hospitals with higher-level pediatric resources, with the exception of severe trauma. Variability exists in EMS protocols about when children warrant transport to hospitals with higher-level pediatric care.

Objective: The objective was to determine how frequently pediatric patients are transported by EMS to hospitals with higher-level pediatric resources and to evaluate distribution patterns based on illness and injury severity.

Methods: We conducted a retrospective analysis of all pediatric (age 0–18 years) transports in three large EMS systems between November 2014 and November 2016. Each community had a hospital with higher-level pediatric resources that was within a 30-minute transport time from any location. Patients were included if they were transported by ground ambulance and the request originated in the 9-1-1 system. We assessed the frequency of transports to a hospital with higher-level pediatric resources. Data were stratified by chief complaint of illness or injury and severity. Potential risk for severe injury was defined as meeting the physiologic step of the field triage guidelines and potential risk for severe illness was defined as having an abnormal vital sign after adjusting for patient age.

Results: A total of 41,345 pediatric patients were transported by a participating EMS agency to an ED and had complete destination data. A total of 55% of all EMS-transported pediatric patients were transported to a hospital with higher-level pediatric resources. There was variation by site (range = 45%–71%) in the percentage of children who went to a hospital with higher-level pediatric resources. Patients over 15 years of age went to general EDs (57%) more often than younger patients. When stratified by severity, 60% of those with potentially severe illness and 74% of those with potentially severe trauma were transported to a hospital with higher-level pediatric resources.

Conclusions: EMS providers commonly transport children to hospitals with higher-level pediatric resources. However, more than one-quarter of children with potentially severe injuries and illnesses are transported to general EDs.
Emergency medical services (EMS) providers have two main roles when treating children. They provide prehospital treatments and make destination decisions based on acuity and family preferences. While all emergency departments (ED) should be capable and ready to treat children, many communities have hospitals that provide a higher level of pediatric care that is unavailable at other hospitals, including comprehensive pediatric surgical and critical care services. It is unknown when or how EMS providers recommend that a pediatric patient seek services at hospitals with higher-level pediatric resources.

Little is known about the frequency with which children are transported to a hospital with higher-level pediatric resources. Most prior research on destination decision-making has focused on the identification of injured patients who need a trauma center. However, transport to hospitals with higher-level pediatric resources can be just as important for patients with medical-related complaints as it is for trauma-related complaints. For example, it has been shown that children treated in pediatric intensive care units have better outcomes than those treated in adult intensive care units.

When patients are seen at a hospital that does not have the resources to care for them, it is necessary to transport them to another facility. These secondary transfers can increase the cost of treatment, delay care, and negatively impact patient safety and outcome. Further, even though all EDs can and should be capable of emergent pediatric stabilization and treatment of children, the National Pediatric Readiness Survey demonstrated that many of our nation’s EDs are not adequately prepared to treat children. In contrast, transporting all pediatric patients who access the 9-1-1 system to hospitals with higher-level pediatric resources is not recommended, since it could overwhelm this valuable regional resource. Offering EMS providers tools that will help them determine when to directly transport a child to a facility with higher-level pediatric resources has the potential to optimize resource utilization and timeliness of definitive care. However, prior to creating these tools we need to better understand current destination practices, particularly in communities where higher-level pediatric facilities are easily accessible. This will assist local communities as well as national organizations in determining if decision support tools are needed to assist EMS providers in directing patients and their families to the most appropriate facility.

A recent study conducted in California determined that 80% of pediatric visits to EDs occurred in general EDs rather than those in hospitals with higher-level pediatric resources. However, in communities that have relatively easy access to this resource, it is unknown what proportion of EMS-transported children goes to hospitals that do not have higher-level pediatric resources, especially among children who have potentially severe illness and injuries. The objective of this study was to determine how frequently pediatric patients are transported by EMS to hospitals with higher-level pediatric resources and to evaluate distribution patterns based on illness and injury severity.

METHODS

Study Design and Setting

This was a retrospective cross-sectional study of EMS patient care records from three EMS systems. Data were analyzed for patient encounters between November 1, 2014, and November 1, 2016. The EMS systems studied were all members of the Charlotte, Houston, and Milwaukee Prehospital (CHAmp) node of the Pediatric Emergency Care Applied Research Network (PECARN) and included the Houston Fire Department (Houston, TX), Mecklenburg EMS Agency (Charlotte, NC), and Milwaukee County EMS (Milwaukee, WI). Collectively, the CHAmp EMS agencies serve over one million individuals younger than 21 years of age. Each agency uses a tiered response system and provides paramedic level care that follows local treatment and transport protocols. These agencies’ protocols addressed destination decision making for children with potentially severe trauma and directed that they be transported to the local hospital with higher-level pediatric resources, which was the pediatric trauma center. For medical illness, all three EMS agencies’ protocols advised transport to the nearest hospital for children who were pulseless or had an unstable airway. There was variability among the three EMS agencies regarding the advised destination for patients with an acute exacerbation of a known chronic illness or those likely requiring intensive care. Apart from the situations noted above, the EMS agencies’ protocols did not provide specific guidance regarding transport destination for children with medical illness. All three communities had access to a hospital with higher-level pediatric resources within approximately 30 minutes of transport time from any location.

Patients were included if the transport originated in the 9-1-1 system and were excluded if they were interfacility transports, through non–9-1-1–based requests...
(e.g., private transports) or by means other than a ground ambulance. Only patients 18 years of age or less were included in the analysis. This study was approved in all three communities by the local institutional review board.

**Data Abstraction and Outcome Designation**

Data were obtained from the three EMS systems’ electronic medical records. The data were abstracted independently at each study site and compiled and analyzed at the Medical College of Wisconsin. The outcome variable was the transport destination. The transport destinations were classified as either an ED in a hospital with a higher-level of pediatric resources or as a general ED. Because there is no standard definition for a hospital with higher level of pediatric resources, we used the local EMS agency’s medical directors’ classification of hospitals to identify those with higher-level pediatric resources. Each study community had at least one hospital with higher-level pediatric resources, and all of these hospitals were designated pediatric trauma centers except for two of the four higher-level pediatric hospitals at site A. Each of the EMS agencies provided Advanced Life Support level care. The three EMS agencies serve a population of approximately 4 million people over 1,365 square miles. Their combined annual call volume is approximately 350,000 calls, with 7% involving a pediatric patient.

**Data Analysis**

Using descriptive statistics we assessed the frequency that pediatric patients were transported to a hospital with higher-level pediatric resources. The data were then stratified by type of chief complaint, illness, or injury and by the severity of illness or injury. These determinations were based solely on the documentation in the prehospital record. The documented primary impression in the prehospital record was used to stratify the data by illness or injury. The classifications were determined by consensus of the investigators after review of all potential primary impressions.

Potential for a severe illness or injury was determined from the EMS provider’s perspective by assessing the patient’s first recorded vital signs. There is no universally accepted definition of severe illness for EMS providers; so for this study risk of severe illness was defined as at least one documented vital sign (i.e., systolic blood pressure, respiratory rate, heart rate) that was outside the age-appropriate range using a previously published table of age-appropriate vital signs or a Glasgow Coma Scale Score (GCS) of 13 or less. If a vital sign was not documented, we did not include the case in the potentially severe illness analysis. A patient was considered to have a potentially severe injury if there was documentation of at least one of the physiologic criteria of the field triage decision scheme, which includes a systolic blood pressure less than 90 mm Hg, a respiratory rate less than 10 or greater than 29 (if less than 1 year old then a respiratory rate less than 20), or a GCS of 13 or less. Given that abnormal vital signs for some pediatric age groups do not match these cutoffs, we conducted a planned secondary analysis by categorizing potentially severe injury using the same age-appropriate cut points for systolic blood pressure and respiratory rate as was used in the medical analysis. A secondary analysis was also conducted for the injured patients where the two site A hospitals that were not designated as pediatric trauma centers were categorized as general EDs. Finally, data were compared by agency to determine if there was a difference in transportation decisions by agency. We also compared destinations by age and normal or abnormal vital signs regardless of primary complaint type.

**RESULTS**

There were 41,345 pediatric transports included in this analysis with 22,797 (55%) transported to a hospital with higher-level pediatric resources. Table 1 displays the percentage of patients transported to a higher-level pediatric hospital stratified by site, chief complaint, and severity. Those who were injured were more likely to go to a hospital with higher-level pediatric resources than those who had medical complaints (61% vs. 56%). Although those with potentially severe illness or injury were more often transported to a higher-level pediatric hospital, over one-quarter of patients went to hospitals without these resources. There was variation by site in the percent of patients who went to a hospital with higher-level pediatric resources. For the secondary analysis of injured patients at site A, when we categorized the two non–trauma centers that provide higher-level pediatric resources for medical illnesses as general EDs, there were slightly less patients at that site that went to a higher-level pediatric facility.

Overall, patients over 15 years of age went to general EDs more often than younger patients (Figure 1).
Table 1
Frequency of Severely Injured and Ill Patients Transported to Hospital With Higher Level Pediatric Resources

<table>
<thead>
<tr>
<th>All Patients</th>
<th>All Injury (Physiologic Step FTDS)</th>
<th>All Illness (FTDS Age Correction)</th>
<th>Severe Injury</th>
<th>Severe Illness</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sites (n = 41,435)</td>
<td>55.1% (54.7–55.6)</td>
<td>60.5% (59.5–61.6)</td>
<td>56.3% (55.7–56.9)</td>
<td>74.2% (71.1–77.4)</td>
</tr>
<tr>
<td>Site A (n = 23,800)</td>
<td>44.7% (44.1–45.3)</td>
<td>46.5% (44.6–48.5)</td>
<td>44.8% (44.0–45.6)</td>
<td>64.3% (57.8–70.8)</td>
</tr>
<tr>
<td>Site A—excluding two nontrauma pediatric hospitals</td>
<td>43.3% (41.3–45.2)</td>
<td>60.5% (53.9–67.1)</td>
<td>48.1% (44.8–51.5)</td>
<td></td>
</tr>
<tr>
<td>Site B (n = 13,559)</td>
<td>68.8% (68.1–69.7)</td>
<td>64.8% (63.4–66.1)</td>
<td>71.4% (70.5–72.4)</td>
<td>75.0% (70.8–79.2)</td>
</tr>
<tr>
<td>Site C (n = 3,986)</td>
<td>70.8% (69.4–72.2)</td>
<td>77.2% (74.4–79.9)</td>
<td>69.7% (68.0–71.4)</td>
<td>88.2% (82.6–93.8)</td>
</tr>
</tbody>
</table>

Data are reported as % (95% CI).
FTDS = field triage decision scheme; physiologic step FTDS = severe injury was determined using the physiologic step of the FTDS; FTDS age correction = severe injury was determined using the physiologic step of the FTDS but using abnormal blood pressure and respiratory rate for age instead of the standard FTDS cut points.

Among children less than 15 years of age, 59% went to a hospital with higher-level pediatric resources. In the entire study population, 59% (95% confidence interval [CI] = 58.4–59.1%) of patients with at least one abnormal vital sign were transported to a hospital with higher-level pediatric resources. Younger children were also more often transported to a higher-level pediatric facility than older children, among those with at least one abnormal vital sign (Table 2). Further, an abnormal GCS was most often associated with transport to a hospital with higher-level pediatric resources, especially for children ages 3 to 11 years (range = 83%–85%). It is important to note that vital signs were frequently not documented (57% systolic blood pressure not documented, 45% respiratory rate, 41% pulse, and 47% GCS).

**DISCUSSION**

Our findings demonstrate that approximately half of all children and more than one-quarter of children with risk of severe illness or injury are transported to a general ED, in communities that have relatively short transport times to hospitals with higher-level pediatric resources. While there may be some time-sensitive conditions where the risk of bypassing a closer hospital for a slightly more distant hospital with higher-level resources is risky, this must be weighed against the benefits of more rapid access to specialists and the secondary hazards and costs related to interfacility transfer. Further, while not every child who accesses EMS requires a hospital with higher-level pediatric resources, it is likely important to give EMS...
providers the tools to identify those pediatric patients that need higher-level resources.

These tools are available for EMS providers who are evaluating an injured patient. The field triage guidelines developed by the American College of Surgeons and updated with collaboration from the Centers for Disease Control and Prevention help EMS providers identify children with potentially severe injuries and the most appropriate destination facility for them. Each of the communities that participated in this study followed the national field triage guidelines for injured patients and had protocols that called for transport of any child who met the physiologic step of the guidelines to the local hospital(s) with higher-level pediatric resources that was designated as pediatric trauma center(s). Therefore, it was surprising that 26% of injured children who met the first step of the field triage decision scheme were transported to a general ED even when a more appropriate destination hospital was within a reasonable transport distance from the scene. While this study could not determine the reason patients were transported to a specific treatment facility, it will be important for future research to determine the reason for this relatively high rate of what appears to be noncompliance with local protocols. One possible explanation is that prior studies have found that the field triage guidelines can have a high rate of both under- and overtriage, providers may not be following the guideline because they are perceived to be inaccurate. Many of the vital sign cut points used in the guideline are abnormal for adults but not children. Another possible explanation is that prior studies have found a general discomfort among EMS providers when transporting children, and this discomfort may prompt providers to select closer hospitals to minimize their time spent caring for a potentially severely injured child.

There are no national EMS guidelines that assist providers in identifying children with medical conditions that would potentially benefit from access to hospitals with higher-level pediatric resources. While this study used abnormal vital signs as an indicator for risk of severe illness, it is important to note that not all pediatric patients with abnormal vital signs will need the resources of a hospital with higher-level pediatric resources. After reviewing EMS protocols at the sites that participated in this study, we found that local protocols provided no specific guidance on when an EMS provider should transport a child with a medical illness to a hospital with higher level of pediatric resources. In many municipalities, the patient or his or her family makes the destination determination, and only in specific cases outlined in the local protocols can the EMS provider override this choice. Many only allow providers to override a parent’s destination facility request in the case of suspicion of severe trauma, cardiac arrest, or an inability to manage the patient’s airway. However, it is the consensus of many experts that there is a much broader set of conditions in children where higher-level pediatric resources are likely to be needed. Whether these conditions warrant overriding parent choice could be debated, but providers should at least be able to make recommendations to families so that they can make an informed destination decision. Our findings support the fact that there is likely a need for a decision support tool to guide EMS providers in determining when ill children require timely transport to a hospital that can provide higher-level pediatric resources. Prehospital identification of children who need higher-level pediatric resources for definitive care may improve patient outcomes by assisting providers in making destination decisions that balance patient need, safety and cost, as well as avoiding the need for secondary transport.

Throughout this paper we used the term hospital with higher-level pediatric resources. We acknowledge that there is no universal definition for this term, and we let each community identify those hospitals for themselves. We did this so that we could capture the decision-making that was made within the community without introducing the bias that may have resulted from using different designations then were used at the time care was provided to our study patients. The

<table>
<thead>
<tr>
<th>Vital Sign Alert</th>
<th>All Vital Signs Documented And Within the Normal Range</th>
<th>At Least One Vital Sign Not Documented Within The Normal Range</th>
<th>At Least One Vital Sign Was Not Documented (Those That Were Documented Were Normal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6 months</td>
<td>71</td>
<td>70</td>
<td>68</td>
</tr>
<tr>
<td>6-11 months</td>
<td>63</td>
<td>69</td>
<td>59</td>
</tr>
<tr>
<td>1-2 years</td>
<td>65</td>
<td>67</td>
<td>58</td>
</tr>
<tr>
<td>3-5 years</td>
<td>66</td>
<td>66</td>
<td>57</td>
</tr>
<tr>
<td>6-7 years</td>
<td>58</td>
<td>63</td>
<td>52</td>
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<tr>
<td>8-11 years</td>
<td>59</td>
<td>60</td>
<td>46</td>
</tr>
<tr>
<td>12-14 years</td>
<td>56</td>
<td>56</td>
<td>44</td>
</tr>
<tr>
<td>15-18 years</td>
<td>47</td>
<td>46</td>
<td>30</td>
</tr>
</tbody>
</table>
required resources for a hospital to be designated as having higher level pediatric resources should likely be defined on a national level and communicated to EMS providers regionally as is currently recommended by the EMS for Children program.20

Finally, our findings sharply contrast with the frequently quoted statistic that 90% of children who access emergency services in the United States are seen in a general ED.25–27 In many areas of the United States children do not have timely access to a hospital with higher-level pediatric resources. When they do have access, this resource should be used wisely to ensure that children at risk for severe illness or injury have the personnel and equipment that can best treat their condition. This study shows that this may not be happening in communities that have that access.

LIMITATIONS

Patients in this study were identified as potentially severe based on prehospital-documented vital signs. This definition has limitations since not all children with an abnormal vital sign will need a hospital with higher-level pediatric resources. The children who actually used higher-level pediatric resources were not identified; therefore, this paper cannot comment on the appropriateness of the destination decisions that were made. We can only describe those decisions.

Further, not all vital signs were documented for all patients. Therefore, there may have been more severe cases in this data set than were identified. This may explain the different ratios of potentially severely injured and ill children at each site, since missing documentation may have decreased identification of potentially severe cases. The outcome for this study was also developed at the local level by having the medical directors at each site identify those hospitals that provided higher-level pediatric resources. While this determination was likely accurate for each site there is variability in defining a hospital that provides higher-level pediatric resources and more effort needs to be expended in clearly defining the criteria that make up these hospitals. Finally, these three sites were largely urban and suburban areas; therefore, the results do not likely transfer to EMS systems operating in primarily rural areas.

CONCLUSIONS

Emergency medical services providers commonly transport children to hospitals with higher-level pediatric resources. However, more than one-quarter of children with potentially severe injuries and illnesses are transported to general EDs.

References

Feasibility of Emergency Department–initiated, Mobile Health Blood Pressure Intervention: An Exploratory, Randomized Clinical Trial

William J. Meurer, MD, MS, Mackenzie Dome, MS, Devin Brown, MD, MS, Destinee Delemos, MD, Sandra Oska, Victoria Gorom, and Lesli Skolarus, MD, MS

ABSTRACT

Objectives: We aimed to assess the feasibility of a text messaging intervention by determining the proportion of emergency department (ED) patients who responded to prompted home blood pressure (BP) self-monitoring and had persistent hypertension. We also explored the effect of the intervention on systolic blood pressure (sBP) over time.

Methods: We conducted a randomized, controlled trial of ED patients with expected discharge to home with elevated BP. Participants were identified by automated alerts from the electronic health record. Those who consented received a BP cuff to take home and enrolled in the 3-week screening phase. Text responders with persistent hypertension were randomized to control or weekly prompted BP self-monitoring and healthy behavior text messages.

Results: Among the 104 patients enrolled in the ED, 73 reported at least one home BP over the 3-week run-in (screening) period. A total of 55 of 73 reported a home BP of ≥140/90 and were randomized to SMS intervention (n = 28) or control (n = 27). The intervention group had significant sBP reduction over time with a mean drop of 9.1 mm Hg (95% confidence interval = 1.1 to 17.6).

Conclusions: The identification of ED patients with persistent hypertension using home BP self-monitoring and text messaging was feasible. The intervention was associated with a decrease in sBP likely to be clinically meaningful. Future studies are needed to further refine this approach and determine its efficacy.
Hypertension is the most prevalent modifiable cardiovascular risk factor, with treatment reducing cardiovascular disease and all-cause mortality. Hypertension is common in the United States affecting 78 million adults. Hypertension control remains well below the Healthy People 2020 goal. While blood pressure (BP) control needs improvement in the overall U.S. adult population, uncontrolled hypertension is even more common among the uninsured and working age Americans. New approaches to hypertension treatment are needed that focus on these difficult to reach populations to achieve health equity.

Currently, there are 136 million emergency department (ED) visits per year—nearly all have at least one BP measured and recorded. About 20% of working age Americans had an ED visit in the past year and the uninsured and Medicaid beneficiaries are high-volume ED users. Even though these high-risk patient groups are generally not presenting to the ED for hypertension, the ED visit provides a unique opportunity to engage them in chronic disease management. However, there is some concern that ED BP readings may be falsely elevated due to pain or anxiety of the ED visit.

In this age of electronic health records (EHRs) and mobile health, it may be possible for the ED to become an active partner in efficient chronic disease management by programming the EHR to identify hypertensive patients and dispense a mobile health behavioral intervention. Text messaging offers an appealing option for behavioral interventions, given its popularity in underserved populations, low cost, ease of adoption, scalability, and ability to reach people in real time yet remain flexible and convenient.

In this context, we designed Reach Out ED—a pilot trial of an ED-based, mobile health, multicomponent, health theory-based, behavioral intervention to reduce BP for future testing in a large scale, randomized controlled trial (see Data Supplement S1, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13691/full). The overarching aim was to develop an automated, low-human-resource, ED-based intervention to improve BP in an at-risk population. A key barrier to ED-based interventions is determining patient eligibility for such an intervention. Thus, our primary objective was to determine the feasibility of our intervention. Specifically, we sought to determine the proportion of ED patients who, after discharge to home, responded to prompted BP self-monitoring and the proportion of responses with persistently elevated BP over 140/90 mm Hg. Our secondary objective was to explore the effect of the Reach Out intervention on BP over time.

METHODS

Study Design

Briefly, Reach Out ED was a randomized feasibility study. We enrolled hypertensive patients meeting eligibility at the University of Michigan Health System ED, which at the time had an approximate yearly patient volume of 70,000 adult patients per year. We prospectively identified patients using EHR-based automatic alert system that notified the study team members to the presence of potentially eligible patients. These were programmed in the EPIC (EPIC Systems) EHR using best practice alerts that automatically sent a page to a study team member and placed the visit ID in a research inbasket within EPIC. We have previously used automated EHR alerts to identify eligible research patients in real time in the ED. Following initial recruitment, we randomized those persistently hypertensive after 3 weeks either into the text messaging intervention or into standard care. The primary objective was to determine the proportion of ED patients who, after discharge to home, respond to text reminders with their home assessed BP and the proportion of responses with persistently elevated BP (>140/90 mm Hg). We have included the study protocol and consent form in Data Supplement S2 (available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13691/full). We report these results in accordance with the CONSORT extension for pilot and feasibility trials and the relevant checklist is also included in Data Supplement S2.

Study Population

Adult ED patients were eligible if they had a documented systolic BP (sBP) of ≥160 mm Hg or a diastolic BP of ≥100 mm Hg, were likely to be discharged from the ED, and possessed a mobile phone with text messaging available. We excluded patients who were critically ill, otherwise unable to give informed consent, incarcerated/institutionalized residents, pregnant, or had a preexisting condition that made follow-up for 4 months unlikely. All materials and text messages were created in English; thus, participants were excluded if they could not read English. Since patients...
were initially entered into a screening phase and randomized after responding during this 3-week period, the study personnel who were conducting recruitment were blinded to treatment group assignment.

**Randomization**

Once enrolled, but prior to randomization, participants underwent a screening phase to determine whether they had persistent hypertension (Figure 1) defined as BP of ≥140/90, based on the prevailing definition at the time the study was designed. The goal of this screening phase was to enrich the population receiving the intervention by allowing the design to focus on participants who were willing to respond and had persistent elevated BP. During the 3-week screening phase, participants received weekly text messages that solely requested their BP. Each week the text-messaging system made three attempts to prompt the participant to text back his/her BP. Participants who responded at least one time and had persistent hypertension (any reported measurement of sBP ≥140 or a diastolic BP ≥90) were randomized. Participants who either did not respond at all or did not report a qualifying BP were not randomized. The screening phase allowed the study to focus resources on participants most likely to benefit. Randomly permuted blocks of 4 and 6 were generated at randomization.org by WJM and assignments were made for up to 150 participants. At the time of initial enrollment, the study staff recruiting participants did not have access to the randomization assignment. When participants in the screening phase met the eligibility criteria for text-messaging response and persistent hypertension, they were initiated on either the intervention or the control pathway by the project manager.

**Study Interventions**

All participants enrolled in the study were given an automatic SureLife 860211 wrist BP cuff, American Heart Association brochures about hypertension and received a text message 1 day/week for 3 weeks prompting the participant to text in his/her BP. During the subsequent 3 months, the intervention group received healthy behavior text messages and weekly reminders to text back their BP. The healthy behavior text messages addressed the most important lifestyle interventions to reduce BP: salt reduction, increased fruit and vegetable intake, and increased physical activity (see Data Supplement S1). In addition to these generic health messages, targeted text messages based on whether the subject took an antihypertensive medication and had a primary care physician were provided. For example, for participants taking antihypertensive medications, text messages also addressed medication adherence (e.g., pillboxes, schedules).

Participants received weekly text message prompts to check and text their BP back. A tailored message comparing their recent BP to their enrollment BP was then sent back to the subject. The control group received no further text messages and were instructed to follow up with their primary care doctor for treatment. All participants received a text message 3 months after randomization requesting a final self-reported BP (Figure 1). Additional details regarding the theory behind the intervention and the content and procedure for the text messaging are provided in Data Supplement S2.

