EDITOR’S PICK

A Multifaceted Intervention to Improve Patient Knowledge and Safe Use of Opioids: Results of the ED EMC2 Randomized Controlled Trial
Danielle M. McCarthy, Laura M. Curtis, D. Mark Courtney et al.

ORIGINAL CONTRIBUTIONS

Video Discharge Instructions for Acute Otitis Media in Children: A Randomized Controlled Open-label Trial
Sheena Belisle, Andrei Dobrin, Sharlene Elsie et al.

Psychiatric-related Revisits to the Emergency Department Following Rapid Expansion of Community Mental Health Services
Parvati Singh, Bharath Chakravarthy, Jangho Yoon et al.

Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluid in Sepsis: The PROMPT BOLUS Randomized Controlled Trial Pilot Feasibility Study
Fran Balamuth, Marlena Kittick, Peter McBride et al.

A Research Agenda for Emergency Medicine–based Adolescent Sexual and Reproductive Health
Melissa K. Miller, Lauren S. Chernick, Monika K. Goyal et al.

Does Shared Decision Making Actually Occur in the Emergency Department? Looking at It from the Patients’ Perspective
Elizabeth M. Schoenfeld, Marc A. Probst, Denise D. Quigley et al.

Contents continued inside.
Prehospital Care of Pediatric Hypoglycemic Seizure Patients in the State of North Carolina: A Retrospective Cohort Study
Zachary T. Burroughs, Michael S. Mitchell, Brian Hiestand et al. 1379

RESEARCH LETTER
Clinical Gestalt for Early Prediction of Delayed Functional and Symptomatic Recovery From Mild Traumatic Brain Injury Is Inadequate
Frederick K. Korley, W. Frank Peacock, James T. Eckner et al. 1384

HOT OFF THE PRESS
Hot Off the Press: Assessing Risk of Future Suicidality in Emergency Department Patients
Justin Morgenstern, Corey Heitz, Chris Bond et al. 1388

THE BRASS TACKS: CONCISE REVIEWS OF PUBLISHED EVIDENCE
Intensive Glucose Control for Critically Ill Patients
John Conway, Benjamin Friedman 1391
Outpatient Treatment for Low-Risk Febrile Neutropenia
Michael Gottlieb, Alex Koyfman, Brit Long 1393

COMMENTARY–INVITED
Opioid Prescribing From the ED: We Can All Do More to Help
Krista Brucker 1395

COMMENTARY–UNSOLICITED
The NNT-WET and NNT-DRI: ( Mostly) Satirical New Metrics to Emphasize the Inherent Inefficiency of Clinical Practice
Mathew J. Reeves, Joshua C. Reynolds 1397

MEDIA REVIEW
Daniel J. Kim 1400

ERRATUM
Re: Feasibility and Reliability of the SHOT: A Short Scale for Measuring Pretreatment Severity of Alcohol Withdrawal in the Emergency Department
1402
A Multifaceted Intervention to Improve Patient Knowledge and Safe Use of Opioids: Results of the ED EMC\(^2\) Randomized Controlled Trial

Danielle M. McCarthy, MD, MS\(^1\), Laura M. Curtis, MS\(^2\), D. Mark Courtney, MD, MS\(^1\), Kenzie A. Cameron, PhD, MPH\(^2,3\), Patrick M. Lank, MD, MS\(^1\), Howard S. Kim, MD, MS\(^1\), Lauren A. Opsasnick, MS\(^2\), Abbie E. Lyden, PharmD\(^4\), Stephanie J. Gravenor, MBA\(^1\), Andrea M. Russell, MS\(^2\), Morgan R. Eifler, BS\(^2\), Scott I. Hur, MPH\(^2\), Megan E. Rowland, MPH\(^1\), Surrey M. Walton, PhD\(^5\), Enid Montague, PhD\(^2,6\), Kwang-Youn A. Kim, PhD\(^3\), and Michael S. Wolf, PhD, MPH\(^2\)

ABSTRACT

Objectives: Despite increased focus on opioid prescribing, little is known about the influence of prescription opioid medication information given to patients in the emergency department (ED). The study objective was to evaluate the effect of an Electronic Medication Complete Communication (EMC\(^2\)) Opioid Strategy on patients' safe use of opioids and knowledge about opioids.

Methods: This was a three-arm prospective, randomized controlled pragmatic trial with randomization occurring at the physician level. Consecutive discharged patients at an urban academic ED (>88,000 visits) with new hydrocodone-acetaminophen prescriptions received one of three care pathways: 1) usual care, 2) EMC\(^2\) intervention, or 3) EMC\(^2\) + short message service (SMS) text messaging. The ED EMC\(^2\) intervention triggered two patient-facing educational tools (MedSheet, literacy-appropriate prescription wording [Take-Wait-Stop]) and three provider-facing reminders to counsel (directed to ED physician, dispensing pharmacist, follow-up physician). Patients in the EMC\(^2\) + SMS arm additionally received one text message/day for 1 week. Follow-up at 1 to 2 weeks assessed “demonstrated safe use” (primary outcome). Secondary outcomes including patient knowledge and actual safe use (via medication diaries) were assessed 2 to 4 days and 1 month following enrollment.

From the \(^1\)Department of Emergency Medicine; \(^2\)Division of General Internal Medicine and Geriatrics; and the \(^3\)Department of Preventive Medicine, Northwestern University; the \(^4\)College of Pharmacy, Rosalind Franklin School of Medicine and Science; the \(^5\)Department of Pharmacy Administration, University of Illinois at Chicago; and the \(^6\)School of Computing, DePaul University, Chicago, IL.


This project was supported by grant R18HS023459 (PI: McCarthy) from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality. REDCap is supported at FSM by the Northwestern University Clinical and Translational Science (NUCATS) Institute. Research reported in this publication was supported, in part, by the National Institutes of Health’s National Center for Advancing Translational Sciences, grant UL1TR001422. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Disclosures: MSW has served as a consultant on health literacy measurement with Merck, Sharp & Dohme Corp. AMR has received support from a predoctoral risk communication fellowship from Amgen Inc. All other authors have no conflicts to disclose.

Clinical Trial registration: NCT02431793.

Author contributions: conception or design of the work—DMM, DMC, KAC, PML, HSK, LMC, SJG, SMW, EM, and MSW; acquisition of data—DMM, AMR, MRE, and MER; analysis of data—LAO, AEL, SIH, SMW, LMC, and KAK; interpretation of data—DMM, DMC, KAC, PML, HSK, LMC, and MSW; drafting the work—DMM, LMC, LAO, SIH; critically revising work—DMM, KAC, PML, HSK, SJG, SMW, EM, AEL, AMR, MRE, KAK, MER, and MSW; and final approval of version to be published—all authors.

Supervising Editor: Zachary F. Meisel, MD, MPH, MSc.

Address for correspondence and reprints: Danielle M. McCarthy, MD, MS; e-mail: d-mccarthy2@northwestern.edu.

ACADEMIC EMERGENCY MEDICINE 2019;26:1311–1325.

© 2019 by the Society for Academic Emergency Medicine
doi: 10.1111/acem.13860
Results: Among the 652 enrolled, 343 completed follow-up (57% women; mean ± SD age = 42 ± 14.0 years). Demonstrated safe opioid use occurred more often in the EMC2 group (adjusted odds ratio [aOR] = 2.46, 95% confidence interval [CI] = 1.19 to 5.06), but not the EMC2 + SMS group (aOR = 1.87, 95% CI = 0.90 to 3.90) compared with usual care. Neither intervention arm improved medication safe use as measured by medication diary data. Medication knowledge, measured by a 10-point composite knowledge score, was greater in the EMC2 group (β = 0.57, 95% CI = 0.09 to 1.06) than usual care.

Conclusions: The study found that the EMC2 tools improved demonstrated safe dosing, but these benefits did not translate into actual use based on medication dairies. The text-messaging intervention did result in improved patient knowledge.

The United States continues to face an epidemic of opioid addiction and overdose, the scale of which is unprecedented and has prompted the declaration of a public health emergency. Accordingly, efforts are being made in all parts of the opioid use continuum to decrease morbidity and mortality (e.g., decreasing initial prescribing, promoting alternatives to opioid therapy, identifying and treating opioid use disorder). Many interventions and guidelines appropriately target decreasing the number of opioid prescriptions and the number of pills per prescription. However, in settings such as the emergency department (ED), where acute or chronic pain account for almost two-thirds of ED visits, use of opioids may be appropriate at times, if prescribed safely.