**Study Endpoints/Outcome**

The primary study endpoint was the proportion of ED patients who, after discharge to home, responded to prompted BP self-monitoring and had persistent hypertension defined as BP of ≥140/90 mm Hg. Among those meeting the primary endpoint who were then randomized to the next phase, the secondary endpoint was self-reported sBP 4 months from the time of enrollment. The primary endpoint was chosen to assess study feasibility.
Sample Size and Statistical Analysis
We defined the maximum sample size as 150. We planned to accrue until the end of the academic year related to resource availability even if the maximum sample size was not reached. Our primary aim was to determine if the proportion of participants remaining...
hypertensive within the 3-week screening phase was at least 33% based on our belief that this would be a reasonable yield for distribution of BP monitoring devices. The 95% confidence interval (CI) for a one-sample proportion (33%) of a total sample size of 150 is 25.5% to 40.5% (binomial method without continuity correction). Therefore, if the observed proportion was greater than or equal to 25.5% we would conclude that the primary hypothesis of the trial (that proportion of participants with persistent hypertension measured within 3 weeks is at least 33%) has been achieved within a reasonable degree of certainty. For the secondary analyses, we calculated the mean change in BP, along with the 95% CI for the change from the baseline randomization phase measures to final measurement for the intervention and control groups. We did not compare the means or conduct a hypothesis test on them. The BP change analyses were intended to assess whether the intervention was in a zone of promise. We did not define this formally a priori but in general we believed that a reduction in sBP of around 3 to 5 mm Hg would be likely to be clinically meaningful based on past cardiovascular trials.21 As such, estimating whether our intervention was potentially consistent with this magnitude of effect was the intent of these analyses.21 We used the median of the up to three home BP measurements during the screening phase as the baseline BP in qualifying participants.

Post Hoc and Graphical Analyses
A large proportion of the final outcomes were missing. We addressed this through graphical exploration of the data and using a last observation carried forward (LOCF) approach. First, we graphed the change from ED initial sBP from the initial visit in the ED, to the median of the screening phase, and finally to the end of study. Second, we graphed each recorded sBP (baseline, final, or subject reported), for each participant by week of the study. This depicted how many readings were at markedly high or low levels. Third, for subjects with a missing final visit, we imputed the value by taking the last recorded BP from the study and carrying it forward—LOCF. For example, a subject with an ED sBP of 247, who did not respond to any texts, would have 247 entered as the final measurement for zero change. We estimated the means and standard errors for the treatment and control groups. It is important to note that no LOCF imputations were used for the graphical analyses reported above. Finally, we stratified the cohort by whether the subjects were taking one or more BP medicines at the time of initial enrollment and estimated the mean change in SBP and standard errors by treatment and control groups as well. Given the small sample size, we only conducted this stratified analysis using the LOCF, imputed population.

Safety and Adverse Event Tracking
Education during initial enrollment included a warning that patients should contact their clinician directly or call 9-1-1 if they have any urgent questions or health problems that should be addressed before their next scheduled visit. Participants self-reporting a weekly BP of >180/110 were sent an automated message advising immediate contact with a doctor to have their BP checked as they are at high risk. Additionally, any participants who spontaneously sent in messages (such as questions or comments) received an immediate automated message advising them that if they have questions they should contact their doctor or in an emergency call 9-1-1. We used a study-specific adverse event reporting plan. We only collected and reported serious adverse events that were definitely, probably, or possibly related to the study (e.g., ED visit from cuff injury).

Human Subjects Protection
The protocol was approved by the University of Michigan Medical School Institutional Review Board (IRBMED) with approval number HUM00091668. Written informed consent was obtained from all participants.

RESULTS
Characteristics of Cohort
During the 7-month enrollment period between October 2014 and April 2015, over 9,300 patients with elevated BP were identified through the EHR-based automatic alerts. A total of 1,908 of these had data on eligibility abstracted. Of these, 169 were approached and 104 patients enrolled (64%) (Figure 2). The enrolled cohort was primarily white and insured and had a history of hypertension (Table 1). Follow-up of the last participant occurred in August 2015. Enrollment ended prior to the recruitment of 150 participants since it was the end of the academic year and this was a preplanned criterion for termination of recruitment.
Proportion Responding With Persistent Hypertension: Primary Endpoint Results

A total of 73 of the 104 enrolled participants responded to at least one text during the screening phase representing 70% (95% CI = 60% to 78%) of our cohort. For our primary endpoint, 55 of 104 enrolled patients (53%, 95% CI = 43% to 62%) responded and were hypertensive; this exceeded our predefined minimum threshold of 25.5%. No participants reported any adverse effects attributable to the study protocol.

Utilization of Text Messaging

During the 3-week screening phase, 43 participants texted BP measurements for 3 weeks, 25 texted BPs for 2 weeks, and seven texted a BP one of the weeks only. Within the treatment group receiving weekly text prompted self-monitoring, we observed a uniform
distribution of text responses with the most frequent number of text responses 6 of the 12 weeks (Figure 3).

**Change in sBP Over Time: Secondary Endpoint Results**

We illustrate the change in sBP or loss to follow-up over the course of the study for all 104 participants in Figure 4. We indicate whether the patient reported taking BP medications at baseline and show how much the BP changed from screening to randomization, and from randomization to the final visit. Very few self-reported BPs were over the threshold to prompt a warning to urgently see a doctor (Figure 5).

The intervention group had significant sBP reduction over time with a mean drop of 9.1 mm Hg (95% CI = 1.1 to 17.6; Table 2). The mean drop for the control group was lower, but substantial at 6.6 mm Hg (95% CI = –2.4 to 15.6), although the CI for this change crossed zero. When we repeated the analysis using the LOCF imputation procedure, we observed similar drops in BP over time across the groups. The stratified analyses using the LOCF data demonstrated that current BP medication use may be important, as the control group without current medication had almost no change in BP, whereas the control and intervention subjects on medication had drops of 11.2 and 9.5 mm Hg, respectively.

**Adverse Events**

We did not observe any serious adverse events during the course to the study that met the definition in our prespecified IRB-approved safety reporting plan.

**DISCUSSION**

In this pilot trial of an ED-based, mobile health, multicomponent, health theory–based, behavioral intervention to reduce BP, we found that ED recruitment of patients who later had persistently elevated BP is feasible. We found that 53% of participants who enrolled had persistent hypertension during the 3 weeks after their ED visit. Our findings show the feasibility of automated, real-time EHR alerts to identify possibly eligible ED patients and confirm the feasibility of the recruitment strategy and text-prompted BP self-monitoring to assess subject eligibility. These findings were instrumental in the successful NIH funding of a larger-scale phase II trial evaluating a multicomponent text-messaging intervention for patients with elevated BPs in the ED. Our post hoc analyses demonstrated potential heterogeneity of sBP trajectory following the ED visit based on whether the participants reported being on BP medications at time of initial enrollment. In our follow-up study, we plan to use this as a stratification variable at the time of randomization and we will hopefully gain better understanding regarding the different prognosis for patients with and without prior antihypertensive treatment.

Our findings suggest that the ED can be a valuable partner in hypertension screening particularly among the working age population who can be difficult to reach and derive substantial benefit from hypertension control. Our automated alerts identified over 9,000 potentially eligible participants in 7 months. Furthermore, of those approached over 50% agreed to enrollment in the screening phase of our trial. Additionally,
Figure 4. Blood pressure trends and early dropout over study period. Each of the 104 patients grouped from left to right by those who did not qualify for randomization, the intervention group and the control group. Within each group participants are arranged from left to right in order of highest ED SBP. Red bars depict the change in sBP from ED visit to median screening phase sBP for patients taking BP medications; the blue bars represent this change for patients not taking BP medications. For patients who never returned any texts, the circles represent the ED sBP for patients taking BP medications and the triangles represent each subject who was not taking BP medications. The narrower, yellow bars represent the change in sBP from the screening phase to the final visit for the intervention group. Subject 73 is an example of a case where the sBP was higher at the final visit. The narrower, purple bars represent the change from screening phase to end of study for the control group. Some subjects with median sBP lower than 140 from the screening phase depicted above were randomized. In one case, a participant had a diastolic BP over 90, in the other cases at least one sBP measurement was 140 or above. BP = blood pressure; sBP = systolic blood pressure.

Figure 5. All study BPs over time. All sBPs, by week of study. Week 1 is the baseline in the ED, Weeks 2 to 4 are the screening period, Weeks 5 to 16 are weekly text messaging-based responses in the intervention group, and Week 17 is the final in-person follow-up visit. Patients who were not eligible (due to SBP < 140) or did not respond to texts are indicated with a plus sign, the intervention group is indicated with triangles, and the control group with circles. BP = blood pressure; sBP = systolic blood pressure.
we found that about one-half of participants who were enrolled in the ED had persistent hypertension defined as ≥140/90. If current definitions of hypertension were used, the proportion of participants with persistent hypertension would likely increase. Our findings are concordant with a single-center observational study in an urban ED that found that 51% of hypertensive patients remained hypertensive 1 week after their ED visit. There are many competing demands on the ED workforce many of which outweigh chronic disease management. Thus, Reach Out was designed with this in mind. With its automated patient identification via EHR, if the Reach Out intervention was effective the ED workforce would only need to dispense a BP cuff. This practical approach increases the possibility of future dissemination and implementation if future studies confirm this approach can meaningfully reduce BP.

Little data exist to guide the management of ED patients with asymptomatic hypertension. While guidelines recommend BP screening, the guidance for management of asymptomatic hypertension in the ED is based on consensus opinion, which varies widely from no intervention, referral for outpatient follow up, or initiation of antihypertensives. We found reductions in BP over time in both the Reach Out intervention and the control groups; however, only the intervention group CI excluded zero change or worsening.

The use of weekly prompted BP self-monitoring both for study inclusion and as a component of the intervention is novel. We found variable adherence to returning text messages in our treatment group, despite using an enrichment strategy to increase the likelihood of including patients who would be willing to respond. Mobile health interventions to reduce BP have shown promise, but are limited by short duration of follow-up, data on the optimal intervention components and delivery, and absence of rigorous clinical trial design. The Reach Out pilot and its future randomized trial will fill some of these scientific gaps.

**LIMITATIONS**

This work has several important limitations. Our results only apply to participants who are expected to be discharged to home from the ED and thus cannot be extrapolated to participants who were admitted to the hospital. There were several participants with missing data for the final measurement of sBP, although the focus of this study was to determine how many participants would respond to text requests for their BP and remain hypertensive and therefore be eligible for randomization. The greater loss to follow-up in the control arm informed the design of our follow-up study. Specifically, in our ongoing phase II trial we provide patient incentives for follow-up and request self-monitored BPs from all participants in all arms of the trial. In our pilot, all potentially eligible participants were not approached for enrollment. However, times of research assistant availability were varied and should therefore reflect the overall ED population at a suburban academic ED. We limited our enrollment to an academic year, as the pilot study had limited funding and we utilized college students gaining academic credit as our primarily recruiters. In addition, patients seek care for different reasons in diverse settings and our study was conducted at a single center in one community. For our secondary analysis, we used a LOCF approach to missing data. This may be conservative, although it is possible that subjects who dropped out had improving or worsening BP so it is not clear the direction of bias or noise this approach is introducing. The application of the LOCF imputation resulted in a difference in means for both groups that were smaller with wider CIs, yet still was within a promising zone for the treatment group. Given the methods we used to tailor our text messages, we focused on an English-speaking population only. In addition, we did not systematically assess whether our intervention induced ED visits that did not result in a

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<td>BP Changes: Baseline Versus Final Visit</td>
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<td>sBP reduction (final minus baseline) with final visit</td>
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Results of BP change analyses. Any negative numbers represent an increase in BP. BP = blood pressure; LOCF = last observation carried forward; sBP = systolic blood pressure.
change in hypertension management—although ED utilization of participants will be monitored in our follow-up trial. We used wrist cuffs to address patient preference and limit the need to size upper arm cuffs. Wrist cuffs may not be as accurate as upper arm cuffs; however, it is unclear whether they would be systematically over- or underestimating arterial BP; in addition, we use the cuff over time within patient and that could mitigate the influence of this potential problem. We did not collect individual data on self-efficacy or medication adherence. Our cohort was majority white and almost entirely insured, which may limit generalizability to other populations. Finally, within this feasibility study, we did not collect data regarding the initiation of new medications or dosage changes. In our ongoing clinical trial, we plan to routinely query participants regarding the timing and frequency of changes in their medications, along with assessing medication adherence.

CONCLUSIONS

In conclusion, weekly prompted blood pressure self-monitoring is feasible and can identify ED patients with persistent hypertension who may benefit from a hypertension intervention. Further research is needed to determine the efficacy of the ED-based, mobile health, multicomponent, health theory–based behavioral intervention to reduce BP.

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Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13691/full

Data Supplement S1. REACH OUT: To Reduce High Blood Pressure (Emergency Department).

Data Supplement S2. Supplemental Material.
Do High-sensitivity Troponin and Natriuretic Peptide Predict Death or Serious Cardiac Outcomes After Syncope?

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ABSTRACT

Objectives: An estimated 1.2 million annual emergency department (ED) visits for syncope/near syncope occur in the United States. Cardiac biomarkers are frequently obtained during the ED evaluation, but the prognostic value of index high-sensitivity troponin (hs-cTnT) and natriuretic peptide (NT-proBNP) are unclear. The objective of this study was to determine if hs-cTnT and NT-proBNP drawn in the ED are independently associated with 30-day death/serious cardiac outcomes in adult patients presenting with syncope.

Methods: A prespecified secondary analysis of a prospective, observational trial enrolling participants ≥ age 60 presenting with syncope, at 11 United States hospitals, was conducted between April 2013 and September 2016. Exclusions included seizure, stroke, transient ischemic attack, trauma, intoxication, hypoglycemia, persistent confusion, mechanical/electrical invention, prior enrollment, or predicted poor follow-up. Within 3 hours of consent, hs-cTnT and NT-proBNP were collected and later analyzed centrally using Roche Elecsys Gen 5 STAT and 2010 Cobas, respectively. Primary outcome was combined 30-day all-cause mortality and serious cardiac events. Adjusting for illness severity, using multivariate logistic regression analysis, variations between primary outcome and biomarkers were estimated, adjusting absolute risk associated with ranges of biomarkers using Bayesian Markov Chain Monte Carlo methods.

Results: The cohort included 3,392 patients; 367 (10.8%) experienced the primary outcome. Adjusted absolute risk for the primary outcome increased with hs-cTnT and NT-proBNP levels. Hs-cTnT levels ≤ 5 ng/L were associated with a 4% (95% confidence interval [CI] = 3%–5%) outcome risk, and hs-cTnT > 50 ng/L, a 29% (95% CI = 26%–33%) risk. NT-proBNP levels ≤ 125 ng/L were associated with a 4% (95% CI = 4%–5%) risk, and NT-proBNP > 2,000 ng/L a 29% (95% CI = 25%–32%) risk. Likelihood ratios and predictive values demonstrated similar results. Sensitivity analyses excluding ED index serious outcomes demonstrated similar findings.

Conclusions: hs-cTnT and NT-proBNP are independent predictors of 30-day death and serious outcomes in older ED patients presenting with syncope.
There are over 1.2 million annual events of syncope/near syncope in the United States leading to an emergency department (ED) visit, resulting in 440,000 annual admissions\(^1\) and $2.4 billion in yearly hospital costs.\(^2\) Despite the high incidence and associated costs of syncope/near syncope, there are currently no effective prediction tools to identify older patients (age ≥ 60 years) who may be at risk for subsequent short-term death or serious cardiac events.\(^3\),\(^4\)

High-sensitivity troponin (hsTnT) and natriuretic peptides (NT-proBNP) are very accurate markers of myocardial dysfunction, structural heart disease, and long-term cardiac death.\(^5\),\(^6\) Cardiac biomarkers are frequently obtained during the ED evaluation for syncope/near syncope, but the prognostic value of and NT-proBNP measurements in the presentation of syncope/near syncope is unclear.

Preliminary work suggests that these biomarkers may be important in syncope/near syncope risk prediction.\(^7\)–\(^12\) However, cardiac biomarkers have not been uniformly measured in these pilot studies, and this may have introduced testing bias due to illness severity. The 2017 American College of Cardiology/American Heart Association/Heart Rhythm Society (HRS) Syncope Guidelines state: “The ability of troponin and natriuretic peptide measurement to influence clinical decision making or patient outcome is unknown.”\(^13\)

This study sought to assess the association of hsTnT and NT-proBNP with composite 30-day all-cause mortality and serious cardiac outcomes after an ED evaluation for syncope/near syncope and their prognostic value. We hypothesize that these biomarkers have independent predictive value, after adjustment for symptoms, comorbidities, physician risk assessment, and electrocardiogram (ECG) abnormalities.

**METHODS**

**Study Design**

We performed a preplanned secondary analysis of a multisite prospective observational cohort study (NCT01802398). The study enrolled older adults (≥60 years of age) at 11 United States EDs who presented with the primary chief complaint of syncope or near syncope as confirmed by the treating physician. The study ended upon attaining enrollment goals. The study, including the biomarker blood draws, was approved by the institutional review boards at all sites. Written informed consent was obtained from subjects.
or their legally authorized representative. Data reported were preplanned analyses of biomarker measurements drawn during the initial index visit enrollment of the patient, within 3 hours of consent, and later analyzed at a central laboratory.

**Study Setting and Population**
Eligible patients were screened and enrolled at 11 U.S. EDs between April 28, 2013, and September 21, 2016. Patient inclusion criteria for eligibility were age ≥ 60 years presenting with a chief complaint of syncope or near syncope as determined by the treating physician. Participating subjects agreed to have blood drawn for biomarkers. Syncope was defined as a transient loss of consciousness with loss of postural tone followed by spontaneous and complete recovery. Near syncope was defined as the sensation of imminent loss of postural tone without loss of consciousness. For this preplanned analysis, patients were only included if they had a biomarker result available.

We excluded patients who presented with seizure, stroke, transient ischemic attack, head trauma, intoxication from drugs or alcohol, or hypoglycemia as the presumptive cause of symptoms. We further excluded patients with persistent confusion relative to baseline mental status and those who required medical or electrical interventions (e.g., intravenous glucose, defibrillation) to restore consciousness. Patients with prior enrollment were also excluded. To minimize attrition, we excluded patients unlikely to complete follow-up, including those who lacked phone access, lacked a permanent address, or did not speak either English or Spanish. Patients or those with legally authorized representatives who were unable or unwilling to provide informed consent or follow-up information were also excluded.

**Study Protocol**
Consistent with published research reporting guidelines pertaining to syncope risk stratification, all participating patients underwent a standardized evaluation, including history, physical examination, and an initial 12-lead ECG. Physician risk assessment was obtained from the treating physician immediately after consent. The physician risk assessment had a range from 0% to 100% and served as a surrogate for the treating physician’s subjective level of concern regarding the potential for 30-day death or serious cardiac outcomes. Serum samples were collected for hscTnT and NT-proBNP within 3 hours of consent, and these were sent to and analyzed at a central laboratory (University of Rochester, Rochester, NY). These results were not available to the treating physicians. Clinical testing at the participating hospitals was at the sole discretion of the clinical providers, and patient disposition was unaffected by this protocol. Research personnel collected objective information about age, sex, and triage vital signs from the ED electronic medical record and symptom data directly from the patients or their legally authorized representatives. The treating physician provided information about comorbidities, examination findings, and physician risk assessment. All 12-lead ECGs were interpreted by a study physician both locally and at the coordinating center.

All local patient records were reviewed for subsequent hospital visits, serious cardiac outcomes, and death within 30 days of the index ED visit by site physician-investigators. Follow-up phone calls performed by the coordinating center at 30 days identified additional medical visits and 30-day serious outcomes. Medical records were obtained and reviewed by the coordinating center for these visits. Site investigators and the coordinating center were blinded to central laboratory biomarker results. Serious cardiac outcomes were dichotomized as occurring during the index emergency department visit or after.

To assess inter-rater reliability of chart review, records for the first five sequentially enrolled patients at each of the 10 external sites (excluding the coordinating center) were independently reviewed by local research staff and the coordinating center. The specific number of charts chosen for this review was restricted by availability of research staff resources. All five serious cardiac outcomes in the training set were identified by local site reviewers.

**Key Outcome Measures**
The primary composite outcome included all-cause mortality and serious cardiac events at 30 days. We defined serious cardiac events a priori. These included sustained ventricular arrhythmia (>30 seconds) or symptomatic ventricular tachycardia; sinusrhythm pause ≥ 3 seconds; third-degree or Mobitz II atrioventricular block; symptomatic supraventricular tachycardia pacemaker/defibrillator malfunctions; symptomatic bradycardia (heart rate ≤ 40 beats/min); myocardial infarction as defined by the universal definition; a new diagnosis of severe aortic stenosis (area ≤ 0.9 cm²), severe pulmonary hypertension, hypertrophic cardiomyopathy, or atrial mass causing
outflow obstruction; aortic dissection; and pulmonary embolism. Symptomatic was defined as the “simultaneous occurrence of dizziness, lightheadedness, hypotension (systolic blood pressure < 90 mm Hg), or syncope with an arrhythmia on ECG monitoring.”8 Atrial fibrillation, atrial flutter, paroxysmal atrial tachycardia, and supraventricular tachycardia were all included in the category of supraventricular tachycardia if symptomatic. Research staff coded serious cardiac events as identified during or after the index ED visit. To address potential bias introduced by “obvious” cardiac conditions identified during the ED evaluation, we analyzed a secondary outcome that included all-cause mortality and serious cardiac events at 30 days that were not identified during the index ED evaluation.

**Independent Predictors and Covariates**

Our independent predictors were the measurements of hscTnT and NT-proBNP (Elecsys, Roche Diagnostics). The hscTnT assay used was the Roche Elecsys Gen 5 STAT, which has a lower detectable limit of 5 ng/L and a U.S. reference 99th percentile cutoff limit of 19 ng/L for hscTnT.17 The NT-proBNP assay used was the Roche Elecsys 2010 Cobas, with recommended use of a 125 ng/L lower limit of normal for patients under 75 years and 450 ng/L for patients over 75 years. We report both. Covariates included demographic characteristics and potentially confounding comorbidities. In a previous meta-analysis, we identified potential predictors of serious outcomes including age, cardiac comorbidities, a complaint of dyspnea, hypotension (ED triage systolic blood pressure < 90 mm Hg), and initial ECG abnormalities.18 These were used as covariates. Additional covariates also included disposition and initial physician risk assessment.

An abnormal initial ECG was defined by the presence of nonsinus rhythms (including paced rhythms), sinus tachycardia > 100 beats/min, multiple premature ventricular complexes (≥2), sinus bradycardia (≤40 beats/min), ventricular hypertrophies, short PR-segment intervals (<100 milliseconds), axis deviations, first-degree blocks (>200 milliseconds), complete bundle branch blocks, Brugada patterns, Wolff-Parkinson-White syndrome patterns, bifascicular block (both complete right bundle branch block and left axis deviation), abnormal QRS duration (>120 milliseconds), abnormal QTc prolongations (>450 milliseconds), or Q/ST/T-segment abnormalities suggestive of acute or chronic ischemia. The supervising physicians’ initial risk assessments were measured as a percentage estimate for 30-day death or serious cardiac events.

**Data Analysis**

This study protocol proposed 3,330 completed enrollments (3,700 patients with a 10% attrition rate) to identify associations between predictors and the primary outcomes with an adjusted odds ratio (OR) of 1.5 or greater. We used chi-square tests to test association of the outcome with discrete predictors and logistic regression to test for association of the outcome with continuous variable predictors, with hscTnT and NT-proBNP on the log scale to check for univariate association with the outcomes. Unadjusted associations between the outcome and hscTnT and NT-proBNP were visually assessed using smoothing splines. Tabled values of hscTnT and NT-proBNP quantiles (20, 68, 77, 90, 96, and 99%) were rounded to the closest easily conceptualized values.

To assess the independent association of hscTnT and NT-proBNP with the primary outcome, we performed multivariate logistic regression using complete case data. The model included all covariates along with hscTnT and NT-proBNP. We explored multiple approaches (linear, categorical, logtransform) to parameterize the continuous independent variables. Log transform of hscTnT and NT-proBNP values provided the best fit models based on Akaike information criterion. We assessed for interaction effects between the two biomarkers. In sensitivity analysis, we performed multiple imputations with the MICE package for missing data to include all observations in regression models.19

We found adjusted OR for specific values of hscTnT and NT-proBNP, compared to reference values of 5 and 125 ng/mL, respectively, and we then calculated adjusted ORs and their 95% confidence intervals (CIs) using coefficient estimates and 95% interval endpoints from the multiply-imputed logistic regression model. We used a p-value of 0.05 as statistically significant. Given the observational nature of the study, the alpha was not adjusted for multiple comparisons. We assumed a linear relationship between the log-odds of an event and the logs of hscTnT and NT-proBNP with all other variables held constant.

We estimated the adjusted absolute risk of the primary outcome for intervals bounded by the quantiles...
described above. We first calculated the risk of an event for each subject and then averaged the values across subjects in the particular range. The risk we calculated for an individual patient is the adjusted probability of an event controlling for other covariates. HscTnT and NT-proBNP were entered as continuous covariates and logged before analysis.

We then ran a multivariate logistic regression, including all variables from the main model on each imputed data set. Each imputed data set had an associated estimated vector of coefficients, $\hat{\beta}$, and an estimated variance-covariance matrix $\Sigma$ for those coefficients. From those we calculated the average of the estimates and the marginal covariance matrix across imputations, denoted $\bar{\beta}$ and $\bar{\Sigma}$.

Using patients with complete data, we performed a Bayesian analysis using Markov Chain Monte Carlo (MCMC) to calculate the predicted probabilities of a 30-day serious cardiac outcome or death for each patient. In each iteration of MCMC, we sampled a vector, $\beta(i)$, which followed a multivariate normal distribution with mean $\bar{\beta}$ and covariance matrix $\Sigma$. We then calculated the predicted probability for each patient using the inverse logit function,

$$\hat{p} = \frac{\exp(X^T\beta(i))}{1 + \exp(X^T\beta(i))},$$

where $X^T$ represents the predictors for the given patient. At each iteration, we calculated the average risk of an event across people within each interval of hscTnT and NT-proBNP. We analyzed individual site of enrollment as a fixed effect and found no appreciable differences. Therefore, in the interest of simplicity, we have not reported site specific breakdowns in the data results.

We repeated all analyses for the secondary outcome of serious 30-day events occurring after the index ED evaluation. All data analyses were performed in R version 3.2.3. It is our belief that collinearity and outliers are not generally a problem with this type of data.

![Study cohort, central figure. pro-BNP = pro-brain natriuretic peptide.](image-url)
collection; therefore, we did not perform postregression diagnostics on our model.

RESULTS

We studied 3,392 patients who had available biomarker data (Figure 1); 367 (10.8%) patients experienced the primary outcome. Characteristics of the study cohort are described in Table 1, and type and timing of serious events are presented in Table 2. Some patients experienced multiple outcomes. The mean ± SD age of participants was 72.8 ± 9.0 years. No significant sex or race/ethnicity differences were noted between those with and without serious outcomes. Cardiac comorbidities, dyspnea, hypotension, and abnormal ECG were associated with serious events (p < 0.01). The majority of patients (80%) were admitted to the hospital. Only 20% of patients were discharged directly from the ED.

Values of cardiac biomarkers were greater in patients who experienced the primary outcome (hsTnT, median [IQR] = 22 [10–51] ng/mL vs. 11 [6–22] ng/mL; NT-proBNP median [IQR] = 776 [244–2,175] ng/mL vs. 210 [82–620] ng/mL). Table 1 and Data Supplement S1, Figures S1 and S2 (available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13709/full), illustrate that the probability of serious outcomes increases with increasing values of both hsTnT and NT-proBNP. We illustrated likelihood ratios and negative/positive predictive values at multiple cut points for both biomarkers (Table 3).

In multivariate logistic regression analysis (Table 4), hsTnT and NT-proBNP measurements were independently predictive of outcomes (p < 0.0001). These results were robust to multiple imputation for missing data (Data Supplement S1, Table S1). We did not find evidence of an interaction effect between hsTnT and NT-proBNP (Data Supplement S1, Table S2).

Either cardiac marker was useful in predicting the outcome even if the other marker was already included as a predictor.

For both hsTnT and NT-proBNP, increasing values were associated with greater adjusted absolute risk

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Cohort Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Overall Cohort (N = 3,392)</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>72.8 (±9.0)</td>
</tr>
<tr>
<td>Male sex</td>
<td>1765 (52.0)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>2824 (83.7)</td>
</tr>
<tr>
<td>Black</td>
<td>443 (13.1)</td>
</tr>
<tr>
<td>Other</td>
<td>105 (3.1)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>428 (12.6)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>920 (27.1)</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>766 (22.6)</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>710 (21.4)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>362 (10.7)</td>
</tr>
<tr>
<td>Abnormal ECG</td>
<td>1842 (55.3)</td>
</tr>
<tr>
<td>Physician risk assessment (%)</td>
<td>9.09 (±13.04)</td>
</tr>
<tr>
<td>Disposition—admitted</td>
<td>2637 (79.5)</td>
</tr>
<tr>
<td>Cardiac biomarkers</td>
<td></td>
</tr>
<tr>
<td>hsTnT (n = 3,296)</td>
<td></td>
</tr>
<tr>
<td>&gt;19 ng/L</td>
<td>1052 (31.9)</td>
</tr>
<tr>
<td>NT-pro-BNP (N = 3,392)</td>
<td></td>
</tr>
<tr>
<td>&gt;125 ng/L</td>
<td>2244 (66.2)</td>
</tr>
<tr>
<td>Median [IQR]</td>
<td>240 [88–742]</td>
</tr>
</tbody>
</table>

Data are reported as mean (±SD) or n (%) unless otherwise reported.

*Logistic regression used on log-transformed continuous variables.
DISCUSSION

In this multicenter cohort of older adults presenting to the ED with syncope or near syncope, both hscTnT and NT-proBNP were associated with increased risk for 30-day serious adverse events. While we found that increasing values of cardiac biomarkers were associated with increased absolute risk for the primary outcome, with an adjusted risk of 29% (95% CI = 26%–32%) for patients with a hscTnT value ≤ 125 ng/L and a NT-proBNP value > 2,000 ng/L, the estimated adjusted risk for patients with a hscTnT value > 125 ng/L or a NT-proBNP value > 2,000 ng/L was 33% (95% CI = 30%–36%). A hscTnT value ≤ 125 ng/L and a NT-proBNP value > 2,000 ng/L was associated with an absolute risk of 29% (95% CI = 26%–32%), whereas a hscTnT value > 125 ng/L and a NT-proBNP value ≤ 2,000 ng/L was associated with an absolute risk of 36% (95% CI = 33%–39%). A hscTnT value ≤ 125 ng/L and a NT-proBNP value > 2,000 ng/L was associated with an absolute risk of 33% (95% CI = 30%–36%), whereas a hscTnT value > 125 ng/L and a NT-proBNP value ≤ 2,000 ng/L was associated with an absolute risk of 29% (95% CI = 26%–32%).}

For example, a hscTnT value ≤ 125 ng/L and a NT-proBNP value > 2,000 ng/L was associated with an absolute risk of 29% (95% CI = 26%–32%), whereas a hscTnT value > 125 ng/L and a NT-proBNP value ≤ 2,000 ng/L was associated with an absolute risk of 33% (95% CI = 30%–36%). A hscTnT value ≤ 125 ng/L and a NT-proBNP value > 2,000 ng/L was associated with an absolute risk of 33% (95% CI = 30%–36%), whereas a hscTnT value > 125 ng/L and a NT-proBNP value ≤ 2,000 ng/L was associated with an absolute risk of 29% (95% CI = 26%–32%).

Table 3: Diagnostic Yield for 30-Day Serious Events by hscTnT and NT-proBNP Cutoffs

<table>
<thead>
<tr>
<th>hscTnT Cut Point</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>NPV (95% CI)</th>
<th>PPV (95% CI)</th>
<th>LR+ (95% CI)</th>
<th>LR− (95% CI)</th>
<th>NT-proBNP Cut Point</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>NPV (95% CI)</th>
<th>PPV (95% CI)</th>
<th>LR+ (95% CI)</th>
<th>LR− (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>0.932 (0.891–0.949)</td>
<td>0.219 (0.204–0.235)</td>
<td>0.960 (0.942–0.973)</td>
<td>0.125 (0.112–0.138)</td>
<td>1.18 (1.14–1.23)</td>
<td>0.35 (0.24–0.50)</td>
<td>125</td>
<td>0.883 (0.845–0.914)</td>
<td>0.365 (0.348–0.383)</td>
<td>0.963 (0.950–0.973)</td>
<td>0.144 (0.130–0.160)</td>
<td>1.39 (1.33–1.46)</td>
<td>0.32 (0.24–0.43)</td>
</tr>
<tr>
<td>19</td>
<td>0.554 (0.500–0.606)</td>
<td>0.709 (0.692–0.725)</td>
<td>0.930 (0.918–0.940)</td>
<td>0.186 (0.163–0.211)</td>
<td>1.90 (1.71–2.12)</td>
<td>0.63 (0.56–0.71)</td>
<td>450</td>
<td>0.646 (0.594–0.695)</td>
<td>0.692 (0.675–0.708)</td>
<td>0.941 (0.930–0.951)</td>
<td>0.203 (0.180–0.227)</td>
<td>2.09 (1.91–2.30)</td>
<td>0.51 (0.45–0.59)</td>
</tr>
<tr>
<td>25</td>
<td>0.464 (0.394–0.500)</td>
<td>0.798 (0.783–0.812)</td>
<td>0.923 (0.912–0.933)</td>
<td>0.210 (0.181–0.241)</td>
<td>2.21 (1.93–2.53)</td>
<td>0.69 (0.63–0.76)</td>
<td>850</td>
<td>0.471 (0.419–0.524)</td>
<td>0.802 (0.787–0.816)</td>
<td>0.902 (0.931–0.936)</td>
<td>0.224 (0.195–0.255)</td>
<td>2.38 (2.09–2.71)</td>
<td>0.66 (0.60–0.73)</td>
</tr>
<tr>
<td>50</td>
<td>0.251 (0.207–0.300)</td>
<td>0.923 (0.912–0.932)</td>
<td>0.911 (0.900–0.921)</td>
<td>0.281 (0.252–0.334)</td>
<td>3.24 (2.61–4.04)</td>
<td>0.81 (0.76–0.86)</td>
<td>2,000</td>
<td>0.264 (0.220–0.313)</td>
<td>0.913 (0.903–0.923)</td>
<td>0.911 (0.900–0.921)</td>
<td>0.270 (0.225–0.319)</td>
<td>2.48 (2.38–2.57)</td>
<td>0.76 (0.72–0.80)</td>
</tr>
<tr>
<td>100</td>
<td>0.147 (0.112–0.188)</td>
<td>0.975 (0.969–0.981)</td>
<td>0.905 (0.894–0.915)</td>
<td>0.416 (0.392–0.508)</td>
<td>5.92 (4.22–8.30)</td>
<td>0.87 (0.84–0.91)</td>
<td>4,000</td>
<td>0.131 (0.098–0.170)</td>
<td>0.965 (0.938–0.972)</td>
<td>0.902 (0.891–0.912)</td>
<td>0.314 (0.241–0.394)</td>
<td>3.77 (2.73–5.21)</td>
<td>0.90 (0.85–0.94)</td>
</tr>
<tr>
<td>250</td>
<td>0.062 (0.039–0.093)</td>
<td>0.995 (0.991–0.997)</td>
<td>0.898 (0.887–0.908)</td>
<td>0.579 (0.478–0.737)</td>
<td>11.43 (6.06–21.55)</td>
<td>0.94 (0.92–0.97)</td>
<td>10,000</td>
<td>0.049 (0.029–0.076)</td>
<td>0.988 (0.984–0.992)</td>
<td>0.895 (0.885–0.906)</td>
<td>0.333 (0.211–0.475)</td>
<td>4.12 (2.37–7.18)</td>
<td>0.96 (0.94–0.98)</td>
</tr>
</tbody>
</table>

LR+ = positive likelihood ratio; LR− = negative likelihood ratio; hscTnT = high-sensitivity troponin; NPV = negative predictive values; NT-proBNP = natriuretic peptide; PPV = positive predictive values.
and NT-proBNP levels were found to be independent predictors of 30-day death and serious cardiac events. Increasing values of both biomarkers corresponded with greater risk of adverse events. These findings are robust to multiple sensitivity analyses, and they are valid for risk prediction in patients without an apparent cardiac cause after the initial ED evaluation. These biomarkers have independent predictive power. To our knowledge, this is the largest study to date that has standardized collection of hscTnT and NT-proBNP in patients with syncope. Our findings suggest that these biomarkers could be helpful in syncope/near syncope risk stratification in older adults.

A systematic review of 11 studies assessing biomarker use in syncope/near syncope concluded that “there is modest predictive value for high-sensitivity troponin and natriuretic peptides for major cardiac adverse cardiovascular events.” However, these conclusions were tempered by limitations of prior studies, including small sample sizes, single-center populations, and nonstandardized data collection of potential confounding variables. Our study design specifically addresses these methodologic challenges and confirms the independent predictive value of these biomarkers.

Prior syncope/near syncope risk stratification studies have been criticized for including patients with serious events identified during the ED evaluation. Patients with dangerous medical conditions identified in the ED require treatment rather than risk stratification, and inclusion of such patients may result in optimistically biased estimates of association between predictors and outcomes. In sensitivity analyses, we found that both hscTnT and NT-proBNP were independent predictors of 30-day serious cardiac outcomes and death even after omitting events identified during the index ED visit. This is important in determining which patients are at risk of serious outcomes and death even when an ED evaluation does not find a significant cause for the syncope or near syncope.

### Table 4
Multivariate Model of 30-Day Outcomes, Complete Data*

| Variable                  | Estimate | SE  | z-value | Pr(|z|) |
|---------------------------|----------|-----|---------|--------|
| Age (10 years)            | -0.236   | 0.074 | -3.180  | 0.001  |
| Male sex                  | -0.033   | 0.132 | -0.253  | 0.800  |
| Black                     | -0.231   | 0.200 | -1.154  | 0.248  |
| Other race                | -0.094   | 0.406 | -0.231  | 0.817  |
| Congestive heart failure  | -0.270   | 0.178 | -1.514  | 0.130  |
| Coronary artery disease   | -0.298   | 0.146 | -2.042  | 0.041  |
| Arrhythmia                | 0.775    | 0.135 | 5.744   | 0.000  |
| Dyspnea                   | 0.436    | 0.139 | 3.134   | 0.002  |
| Hypotension               | 0.294    | 0.176 | 1.668   | 0.095  |
| Abnormal electrocardiogram| 0.414    | 0.149 | 2.782   | 0.005  |
| Physician risk assessment | 0.015    | 0.004 | 4.089   | 0.000  |
| Log(hscTnT)               | 0.415    | 0.069 | 6.005   | 0.000  |
| Log(NT-proBNP)            | 0.245    | 0.054 | 4.545   | 0.000  |

hscTnT = high-sensitivity troponin; NT-proBNP = natriuretic peptide.
* AIC = 1,801; AUC = 0.7751.
† n = 3,043 complete cases.

### Table 5
Unadjusted and Predicted Adjusted Absolute Risk Association Between Biomarkers and Outcomes

<table>
<thead>
<tr>
<th>hscTnT (ng/L)*</th>
<th>Patients</th>
<th>Event</th>
<th>Event Proportion</th>
<th>Adjusted Absolute Risk</th>
<th>Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤5</td>
<td>672 (20.4)</td>
<td>27</td>
<td>0.04</td>
<td>0.04</td>
<td>(0.03-0.05)</td>
</tr>
<tr>
<td>6–19</td>
<td>1,572 (47.7)</td>
<td>131</td>
<td>0.08</td>
<td>0.08</td>
<td>(0.07-0.09)</td>
</tr>
<tr>
<td>20–25</td>
<td>299 (9.1)</td>
<td>38</td>
<td>0.13</td>
<td>0.14</td>
<td>(0.12-0.15)</td>
</tr>
<tr>
<td>26–50</td>
<td>442 (13.4)</td>
<td>70</td>
<td>0.16</td>
<td>0.17</td>
<td>(0.15-0.18)</td>
</tr>
<tr>
<td>&gt;50</td>
<td>311 (9.4)</td>
<td>88</td>
<td>0.28</td>
<td>0.29</td>
<td>(0.26-0.33)</td>
</tr>
<tr>
<td>Total</td>
<td>2942</td>
<td>354</td>
<td>0.11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NT-proBNP (ng/L)†</th>
<th>Patients</th>
<th>Event</th>
<th>Event Proportion</th>
<th>Adjusted Absolute Risk</th>
<th>Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤125</td>
<td>1,148 (33.8)</td>
<td>43</td>
<td>0.04</td>
<td>0.04</td>
<td>(0.04-0.05)</td>
</tr>
<tr>
<td>125–450</td>
<td>1,074 (31.7)</td>
<td>87</td>
<td>0.05</td>
<td>0.08</td>
<td>(0.08-0.10)</td>
</tr>
<tr>
<td>451–850</td>
<td>398 (11.7)</td>
<td>64</td>
<td>0.16</td>
<td>0.13</td>
<td>(0.12-0.14)</td>
</tr>
<tr>
<td>851–2,000</td>
<td>413 (12.2)</td>
<td>76</td>
<td>0.18</td>
<td>0.18</td>
<td>(0.16-0.20)</td>
</tr>
<tr>
<td>&gt;2,000</td>
<td>359 (10.6)</td>
<td>97</td>
<td>0.27</td>
<td>0.29</td>
<td>(0.25-0.32)</td>
</tr>
<tr>
<td>Total</td>
<td>3,025</td>
<td>367</td>
<td>0.11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

hscTnT = high-sensitivity troponin; NT-proBNP = natriuretic peptide.
* Limit of detection of HscTnT is 5 ng/L; 99th% (U.S.) reference limit 19 ng/L.
† Recommended clinical threshold of NT-proBNP 125 ng/L for age < 75 years and 450 ng/L for age ≥ 75.
Elevated hscTnT and NT-proBNP have been shown in previous studies to be predictive of long-term cardiac events, and hscTnT has strongly correlated with NT-proBNP in the same studies. Syncope/near syncope may be the presenting event for these cardiac comorbidities and therefore portend increased risk of serious events. An abnormal serum concentration of hscTnT has been found to be an independent predictor of adverse outcome and risk of cardiac event in patients with hypertrophic cardiomyopathy. Elevation of hscTnT and NT-proBNP have been shown to be predictive of future cardiac events such as acute myocardial infarction, pulmonary embolus, and acute decompensated heart failure. This prior literature provides a conceptual foundation for why elevations of hscTnT and NT-proBNP in syncope/near syncope may be useful in predicting further cardiac events.

A major clinical challenge is identifying which patients presenting with syncope/near syncope would benefit most from hospital admission, observation, or discharge with outpatient follow-up. In our cohort, the majority of patients (79.5%) were admitted. hscTnT and NT-proBNP may help identify patients at low risk of subsequent short-term events who could be discharged. Likelihood ratios and predictive values confirm this (Tables 3 and 8). After patients who have obvious cardiac pathology after ED evaluation were excluded, cardiac biomarkers were able to identify patients with ≤2% risk of serious outcomes at 30 days (Table 7). This finding may inform shared decision making and disposition choices. The ability to safely discharge these patients may save unnecessary admissions and cost. This is an important finding in our study.

We found that hscTnT and NT-proBNP are independent predictors of short-term 30-day risk. These findings should be combined with other clinical data, such as known cardiac disease, historical elements, and findings on the 12-lead ECG to assess which patients can safely be discharged home after a syncopal event. Our findings can be used to inform the development of a comprehensive risk scoring system. To our knowledge, none of the published risk tools include these biomarkers.

**LIMITATIONS**

Our study does have limitations. We used data from a single blood draw, and it is possible that serial biomarker testing may provide additional prognostic information. Our study focused on older adults, as adverse outcomes and health service use are concentrated in this population. Our results will need to be verified in younger cohorts.

We analyzed NT-proBNP values, and these results may not be generalizable to other NT-proBNP assays. However, multiple studies in other disease states suggest that BNP and NT-proBNP are functionally interchangeable. We did not code symptomatic

---

**Table 6**

<table>
<thead>
<tr>
<th>hscTnT Value (ng/L)</th>
<th>OR Reference</th>
<th>OR (95% CI)</th>
<th>NT-proBNP Value (ng/L)</th>
<th>OR Reference</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>1.52</td>
<td>(1.21–1.92)</td>
<td>450</td>
<td>1.49</td>
<td>(1.24–1.78)</td>
</tr>
<tr>
<td>19</td>
<td>1.66</td>
<td>(1.25–2.20)</td>
<td>850</td>
<td>1.82</td>
<td>(1.39–2.38)</td>
</tr>
<tr>
<td>25</td>
<td>2.07</td>
<td>(1.38–3.09)</td>
<td>2000</td>
<td>2.38</td>
<td>(1.61–3.50)</td>
</tr>
<tr>
<td>50</td>
<td>2.57</td>
<td>(1.52–4.34)</td>
<td>4000</td>
<td>3.16</td>
<td>(1.88–5.30)</td>
</tr>
<tr>
<td>100</td>
<td>3.43</td>
<td>(1.73–6.80)</td>
<td>10000</td>
<td>3.92</td>
<td>(2.12–7.25)</td>
</tr>
</tbody>
</table>

hscTnT = high-sensitivity troponin; NT-proBNP = natriuretic peptide.

**Table 7**

<table>
<thead>
<tr>
<th>hscTnT (ng/L)</th>
<th>Absolute Risk</th>
<th>Risk (95% CI)</th>
<th>NT-proBNP (ng/L)</th>
<th>Absolute Risk</th>
<th>Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤5</td>
<td>0.02</td>
<td>(0.01–0.02)</td>
<td>≤125</td>
<td>0.02</td>
<td>(0.01–0.02)</td>
</tr>
<tr>
<td>5–19</td>
<td>0.04</td>
<td>(0.03–0.04)</td>
<td>126–450</td>
<td>0.04</td>
<td>(0.03–0.04)</td>
</tr>
<tr>
<td>20–25</td>
<td>0.06</td>
<td>(0.05–0.07)</td>
<td>451–850</td>
<td>0.05</td>
<td>(0.05–0.06)</td>
</tr>
<tr>
<td>25–50</td>
<td>0.07</td>
<td>(0.06–0.09)</td>
<td>851–2,000</td>
<td>0.08</td>
<td>(0.06–0.09)</td>
</tr>
<tr>
<td>&gt;50</td>
<td>0.14</td>
<td>(0.11–0.17)</td>
<td>&gt;2,000</td>
<td>0.15</td>
<td>(0.12–0.18)</td>
</tr>
</tbody>
</table>

hscTnT = high-sensitivity troponin; NT-proBNP = natriuretic peptide.
Table 8
Diagnostic Yield for 30-Day Serious Events Identified After Index ED Visit by hscTnT and NT-proBNP Cutoffs

<table>
<thead>
<tr>
<th>hscTnT</th>
<th>NT-proBNP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut Point</td>
<td>Sensitivity (95% CI)</td>
</tr>
<tr>
<td>5</td>
<td>0.934 (0.882-0.968)</td>
</tr>
<tr>
<td>19</td>
<td>0.592 (0.510-0.671)</td>
</tr>
<tr>
<td>25</td>
<td>0.467 (0.386-0.550)</td>
</tr>
<tr>
<td>50</td>
<td>0.257 (0.189-0.334)</td>
</tr>
<tr>
<td>100</td>
<td>0.138 (0.088-0.203)</td>
</tr>
<tr>
<td>250</td>
<td>0.046 (0.019-0.093)</td>
</tr>
</tbody>
</table>

hscTnT = high-sensitivity troponin; LR+ = positive likelihood ratio; LR- = negative likelihood ratio; NPV = negative predictive values; NT-proBNP = natriuretic peptide; PPV = positive predictive values.

CONCLUSIONS

In older adults who presented to the ED for evaluation of syncope, elevated troponin and natriuretic peptide levels are independent predictors of 30-day mortality and serious cardiac events. Future clinical decision making should consider these biomarkers.

Finally, the hscTnT assay was approved for clinical use in the United States in 2017, and this assay may not be currently available in many EDs. However, we believe that many EDs will continue to use hscTnT assays in the near future.

Supporting Information
The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13709/full

Figure S1. Event Rate vs Biomarker Levels
Figure S2. Event Rate vs log of Biomarker Levels
Table S1. Multivariate Model of 30-Day Outcomes, Multiple Imputation for Missing Data
Table S2. Multivariate Model of 30-Day Outcomes, Interactions Between Cardiac Biomarkers
ABSTRACT

Objectives: We wanted to estimate the frequency and describe the nature of emergency department (ED) procedural sedation restrictions in the State of California.

Methods: We surveyed medical directors for all licensed EDs statewide regarding limitations on procedural sedation practice. Our primary outcome was the frequency of restrictions on procedural sedation, defined as an inability to administer moderate sedation, deep sedation, and typical ED sedative agents in accordance with American College of Emergency Physicians (ACEP) guidelines. Our secondary outcomes were the nature of these restrictions, who has imposed them, why they were imposed, and the perceived clinical impact.