In those moments of appropriate prescribing, patient education and the physician patient interaction at the time of prescribing must be optimized to ensure patients are aware both of the risks of opioids and how to take them safely. The ED is widely recognized as a difficult environment for ensuring adequate communication due to factors including time constraints, unpredicted interruptions, shift changes, overcrowding, and the lack of a preexisting relationship with patients. In this setting, existing ED discharge processes may more often than not be inadequate for confirming patient understanding, increasing the risk that self-care instructions were not appropriately conveyed or followed. This lack of knowledge for patients newly prescribed opioids is potentially dangerous, as preliminary research indicates patients rarely recall counseling about opioid pain relievers. When counseling does occur it is highly variable and the potential for addiction is very rarely addressed.

The Agency of Healthcare Quality and Research (AHRQ) has made recommendations for topics to be covered in conversations with patients about any new prescriptions (not limited to opioids) to ensure safe and appropriate use. Responsible ED prescribing of opioid analgesics should include both spoken counseling and written information for patients. These instructions should not only fulfill new medication counseling recommendations, but also directly address the potential for opioid abuse and misuse so patients can be informed consumers. With other classes of medications, one-on-one educational counseling efforts have been demonstrated to improve patient adherence to physician recommendations about medications and to improve medication-related outcomes.

Our team developed an Electronic Medication Complete Communication (EMC2) Opioid Strategy with a goal of supporting and improving one-on-one communication to ED patients about newly prescribed opioid pain relievers. This intervention is an electronic health record (EHR)-integrated strategy that activates a series of two patient-facing educational tools (a hard-copy one-page MedSheet about opioids, patient-centered wording on prescriptions [Take-Wait-Stop]) and three automated provider-facing EHR-based reminders to counsel patients (directed to ED physician, pharmacist, and follow-up physician) when a new prescription for an opioid is written. The strategy was designed to not only meet AHRQ recommendations for counseling, but also to support patients in all phases of the National Academy of Medicine’s Medication Use Process (prescribing, dispensing, self-administration, and monitoring). Herein we describe our intervention and its ability to improve safe use and patient knowledge of newly prescribed opioids.

METHODS

We conducted a three-arm, physician randomized pragmatic trial of the ED EMC2 Opioid Strategy to improve safe use and patient knowledge of newly prescribed opioids. A description of the study protocol and trial is described in greater detail in a previous publication. In brief, the primary goal of the study was to determine if the EMC2 intervention could improve demonstrated safe use of newly prescribed
opioids. As a “point of care” intervention, the need for “post visit” reinforcement of the safe use educational messages was also considered. Thus, our approach was tested with and without a short message service (SMS) text-messaging promotional component, understanding the need for a scalable follow-up component within a clinical context that does not routinely track patients beyond acute visits. Secondarily, we sought to determine if the EMC2 intervention could increase patient knowledge about opioid pain relievers. We hypothesized that compared to patients in the usual care arm, patients receiving EMC2 interventions would demonstrate higher rates of safe use of their prescribed opioid as measured by a demonstrated dosing task and secondarily demonstrate higher rates of opioid-related medication knowledge. The institutional review board at Northwestern University approved all study procedures, a data safety and monitoring board was established and met annually, and the trial was registered at clinicaltrials.gov (NCT02431793).

Randomized Controlled Trial Study Design
The trial employed a cluster-randomized design wherein the prescribing provider was the unit of randomization. This choice was made because of the automated nature of the EHR-based interventions. To increase the chances of having similar patient populations in each intervention arm, providers were placed into strata based on their roles (attending physician, resident physician, and advanced practice providers [APPs]), and historical volume of opioid prescriptions dispensed (high, medium, low) over the preceding two years (physician, APP) or by postgraduate year (residents). Providers from each strata were then randomized to one of three study arms; provider identities were revealed to study personnel after randomization was complete. Patients participating in the study received one of three care pathways based on the randomization allocation of the treating provider was who was ordering their discharge prescription within the EHR.

Participants
All attending and resident physicians and APPs based in the ED were approached for study inclusion. Those who agreed to be in the study were randomized as described. After consent, physician participants were informed of the changes that would be made to their EHR, but were not otherwise given targeted education and were not aware of study outcome measures.