Results: We obtained responses from 211 (64%) of the 328 EDs. Ninety-one (43%) reported conditional or total limitations on their ability to administer one or more of the following: moderate sedation, deep sedation, propofol, ketamine, or etomidate. Thirty-nine (18%) reported total restriction of at least one of these—most frequently a prohibition of deep sedation (18%). Local anesthesia directors were the most frequently cited creators and enforcers of these restrictions. Some respondents reported that, due to these restrictions, they used less effective sedatives, they performed procedures without sedation when sedation would have been preferred, and they observed inadequate sedation and pain control.

Conclusions: In this statewide survey we found a substantial prevalence of practice limitations—mostly created by local anesthesia directors—that restrict the ability of emergency physicians to provide procedural sedation for their patients in accordance with ACEP guidelines. Deep sedation was prohibited in 18% of responding EDs. Our respondents describe adverse consequences to patient care.

Emergency department (ED) patients frequently require procedures that are either extremely painful (e.g., fracture reduction, abscess drainage, cardioversion) or emotionally distressing (e.g., facial laceration repair in a young child), and humane care in such circumstances often requires pharmacologic...
sedation and analgesia. Such procedural sedation has been a daily occurrence in United States EDs now for decades, with well-documented safety and efficacy.\textsuperscript{1–12}

The U.S. Centers for Medicare & Medicaid Services (CMS) has specifically acknowledged the special situation and training of emergency medicine: “The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity or mortality.”\textsuperscript{13} They continue: “... emergency medicine–trained physicians have very specific skill sets to manage airways and ventilation that is necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation.”\textsuperscript{13}

Procedural sedation protocols and privileging are governed at the local hospital level based on standards from the Joint Commission and CMS, and hospitals frequently differ in how they specifically implement and regulate such sedation.\textsuperscript{9–11} Despite compelling existing evidence of safety\textsuperscript{3–12} and the above CMS verification of emergency physician credentials,\textsuperscript{13} there remain frequent reports of EDs in which either specific sedation practices (e.g., deep sedation) or drugs (e.g., propofol) are restricted or prohibited by anesthesia chiefs or other hospital leaders.\textsuperscript{9–12}

Hospitals that restrict ED procedural sedation deny patients the benefits of optimal procedural comfort and anxiolysis and can force emergency physicians to administer alternative sedative agents widely regarded as less safe and less effective. A formal appraisal of the frequency and extent of such limitations could inform emergency medicine leaders and hospital policymakers and assist emergency physicians in California and elsewhere whose patients face local sedation care barriers. We administered a statewide ED survey to assess the frequency and nature of ED procedural sedation restrictions, including who has imposed them, why they were imposed, and the resulting clinical impact.

**METHODS**

**Study Design and Setting**

We administered a survey to all licensed general and pediatric EDs in the State of California. The board of the California Chapter of the American College of Emergency Physicians (ACEP) and the Loma Linda University Institutional Review Board approved the study.

**Selection of Participants**

We downloaded the most recent (2016) hospital utilization database available from the California Office of Statewide Health Planning and Development (OSHPD, \url{https://www.oshpd.ca.gov}). This database includes all licensed California hospitals and itemizes numerous information fields including license type, ED volume, trauma center designation, and teaching hospital status. We then crosschecked it against OSHPD’s licensed facility listing effective December 31, 2017, to identify recent changes.

We then matched this database with names and e-mail addresses of ED medical directors known to California ACEP, and by personal knowledge of the study authors, and validated the information against the hospitals’ website and/or calling the hospitals directly. Throughout this document we use the term “medical director” to refer to the physician in charge of the ED, while recognizing that in some locations this individual might be referred to as chief, chair, or other designation.

**Survey Instrument**

The survey instrument was drafted by the authors, vetted by a convenience sampling of sedation experts and medical directors, and then modified to incorporate their suggestions and clarify confusing elements. It was then pilot tested on a separate sample of 10 California ED medical directors and again refined based on this feedback. The final survey instrument (Data Supplement S1, Web Appendix A [available as supporting information in the online version of this paper, which is available at \url{http://onlinelibrary.wiley.com/doi/10.1111/acem.13619/full}) was produced in paper and electronic (Qualtrics Inc.) formats.

**Interventions**

In February 2018 the survey was sent to ED medical directors with available e-mail addresses electronically, and to all others, paper versions were mailed by the postal service to either their name or “Emergency Department Medical Director” at their hospital’s official mailing address. Confidentiality for the responses was assured; however, the surveys were not anonymous to prevent duplicate responses and to permit recontacts to nonresponders.

We sent repeated e-mail reminders to nonrespondents beginning 2 weeks after the survey was first sent and a repeat mailed copy of the paper survey to all nonrespondents. We made telephone contacts to nonresponding EDs to encourage survey completion and
contacted leaders at multiple large ED groups and asked them to encourage their medical directors to participate. When medical directors were nonresponsive after repeated contacts, we then networked to identify staff emergency physicians active at missing facilities and asked them to complete the survey.

Outcomes
Our primary outcome was the frequency of restrictions on procedural sedation, defined as an inability to administer moderate sedation, deep sedation, and typical ED sedative agents (propofol, ketamine, midazolam, fentanyl, etomidate) in accordance with ACEP sedation guidelines.3–5,7,8 Our secondary outcomes were the nature of these restrictions, who has imposed them, why they were imposed, and the perceived resulting clinical impact.

We preplanned that if we encountered a frequency of restrictions high enough to power a multiple logistic regression, we would additionally analyze independent predictors of such restrictions. Preselected candidate variables taken from OSHPD data were ED annual volume, population served (general vs. pediatric), ownership (government, nonprofit, for profit), teaching hospital (yes/no), and trauma center designation (yes/no); from census data (https://factfinder.census.gov/ faces/nav/jsf/pages/index.xhtml) was the population density (people per square mile) based on hospital zip code; and from survey responses was the presence or absence of 24-hour coverage with a physician who is certified or eligible to be certified by the American Board of Emergency Medicine (ABEM) or the American Board of Osteopathic Emergency Medicine (ABOEM).

Data Analysis
We descriptively report all results, except for the logistic regression which we performed using Stata 15.1 (StataCorp).

RESULTS
Characteristics of Study Subjects
Figure 1 outlines the identification of statewide hospital EDs and the resulting survey responses. We received responses from 211 (64%) of the qualifying EDs. When contrasted with responding EDs, nonresponding EDs were lower volume and in hospitals more likely to be for profit and nonteaching (Table 1). Eighty percent of responding EDs

![Figure 1. Identification of licensed California EDs and survey response](image-url)
reported 24 hours of daily coverage with a physician who is certified or eligible to be certified by ABEM or ABOEM, with 91% reporting 12 or more daily hours of such coverage (Data Supplement S1, Web Appendix B).

**Main Results**

Ninety-one (43%) of the 211 responding EDs reported conditional or total limitations on their ability to administer one or more of the following: moderate sedation, deep sedation, propofol, ketamine, midazolam, fentanyl, or etomidate. Thirty-nine (18%) reported total restriction of one or more of these sedation levels or drugs—most frequently deep sedation (18%). Table 2 details the distribution of these limitations. In associated free-text comments, respondents frequently reported the need for special tests and other credentialing requirements even when they regarded their sedation practice as unrestricted.

Although limitations were more frequent in EDs without 24-hour ABEM/ABOEM coverage, conditional or total limitations were present in 38% of EDs with full 24-hour coverage, and total limitations of one or more sedation states or sedative agents were present in 14% (Data Supplement S1, Web Appendix B).

For those EDs reporting conditional or total limitations (n = 91), the most frequently cited creator and enforcer of these restrictions was the anesthesia director (Table 3A). Common reasons used to support these restrictions were Joint Commission standards, anesthesia chief’s personal judgment, CMS regulations, and American Society of Anesthesiology (ASA) guidelines (Table 3B). The most commonly described alternative care provided due to these restrictions is the use of less effective or less safe sedatives, having anesthesia on call or sending patients to the operating room, or performing procedures without sedation in situations where sedation would have been preferred (Table 3C). The most commonly cited clinical results of these alternative care options were inadequate levels of sedation and pain control, extended ED stays, and less safe sedation conditions (Table 3D).

Seventy-three (35%) of EDs overall report limitations (whether conditional or total) on the ability of an emergency physician to simultaneously perform the procedure and oversee sedation (Table 4). Although nurses widely administer fentanyl and midazolam, in most EDs physicians must “push the plunger” for propofol administration and often are required to personally administer ketamine and etomidate as well (Table 5).

**Predictors of Sedation Restrictions**

Given that we had 91 EDs reporting limitations we were able to perform our multivariable analysis using all seven preplanned predictor variables (Table 6)—none of which were found to independently predict sedation restrictions.

**DISCUSSION**

In this statewide survey we found that 43% of responding EDs report limitations to their procedural sedation practice, in noncompliance with ACEP
Responses to Question (n = 211): “What Is the Current Status of Procedural Sedation Practice and Agents in Your ED? (Answer Only for Procedural Sedation, Not Other Indications Like Rapid Sequence Intubation, Postextubation Sedation, etc., and These Questions Refer to Specific Restrictions Related to Sedation Depth or Agent, Not Policies Applicable to All Sedation Like Standard Personnel and Monitoring.)”

<table>
<thead>
<tr>
<th>We Can Freely Administer; No Restrictions</th>
<th>We Can Administer in Some or Many Situations (Explain)</th>
<th>We Are Not Permitted to Administer</th>
<th>Other, Explain</th>
<th>Missing Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Moderate sedation”</td>
<td>176 (83)</td>
<td>32 (15)</td>
<td>1 (0.5)</td>
<td>1*</td>
</tr>
<tr>
<td>“Deep sedation”</td>
<td>128 (61)</td>
<td>41 (19)</td>
<td>37 (18)</td>
<td>2†</td>
</tr>
<tr>
<td>Propofol</td>
<td>146 (69)</td>
<td>49 (23)</td>
<td>13 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Ketamine</td>
<td>174 (82)</td>
<td>33 (16)</td>
<td>2 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>199 (94)</td>
<td>7 (3)</td>
<td>2 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Midazolam</td>
<td>197 (93)</td>
<td>10 (5)</td>
<td>1 (0.5)</td>
<td>0</td>
</tr>
<tr>
<td>Etomidate</td>
<td>177 (84)</td>
<td>28 (13)</td>
<td>3 (1)</td>
<td>1†</td>
</tr>
</tbody>
</table>

Data are reported as n (%).

*“We don’t use the moderate and deep sedation terms.”
†“Hospital policy says ‘deep sedation’ is done in the OR. We continue to try to re-name our sedation to ‘procedural sedation’ to avoid the moderate or deep sedation terminology.”
‡“Our facility does not use etomidate.”

Comments from EDs not permitted to administer one or more of the above:
- No deep sedation. All of our procedural sedation is labeled as “moderate sedation.”
- Anesthesiology does not allow propofol.
- All drugs are fine for moderate sedation. Deep sedation not allowed for procedures.
- ED physician may do moderate but not planned deep sedation.
- Our facility is permitted to use moderate sedation only.
- Can do moderate in ED but not deep.
- We are technically not allowed to perform “deep sedation” in the ED.
- Moderate procedural is permitted if nursing ratios are adequate.
- Anesthesia is available if we need propofol.
- Small community hospital, single coverage, practices by general med staff somewhat behind from EBM.
- We are currently negotiating with anesthesia about propofol. Currently no propofol in ED. If you want it must be given by anesthesia. This may change in next 1–2 months.
- Do not have propofol or etomidate in ED.
- Anesthesiology will not allow us to use propofol.
- For any possible deep sedation, we are to call CRNA (we are currently clarifying our procedure).

Comments from EDs permitted to administer in some or many situations (selected; see Data Supplement S1, Web Appendix C, for complete responses):
- The younger anesthesiologists are more likely to agree with ACEP’s sedation guidelines, but they are held to the ASA’s guidelines. We had to agree to strictly follow ASA guidelines to use propofol. Because we must wait 8 hours to give propofol, we seldom use it.
- Propofol only for ventilator pts needing sedation.
- We can only use deep sedation medications by MD who are credentialed. The credentialing is extremely difficult requiring physicians to do repeat courses to obtain privileges.
- ER doc needs to be “deep sedation privileged.”
- If viewed as necessary when risks vs. benefits considered in context of OR or other options.
- We are required three proctored cases with protocol before we can use it freely.
- Each emergency physician (or other specialist administering deep sedation) must complete an online course prior to being granted privileges. This includes radiologists, intensivists, orthopedists, and emergency physicians. The course is provided by the hospital and is not difficult to complete.
- Usually depends on the indications and has to be documented prior to administration of medications.
- Etomidate, propofol and ketamine are automatically regarded as deep sedation drugs.
- Propofol requires 8 hours of NPO (solids) by hospital policy. Ketamine is officially under the same policy but the ED follows the ACEP guidelines for sedation with this medication.
- Can only sedate ASA I or II.

Comments from EDs reporting unrestricted use of all of the above:
- We fought this battle when we first took the contract. All attendings take a sedation test coordinate with the anesthesia department. Then they go through a proctoring process: 3 deep sedations (IV ketamine propofol, etomidate) and they get signed off on moderate and deep sedation and can perform independently. Currently only ICU/ER physicians outside of anesthesia have this privilege.
- Can administer meds but need to be proctored for 3 “deep” cases (IV ketamine, propofol, etomidate) which would cover “moderate” sedation (IM ketamine, fentanyl, versed) and need to pass the sedation test. And these privileges are renewed with recredentialing every 2 years.
- We were just advised that we’ll have to be ACLS/PALS certified to administer sedation.
- All ED physicians have to pass a competency test provided by anesthesia department.
- Just need extra privilege granted by med staff.
- There is sedation credentialing and testing, but once approved we are able to utilize all of the above drugs in the ED.
- Required to complete a training module prior to receiving privileges.
- We have an annual procedural sedation module that must be completed online and must pass the test at the end of the module.
- My biggest barrier is not a hospital policy, but rather not having appropriate staff present such as nurses that aren’t credentialed to participate in sedation.
- We can do deep or moderate sedation. We all have to take a test to obtain the privilege.
- We have to take a simple competency test once every 2 years.
- We (new ED docs) take a competency test when you apply for privileges.
- Need to have sedation privileges—renewed every 2 years. Requires passing a written test and showing you have adequate number of cases.
sedation guidelines and at variance with the CMS acknowledgement that emergency physicians “are uniquely qualified to provide all levels of analgesia/sedation.”

Our surveyed ED medical directors report occurrences of adverse clinical consequences, with patients not receiving optimal alleviation of their procedural pain and anxiety in accordance with current and widely accepted standards of care.

Most concerning is the prohibition of deep sedation at 18% of our responding EDs. Deep sedation is now a well-established core skill in our specialty, is widely and safely practiced, and has a substantial supporting literature. It has permitted our patients to receive humane and effective relief of pain and anxiety during extremely painful emergency procedures for which moderate sedation alone is typically inadequate, e.g., cardioversion, fracture reduction, and joint dislocation reduction.

Why are ED practice restrictions so prevalent? They are not required or even encouraged by the Joint Commission or by CMS. They instead result from local sedation policies and protocols created by anesthesiologists or other hospital leaders based on local biases and unduly conservative visions of regulatory compliance. We found that such restrictions could not be predicted by hospital type, ED volume, or local population density, supporting an idiosyncratic impact of these local political forces. Such restrictions of procedural sedation practice are paradoxical in that emergency physicians are automatically and fully credentialed for rapid sequence intubation—a far more technically and cognitively complex intervention. The political issues and motivations that have prevented organized anesthesiology from acknowledging emergency medicine sedation skills have been reviewed in detail elsewhere.

The free-text comments from multiple EDs indicate that their emergency physicians are frequently not fully credentialed for procedural sedation in the same fashion as their other clinical practice credentials, but rather are required by their anesthesia director and/or hospital to pass extra tests or undergo proctoring to obtain such privileges. This is not necessary or appropriate, as the core curricula of emergency medicine residency and fellowship training programs include broad training in advanced airway management,

---

**Table 3A**

<table>
<thead>
<tr>
<th>Restriction source</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia medical director, chief, or chair</td>
<td>56 (62)</td>
</tr>
<tr>
<td>Emergency department medical director, chief, or chair</td>
<td>15 (16)</td>
</tr>
<tr>
<td>Hospital administration</td>
<td>15 (16)</td>
</tr>
<tr>
<td>Hospital medical staff or medical executive committee</td>
<td>27 (30)</td>
</tr>
<tr>
<td>Hospital-wide sedation committee</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Unknown or other, please specify below.</td>
<td>5 (5)</td>
</tr>
<tr>
<td>No response to question</td>
<td>8 (9)</td>
</tr>
</tbody>
</table>

Selected illustrative comments: see Data Supplement S1, Web Appendix D, for complete responses:
- Historical anomaly. Anesthesia thinks propofol is “too dangerous” for ERPs to administer.
- Anesthesia has responsibility for all sedations in our hospital. They listen to our input but follow ASA guidelines, not ACEP’s.
- Nursing leadership, anesthesiology.
- The deal was brokered through the P&T committee.
- Input from anesthesiology but ED makes their policy.
- Clinical pharmacist.

Complete “unknown or other” text responses:
- ED director + anesthesiology director, then executive committee.

---

**Table 3B**

<table>
<thead>
<tr>
<th>Restriction reasons</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia chief’s personal judgment</td>
<td>20 (22)</td>
</tr>
<tr>
<td>Joint Commission standards</td>
<td>21 (23)</td>
</tr>
<tr>
<td>CMS regulations</td>
<td>16 (19)</td>
</tr>
<tr>
<td>ASA guidelines</td>
<td>18 (20)</td>
</tr>
<tr>
<td>ACEP guidelines</td>
<td>9 (10)</td>
</tr>
<tr>
<td>Department of Public Health, state or local</td>
<td>8 (9)</td>
</tr>
<tr>
<td>Concern regarding insufficient emergency physician sedation skills</td>
<td>7 (8)</td>
</tr>
<tr>
<td>Unknown or other, please specify below.</td>
<td>26 (29)</td>
</tr>
<tr>
<td>No response to question</td>
<td>13 (14)</td>
</tr>
</tbody>
</table>

Selected illustrative comments: see Data Supplement S1, Web Appendix D, for complete responses:
- [Hospital chain redacted] pushed out a systemwide sedation policy and essentially forced MECs at each hospital to adopt. The references were primarily ASA and CMS literature and guidelines, with very little attention to ACEP or EM literature.
- Deep sedation. Anesthesia can administer. Limiting factor—getting them to come on.
- Nursing has erroneously misinterpreted California Department of Public Health all-facilities letter.
- 1) Liability concerns—if we have readily available CRNA, a poor outcome would be indefensible. 2) Traditionally we’ve used the readily available CRNA and only recently have we added ER physicians with significant procedural sedation experience.
- California Nurses Association.
- New chief of anesthesia is negotiating with ED for use of propofol.
- Awaiting discussion with anesthesia regarding these matters.

Complete “unknown or other” text responses:
- Hospital policy.
- Awaiting discussion with anesthesia regarding these matters.
- Policies were in place prior to our contact.
- Head of ICU has concerns.
- In general, we are trusted to use our judgment.
resuscitation, critical care and vascular access, monitoring, pharmacology, minor surgical techniques, and training and practice in moderate, deep, and dissociative sedation and pain management. Emergence physician sedation and rescue skills are a core skill for the specialty.

Table 3C
Questions Posed Only to EDs With Conditional or Total Limitations Reported in Table 2 (n = 91): “Given the Above Restrictions, What Is the Alternative Care Being Provided? (Rank the Most Common as a “1,” the Second Most Common as a “2,” and so on, While Designating With an “X” Any Alternatives That Essentially Never Occur.)”

<table>
<thead>
<tr>
<th>Alternative Care</th>
<th>First Most Common</th>
<th>Second Most Common</th>
<th>Third Most Common</th>
<th>Fourth Most Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of less effective or less safe sedatives in situations where other agents would be preferred</td>
<td>27</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Performance of procedures without sedation in situations where sedation would have been preferred</td>
<td>4</td>
<td>15</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Procedures performed instead in the operating room</td>
<td>7</td>
<td>5</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Anesthesia service on call to provide the needed sedation care</td>
<td>10</td>
<td>4</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Unknown or other, please specify below.</td>
<td>15</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Selected illustrative comments: see Data Supplement S1, Web Appendix D, for complete responses:
• Transfers to other facilities.
• Anesthesia states they are available, but then usually refuses to come to the ED to assist.
• We still perform all necessary sedations in the ED and call them “moderate sedation.”
• We are quite comfortable with ketamine, which is our usual medication. We would rather get experience with propofol but with the restrictions are less likely to use it.
• We still use the drugs but its a hassle when we have to push our own drugs and do the procedure.
• We are providing sedation, and for deep we would send to the OR. The only difference is the MD will push the medication.

Complete “unknown or other” text responses:
• We are providing sedation and for deep we would send to the OR. The only difference is the MD will push the medication.
• Transfers to other facilities.
• Two providers required for all procedural/moderate sedation. Can cause delays waiting for second provider.
• We still continue with the propofol for our conscious sedation with just document that the physician administered the medication.
• ED physicians push propofol or ketamine if needed.
• No significant restrictions that completely restrict use of any agent.
• I’ve seen no instances where patients did not receive appropriate sedation or inadequate procedural performance in our department.
• N/A.

Table 3D
Questions Posed Only to EDs With Conditional or Total Limitations Reported in Table 2 (n = 91): “What Is the Clinical Result of Using the Alternative Care Options in the Last Question? (Check All That Apply.)”

<table>
<thead>
<tr>
<th>Result of Alternative Care</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate levels of sedation and pain control</td>
<td>29 (32)</td>
</tr>
<tr>
<td>Less safe sedation conditions</td>
<td>19 (21)</td>
</tr>
<tr>
<td>Procedures that are hurried and less thorough than would be optimal</td>
<td>14 (15)</td>
</tr>
<tr>
<td>Extended ED stays</td>
<td>28 (31)</td>
</tr>
<tr>
<td>Procedure delayed because it cannot be performed in the ED</td>
<td>16 (18)</td>
</tr>
<tr>
<td>Unknown or other, please specify below.</td>
<td>26 (29)</td>
</tr>
</tbody>
</table>

Selected illustrative comments: see Data Supplement S1, Web Appendix D, for complete responses:
• Typically patient forced into the OR at 10x the expense for brief procedures usually carried out in the ED.
• Requires transfer to higher level of care occasionally.
• At times a short wait for anesthesia. But usually available quickly.
• Transfers.
• We mainly use ketamine, which has more side effects and a longer ED stay than propofol.
• Possible admissions if deep required.

Complete “unknown or other” text responses:
• No known clinical result.
• Transfers.
• Possible admissions if deep required.
• Requires transfer to higher level of care occasionally.
• There is policy confusion and the risk that our malignant, mercurial medical staff will accuse us of practicing outside of our scope.
• Delay waiting for second provider.
• N/A.
• None. It is very rare to use sedation in age less than 6 months.
• No detriment to service as we are performing sedation at the level we feel indicated.
• Patient safety in those rare situations when needed.
More than one-third of our EDs reported restrictions or prohibition of the emergency physician performing the procedure while simultaneously overseeing sedation (Table 4). Although such a precaution may be considered optimal for elective procedures, there is a longstanding track record of emergency physicians simultaneously performing procedures while managing moderate, dissociative, and deep sedation and without evidence of any increased frequency of clinically important adverse events or outcomes.\textsuperscript{3,14–17} The presence of two emergency physicians is frequently a physical impossibility in many lower-volume EDs, and thus any restriction threatens the ability of the emergency physician to provide humane, effective relief of procedural pain and anxiety.

The majority of EDs surveyed reported that physicians were required to personally administer propofol when used for procedural sedation, and more than one-third were similarly required to administer their own ketamine and etomidate—despite nurses being able to administer these same drugs when used for rapid sequence intubation. ACEP supports the

**Table 4**

<table>
<thead>
<tr>
<th>Response</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always emergency physicians are permitted to perform the procedure and simultaneously oversee sedation.</td>
<td>125 (60)</td>
</tr>
<tr>
<td>Sometimes emergency physicians are permitted to perform the procedure and simultaneously oversee sedation (specify restrictions below).</td>
<td>42 (20)</td>
</tr>
<tr>
<td>Never can emergency physicians perform the procedure and simultaneously oversee sedation.</td>
<td>31 (15)</td>
</tr>
<tr>
<td>Unknown or other, please specify</td>
<td>4*</td>
</tr>
<tr>
<td>Missing response</td>
<td>10</td>
</tr>
</tbody>
</table>

“I believe there is a policy restricting us from doing both simultaneously but we often violate the policy because of limited provider resources, i.e. overnight shift, pediatrics and APPs who are unable to provide the required services, etc.”