Study participants were patients being discharged from an urban academic ED (annual volume > 88,000) with a new prescription for hydrocodone-acetaminophen between July 2015 and August 2017. Patients were eligible for enrollment if they met the following five conditions: 1) 18 years of age or older, 2) English speaking, 3) prescribed a tablet form of hydrocodone-acetaminophen (nonliquid formulation), 4) responsible for self-administering their own medication, and 5) were discharged by a provider who consented to the study. Patients were excluded if they were clinically unstable, psychologically impaired or intoxicated as judged by the research staff or ED provider, chronically taking opioids (as defined by self-report of “daily or near daily” use of opioids for the past 90 days), being admitted to the hospital, unable to complete study follow-up, or pregnant. Hydrocodone-acetaminophen was selected for study because, at the time of study initiation, it was the most frequently prescribed medication at the both the study site and nationally.22 Additionally, it is commonly abused,23–25 frequently results in ED visits for overdose26 and is among the top prescription opioids related to overdose death.27

Study Arms
The trial had three arms: usual care and two intervention arms named EMC2 and EMC2 + SMS text messaging. In the usual care (control) arm, providers had no modifications to their EHR interface, and their patients received discharge instructions, prescription instructions, and counseling about safe use per that provider’s customary practice. Of note, usual practice of the trial ED did not automatically include medication information sheets with discharge paperwork, as is done in some EDs; however, medication information documents could be manually added to the discharge documents at providers’ discretion. For providers assigned to the EMC2 arm, the three provider facing functions were “turned on” and their patients were eligible to receive two of the educational materials from the ED EMC2 Opioid Strategy. Patients of providers in the EMC2 + SMS arm also received daily text messages to prompt safe use for 1 week following their ED visit.

Intervention
The ED EMC2 Opioid Strategy comprised five changes to the EHR that automatically triggered when any prescription for hydrocodone-acetaminophen was
signed electronically (Figure 1). The first three components targeted providers, whereas the latter two components targeted the patient directly. The three prescriber facing components included: 1) a provider medication alert reminding the prescribing ED physician to counsel the patient about safe use of opioids, 2) an inbox message delivered to the primary care outpatient provider informing them of the new prescription and pill quantity and requesting that they follow up with the patient to provide additional counseling about safe use, and 3) a request to the dispensing pharmacist to counsel the patient about safe use (printed automatically on the paper prescription requisition). In the event that there was no primary care provider, the inbox message could not be sent; however, the other two provider-facing components applied to all patients.

The last two components of the ED EMC2 Opioid Strategy, both patient facing, were plain language MedSheets about hydrocodone-acetaminophen and Take-Wait-Stop patient-centered medication labeling changes made to the print prescription requisition.

The MedSheets were previously developed by our team to provide the patient with understandable, actionable information written at an eighth-grade reading level or below and formatted to result in higher recall of drug information compared to current FDA standard medication guides. Preliminary data demonstrated that inclusion of an opioid MedSheet in ED discharge instructions increased some aspects of patient knowledge.

The Take-Wait-Stop prescription wording translates medications prescribed “as needed” into plain language with three deconstructed, actionable steps (Figure 2). The Take-Wait-Stop label was first developed by members of our team as an extension of the universal medication schedule and based on tenets of patient-
centered prescription label design. The prescription wording places emphasis on action terms (Take-Wait-Stop) and deconstructs the components of PRN instructions to support understanding and recall. Anticipating the wording would be unfamiliar to community pharmacists, we additionally worked with a national community pharmacy chain manager to ensure that the wording fit on a standard label. Further, the default Sig (i.e., signetur which is Latin for “let it be labeled”) on the print requisitions was changed to “special sig” and each prescription contained a “Note to Pharmacist: Please print the ‘Take-Wait-Stop’ instructions on the medication label” to draw attention to the wording change. This study was a pragmatic trial, so we did not ensure that each pharmacy could print the prescriptions, but had a planned analysis of prescription bottle implementation.

The sixth intervention component, only available to patients in the EMC2 + SMS study arm, was SMS text messaging. Patients in this arm followed instructions on a preprinted card and self-enrolled into an automated texting program that sent one text message per day for the week following enrollment. These educational messages focused on safe use, side effects, and safe behaviors related to prescription opioids (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.13860/full).

The intervention was designed with the dual goal of maximizing communication while providing a scalable intervention with minimal workflow interruption. Further detail related to the pilot work supporting the design of this intervention and detail of each intervention component can be found in previous publications.