**Table 5**

<table>
<thead>
<tr>
<th>Response</th>
<th>Nurses Usually Administer</th>
<th>Physicians Must Administer</th>
<th>Other, Explain</th>
<th>Missing Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propofol</td>
<td>41 (19)</td>
<td>148 (70)</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Ketamine</td>
<td>92 (44)</td>
<td>96 (45)</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>175 (83)</td>
<td>22 (10)</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>Midazolam</td>
<td>174 (82)</td>
<td>24 (11)</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Etomidate</td>
<td>110 (52)</td>
<td>81 (38)</td>
<td>6</td>
<td>14</td>
</tr>
</tbody>
</table>

Data are reported as n (%). Selected illustrative comments: see Data Supplement S1, Web Appendix F, for complete responses.

• Nurses can give IM ketamine for sedation. Physicians administer it if IV is the route.
• Propofol and all “deep sedation” must be administered by the physician, but what counts for that (etomidate, ketamine, brevital) is less clear so some RNs will push it but some will not.
• Both our nurses and our docs think this is ridiculous.
• Physicians are supposed to administer ketamine, but in practice nurses do it.
• Nurses just received “green” light to push ketamine.
• Seems less safe for MD providers to push IV meds only for this as they seldom do this.
• I feel strongly that the above is ludicrous and has no safety benefit or medical basis.
• Restrictions only for intended deep sedation.
• Nurses can push ketamine in subdissociative doses for pain control and can give IM ketamine for sedation. Physician had to push IV for sedation.
• DNV surveyor (an anesthesiologist) told us that for deep sedation the physician has to be the one who pushes the plunger. In order for our hospital to pass his inspection we had to change our deep sedation documentation sheet to demonstrate that the propofol was being pushed by the physician. He also required that we show that this deep sedation sheet was being filled out contemporaneously during the case, not afterward.
• Nurses by policy are allowed to push these medications in the ER. Sometimes the physician will push based on provider preference.
these responding physicians identified themselves as the general reliability of these responses. Many of deep sedation and so we have no reason to doubt whether they can administer propofol, ketamine, or other emergency physicians working at that facility. directors (due to their nonresponse), but instead byveys were completed not by current ED medical widespread barriers to optimal patient care. sedation privileges, our respondents still describe less, even if all of the nonresponsive EDs have full frequency of sedation restrictions in our state. Neverthe-estimate but cannot reliably establish the true fre-achieve a 64% response rate. Our results therefore repeated contacts and mailings, we were only able toThe principal limitation to our survey is that, despite repeated contacts and mailings, we were only able to achieve a 64% response rate. Our results therefore estimate but cannot reliably establish the true fre-edom to variably and arbitrarily designate ketamine sedation as moderate sedation, deep sedation, or gen-eral anesthesia. Accordingly, there may be variance in how those surveyed responded based on their local categorization for the effects of this drug. To address this concern, our survey queried restrictions based both on sedation level and by drug. This ensured that we would capture hospital restrictions specifically focused on one or the other.

We asked respondents to identify the alternative care being provided in the presence of sedation restrictions. These responses are of necessity the perceptions of those surveyed and cannot be independently confirmed. Finally, our survey was limited to a single state, which may not be representative of other states or regions.

CONCLUSION

Our statewide survey found a substantial prevalence of practice limitations—mostly created by local anesthesia directors—that restrict the ability of emergency physicians to provide procedural sedation for their patients in accordance with American College of Emergency Physicians guidelines. Our respondents describe adverse consequences to patient care.

Table 6
Multivariable Regression Predictors of Procedural Sedation Limitations \( (n = 196)^* \)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric-only ED(^1)</td>
<td>7.40 (0.66–83.5)</td>
</tr>
<tr>
<td>Ownership</td>
<td></td>
</tr>
<tr>
<td>For profit</td>
<td>Reference</td>
</tr>
<tr>
<td>Nonprofit</td>
<td>1.11 (0.45–2.73)</td>
</tr>
<tr>
<td>Government</td>
<td>2.20 (0.69–6.98)</td>
</tr>
<tr>
<td>Teaching hospital</td>
<td>0.51 (0.15–1.75)</td>
</tr>
<tr>
<td>Trauma hospital</td>
<td>0.67 (0.29–1.54)</td>
</tr>
<tr>
<td>Population density (people/square mile)</td>
<td></td>
</tr>
<tr>
<td>Quintile 1 (2 to 2,462)</td>
<td>Reference</td>
</tr>
<tr>
<td>Quintile 2 (2,525 to 3,625)</td>
<td>1.04 (0.38–2.82)</td>
</tr>
<tr>
<td>Quintile 3 (3,690 to 4,721)</td>
<td>1.12 (0.40–3.13)</td>
</tr>
<tr>
<td>Quintile 4 (4,730 to 7,500)</td>
<td>1.39 (0.49–3.94)</td>
</tr>
<tr>
<td>Quintile 5 (7,608 to 19,288)</td>
<td>1.35 (0.48–3.84)</td>
</tr>
<tr>
<td>24-hour continuous ABEM/ABOEM coverage</td>
<td>0.46 (0.19–1.08)</td>
</tr>
</tbody>
</table>

\( \text{ABEM} = \text{American Board of Emergency Medicine}; \text{ABOEM} = \text{American Board of Osteopathic Emergency Medicine.} \)

\( ^* \)This analysis excludes eight hospitals for which ED volume was unavailable, and seven for whom respondents did not specify the presence or absence of 24-hour ABEM/ABOEM coverage. The area under the model receiver operator curve was 0.666. The model demonstrated satisfactory goodness-of-fit, with the Hosmer-Lemeshow, \( p = 0.140. \)

\( ^\dagger \)Compared to EDs serving general populations.

qualifications of ED nurses to administer any sedative agent while under the direct supervision of the ordering physician.\(^3\) Regulations that restrict such nursing practice lack an evidentiary basis.\(^3\)

LIMITATIONS

The principal limitation to our survey is that, despite repeated contacts and mailings, we were only able to achieve a 64% response rate. Our results therefore estimate but cannot reliably establish the true frequency of sedation restrictions in our state. Nevertheless, even if all of the nonresponsive EDs have full sedation privileges, our respondents still describe enough other restrictions to suggest substantial and widespread barriers to optimal patient care.

A further limitation is that 17% of returned surveys were completed not by current ED medical directors (due to their nonresponse), but instead by other emergency physicians working at that facility. Few emergency physicians should be confused as to whether they can administer propofol, ketamine, or deep sedation and so we have no reason to doubt the general reliability of these responses. Many of these responding physicians identified themselves as former medical directors or as other administrators within their group, e.g., quality improvement, regional director.

Another potential limitation is that dissociative sedation\(^1,7\) is omitted from regulatory entity (i.e., Joint Commission, CMS) documentation and from many specialty society sedation guidelines, leaving individual hospitals to variably and arbitrarily designate ketamine sedation as moderate sedation, deep sedation, or general anesthesia. Accordingly, there may be variance in how those surveyed responded based on their local categorization for the effects of this drug. To address this concern, our survey queried restrictions based both on sedation level and by drug. This ensured that we would capture hospital restrictions specifically focused on one or the other.

We asked respondents to identify the alternative care being provided in the presence of sedation restrictions. These responses are of necessity the perceptions of those surveyed and cannot be independently confirmed. Finally, our survey was limited to a single state, which may not be representative of other states or regions.

CONCLUSION

Our statewide survey found a substantial prevalence of practice limitations—mostly created by local anesthesia directors—that restrict the ability of emergency physicians to provide procedural sedation for their patients in accordance with American College of Emergency Physicians guidelines. Our respondents describe adverse consequences to patient care.

References


Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13619/full

Data Supplement S1. Supplemental material.
Emergency Medical Services Administration of Systemic Corticosteroids for Pediatric Asthma: A Statewide Study of Emergency Department Outcomes

Jennifer N. Fishe, MD, Shiva Gautam, PhD, Phyllis Hendry, MD, Kathryn V. Blake, PharmD and Leslie Hendeles, PharmD

For children with an asthma exacerbation, systemic corticosteroids (CS) administered in the emergency department (ED) decrease hospital admission rates and ED length of stay (LOS).1–4 Time-dependent effects favor earlier CS administration, ideally within the first hour of ED arrival.2,3 Only one pediatric study has examined if earlier emergency medical services (EMS) administration of CS improves patient outcomes.5 That study found decreased hospital admission rates and ED LOS after adding dexamethasone to intravenous (IV) methylprednisolone as options for pediatric asthma. However, the study was of a single EMS agency and overall EMS CS use was low (<20%).5 To date, no large study has examined pediatric asthma outcomes after EMS treatment. This study’s objective was to examine a statewide population of pediatric asthma patients to determine the effects of EMS administration of CS on ED outcomes.

This was a retrospective observational cohort study of pediatric asthma patients treated by EMS from 2011 to 2016. Patients were identified from Florida’s EMS Tracking and Reporting System (EMSTARS) database. EMSTARS contains information on ED outcomes for patients deterministically linked to the Agency for Healthcare Administration (AHCA) database of hospital and ED information. Both the study institution and Florida DOH Institutional Review Boards approved the study (IRB201702645 and Protocol 180000U11, respectively). This study was funded by the National Center for Advancing Translational Sciences of the National Institutes of Health under awards KL2TR001429 and UL1TR001427.

Inclusion criteria were patients 2 to 18 years of age, transported by EMS to an ED, with an EMS provider primary impression of respiratory distress, and who were administered albuterol at least once to indicate...
an acute asthma exacerbation. Patients were excluded if they were classified as a trauma/injury, seizure, pregnancy-related complication, or interfacility transport. Patients less than 2 years of age were excluded to avoid confounding with wheezing from bronchiolitis. Patients who were not successfully linked with the AHCA database were excluded.

Emergency department discharges to home, law enforcement custody, or a psychiatric facility were classified as discharges. Admissions to the same facility and transfers to another facility (ED or inpatient) were classified as admissions. We chose to classify transfers to another ED (even if subsequently discharged) as admissions because most pediatric interfacility transports are for inpatient admission.6 ED LOS was documented by hour, not minute, which precluded further LOS analysis.

Demographic, clinical, and EMS variables were analyzed using descriptive statistics. Continuous variables were compared using Student’s t test and Kruskal-Wallis tests, as appropriate. Categorical variables were compared using the chi-square test or Fisher’s exact test, as appropriate. Missing data were excluded.

To determine EMS administration of CS’s association with ED discharge, we used candidate variables identified by univariate analysis to create a parsimonious logistic regression model using forward selection. Propensity scoring with a nearest-neighbor 1:1 matching algorithm was also used to compare more homogenous case (received CS) and control (did not receive CS) pairs. Statistical analysis was performed using SAS version 9.4.

Of the 388,187 patients ages 2 to 18 years in the EMSTARS database from 2011 to 2016, 11,667 met the study’s definition of an asthma exacerbation. Of those patients, 3,812 had known ED outcomes. During the EMS encounter, in addition to albuterol, 37.7% of patients received nebulized ipratropium bromide and 9.7% of patients received CS in the form of IV methylprednisolone (only nine patients received dexamethasone; therefore, dexamethasone was excluded from further analyses). Most patients (75.3%) were discharged from the ED. Significant differences between admitted and discharged patients included age, race, initial prehospital heart rate, respiratory rate, pulse oximetry, respiratory effort, level of alertness, and EMS administration of magnesium sulfate or epinephrine (all p < 0.001).

In the final adjusted model, receiving CS from EMS was associated with decreased odds of ED discharge (odds ratio [OR] = 0.7, 95% confidence interval [CI] = 0.5–0.9). Other significant variables associated with ED discharge are detailed in Table 1.

The propensity score was comprised of variables significantly associated with receiving CS from EMS: scene and transport time; systolic and diastolic blood pressure; sex; EMS administration of ipratropium bromide, oxygen, magnesium sulfate, normal saline, and subcutaneous epinephrine; IV access; electrocardiogram; and “adult assessment” (treating the patient as an adult rather than a child). The propensity score (reflecting the probability of receiving CS) was associated with significantly decreased odds of ED discharge (OR = 0.3, 95% CI = 0.2–0.6). Propensity scoring produced 266 matched pairs. Among those pairs, EMS administration of CS did not have a significant effect on ED discharge (chi-square p = 0.25; logistic regression OR = 0.8, 95% CI = 0.6–1.2).

To date, this is the largest study linking EMS administration of CS with pediatric asthma patients’ ED outcomes. This study found that EMS administration of CS was associated with decreased odds of ED discharge. Several potential reasons for this result (which conflicts with ED studies) are revealed by the data. First, few patients received CS from EMS (<10%), in contrast to ED studies where the vast majority of patients were given CS.1–3 In this study CS were reserved for more severe patients, as evidenced by the propensity score’s association with significantly decreased odds of ED discharge.

### Table 1: Significant Predictors of ED Discharge for Pediatric Asthma Patients treated by EMS

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate</td>
<td>0.98</td>
<td>0.97–0.98</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>0.98</td>
<td>0.96–0.97</td>
</tr>
<tr>
<td>Pulse oximetry</td>
<td>1.04</td>
<td>1.02–1.06</td>
</tr>
<tr>
<td>Glasgow Coma Scale score</td>
<td>1.27</td>
<td>1.17–1.37</td>
</tr>
<tr>
<td>EMS scene location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare facility</td>
<td>0.29</td>
<td>0.21–0.39</td>
</tr>
<tr>
<td>Public building</td>
<td>1.84</td>
<td>1.20–2.82</td>
</tr>
<tr>
<td>Business</td>
<td>1.69</td>
<td>1.12–2.54</td>
</tr>
<tr>
<td>Lights and sirens</td>
<td>0.71</td>
<td>0.59–0.85</td>
</tr>
<tr>
<td>EMS destination decision: physician choice</td>
<td>0.27</td>
<td>0.13–0.59</td>
</tr>
<tr>
<td>Labored respiratory effort</td>
<td>0.80</td>
<td>0.66–0.98</td>
</tr>
<tr>
<td>Fatigued respiratory effort</td>
<td>0.51</td>
<td>0.30–0.85</td>
</tr>
<tr>
<td>Systemic corticosteroid administration</td>
<td>0.71</td>
<td>0.54–0.95</td>
</tr>
<tr>
<td>Magnesium sulfate administration</td>
<td>0.30</td>
<td>0.17–0.53</td>
</tr>
<tr>
<td>EMS procedure: suction</td>
<td>0.24</td>
<td>0.07–0.89</td>
</tr>
</tbody>
</table>

Multivariable logistic regression model: Akaike Information Criterion = 3131.0, area under the curve = 0.77, Hosmer and Lemeshow goodness-of-fit test = 0.92.
discharge and its composite variables. Additionally, a prior study of ED administration of CS showed more pronounced benefits to patients with mild and moderate exacerbations. Our results may reflect a population of severe patients who were likely to be admitted to the hospital regardless of EMS interventions.

An important question raised is why were CS reserved for only severe patients? The vast majority of CS were administered in the form of methylprednisolone, with only nine administrations of dexamethasone. Methylprednisolone administration requires IV placement, which may not be otherwise necessary for a mild or moderate asthma patient. Additionally, studies of pediatric IV placement by EMS show low percentages of attempts. Yet based on publicly available EMS protocols, IV methylprednisolone is the most common form of CS authorized. Therefore there is a practical mismatch between ED research and guidelines incorporating oral CS and EMS protocols authorizing only IV CS.

The latest 2018 version of the National Association of State EMS Officials model clinical guidelines makes a first step in correcting that mismatch by listing oral dexamethasone after IV methylprednisolone as a CS option. That guideline also states that other CS formulations at equivalent dosing may be used. However, the NASEMSO guideline is not pediatric-specific and does not proscribe interventions by patient severity or EMS transport time. Only a prospective, pediatric-specific study can answer the those questions and ascertain if earlier, EMS-administered oral CS improve patient outcomes.

This is a retrospective study of one state and so its conclusions may not be generalizable to other areas of the United States. Only one-third of patients had known ED outcomes. We were unable to ascertain any medications patients received prior to EMS arrival or in the ED. It is possible that patients with asthma did not receive albuterol and were excluded; however, >99% of all pediatric respiratory distress encounters in EMSTARS were serviced by paramedics, who are licensed to give albuterol, suggesting respiratory distress from another source (e.g., pneumonia). Compared with previous EMS research, most variables in EMSTARS had few missing values.

In the largest study to date linking emergency medical services interventions to ED outcomes for pediatric asthma, corticosteroids administered by emergency medical services did not significantly affect ED discharge rates. Corticosteroids were administered to the most severe patients, perhaps due to emergency medical services protocols authorizing only intravenous methylprednisolone. To extend evidence-based pediatric asthma care beyond the ED, a prospective trial of oral corticosteroids administered by emergency medical services is warranted.

The study investigators acknowledge Steve McCoy; Brenda Clotfelter; Karen Card, DrPH; and Joshua Sturms from the Florida Department of Health’s Bureau of Emergency Medical Oversight for their assistance and data management. The study investigators also acknowledge Colleen Kalynch, Michelle Lott, and Justin Masud from the Department of Emergency Medicine, Division of Research, University of Florida–Jacksonville, and Alexis Thomas and Paul Zwic, from the University of Florida GeoPlan Center, for their assistance with this study.

References

Acut.e coronary syndrome (ACS) is the leading cause of worldwide mortality and morbidity.¹ The evaluation of suspected ACS typically occurs in an emergency department (ED) setting and accounts for over seven million annual ED visits in the United States.² Risk stratification with a careful history, examination, 12-lead electrocardiogram (ECG), and cardiac biomarkers is the cornerstone of the ED evaluation,³ but can be challenging due to atypical presentations of ACS.

Published risk scores may help to supplement clinical judgment in the assessment of patients with chest pain. The HEART score, derived in undifferentiated ED chest pain patients, has been validated in multiple settings⁴,⁵ and appears to have superior test characteristics compared to other risk scores.⁶,⁷ Values of the HEART score range from 0 to 10, and scores less than or equal to 3 identify very low-risk patients that potentially can be discharged safely without further immediate cardiac testing.⁷

Two of the HEART score components require physician interpretation: an assessment of how suggestive the patient’s presentation is for ACS (the “history”) and an interpretation of the ECG. There may also be variability in assessing the number of ACS risk factors. The inter-rater reliability of the HEART score appears to have been assessed in only one study to date,⁸ in which “substantial” (0.6 < κ < 0.8) inter-rater reliability was found. Inter-rater reliability is important because variations in scoring may affect management, particularly across the lowest risk threshold (HEART ≤ 3).

We prospectively evaluated the inter-rater reliability of the overall HEART score as well as the HEART score components of history, ECG, risk factors, and troponin individually. Our primary hypothesis was that the HEART score is reliable (κ > 0.6) for identifying low-risk (HEART score ≤ 3) adults presenting to the ED with chest pain.

This was a prospective cohort study of pairs of physicians who independently evaluated patients and then independently calculated HEART scores on each patient. No patient identifying information was collected. A full waiver of consent and HIPAA authorization was granted by the university institutional review board.

We identified pairs of attending and second- or third-year emergency medicine resident physicians who were working together in a single university ED. To mitigate against bias from limited clinical experience, we excluded pairs that included a first-year emergency medicine residents or rotating non-emergency medicine residents.

The unit of analysis was paired HEART ratings. Eligible encounters were for adult patients (age > 20 years) with a chief complaint of chest pain, for whom the treating team had ordered a troponin and 12-lead ECG and who were seen by two ED physicians.
Research assistants screened for eligible encounters between 7 AM and 11 PM, 7 days per week.

For each eligible physician pair and patient encounter, we collected data on all elements of the HEART score. Research assistants abstracted objective data on age from the electronic medical record.

The attending and resident physicians independently completed evaluations of the other elements of the HEART score, including history, ECG interpretation, risk factors, and troponin value (Data Supplement S1, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13665/full). The number of troponin tests for each patient was at the discretion of the clinical team but the HEART score was based on the first troponin. Each physician was blinded to the ratings of the other paired physician. The physicians rated the elements of the HEART score on a standardized form shortly after the patient encounter. From these data, we calculated overall HEART scores and subscale scores for each physician rating.

We calculated the kappa statistic and total agreement for dichotomized low-risk HEART rating (≤3) and for the ordinal subscale components (history, ECG, risk factors, and troponin), we used weighted kappa and total agreement statistics. Kappa statistics can be used when calculating inter-rater agreement for a dichotomous variable and weighted kappa statistics extend this to ordinal variables with greater than two categories. We calculated weighted kappa statistics and intraclass correlations (ICC) across all possible values (0–10) of the HEART score. ICC was calculated as the ratio of variance components produced by a oneway random-effects model and provides a way to quantify the degree of consistency between raters on the values of the HEART score by accounting for both the correlation and agreement. As a subanalysis, we compared agreement statistics between second and third year residents using a two-sample test of binomial proportions.

Our sample size calculation was based on a traditional Cohen’s kappa. We assumed 60% of each raters’ classifications would be for low-risk scores (i.e., HEART 0–3) and a modest-sized kappa, $\kappa = 0.5$, for a 0.05 alpha-level test. We required a sample size of $N = 300$ patients to attain statistical power of 80%. Data entry and management were performed with RedCAP. Analyses were performed using SAS 9.4.

We collected paired physician assessments on 311 patients from October 2017 through April 2018. (Participant characteristics are presented in Data Supplement S2, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13665/full.) Our participants were a mean (±SD) age of 55.8 (±14.6) years old and 173 (55.6%) were male. The mean (±SD) HEART score was 3.5 (±1.9). Approximately half (49.2%) of our patients had a HEART score of ≤3.

We calculated a kappa score for low risk (HEART ≤3) of 0.68 (95% CI = 0.60–0.77; Figure 1). There was 84.2% agreement between physicians on this dichotomized scale. Weighted kappa statistics for the individual HEART subscales ranged from 0.46 to 0.83. The weighted kappa statistic for the full scale of the HEART score (0–10) was 0.68 (95% CI = 0.64–0.72). The ICC was 0.86 (95% CI = 0.81–0.92) indicating good to excellent reliability (Data Supplement S3, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13665/full).

Of the five components of the HEART score, only the history component was significantly different between the attending physicians and second-year residents versus the attending physicians and third-year residents ($p \leq 0.01$), where the attending and second-year resident pairs had greater inter-rater reliability than the attending and third-year resident pairs.

The HEART pathway has been validated as effective in identifying patients with chest pain who can be safely discharged safely from the ED without further
immediate cardiac testing. Risk stratification tools such as the HEART score will have greater clinical utility if they can demonstrate robust inter-rater reliability. The only study known to these authors to have examined inter-rater reliability of the HEART score showed substantial inter-rater reliability ($\kappa > 0.6$) for classifying low risk patients (HEART $\leq 3$). Our study also found substantial ($\kappa = 0.68$) inter-rater agreement on this variable.

Our study was the first to examine the inter-rater reliability of four subscales of the HEART score (history, ECG, risk factors, and troponin). We found that the history and ECG components had lower agreement ($\kappa = 0.52$ and 0.46, respectively) compared to risk factors and troponin components ($\kappa = 0.67$ and 0.83, respectively). The history component was originally scored using a list of predefined, specific chest pain characteristics that were categorized as either suggestive or not suggestive of ACS. In our study, physicians scored the history as they do in clinical practice—without reference or strict adherence to such a list. Some of the disagreement in the score for history, therefore, may be attributable to variability in physician conception of what constitutes chest pain suspicious for ACS.

The agreement on ECG interpretation was comparable to other studies assessing inter-rater reliability of ED physician ECG reads. The fact that the agreement for troponin (an objective number that should have been easily classified) was less than 100% suggests that the physicians did not consistently score the variables fully utilizing all of the tools (electronic health record, HEART score calculator) available to them.

Our study had several limitations. First, while the physicians were blinded to each other’s HEART scores, they may have discussed some patients’ clinical picture prior to estimating their HEART score. This may lead to a bias toward higher levels of agreement.

Second, we utilized the kappa score to evaluate inter-rater reliability given strong precedent for this test in the health care literature, with $\kappa > 0.6$ indicating substantial inter-rater reliability. However, many clinical risk tools for chest pain in the ED setting aim for a negative predictive value of >99%—effectively, a miss rate of <1% for patients with a major cardiac event.

Third, our study examined patients who presented to the ED between 7 AM–11 PM. Patients who presented to the ED with chest pain between 11 PM and 7 AM may have different demographic and epidemiologic profile compared to patients at other times of day.

Finally, this analysis was performed at a tertiary care academic medical center ED. Our results may not be generalizable to the primary care, urgent care, or inpatient settings.

In conclusion, we found substantial inter-rater reliability of the HEART score to identify low-risk patients. Our findings support the adoption of the HEART score into ED chest pain management algorithms. Given the importance of accurate cardiovascular risk stratification in the ED, further studies should elucidate how higher concordance between providers might be achieved.

References

Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13665/full

Data Supplement S1. Evaluations of the other elements of the HEART score.

Data Supplement S2. Participant characteristics.

Data Supplement S3. Agreement statistics for dichotomous, ordinal and continuous data.
BACKGROUND
Unfortunately, physicians are not perfect. Mistakes are occasionally made, and those mistakes can harm our patients.1 Although patient well-being is the primary concern of every physician, the threat of malpractice looms large in medicine. A search on PubMed will reveal hundreds of papers discussing malpractice risk in emergency medicine, but very few address the risk for trainees. Medical care provided by trainees involves some added risks. In U.S. emergency departments (EDs), care provided by trainees has been associated with a higher chance of hospital admission and a longer length of stay in the ED.2 In an internal medicine setting, problems with handoffs, teamwork, and lack of supervision were identified as issues in trainee malpractice cases.3 However, little is known about the malpractice risk of emergency medicine trainees. This study aimed at identifying factors in malpractice claims naming resident physicians compared to claims that did not involve a trainee.4

ARTICLE SUMMARY
This is a retrospective observational study using a large malpractice claims database to compare emergency medicine malpractice claims involving trainees (resident physicians) to those not involving trainees. The Comparative Benchmarking System database covers more than 400 hospitals and 165,000 physicians, representing more than 30% of all malpractice claims in the United States. Malpractice claims were coded in a number of domains, including average payment, case severity, allegation type, whether a procedure was involved, the final diagnosis, and contributing factors. Over a 3-year period they identified 845 malpractice claims, 113 (13%) of which included a resident physician. The majority of cases were the result of a failure to make a diagnosis, delayed diagnosis, or misdiagnosis. The most common contributing factors were clinical judgment, communication, and documentation. A few minor differences were seen between the two groups, but those differences should be interpreted with caution considering the small numbers and observational nature of these data.

QUALITY ASSESSMENT
This observational study makes use of a very large database that includes over 30% of all malpractice claims in the United States, with most states represented. However, it is unclear whether this database is a representative sample. Malpractice systems vary significantly between states and even more so between countries. That variability probably decreases the external validity of these results outside of the regions.
included in the database. The Comparative Benchmarking System database is considered an industry standard, but we are unsure about the reliability of the data within the database. The authors report statistically significant differences for a number of outcomes, but those results should be viewed with caution. The total number of events was quite small, resulting in a low fragility index.\(^5\) In other words, it would have only taken one or two extra events for the results to become statistically insignificant. Furthermore, multiple comparisons were made without statistical adjustment for multiple comparisons. Finally, although a retrospective observational study was an appropriate design for the authors’ question, observational data are always limited by the potential for unobserved confounders. Residents might work in different hospital settings and see different patients than staff physicians. Patients may use different criteria when deciding whether to name a trainee in a lawsuit. Ultimately, from observational data, we can make conclusions about associations only.

**KEY RESULTS**

Over a 3-year period they identified 845 malpractice claims, 113 (13%) of which included a resident physician. In 45 cases (40%) the resident was the only person named. The majority of cases were the result of a failure to make a diagnosis, delayed diagnosis, or misdiagnosis. The most common contributing factors were clinical judgment, communication, and documentation.

Resident cases looked very similar to nonresident cases across most domains. There were a few statistical differences. The average losses incurred were lower for the resident cases ($51,163) than for the nonresident cases ($156,212). The final diagnosis in resident cases was more likely to be cardiac-related (19% vs 10%, \(p < 0.005\)) and less likely to be orthopedic (3% vs 10%, \(p = 0.01\)). Overall, there was not a statistical difference in whether a procedure was involved, but vascular (3% vs. 0%, \(p < 0.008\)) and spinal procedures (4% vs. 1%, \(p < 0.04\)) were both more common in the resident group.

**AUTHORS’ COMMENTS**

This is a valuable look into residents’ malpractice risk. Rather than focus on the small differences between the groups, our major takeaway is that in both groups’ clinical judgment, communication, and documentation were the most prevalent contributing factors. Ultimately, it is important to make a distinction between making an error and getting sued. The two are not necessarily related. We are not aware of any technique that is 100% protective against getting sued, so will instead focus on being kind, curious, and understanding with our patients, while practicing high-quality evidence-based medicine.
**Comments from Twitter**

SpaceMan Spiff (@movinmeat). Q—the $ per case cited in the episode—is that per case in which there was an indemnity payout, or was that across all cases? #denominatormatters

Dr. Gurley (@Tusm2013) responds: Thanks for the question. A—the $ per case was an average that included total incurred reserves made in indemnity and expenses on open cases and payments made in indemnity and expenses on closed cases Really the amount the insurance company set aside for open and closed cases.)

Allan McDougall (@phdhpe). Mistakes form the basis of some medical legal cases. But system complexity, patient complexity, team interactions, etc. also lead to patient safety incidents. We’ve explained our approach to researching these factors in a recent manuscript. #SGEMHOP https://twitter.com/CMPAme mbers/status/1035588288726396929.

Ken Milne (@TheSGEM): Hey @TUSM2013 Do you know if Rural EM docs get sued more often?

Dr. Gurley (@Tusm2013) responds: Hey @TheSGEM we don’t know if rural or docs are sued more. But something to look at in the future.

**TAKE-TO-WORK POINTS**

This observational study demonstrates that residents are also at risk of being sued and that the biggest contributing factors were clinical judgment, communication, and documentation. Although you can make no mistake and still get sued, the best approach is still to focus on providing great care in a kind and compassionate way.

**References**

Study Enrollment When “Preconsent” Is Utilized for a Randomized Clinical Trial of Two Treatments for Acute Agitation in the Emergency Department

Jon B Cole, MD, Lauren R. Klein, MD, MS, Samuel Z. Mullinax, MD, Kimberly D. Nordstrom, MD, JD, Brian E. Driver, MD, and Michael P. Wilson, MD, PhD

ABSTRACT

Background: Acute agitation in the emergency department (ED) represents a danger to both patients and their caregivers. Medication is often needed, and few high-quality randomized trials have evaluated the optimal drugs for this vulnerable population. In the United States, as of 2017, randomized trials of drugs typically cannot be conducted under Waiver of Consent (46 CFR 45.116), and Exception From Informed Consent trials (21 CFR 50.24) are limited to life-threatening conditions, are onerous, and require filing an investigational new drug application with the FDA. We sought to conduct a randomized double-dummy trial of inhaled loxapine versus intramuscular haloperidol + lorazepam for acute agitation in the ED by obtaining consent in advance (“preconsent”) in patients at risk of future agitation, allowing study drug administration up to 3 years later if the patient presented with acute agitation.

Objective: We sought to report the successful enrollment rate of patients preconsented at an earlier ED visit for this trial.

Methods: This was an analysis of patients age 18 to 64 with bipolar I disorder or schizophrenia preconsented for enrollment in the trial (clinicaltrials.gov, NCT02877108) conducted at a single urban academic center seeing approximately 60,000 patients per year. Eligible patients were assessed for capacity to consent by trained research associates, and informed consent was obtained at an ED visit for the possibility of administering drugs for agitation within the next 3 years. In the event the patient later presented to the ED and the attending physician deemed the patient required treatment for acute agitation, preconsent was confirmed and study drug would be administered.

Results: Over 67 days, 1,461 patients were screened in the ED, 269 had bipolar I or schizophrenia, 194 of whom had a contraindication to inhaled loxapine leaving 75 eligible patients; preconsent was obtained in 43 patients. Four additional patients who had not preconsented were consented for the trial in real time (three by surrogate, one patient had capacity while agitated) resulting in a total of 47 consented patients. Of these 47, a total of 12 were later removed from the study: 10 patients had unrecognized exclusion criteria for inhaled...
Acute agitation in the emergency department (ED) is common, representing up to 2.6% of all ED visits, and represents a danger to both patients and their caregivers. Medication is often needed to keep patients and caregivers safe while simultaneously facilitating a rapid assessment to rule out underlying critical illness. Few high-quality randomized trials have evaluated the optimal drug for this vulnerable population, and much of the existing evidence utilized by expert consensus panels is either retrospective or observational in nature. Thus, emergency physicians are subject to a dearth of high-quality evidence upon which to base pharmacotherapeutic choices for agitated patients.

In the United States, investigators may conduct studies without informed consent under one of two federal regulations: Waiver of Informed Consent (WIC; 46 CFR 45.116), and Exception From Informed Consent (EFIC; 21 CFR 50.24). Under WIC regulations the research must involve no more than minimal risk, meaning that the probability and magnitude of harm or discomfort anticipated in the research is not greater than encountered in routine medical examination and testing (21 CFR 50.3[k]). WIC has been utilized for many prospective comparative effectiveness investigations comparing standards of care, such as medical devices or clinical protocols. WIC trials have not generally been used for comparative drug investigations, such as randomized, blinded drug intervention trials. If such trials are intended, EFIC may be pursued. Per the current federal guidelines, EFIC trials must involve patients with a “life-threatening condition” where the proposed treatments are “unsatisfactory or unproven.” EFIC trials are more strictly regulated by federal agencies and have extensive and specific requirements that the investigators must meet.

Quality research on treating agitation has been profoundly limited by these issues surrounding consent. Because it is well established that the majority of agitated patients in the ED are incapable of giving meaningful informed consent, alternative consent methods must be employed. Agitation trials may not qualify for EFIC because agitation is not necessarily a “life-threatening condition.” WIC may not be appropriate because a blinded randomized drug intervention trial historically has been unlikely to be deemed minimal risk by local institutional review boards (IRBs).

Another option for consent in agitation trials that has been suggested by federal agencies is a “preconsent” method, where consent is sought in advance of agitation occurring. With this method, after preconsent is obtained, when patients present at a later time or date with agitation, they can be enrolled in the trial. To our knowledge, preconsent (or a similarly named method) has not been used to study agitation in the ED. We attempted this method of consent in a randomized double-dummy trial of inhaled loxapine versus intramuscular haloperidol plus lorazepam for acute agitation. The purpose of this study is to report our experience with obtaining informed consent with preconsent methodology.

METHODS

Study Design
This is an observational cohort study of patients screened and consented for a randomized trial examining treatments for acute agitation in the ED. This investigational trial that we screened and consented for was an analysis of ED patients age 18 to 64 with bipolar I disorder or schizophrenia in a double-blind, double-dummy, noninferiority study of inhaled loxapine (10 mg) versus an intramuscular injection of haloperidol (5 mg) and lorazepam (2 mg; hereafter referred to as the “investigational trial”). The trial was registered at clinicaltrials.gov (NCT02877108) and was expected to run for 2 years. The study was approved by the local institutional review board at each site.

Study Setting and Population
This study was planned to be conducted at two ED sites. Site A is a single urban university-based center seeing approximately 60,000 patients/year. Site B is an urban county Level I trauma center seeing approximately 110,000 patients/year. This study was funded...
by an Emergency Medicine Foundation grant that was sponsored by Alexza Pharmaceuticals. A stipulation of the grant was that inhaled loxapine was included as a study arm.

**Selection of Participants**

All available ED patients were approached consecutively to discuss participation in the investigational trial from 11 AM to 3 AM, 7 days per week. Trained research associates screened interested patients for eligibility criteria by administering a medical history survey using tablet computers running REDCap software. Patients were eligible to be included in the study if they were between 18 and 64 years of age, had a diagnosis of schizophrenia or bipolar I disorder, and did not meet any exclusion criteria. Patients were excluded if they were medically unstable (defined by the treating physician), pregnant, or breastfeeding; exhibiting acute respiratory symptoms; or reported a history of asthma, chronic obstructive pulmonary disease (COPD), acute narrow-angle glaucoma, Parkinson’s disease, central nervous system depression, comatose states, seizure disorders, or allergies to antipsychotics or benzodiazepines. Patient responses to screening questions were verified in the electronic medical record (EMR). As preconsent had never been attempted at either study site, making calculation of a necessary preconsent sample size impossible, we planned for recruitment to be ongoing throughout the study.

Research associates assessed all eligible patients for the capacity to consent. Informed consent was then obtained to allow for future administration of the study drug(s) for acute agitation within 3 years following the date of consent. In the event the patient later presented to the ED and the attending physician deemed the patient required treatment for acute agitation, preconsent was confirmed in the EMR and the patient’s enrollment in the trial was completed. This trial also stipulated two additional consent methods: 1) real-time consent from a legally authorized representative (LAR) if available and 2) consent from the patient, if deemed to have capacity to consent despite mild agitation, which was determined clinically by the ability to cooperate with the consent process and then quantified using the Positive and Negative Syndrome Scale Excited Component Subscale (PANSS-EC) score.

**Data Analysis**

For this study, we report the number of patients screened, consented, and enrolled in the investigational trial during the study period. All data are presented using descriptive statistics (Stata, Version 15).

**RESULTS**

Over 67 days, 1,461 patients were screened in the ED at site A: 269 had bipolar I or schizophrenia, 194 of whom had a contraindication to inhaled loxapine (most commonly COPD), leaving 75 eligible patients. In 43 of these patients, we successfully obtained preconsent. An additional four patients who had not preconsented were consented in real time: three were consented by a LAR and one patient was deemed to have capacity while agitated. This resulted in a total of 47 patients consented for the study.

Of these 47 patients, 12 patients were removed from the study prior to completion of enrollment and study drug administration: 10 patients had unrecognized exclusion criteria for inhaled loxapine, one patient later asked to be removed after preconsenting, and 1 surrogate immediately revoked consent real time.

Only two patients in total received study medication; neither was consented by preconsent: one was consented via a LAR the day of enrollment, and the other was mildly agitated and was determined to have capacity to consent. The remaining patient with a valid surrogate consent did not receive study medication. Enrollment is fully delineated in Figure 1.

**Study Termination**

Sixteen months after the grant was awarded (and 1 month after enrolling the first patient), the sponsoring agency terminated the contract for grant support of the study for not initiating the research project in a manner that would be sufficient to complete the study by the initial agreed upon date, and the study was closed before the study protocol could start at site B. Thus our results only reflect patients screened at site A over a period of 67 days, as the study never launched at site B. In total $122,550 of the $489,243 grant had been dispensed at the time of study termination. Approximately 300 hours were spent at site A by the primary investigator in preparation for the study initiation; 100 hours were spent at site B by the site primary investigator. The cause of the study closure was multifactorial. For example, the study initially suffered from administrative issues, as contract disputes delayed acceptance of the grant by
the university for 7 months after the grant was awarded.

**DISCUSSION**

In this randomized, blinded, clinical trial of two treatments for acute agitation secondary to bipolar I or schizophrenia, despite screening > 1,400 patients and obtaining preconsent in 43 patients, we were unable to successfully enroll a single patient using preconsent methods. Only two patients were enrolled in the trial: one who was deemed to have capacity to consent and one via a LAR. Because the study was slow to launch and progress for various reasons, including IRB concerns about the consent mechanism, the trial sponsor revoked funding, forcing the trial to close. These data suggest that utilization of preconsent may not be feasible for trials of agents to treat acute agitation in the ED, despite recommendations to use this consent method by federal agencies.

While patients have been successfully enrolled in randomized trials of parenteral treatments for agitation in either medical or psychiatric inpatient units using traditional methods of consent (either the patient consenting themselves or via LAR), enrollment in trials via these mechanisms in the ED is likely not feasible. First, while some mildly agitated patients may have capacity to consent, the preponderance of evidence suggests most agitated patients in the ED do not have capacity. A common reason is that, unlike inpatients, ED patients with acute agitation are frequently acutely intoxicated. Some have proposed the use of brief consent tools, such as the University of California at San Diego Brief Assessment of Capacity to Consent (UBACC) to mitigate this issue. One convenience sample found that when using the UBACC, 16 of 19 intoxicated ED patients were deemed to have capacity to consent. These patients had multiple ED visits and were studied as a cohort highly likely to return to the ED. The UBACC was applied when the patients were clinically sober after observation in the ED but still had elevated ethanol concentrations. This observation period limits the generalizability of these findings when applied to patients presenting with acute agitation, which, in the ED, is frequently due to acute intoxication. The UBACC when subsequently applied to a larger random sample of 415 acutely intoxicated ED patients shortly after a medical screening examination on ED arrival found that only 16 of 415 (3.9%) intoxicated ED patients had capacity to consent; furthermore, of these 16 patients, eight did not recall taking the assessment once clinically sober, suggesting that consent tools have limited utility in the intoxicated, agitated ED patient. Use of LARs to obtain consent may be possible for studies of some agitated ED patients; however, obtaining consent from a LAR for a patient with agitation who requires immediate treatment, such as in excited delirium syndrome, is not feasible because of the immediate need to treat the patient. Furthermore enrollment solely via LARs is
likely to result in a smaller sample skewed toward less ill patients with good social support, severely limiting the generalizability of the data. For example, in a previous randomized trial of three parenteral agents for acute agitation in the ED, of 144 enrolled patients only three were successfully enrolled via a LAR.²⁵

To obtain high-quality data and better inform practice, randomized trials of a broad range of agitated patients, including those who cannot consent, are needed. One mechanism to accomplish this is utilization of EFIC (21 CFR 50.24) for enrollment. EFIC trials have numerous requirements, including the fact that the condition to be studied must be life-threatening and that current treatments are unproven or unsatisfactory.²¹ Since EFIC trials are FDA regulated, investigators must also notify the FDA by filing an investigational new drug (IND) application after local IRB approval and completion of the other elements of EFIC, such as community consultation and public disclosure.²⁸ FDA has been inconsistent on whether or not they deem agitation in the ED to be a life-threatening condition. Martel et al.⁵ conducted a trial of three common intramuscular drugs on agitated ED patients utilizing EFIC; however, when researchers from the same institution approached the FDA about a follow-up trial, FDA did not approve the IND, citing insufficient evidence that the patients could not provide informed consent⁴ and that the researchers did not provide adequate evidence that agitation was a life-threatening condition. Of note, the FDA suggested the researchers pursue consenting “psychiatric patients highly prone to agitation” when they have capacity at another time, effectively suggesting preconsent be applied. Setting aside the fact that a substantial portion of ED agitation is due to acute intoxication, not psychiatric disease, this method of preconsent, in our current study, we found to be infeasible. FDA’s criticism of the life-threatening nature of agitation may be a more accurate rationale for not approving an EFIC trial; the life-threatening nature of agitation exists on a spectrum. While the most severe form of agitation, excited delirium syndrome, has an associated mortality rate of 8% to 16%,²⁹ a recent prevalence study of 1,146 agitated ED patients observed no deaths in the ED.¹ As currently written, there is a gap within the EFIC regulations for completion of randomized trials on therapies for agitation in the ED, with the possible exception of excited delirium syndrome, until the “life-threatening” clause is revisited.

Complicating the matter of using EFIC to study agitation further is the concept of treatments being “unproven or unsatisfactory.” Although scant comparative effectiveness trials of therapies for agitation exist, it is likely that over time supportive care has generally improved for this patient population. A parallel likely exists in a similar patient population with agitation: those with delirium tremens. The mortality rate for delirium tremens in the early 20th century was estimated at 70%.³⁰ As demonstrated in a retrospective analysis of patients with delirium tremens at an urban city hospital, mortality from delirium tremens dropped from 52% to 14% over a 20-year period from 1915 to 1935, largely due to advances in general supportive care.³⁰ However, it was not until a landmark double-blind study of four common agents used for alcohol withdrawal established the superiority of benzodiazepines for alcohol withdrawal³¹ that mortality for delirium tremens began to fall again to the 1% to 4% rate observed currently.³² It is likely the care of agitated patients in the ED has undergone a similar evolution as emergency medicine has become hypervigilant about the underlying critical illness agitation may represent.³ It is now standard of care that agitated patients are brought immediately to the ED by police and EMS and when indicated receive rapid sedation to prevent physical injury and metabolic derangements. Anecdotally, in the practice at site B, metabolic acidosis and restraint-related injuries were far more common before the more liberal use of both antipsychotics and sedatives for agitated patients.³³ This overall improvement in supportive care may be the reasoning for the FDA’s changed position on acute agitation as a life-threatening condition that qualifies for EFIC research. However, unlike delirium tremens, high-quality randomized trials have not yet defined which of several, commonly used treatments for agitation in the ED are superior. While medications such as benzodiazepines, antipsychotics, and ketamine all appear effective⁴,¹¹,³⁴ (and, perhaps, “proven and satisfactory”), some acutely agitated patients, such as those with sympathomimetic or novel psychoactive drug intoxication, still die.³⁵,³⁶ Great progress has been made thus far in the care of agitated patients; however, without high-quality randomized trials to better inform practice, we will not take the next step to advance care as we once did with delirium tremens.

Recently, some comparative effectiveness trials for agitation treatments have been published that utilized WIC (46 CFR 45.116).⁴,³⁷ This method observed
open-label changes to ED or EMS clinical protocols instituted by departmental leadership, in which one drug is recommended as the first-line agent for a period of time, followed by a change to a different first-line drug for a second period of time. Since this type of research is merely observation of the outcomes of the clinical protocols, which provided recommendations for all patients without regard to whether they were enrolled in the WIC study or not, an IRB may determine these studies do not exceed minimal risk and are therefore eligible for WIC. While this pragmatic method allows for gathering prospective data, it has significant limitations. First, it involves data collection in a nonblinded manner. Second, “before–after” designs are far more subject to secular trends, such as the sudden introduction of an abusable novel psychoactive substance in a community, that may disproportionately affect one arm in an adverse manner. Third, while the research activities (observational data collection) are minimal risk, the design of alternating clinical protocols offers no additional protections to the subjects compared to a blinded, randomized trial such as those conducted under EFIC, as in both approaches the patient receives a medication per protocol rather than by physician decision, although the protocol can be overridden in both designs. These recently published before–after studies, from a methodologic standpoint, are clearly inferior to higher-quality blinded randomized trials. A collaborative approach from investigators with expertise in emergency medicine, critical care medicine, medical toxicology, and emergency psychiatry, in conjunction with regulatory bodies such as the FDA and local IRBs, will be needed to design future research protocols to better study this patient population.

Fortunately there exists a potential pathway to conduct higher-quality comparative effectiveness trials of drugs in patients who cannot provide consent that are not necessarily in an immediate life-threatening condition, which encompasses the majority of agitated ED patients needing parenteral sedation. The 21st Century Cures Act, passed December 13, 2016, provides the FDA with the authority to permit an EFIC when proposed clinical trials poses no more than minimal risk to human subjects, provided that appropriate safeguards are in place to protect their rights, safety, and welfare. This new authority allows local IRBs to approve waived consent research for minimal risk comparative-effectiveness drug studies of two accepted standards of care, such as our proposed trial of inhaled loxapine versus haloperidol + lorazepam. In July 2017, the FDA issued guidance that until such regulations are finalized, FDA does not intend to object to a local IRB approving a waived consent study when the IRB finds and documents that traditional WIC criteria have been met (see Table 1). To our knowledge no such trial has yet been conducted under this new FDA authority, although one small randomized trial of midazolam versus haloperidol for prehospital agitation was conducted under WIC criteria prior to passage of the 21st Century Cures Act.

**LIMITATIONS**

This study has several limitations. Specifically the short study duration does not reflect the overall enrollment rate had the study been able to be conducted over the full 2-year period. The termination of the study before site B could launch also limits generalizability; in terms of successful preconsent enrollments we report only single-center data. However, the study period was truncated by the sponsor partly because of low enrollment, highlighting the limitation of this method. Substantial resources were committed to this trial with no successful preconsent enrollments. Even if preconsent were viable, the resources required to enroll enough patients would likely make trials for agitation treatments infeasible.

**CONCLUSIONS**

Utilization of preconsent to enroll patients in a randomized trial of parenteral treatments for acute agitation in the ED requires substantial resources and may not be feasible. New FDA authority may allow for Waiver of Informed Consent (45 CFR 46.116) for minimal risk clinical trials of drugs. Trials involving the highest-risk agitated patients, such as those with excited delirium, may qualify for Exception From
Informed Consent (21 CFR 50.24). Future comparative effectiveness trials on treatments for acute agitation in the ED are needed to advance care for this vulnerable patient population.

REFERENCES


Single Maintenance and Reliever Therapy (SMART) Regimen for Management of Persistent Asthma

Arjun Mohan, MD, Gregory D. Kearney, DrPH, MPH, and Andrew C. Miller, MD

<table>
<thead>
<tr>
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<td>For every 16 patients who took single maintenance and reliever therapy (SMART), 1 case of asthma exacerbation was prevented</td>
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<td>Benefits in NNT</td>
<td>NNT of 12 for prevention of one asthma exacerbation with SMART, compared to same-dose inhaled corticosteroid alone (NNT of 9 compared to higher dose inhaled corticosteroids alone)</td>
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<td>NNT of 16 for prevention of one asthma exacerbation with SMART, compared to the same dose of inhaled corticosteroid combined with a long-acting beta-agonist (NNT 37 compared to higher dose inhaled corticosteroid combined with a long-acting beta-agonist)</td>
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<td>Benefits in percentages</td>
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<td>6.3% lower risk of asthma exacerbation with SMART, compared to the same dose of inhaled corticosteroid combined with a long-acting beta-agonist (2.7% lower risk of asthma exacerbation when compared to higher dose inhaled corticosteroid combined with a long-acting beta-agonist)</td>
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<td>Harms in percentages</td>
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<td>Harm endpoints</td>
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<tr>
<td>Who was in the studies</td>
<td>22,748 patients (aged ≥ 5 years) with persistent asthma, already receiving inhaled corticosteroids from 16 randomized clinical trials</td>
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NARRATIVE

Asthma is a chronic respiratory disease affecting 235 million people worldwide,1 burdening both patients, their families, and society in terms of lost work and school, lessened quality-of-life, avoidable emergency department (ED) visits, hospitalizations, and deaths. Data from the Centers for Disease Control and Prevention report that asthma affects roughly 8% of the U.S. population (approximately 26 million people), accounting for 2 million ED visits, 480,000 hospitalizations, and 3,400 deaths annually with an economic burden of about $82 billion.2,3

The National Asthma Education and Prevention Program (NAEPP) guidelines (1991, 1997, 2002) were last updated in 2007 with the Expert Panel Report 3 (EPR-3). The NAEPP–EPR-3 guidelines highlighted a new focus on monitoring asthma control (degree to which manifestations are minimized by interventions)
compared to asthma severity (intrinsic disease intensity) as the therapeutic goal with new foci on impairment (symptom frequency, intensity, functional limitations) and risk (exacerbation likelihood, decline in lung function, medication adverse events). The stepwise treatment approach is illustrated in Data Supplement S1 (available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13659/full). For patients with worsening symptoms, a step-up in treatment may be indicated.

Given the shortage of primary care physicians, the ED is the primary source of care for many asthmatics, with asthma-related ED visits increasing by 13% over the past decade. Emergency physicians must be familiar with various proper treatment strategies. Single maintenance and reliever therapy (SMART) is an emerging strategy aimed at reducing asthma exacerbations. The aim of this evidence-based medicine summary is to familiarize emergency physicians with the SMART regimen. While we are keenly aware that some may perceive controller medication to be a primary care provider issue, the onus of mitigating asthma’s $82 billion footprint falls on all involved providers.

Patients with severe persistent asthma (3%–10% of asthmatics) have a sixfold higher risk of exacerbations and treatment costs compared to nonsevere asthmatics. Asthma therapy is centered on inhaled delivery of anti-inflammatory agents and bronchodilators. In the traditional stepwise asthma guideline regimen (Data Supplement S1), therapy is added based on symptom control, with most patients using separate inhalers for controller versus reliever purposes. Controller inhalers are typically an inhaled corticosteroid alone (ICSmono) or in combination with a long-acting beta-agonist (LABA), while relievers are typically short-acting beta-agonists (SABA; e.g., albuterol) or anticholinergics. During periods of worsened control, patients increase their beta-agonist therapy using the SABA reliever, and when control remains inadequate despite higher ICSmono doses a LABA is added. Recently, however, use of the ICS + LABA as both controller and reliever therapy has become popular, termed single inhaler therapy or SMART. Theoretical benefits for using an ICS + LABA combination such as formoterol-budesonide (Symbicort, AstraZeneca) for both roles includes: 1) ICS dose varies per symptoms and 2) LABA onset-of-action is nearly as rapid as SABA but allows for more sustained relief. Together, these may lower exacerbation rates. In this review (and the source meta-analysis), the terms same dose and higher dose reflect the controller ICS dose (not the LABA) in the traditional stepwise approach. Although used in the traditional stepwise regimen, SABA is not used in the SMART regimen.

The meta-analysis discussed here, assesses the effectiveness of the SMART regimen for decreasing asthma exacerbations defined as requiring systemic steroids (≥3 days), ED visit, hospitalization, intensive care admissions, or intubation. The meta-analysis included 16 randomized controlled clinical trials enrolling 22,748 patients. The SMART regimen was compared to same-dose ICSmono, higher-dose ICSmono, same-dose ICS + LABA, and higher-dose ICS + LABA. In patients ≥12 years of age, SMART reduced exacerbation rates compared to same-dose ICSmono (relative risk [RR] = 0.64, 95% confidence interval [CI] = 0.53 to 0.78, absolute risk difference [ARD] = 8.1%, number needed to treat [NNT] = 12; quality of evidence = moderate), and higher-dose ICSmono (RR = 0.59, 95% CI = 0.49 to 0.71, ARD = 11%, NNT = 9; quality of evidence = low). Additionally, SMART reduced exacerbation rates compared to same-dose ICS + LABA (RR = 0.68, 95% CI = 0.58–0.80, ARD = 6.3%, NNT = 16; quality of evidence = High), and higher-dose ICS + LABA (RR = 0.77, 95% CI = 0.60–0.98, ARD = 2.7%, NNT = 37; quality of evidence = high).

**CAVEATS**

There have been no additional trials published on this subject since this meta-analysis was conducted. Most trials had a low risk of bias for random-sequence generation, allocation concealment, incomplete data reporting, and other types of bias. Six studies had a high risk of bias for blinding methods (performance and detection biases) and nine had an unclear risk of bias for selective outcome reporting (reporting bias). This degree of performance, detection, and reporting bias may limit one’s capacity to make valid inferences about intervention effects. Unfortunately, a subgroup analysis after excluding these trials was not performed.

While statistical heterogeneity was low ($I^2 < 50$%), clinical heterogeneity was substantial. Studies variably included patients based on control and severity classification or symptoms. The existing discrepancies between the severity classifications schemes adds to this heterogeneity. For example, the NAEPP–EPR-3 uses symptom
severity, whereas guidelines by the American Thoracic Society and The European Respiratory Society (ATS/ERS) rely on medication need plus control. As emergency physicians’ encounter a wide range of asthma patients, baseline severity classification during the visit may not be as important as acute symptom management and return visit prevention.

Other outcomes (e.g. all-cause mortality) were rare. Most trials lasted only 6 to 12 months, so long-term outcomes data are not available. Improvement in forced expiratory volume in 1 second (FEV1) was inconsistently reported and fell short of the threshold difference of 0.2 L. Asthma control (defined by the asthma control test and the asthma control questionnaire) did not support the SMART regimen. Additionally, since the trials reported a composite endpoint, it is unclear which outcome(s) drove most of the result. Separating the outcomes would improve clarity; however, individual outcomes were rarely reported in the included trials. However, it is reassuring to note that this composite outcome (systemic corticosteroids, hospitalizations, and ED visits) is standard in most asthma trials.

While attractive, the SMART regimen has limitations. For example, the only SMART medication studied (budesonide-formoterol, Symbicort) was a dry powder inhaler, but only the metered-dose inhaler (MDI) is available in the United States. This may not be of great significance as data suggest therapeutic equivalence between the two forms.

Long-term SMART adherence also appears to be poor, with up to 53% of patients reinitiating their SABA reliever within 1 year. Of concern, physician insight into SMART application appears to be poor. In one study, 72% of physicians prescribed SMART, but a majority (91%) also prescribed a SABA at some point. Limited data also suggest that asthma control with combination budesonide-formoterol is poorer in younger patients (age < 30 years) and those with a newer diagnosis (<5 years). Moreover, the influence of additional factors (e.g., smoking) remains unclear.

Finally, cost may be a prohibitive barrier for some patients. It’s been reported that the annual (per-person) cost of asthma was $3,266 in 2013 ($1,830 for prescriptions), translating to roughly $82 billion per year. In multiple “Express Scripts Drug Trend” reports, asthma inhalers are consistently among the top 10 most expensive prescribed medications for a chronic condition, with costs increasing 50% on average since 2009. Symbicort costs $350 to $400 per inhaler in the United States. While it is tempting to assume that the SMART regimen would inflate costs by increasing Symbicort use, costs may be offset at least in part by decreased exacerbations (direct savings) and fewer work-days lost (indirect savings). Finally, it remains unclear how insurance companies will handle prescription reimbursement in the setting of decreased longevity of individual Symbicort MDIs. It is important to note that the U.S. Food and Drug Administration removed the Black Box Warning for ICS + LABA asthma medications in January 2018.

In conclusion, moderate quality evidence suggests that SMART decreases asthma exacerbation. However, possible harms associated with this treatment have not been assessed or reported. Therefore, we have assigned a yellow color recommendation (unclear if benefits) to this strategy.

Editor’s Note: Brass Tacks are concise reviews of published evidence. This series is a result of collaboration between Academic Emergency Medicine and the evidence-based medicine website, www.TheNNT.com. For inquiries please contact the section editor, Shahriar Zehtabchi, MD (Shahriar.Zehtabchi@downstate.edu).

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The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13659/full
Data Supplement S1. Description of asthma “Step Therapy” as described in the National Asthma Education and Prevention Program Expert Panel Report 3 (2007).
Prevalence of Pulmonary Embolism in Patients Presenting With Syncope

Brit Long, MD, Alex Koyfman, MD, and Michael Gottlieb, MD, RDMS

NARRATIVE

Syncope accounts for 1% to 3% of emergency department (ED) visits and 1% to 6% of hospital admissions. There are numerous etiologies, ranging from relatively benign vasovagal syncope to dangerous dysrhythmias. The ED evaluation and management of syncope is composed of history, examination, and typically an electrocardiogram, with further investigation dependent on clinical decision making and suspected conditions. Previously, pulmonary embolism (PE) was thought to account for a small minority of patients with syncope. However, a recent study by Prandoni and colleagues reported a high prevalence of PE in admitted patients with syncope (3.8% of ED patients and 17.3% of hospitalized patients). Evaluating for PE in all patients with syncope carries significant risks including radiation exposure, contrast-induced nephropathy, and adverse events from anticoagulation therapy. In this evidence-based review, we summarize and critically appraise a published meta-analysis that evaluated the overall prevalence of PE in patients presenting with syncope to provide guidance to clinicians regarding testing decisions in this population.

This meta-analysis included studies evaluating patients with syncope who presented to the ED or were admitted to the hospital that reported underlying etiologies, which included PE. There were no limitations on age, language, time, or setting, and to assess methodologic quality, authors modified an existing quality scale. The authors identified 1,920 studies, of which 6,608 ED patients (nine studies) and 975 hospitalized patients (three studies) presenting with syncope were included.

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571
which 12 papers (excluding Prandoni et al.) met inclusion criteria. Nine studies \( (n = 6,608 \text{ patients}) \) took place in the ED, and three studies \( (n = 975 \text{ patients}) \) occurred in the hospital environment. Weighted median age in ED patients was 61.5 years, compared to 67.1 years in hospitalized patients. PE was confirmed through computerized tomography angiography (CTA) of chest, ventilation perfusion scan, pulmonary angiography, or autopsy.

Results of the current meta-analysis suggest a low prevalence of PE in patients presenting with syncope: 0.8% (95% confidence interval [CI] = 0.5%–1.3%) in ED patients \( (\text{number needed to screen} = 125) \) and 1.0% (95% CI = 0.5%–1.9%) in hospitalized patients \( (\text{number needed to screen} = 100) \), with an overall prevalence of 0.9% (95% CI = 0.6%–1.3%).

**CAVEATS**

The meta-analysis discussed here had several important limitations. First, the authors included both prospective and retrospective data. Additionally, only four of the included studies discussed specific diagnostic strategies for PE in this meta-analysis. Another concern is that the authors utilized their own modified scale to assess methodologic quality, rather than using one of the more established tools, such as QUADAS-2 or the Newcastle-Ottawa criteria. Moreover, the decision to order CTA was mostly based on clinician judgment. Finally, the presenting symptoms, patient characteristics, and rationale for obtaining the CTA were not discussed in most of the included trials. While CTA of chest with contrast possesses high sensitivity and specificity for diagnosis of PE in low pretest probability patients, test characteristics decrease in patients with high pretest probability. Discordance among radiologists for diagnosis of PE can also be severe, with poor interreader reliability.

A second important consideration is that syncope has a significant number of potential etiologies, and determining a specific cause can be difficult. Therefore, as expected, clinical heterogeneity among the included studies was significant. Since the studies did not systematically screen for PE, it is unclear how many cases may have been missed. Follow-up for patients discharged from the ED to ensure they did not have PE was unclear in the majority of studies. Studies also demonstrated variable patient populations and baseline characteristics.

Most importantly, whether identifying these positive cases of PE affected long-term outcomes (e.g., mortality) of the patients is not known. PE can be asymptomatic and/or an incidental finding. A significant portion of patients demonstrate incidental PE at the time of autopsy, with rates ranging from 9% to 63%. Thus, PE may occur and resolve without clinical effect.

Another major caveat for diagnostic evaluation of syncope patients for PE is establishing causality. To cause syncope, a pulmonary blood clot must result in dysrhythmia, acute right ventricular failure, or a Bezold-Jarisch reflex. The literature suggests only PE located in the main pulmonary or lobar arteries are associated with syncope. However, in the study by Prandoni et al., approximately one-third of PE were segmental or subsegmental, which would be unlikely to result in syncope. Therefore, it is unclear whether the diagnosed PEs were associated with the syncope or incidental findings. Additionally, it is unclear how many cases were false positives due to imaging artifact.

Based on the low prevalence of PE in patients with syncope in this meta-analysis (low-quality evidence), dedicated testing for PE in all syncope patients is not recommended. Overtesting for PE may result in risks from the testing itself, as well as side effects from anticoagulation given in cases with false-positive test results or clinically insignificant cases. We assign testing for PE in all syncope patients red (harm > benefit). While consideration of PE in patients with syncope is warranted, the decision to trigger diagnostic evaluation for PE should be guided by proper risk stratification using history and physical examination.

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Psychiatric EMTALA Enforcement Has Gone Off the Rails: Comments on “Civil Monetary Penalties Resulting From Violations of EMTALA Involving Psychiatric Emergencies, 2002 to 2018”

The authors’ stated objective is to describe characteristics of EMTALA civil monetary penalties (CMPs) levied by the Office of Inspector General (OIG) between 2002 and 2018. However, the description provided is just the government’s version of the “description,” it leaves out the affected hospitals’ side of the story, and the authors’ statistical analysis of the penalties assessed overlooks known critical factors that could substantively undermine their conclusions.

For example, the case study provided by the authors is the AnMed Health case—which set off a firestorm in the hospital and emergency medicine community. It was the only settlement for which the authors obtained “reports from the EMTALA investigation.” They specifically state that they obtained the hospital’s corrective action plan, but don’t identify the others. They read “news reports” to better understand the context in which the hospital operated, although they don’t cite which news reports (some news reports were simply interviews of the OIG attorney who prosecuted AnMed, furthering her narrative of the case). There’s much more to the story, sourced primarily from the available FOIA documents.

Due to South Carolina’s budget woes the inpatient capacity at the state psychiatric hospital near AnMed was cut from 200 beds to 96 beds, which markedly increased the burden and boarding of psychiatric patients in AnMed’s emergency department (ED) and other referring hospitals. In an attempt to compensate, AnMed spearheaded an effort with the other hospitals to reopen, operate, and fund with their own money 15 inpatient beds at the state hospital and also established, again primarily with their own funds, an outpatient psychiatric...
treatment program to treat the patients after discharge from the hospital and diminish future ED visits, ED boarding, and repeated admissions. AnMed also aided psychiatrists in the county outpatient mental health clinics, who were similarly stymied by the lack of state inpatient beds, by allowing them to send their involuntarily committed patients to AnMed’s ED to be held and treated in its five-bed ED psychiatric unit until space opened up at the state hospital. Prior to the CMS EMTALA investigation and OIG monetary penalty, AnMed even received a commendation from the South Carolina State Director of Mental Health for its efforts to improve psychiatric health care in its community.

Years ago AnMed actually admitted both voluntary and involuntarily committed (IVC) patients to its psychiatric inpatient unit. One of its IVC inpatients burned himself to death, prompting the hospital to seek outside expertise to review its psychiatric services. The consultant advised the hospital to cease admitting involuntary patients because its psychiatric unit lacked the necessary physical plant, clinical and ministerial expertise, and security measures to appropriately and safely service the involuntarily committed population. The hospital board, after due consideration of the issues, converted the unit to accept only “voluntary” admissions that met the hospital’s published admission criteria. Historically, approximately 20% of the patients admitted under the voluntary status were indigent no-pay patients, and the payer mix of the admissions after CMS mandated that the hospital begin admitting IVC patients was about the same.

CMS and the OIG deemed that if the hospital could treat voluntary psychiatric patients on its inpatient unit then it could just as well treat involuntarily committed patients on its inpatient unit. This contention was undeniably belied by the fact that the hospital spent an extra $600,000 annually to meet acceptable standards of care for the IVC population. Besides, any experienced emergency psychiatrist will tell you that running a unit that accepts IVC patients is vastly different than a unit for only voluntarily admitted patients.

What was most disturbing is that the government was simply substituting its judgment about what services the hospital could or should provide over the considered judgment of the hospital’s governing board, the administration, and the medical professionals of what they believed the hospital could provide without seriously jeopardizing the safety of its other patients or even its own staff.

AnMed had another option to assure its compliance with EMTALA—close its inpatient psychiatric unit—an option it considered. However, it felt obligated to and wanted to meet the psychiatric needs of the community it served, so it accepted the cost, effort, and risk associated with upgrading its psychiatric inpatient unit to appropriately manage involuntarily committed patients.

When the study authors reviewed AnMed’s plan of correction they would not have found any disagreement with the CMS or OIG allegations because, first, there is no due process during the investigation and termination proceedings—the hospital has no recourse except to meet CMS’s demands or it is terminated from Medicare; and second, the CMS regional offices will not allow the hospital to present its factual and/or legal disagreements with the government’s assertions in the plan of correction, contrary to explicit direction from central CMS in Washington, DC, that the hospitals be allowed to include their disagreements in their submitted plan.\(^3\)

Examination of the 5-day and 60-day QIO physician reviews would have revealed three interesting items underpinning the settlements (the 5-day review is done at the time of the investigation for CMS to use in determining whether to cite the hospital for violating the law and the 60-day review, which allows the hospital a hearing to present its side of the case, is required before the OIG can assess a CMP).

First would be the striking misunderstanding of the EMTALA statute by the reviewing physicians. Second was the refusal of CMS and the OIG to provide a copy of the 60-day physician review to AnMed Health prior to the settlement negotiations, despite unambiguous federal regulations that specifically require the government to provide a copy to the hospital, not just the OIG\(^4\) (and that inexplicably the hospital’s attorneys failed to seek judicial enforcement of the regulations to obtain the report before negotiating with the OIG). Third, that after the hospital’s hearing with the QIO, the QIO reversed its 5-day review determination that the AnMed ED had transferred 20 patients in an unstable condition to the state psychiatric hospital. Instead, the QIO now opined in its 60-day report that “The patient was stabilized by the ED ‘in the sense that’ his/her condition was unlikely to deteriorate upon transfer.” This “sense,” which is the legally correct “sense,” was ignored by the OIG.

A review of the hospital’s submission for the 60-day QIO hearing addressing the CMS statement of
EMTALA deficiencies and the 5-day QIO physician review would have likewise afforded a thought-provoking counter to the settlement as described by the OIG on its website and the authors’ case study.

Specifically, the authors note that “while patients in the investigation received medical screening exams by an emergency physician, the facility [AnMed] was cited for failing to obtain psychiatric screening exams.” CMS and the OIG actually made a blanket assertion that EMTALA required the hospital’s on-call psychiatrist to personally come to the ED to screen and stabilize every patient who presented to the ED with psychiatric symptoms. In essence, the government claimed that residency-trained, board-certified emergency physicians were incapable of providing the appropriate screening and stabilization required by EMTALA for psychiatric patients.

But, the sole purpose of EMTALA’s required medical screening examination (MSE) is to simply determine whether or not an emergency medical condition (EMC) exists. Consequently, the only EMTALA duty of the physician performing the MSE is to determine whether the patient has an acute medical condition of sufficient severity that the absence of immediate medical attention could reasonably be expected to result in serious adverse consequences. That’s precisely the role and expertise of emergency physicians. Once the emergency physician determines an EMC exists, the MSE is legally completed, and there is no clinical rationale, nor is there any legal duty under EMTALA, to summon an on-call physician to the ED to “confirm” or “check” the emergency physician’s determination that an emergency condition exists.

Moreover, there is absolutely no obligation in the EMTALA statute, in CMS’s regulations, or in the EMTALA interpretive guidelines that requires an on-call psychiatrist to provide psychiatric screening or stabilizing treatment on behalf of the hospital. An on-call physician must provide care to patients in the ED under EMTALA only when requested by the emergency physician on-duty to assist in determining if an EMC exists or to stabilize an EMC, and this is true regardless if the medical condition is a medical problem, a surgical problem, a pediatric problem, a neurosurgical problem, or a psychiatric problem.

AnMed provided 24/7 mental health professionals (MHPs) under the direction of the on-call psychiatrist to assist the emergency physicians in screening and stabilizing psychiatric patients in the ED as needed. The on-call psychiatrist provided telephone consultation or in-person consultation in the ED whenever requested by the MHP or the emergency physician. CMS and the OIG also claimed that utilizing MHPs in this manner violated EMTALA, even though the EMTALA guidelines specifically allow a hospital to use nonphysicians under the direction of an on-call physician to provide screening or stabilizing services in its ED. The guidelines even state “in the event that the treating physician disagrees with the on-call physician’s decision to send a representative and requests the actual appearance of the on-call physician, then the on-call physician is required under EMTALA to appear in person.”

The authors also write that the OIG’s website description “indicates that the on-call psychiatrist was not following the medical staff rules and regulation regarding urgent consultations (a two hour requirement).” However, they would have noted that this “violation” was absent from the formal settlement agreement between the parties; the 2-hour rule applied to inpatient consults, not ED consults. In the ED, the psychiatrist on call was duty bound to present to the ED whenever requested by the emergency physician, just like any other physician on-call.

Finally, in their case study the authors’ state, “Additionally, though the on-call psychiatrist was prescribing treatment modalities to the ED provider when requested, CMS noted that they were not providing stabilizing treatment on a daily basis to the patients in the ED.” This is the crux of the entire issue of dealing with psychiatric patients under EMTALA. When is a psychiatric patient stabilized? The AnMed emergency physicians truly believed that they had stabilized the psychiatric patients and that while the on-call psychiatrists may have been needed to treat the patient’s emergency condition they certainly were not needed to stabilize the emergency condition.

The distinction between providing legally required stabilizing care compared to providing additional medical treatment poststabilization is what the government (and many a physician) fails to understand. EMTALA only requires stabilization of the patient’s emergency condition; it does not require definitive treatment of that emergency condition (or at least this used to be true prior to CMS’s recent misapplication of the law).

EMTALA defines “stabilized” to mean “with respect to an emergency medical condition... that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility.”
CMS’s own interpretive guidelines state that psychiatric patients are stable “when they are protected and prevented from injuring or harming him/herself or others.”

Consequently, once the hospital ED utilizes its usual interventions to “protect and prevent psychiatric patients from injuring or harming themselves or others” (medical clearance, searched, secured, removal of means and opportunity to harm self or others) and provides sufficient treatment to ensure that the patient’s condition is unlikely to deteriorate as a result of transfer, the patients with psychiatric emergencies have been “stabilized,” as that term is defined by EMTALA. Thereafter, the treatment on a “daily basis,” whether it’s while the patient is boarded in the ED or an inpatient setting is simply not governed by EMTALA. State licensing laws, Medicare Conditions of Participation, professional standards of care, or public pressure from society as a whole may necessitate the utilization of hospital resources post stabilization, such as consultation from a psychiatrist or inpatient admission, but not EMTALA. The law only reaches so far. It is up to Congress to extend the protection of EMTALA to other situations, if it so chooses, not the executive branch agencies such as CMS or the OIG.

The EMTALA interpretations by CMS and the OIG in the AnMed case so concerned the American College of Emergency Physicians (ACEP) that it invited a CMS representative and the OIG attorney who prosecuted AnMed to its national meeting in 2017 to discuss the issues. Emergency physicians were startled to learn that CMS and the OIG interpret EMTALA to mean that “suicidal patients remain unstable until no longer suicidal.” This explained why the agencies believed the care of boarded psychiatric patients is governed by EMTALA and why they believed AnMed (and many other hospitals) illegally transferred patients in an unstable condition when they transferred patients to state hospitals for economic reasons. (It is not illegal under EMTALA to transfer patients for economic reasons, provided that they are stabilized at the time of transfer.)

The interpretation proffered by CMS and the OIG is unquestionably wrong. It totally ignores the express definition of “stabilized” in the EMTALA statute, CMS regulations, and CMS’s EMTALA interpretive guidelines. It is also contrary to every single federal appellate court opinion on the definition of “stabilized” under the law. (For a detailed legal analysis of when psychiatric patients are stabilized under EMTALA see Bitterman.)

The American Hospital Association and Federation of American Hospitals also believe that the government has overstepped its authority and is misinterpreting EMTALA with respect to who can screen or stabilize psychiatric patients, when a psychiatric patient is stabilized, and which patients hospitals must admit to their inpatient psychiatric units. They recently sent an extensive white paper to the Chief Medical Officer of CMS expressing their concerns and requesting that CMS rein in the regional offices. ACEP is presently considering doing the same, again.

In their statistical analysis of the OIG’s assessment of CMPs under EMTALA, the authors conclude that settlements related to psychiatric emergencies compared to those for nonpsychiatric emergencies were more costly (~$85K vs. $32K), more frequently associated with multiple violations per settlement, more often associated with failure to stabilize violations, and constituted the vast majority of the largest settlements during the study period of 2002 to 2018. However, it is difficult to ascertain the meaning or the significance of these findings without considering the relevant variables governing CMPs that were not addressed in the study. These include the number of violations per settlement, the bed size of the hospital involved, and the time period of the violations and settlement.

Each settlement with a hospital may encompass only one violation from one patient encounter, or it may encompass many violations from many patient encounters, and a penalty can be imposed for each violation. The care of any one individual patient can and often does result in multiple violations. It would be more helpful to know how many violations there were per settlement when comparing the settlements.

Psychiatric settlements, particularly in recent years due to the change in the enforcement of the statute by CMS and the OIG, typically include more patients and more violations per patient than nonpsychiatric settlements because the violations often stem from a set hospital policy or practice, such as in the AnMed Health case, rather than the care of each individual patient.

The study also does not differentiate hospitals based on bed size. This is especially pertinent when comparing the amount of CMPs because the maximum penalty that can be assessed for each EMTALA violation is half as much for hospitals with less than 100 beds than for hospitals with 100 or more beds. What if the psychiatric settlements occurred at the larger
hospitals and the nonpsychiatric settlements came more from the smaller hospitals?

Additionally, both the maximum allowable penalty and the factors the OIG used to impose the penalties changed during the study period. The authors noted that the maximum penalty increased from $50,000 to $103,139 in 2016. The maximum also increased in 2017 and 2018 by an inflation factor and is now $106,965.13 Was there a disparity in the timing of the settlements, such that more of the psychiatric settlements, especially ones with more violations per settlement, occurred during the “larger penalty amount” period?

In late 2016 the OIG changed the factors it uses to determine the amount of penalty it could assess for EMTALA violations. These factors allowed for greater penalties than previously for the same conduct, although the factors themselves are applied exactly the same whether it is psychiatric violation or a nonpsychiatric violation. They also boosted the OIG’s ability to assess the maximum penalty in more cases.14 For example, the OIG deemed “aggravating circumstances” to include patient harm or even the risk of harm resulting from the EMTALA violation or the simple fact that the patient presented to the ED with an emergency condition. Moreover, the presence of any single aggravating factor was then sufficient to impose the maximum allowed CMP.14

What one cannot conclude under the study data is that one psychiatric-related violation of the statute was any more or less likely to result in a larger settlement with the OIG than was one nonpsychiatric violation of the statute. This apple-to-apple comparison would be more meaningful.

That “failure to stabilize” settlements were more common in psychiatric settlements can be explained, at least in large part, due to the fact that CMS and the OIG used a different (and improper) definition of “stabilized” in the psychiatric cases to assess the hospital’s care under the law than the definition of stabilized it used in the nonpsychiatric cases.

The fact that none of the CMPs for psychiatric emergencies were assessed against individual physicians is an interesting observation. Why did the OIG not seek to impose monetary penalties on the physicians in the AnMed case? It was the emergency physicians that failed to consult the on-call psychiatrist to screen and stabilize the psychiatric patients, it was the emergency physicians and/or on-call psychiatrists who allegedly failed to stabilize the patients in the ED, and it was the emergency physicians who allegedly inappropriately transferred the patients in an unstable condition to the state hospital. Perhaps the OIG did not really think the physicians’ actions violated the statute and it was just angry that the hospital boarded the patients for days on end instead of admitting them or arranging prompt transfer to an inpatient psychiatric hospital. It may have been less confrontational to settle with the impersonal bricks and mortar instead of making it personal with a named physician who would have been much more disposed to challenge the OIG in court to protect both reputation and pocketbook.

The study also found regional differences in the source of psychiatric violations resulting in CMPs, with Region IV in Atlanta well outside the norm, and the authors suggested that further work is needed to determine if this reflects inadequate psychiatric care or enhanced enforcement. They may want to include two additional possibilities—a regional staff harboring an overzealous agenda and/or simple incompetence in interpreting the law.

In conclusion, the authors are to be commended for raising the issues of psychiatric care under EMTALA and highlighting the difficulties hospitals and physicians have in managing these patients in compliance with the law. However, it is respectfully suggested that a little more homework is in order to verify their conclusions.

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In this issue of Academic Emergency Medicine, Viau et al.1 assess the yield of computed tomography (CT) of the head among patients presenting with syncope. The systematic review included a total of 17 studies (15 retrospective chart reviews and two prospective) that included adult emergency department (ED) patients presenting with the chief complaint of syncope or those admitted to the hospital for syncope. Approximately half of these ED patients underwent head CT with a 1.2 and 3.8% yield of serious intracranial conditions identified in admitted patients and ED patients, respectively. Serious intracranial conditions were selected based on clinical relevance, previous literature, and consensus among the coauthors.1 While this systematic review is not directly a diagnostic accuracy trial, it gives us an opportunity to discuss how to appraise the evidence pertaining to diagnostic tests within the context of clinical efficiencies in an era of value-based purchasing.

PARADIGM SHIFTS

Over the past 20 years there has been a shift in the understanding and approach to diagnostic testing in medicine.

1. Tests rarely produce yes and no answers. Better understanding of diagnostic test interpretation in the clinical setting has resulted in dismissing the notion of yes or no answers (i.e., rule in or rule out). Diagnostic tests, which include history, physical exam, labs, and imaging, typically change the probability of the disease or condition and the concept of test and treatment thresholds originated to assist in managing these posttest probabilities. If a test result increases the probability of the condition to a level beyond the treatment threshold, the probability is high enough to indicate that the benefits of treatment outweigh the harms. If the diagnostic test result reduces the probability of the disease below the test threshold (i.e., acceptable miss rate), the presence of the disease is unlikely enough that the clinician should consider other diagnoses to explain the patient’s symptoms. In cases where the posttest probability of the condition falls between these thresholds, additional testing will typically be necessary. These thresholds vary based on factors such as the severity of the medical condition and the potential benefits and harms associated with treatment.2 For example, the treatment threshold for uncomplicated urinary tract infection in a healthy young woman3 would be quite different from the treatment threshold for acute pulmonary embolism.4 In fact, statistical models can produce test and treatment thresholds for most medical conditions based on the operating characteristics of the tests as well as benefits and harms of treatment.5 For example, the test (synovial fluid white blood cell analysis) and treatment thresholds for septic arthritis in adults have been reported to be approximately 5 and 39%, respectively.6 This means that if the clinical probability of septic arthritis is below 5%, further testing might not be helpful (or even harmful). On the other hand, if the probability of septic arthritis is above 39%, treatment should be started as further diagnostic testing is not likely to increase the yield and could potentially harm the patient.6

2. Using likelihood ratios to measure probability of the disease. Likelihood ratios are the tools that are used to manage probability of the disease in diagnostic
testing. This initial probability of a disease is usually determined based on the prevalence of the disease or from previous studies and is called pretest probability. The pretest probability is determined before any medical history is obtained, any physical examination is performed, or any test is ordered. Each additional pertinent positive or negative information or test will change the pretest probability and produce a new probability called posttest or posterior probability. The change from one probability to another is possible because of likelihood ratios. The likelihood ratio for a positive test increases the probability of the disease and the likelihood ratio for a negative test decreases the probability of the disease. The extent by which the probabilities are changed depends on the numerical value of the likelihood ratios. As a rule of thumb, positive likelihood ratios more than 10 significantly increase the disease probability and negative likelihood ratios less than 0.1 significantly reduce it.

3. Focusing on what matters. Another shift in paradigm pertaining to diagnostic testing is measuring the value of a diagnostic test by its impact on patient-centered outcomes. Nowadays patients, clinicians, and payers require more than analytical or technical characteristics and accuracy from a diagnostic test. They would also expect the test to lead to health benefits. Highly accurate tests might not change the outcome of the patients. For example, N-terminal-pro brain natriuretic peptide (NT-proBNP) and brain natriuretic peptide (BNP) are very sensitive diagnostic tests in identifying acute decompensated congestive heart failure. However, the knowledge of these values rarely affects the patient-centered outcomes of patients with this condition.

Coronary angiography, a highly accurate diagnostic test in diagnosing coronary artery stenosis, might not be beneficial or could even be harmful. The extent by which the probabilities are changed depends on the numerical value of the likelihood ratios. As a rule of thumb, positive likelihood ratios more than 10 significantly increase the disease probability and negative likelihood ratios less than 0.1 significantly reduce it.

4. Diagnostic yield. In addition to accuracy, the value of a diagnostic test lies in the probability that it provides the information needed to establish a definitive diagnosis. The difference between diagnostic accuracy and diagnostic yield is that the latter varies in each clinical scenario. The diagnostic yield of CT scan of the head in patients with a focal neurologic deficit and for diagnosing stroke might be quite different from that of CT scan of the head for syncope for identifying a possible etiology. Diagnostic yield is generally higher when the probability of the disease is higher, and the test is used in a proper clinical context. This is impacted by spectrum bias: when patients are at the milder end of the disease spectrum, many tests are not definitive. Overuse of the test, whether because of a “just-in-case” strategy or defensive medical practice, significantly reduces the diagnostic yield. Routine ordering of coagulation profile (PT and PTT) in patients who are not on anticoagulants or have no evidence of liver failure is an example of a low-yield test. Blindly ordering tests with low diagnostic yield in any clinical scenario has implications for the patients, physicians, and also the laboratory. Overuse of tests and “overdiagnosing” may make the patients’ management more confusing and problematic. This practice may produce unexplained, abnormal results that generate additional testing that could be harmful to the patient. However, these harms are rarely measured as a quality indicator. In addition to overburdening the laboratories and radiology suites, overtesting certainly contributes to already inflated health care costs.

5. Do no harm. There is an increasing awareness that preventing medical harm must become one of the pillars of modern health care. Similar to treatment strategies, diagnostic tests are associated with harms. No test is perfect, so patients require nuanced decisions rather than groupthink conformity. Understanding of this concept has resulted in the proposal of a strategy called “deliberate clinical inertia.” This refers to the art of doing nothing as a positive response. Adopting deliberate clinical inertia, i.e., the art of not intervening, as a specific measurable indicator, would be a novel patient-centered quality initiative that could counterbalance the current perspective of overtesting. This overtesting reflects our cultural intolerance of uncertainty that drives imaging requests.
Developing skills in dealing with uncertainty, competing diagnostic approaches, harm–benefit trade-offs, societal pressures, and shared decision making is essential in developing deliberate clinical inertia. When these issues are explained to patients in a patient-friendly format, patients often choose the “less is more” option.\textsuperscript{14,15}

This approach is particularly important for heterogeneous conditions such as syncope. The systematic review by Viau et al.\textsuperscript{1} likely overreports the proportion having a serious diagnosis as the proportion of syncope cases undergoing head CT was only about half. It is very likely that patients with higher pretest probability of serious intracranial pathology were selected for head CT. This also means that doctors are already making patient-centered decisions without high-quality evidence, using information derived from experience and intuition (which is also a component of evidence-based medicine). Clinical training needs to go beyond robotic rule following to hone expert clinical judgment. Getting information (e.g., CT head) in the absence of judgment can be misleading, as we must have a pretest probability.

6. Using systematic reviews for assessing the accuracy of diagnostic tests. Systematic reviews with or without meta-analysis remain the highest level of evidence for assessing the diagnostic accuracy of diagnostic tests. However, the process is not as straightforward as interventions. Some of the challenges facing such systematic reviews are related to the method of reporting the results. It is not always feasible to distinguish the limitations in methodology of the original trials from limitations of reporting the results. Recently, most journals encourage investigators to follow specific guidelines for reporting their findings such as those recommended by STARD (Standards for Reporting of Diagnostic Accuracy) statement.\textsuperscript{16} Following these guidelines are a positive move toward standardized reporting of such trials, reducing the confusion when distinguishing methodologic flaws from reporting flaws. Unfortunately, such guidelines are frequently ignored in emergency medicine diagnostic trials.\textsuperscript{17} Another challenge of systematic reviews addressing diagnostic tests is difficulty in measuring publication bias.\textsuperscript{18} Currently, there is no registry for trials measuring the accuracy of diagnostic tests and it is not possible to predict which diagnostic test trial gets published and which ones do not.

Commonly, there are many differences in the design and quality of diagnostic accuracy studies. These differences (also known as heterogeneity) could affect the interpretation of their results. Heterogeneity may reflect differences between the studies in their definition of a positive test, study design, patient characteristics, place of test in diagnostic pathway, etc.\textsuperscript{19} Excessive heterogeneity might result in systematic biases and affect the estimates of diagnostic performance. Therefore, a structured appraisal of methodologic quality of studies included in the systematic reviews and meta-analyses is a critical step. The quality assessment is performed with the objective of evaluating the effects of potential sources of bias on estimates of test accuracy. Additionally, quality assessment allows for evaluating the effect of hypothesized clinical sources of heterogeneity on estimates of test accuracy. Unfortunately, when it comes to diagnostic testing accuracy, the use of statistical tests of heterogeneity does not reliably indicate absence of heterogeneity. It is recommended that the authors of systematic reviews assume the presence of heterogeneity and develop models that can identify heterogeneity and account for it.\textsuperscript{19}

While this systematic review fails to produce an exact diagnostic yield for CT scan of the head in patients with syncope due to certain limitations, it produces valuable information that could be used in clinical practice.\textsuperscript{1} The authors of the systematic review recommend estimating a pretest probability for serious intracranial pathologies for each patient with syncope before ordering the test. This pretest probability is estimated based on patients’ risk factors, possibility of other pathologies mimicking syncope (e.g., seizure), and also preferences. The authors suggest that when this assessment generates a low pretest probability, CT scan of the head should be deferred.\textsuperscript{1}

This systematic review also provides the opportunity to broaden our views of diagnostic testing in light of many recent paradigm shifts. There are many elements beyond diagnostic accuracy that should be considered before a test is ordered or interpreted. When benefits of the test in question are not clear or the possible harms are considerable, adopting a deliberate clinical inertia strategy might be a reasonable alternative to diagnostic testing. The benefits of this strategy should be explained to the patients and their families to ensure respect for the patient’s circumstances and preferences, and to incorporate them in the shared clinical decision-making process.
In summary, diagnostic strategies require adopting a global view and diligent consideration of patient-centered factors. As an anonymous proverb indicates, “For most diagnoses all that is needed is an ounce of knowledge, an ounce of intelligence, and a pound of thoroughness.”

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As health care providers we all seek to do good for our patients, or at the very least, do no harm. This core principle is and always should be independent of where one is educated or trains, specialty, practice setting, payer mix, etc. However, interlaced with this is a self-protective mechanism that draws a line in the sand when it comes to action or inaction for certain aspects of patient care. For emergency physicians, the distinction of “my job” versus “your job” often hinges on the perceived acuity of the condition, with a general tendency to abdicate responsibility for things that are felt to be chronic and, for the most part, can be effectively managed by a primary care provider. While we are not alone in this perspective—indeed kicking the can into someone else’s road is all too common in medicine—we are unique as emergency departments (EDs) have a legal (and daresay moral) obligation to provide a medical screening examination in one form or another to all who enter our doors.

What then should we do when our screening reveals something that could, unequivocally, do long-term harm to our patients? This quandary could be boundless if the basket of items screened for were to expand beyond the realm of what is deemed medically necessary for a given encounter. Fortunately, there is consensus that, at the least, things such as blood pressure, heart rate, and respiratory status are crucial, providing objective signs of an individual’s physiologic vitality. When abnormal, the latter two are generally seen as reliable indicators of an acute problem; the former is not as easy to interpret. To wit, hypotension, is an undeniable marker of instability yet the same cannot be said for elevated blood pressure—an exceedingly common finding in our setting—as it rarely represents a true emergency. However, hypertension itself is widely recognized as the single most important risk factor for cardiovascular and cerebrovascular disease and failure to achieve blood pressure control is a major contributor to premature morbidity and mortality worldwide. Despite this, there has been reluctance on the part of emergency physicians and the specialty as a whole, to espouse public health considerations as they relate to elevated blood pressure in the ED. Specific barriers that have been cited by clinicians include a disbelief in the accuracy of ED blood pressures (a consideration that has been largely disproven), a lack of time to address nonacute problems, concerns about lacking continuity for ongoing management, and perspectives that intervening will encourage future inappropriate use of the ED for primary care.

It is with this backdrop that Meurer and colleagues devised Reach Out ED—a pilot study of text message support that was primarily designed to compile feasibility data to justify a subsequent large-scale, randomized controlled trial aimed at testing the effect of a mobile-health (mHealth) behavioral intervention on blood pressure control for ED patients. While there are some unique aspects of this effort such as the use electronic health alerts to identify potentially eligible subjects, this is far from the first attempt to systematically address the problem of elevated blood pressure in the ED. Similar studies with similar goals and methods have been undertaken including a recently completed trial evaluating a text message intervention for hypertension (BPMED) that also demonstrated the ability to effectively maintain postdischarge communication with enrolled ED participants over a 30-day follow-up period. While both studies focused on hypertension, Meurer et al. enrolled a cohort that was predominantly white (75%) and insured (100%) with a high rate of stable primary care (91%). In contrast, BPMED included only African Americans, most of whom (68%) were low socioeconomic status (annual income < $20,000), with split recruitment of patients from the ED (n = 65) and local primary care clinics (n = 58). Moreover, only 75% of the cohort of Meurer et al. carried a baseline diagnosis of
hypertension and just 48% reported taking antihypertensive therapy at the time of randomization, while BPMED exclusively enrolled patients with known hypertension, all of whom had to be on at least one blood pressure medication to be eligible. Such differences might have impacted what is perhaps the most important study result with a substantially higher postrandomization dropout rate for Reach Out ED (45%) compared to BPMED (11% overall; 12% for those recruited from the ED versus 9% from primary care). Although such a difference may seem paradoxical with greater retention among a higher risk cohort, on closer analysis it makes logical sense as individuals with hypertension who are actively being treated for it may be more engaged in efforts to improve self-management and thus more compliant with a bidirectional exchange through text messaging. In addition, individuals with lesser socioeconomic means may be more receptive to opportunities that provide ongoing, supportive interactions with healthcare providers—something that is often lacking in underserved communities.

Given that the stated purpose of Reach Out ED was to derive pilot data to inform a subsequent larger study, nuances of the enrolled cohort are highly relevant to future research aimed at improving hypertension control for ED patients. The high dropout rate postrandomization suggests that the intervention may not have resonated with the target population—an assertion that is supported by the fact that 30% of those initially identified during the screening phase did not respond to a single text message postenrollment. As we and others have written, inclusion of patients who are the intended recipients of an intervention during the design phase is critical to both acceptance and uptake\textsuperscript{11} such outreach in Reach Out ED might have identified unappreciated considerations and enhanced trial success. Like Reach Out ED, BPMED also provided pilot data that was successfully leveraged to secure NIH funding (1 R01 HL127215; Buis, PI) for an ED specific trial of multicomponent mobile health support (ClinicalTrials.gov NCT02955537).\textsuperscript{12} Known as MI-BP (mHealth to Improve Blood Pressure Control in Hypertensive African Americans), this study incorporates perspectives from our Detroit-based hypertension community advisory board in its design and is well under way with randomization of more than 75

Figure 1. Mean ED systolic blood pressure data mapped by census tract in metropolitan Detroit—December 2016 to February 2019.
participants to date. Collectively, these two follow-up investigations will help to determine the efficacy of mobile health supported behavioral interventions to reduce blood pressure.

In addition to providing insights into what may influence retention in ED-based clinical trials aimed at improving hypertension self-management, Reach Out ED provides an intriguing lesson in how to (and how not to) interpret related blood pressure data in such studies. Simply put, in a study where short-term blood pressure change is an endpoint yet data are incomplete for nearly half the participants, imputation of missing values using a last observation carried forward or any other correction method is not valid. This is particularly true when such missingness may not be random, duration of the exposure and lag time from baseline measurement may not be consistent, and important group imbalances are known to exist. Case in point, 33% of control versus 57% of intervention patients were on baseline antihypertensive therapy yet analyses stratified by this variable suggest potentially greater benefit in controls. However, no data are provided on the proportion of participants in each group who completed the study that were actually on baseline antihypertensive therapy. Knowing this and the relative blood pressure changes within respective subgroups would have been informative. Finally, as acknowledged by the authors, the lack of information on what therapeutic adjustments, if any, were initiated during the course of follow-up is a critical limitation that really precludes any interpretation of causal relationships.

Perhaps the greatest value of studies like Reach Out ED and BPMED, as well as their NIH-funded follow-up trials, is that they call attention to the issue of uncontrolled hypertension and remind us that EDs do indeed have an important role to play in battling this epidemic. Figure 1, which displays aggregated data from 551,690 Detroit-based ED encounters (77% African American) over a 26-month period compiled as part of our ongoing Hypertension Surveillance Project, highlights the overwhelming magnitude of this problem, with mean systolic blood pressures that exceed the current guideline threshold of 130 mm Hg in nearly every census tract. When faced with such facts, the imperative is clear. EDs must be involved in systematic efforts to address this crucial public health challenge and emergency physicians must recognize that doing so does not deviate from our job but instead reflects the nobility of our profession.

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A child gets rushed into the resuscitation room—chest compressions in progress, pale and mottled, emesis and blood streaking his matted hair and ashen face. Everyone springs into action, instinctively assuming the roles we were trained to do. The respiratory therapist seamlessly takes over ventilations; the nurses simultaneously obtain access, prime lines, and connect monitors; and I stand at the foot of the bed acting as the conductor among the cacophony of sound and motion. As emergency medicine providers, we thrive in a fast-paced, unpredictable work environment. A resuscitation room is heavy with a palpable air of adrenaline, chaos, and excitement—and we are drawn to this. But after the resuscitation is over, as the hectic pace abruptly halts and the timbre of the emergency room changes from a roar to its usual humming, the calm that settles is disquieting. Whether the patient is stabilized or the patient passes away, I find the moments following code situations and lifesaving resuscitations to be one of the hardest in the practice of pediatric emergency medicine.

In the moment, the gravity of resuscitating a child is often ignored to effectively do the job. Whatever the cause and whatever the outcome, the emotional undertow comes rushing back once the resuscitation is over, because every acutely ill child comes in with an emotional charge. Sometimes it is a powerful current when the sound of sobbing family members is audible even above the din of the resuscitation room. Other times it is a mere flicker at first, and only after self-reflection I feel the magnitude of the undertorrent. After the resuscitation I take a brief moment to reign in my wandering thoughts and torrent of emotions, but new patients are piling up on the board and so I carry on.

Entering a patient room, I apologize and say, “I’m sorry it’s taken so long to see your child. There was another sick child in the ER, but now I’m here for you guys.” I emphasize this with a practiced smile to convey hopefulness and imply that everything went well. Yet more often than not, the parent will ask how the other child is doing. When the resuscitation has gone smoothly, it is easy to give a generic answer of reassurance and move onto this new patient. But when there was a negative outcome, the unease feels like a sigh caught in my chest. The same generic answer feels disingenuous and I am acutely aware that my strained smile may belie my easy words. For a few moments with this new patient, I feel like I am back in medical school, relying on my rehearsed history taking and physical examination before I am able to ease back into my usual routine.

The rapid deescalation and transition from lifesaving emergency mode back to more routine urgent care can be jarring and difficult. In training, we learn very quickly how to accelerate our pace and direct our energy to meet the demands of our patients. The escalation of care is easy; it is practiced and repeated and expected. There are learned algorithms, pathways, and numerous patient simulations and encounters that prepare us for this. However, the process of deescalation is not taught or emphasized. Although group debriefings can be valuable in identifying learning opportunities and fostering teamwork, they still do very little to quell the desperate sense of emotional closure I yearn for. Forcibly acknowledging that the sense of uneasiness is a valid and appropriate feeling has been helpful and reassuring at times. It is challenging, but this is the job we have signed up for—patients come in and out of the emergency department and we are only able to play a small part in their
convalescence and likewise in their end of life care. The ER is often the start of the emotional upheaval for families and we are not privy to the emotional reconciliation that comes much later.

After each encounter, I am always a little surprised to find that the moments following a resuscitation do not get any easier with time or experience. And perhaps it is meant to be this way—to remind us that our job is filled with passion and exhilaration, but also heartache and tension; to reinforce that we too are also human and, as such, inevitably share a part of the patient experience.

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