Outcomes and Measures
Patients completed a baseline assessment and follow-up assessments at 2 to 4 days, 1 to 2 weeks, and 1 month after enrollment and completed a paper medication diary for 10 days following discharge (returned via prepaid envelope). Baseline questions assessed sociodemographic characteristics, including health literacy (measured by the Newest Vital Sign [NVS]) and self-report of prior use of hydrocodone. Visit characteristics (e.g., diagnosis, medications received in ED, pain scores) were obtained from the EHR. The 2- to 4-day and 1-month assessments were via telephone. The 1- to 2-week assessment was initially conducted in person. However, due to low retention the assessment was switched to telephone.

The primary outcome was the patients’ ability to safely dose their opioid medication in a “demonstrated” dosing task. As part of this task, patients were asked to tell the research assistant (RA) how they would take their medication if they were in pain (“starting at 8AM”). Participants were continually prompted as to when and how they would take their next dose if they were still in pain with prompting continuing until either 24 hours was reached or the patient reported that they would not take any additional pills. The prompt was left intentionally vague as to the degree of hypothetical pain to allow more freedom of response, better simulate the medication taking experience at home, and avoid patients feeling as if they had to “take” the medication because of “severe” pain. Three error types were assessed in a binary fashion: proper number of pills per dose, correct spacing of doses (recommended minimum number of hours between doses), and total pills per day (not exceeding the recommended/safe number of pills per day). As the prescription details varied patient to patient, each individual’s performance on the dosing task was assessed according to the wording of their prescription at discharge. For patients who did not have a “do not exceed” statement on their prescription, the manufacturer’s recommendation was used (8 tabs daily for hydrocodone/acetaminophen 5/325 mg strength and 6 tabs daily for the 10/325 mg strength).

The outcome measure of patient’s demonstrating dosing and frequency was informed by nearly decade of research by Wolf and colleagues. Tasks of patient demonstration of medications dosing have been applied in studies examining inhaler technique in chronic obstructive pulmonary disease, immunosuppressants after transplant, pediatric liquid
dosing\textsuperscript{46} and nonprescription acetaminophen use\textsuperscript{47} and among patients with complex regimens.\textsuperscript{48} These studies have consistently found that regimen dosing is associated with lower health literacy, cognitive function and visual acuity, and in some contexts, predictive of health care utilization.\textsuperscript{44}

Secondary outcomes assessed included medication knowledge and actual safe hydrocodone-acetaminophen use. Medication knowledge was assessed using open-ended questions (e.g., “Do you know what ingredients are in this medicine?” “Do you think the type of pain medicine that you were prescribed can be addictive?”). Responses were scored by trained RAs and reviewed by the study PI. A composite knowledge score (scale 0–10) was created composed of ten items ( 1] medication brand name, 2] acetaminophen as ingredient, 3] hydrocodone as ingredient, 4] classification as opioid [or narcotic or controlled substance], 5] safe amount of alcohol to drink, 6] need to avoid sedating medicines, 7] potential for addiction, 8] need to avoid acetaminophen, 9] at least one gastrointestinal side effect (e.g., nausea, constipation), and 10] at least one sedating side effect [e.g., sleepy, dizzy, tired]). Baseline knowledge was not assessed to avoid priming patients to knowledge items (e.g., the assessment would have been an intervention in and of itself); instead, a randomized controlled study design was chosen. The EMC\textsuperscript{2} intervention was expected to optimize knowledge on all of the above topics; messages related to numbers 2, 5, 6, 8, and 9 were additionally targeted specifically by text messages.

Safe use in actual practice was assessed from medication diary data. The outcome was assessed in two parts: 1) an aggregate of the same three error types for the demonstrated use assessment described above (“actual safe dosing”) and 2) “actual safe dosing + no sedating medications” composed of the three error types above and a binary assessment of concomitant use with sedating medications. For the assessment of concomitant use of hydrocodone-acetaminophen with sedating medications, a list of drug categories was determined a priori by an experienced ED Clinical Pharmacist and Doctor of Pharmacy (AEL) based on a review of risk level and interaction classification within Micromedex, Lexi-Drugs, Clinical Pharmacology, and primary literature. This list was reviewed and modified by a board-certified toxicologist and addiction medicine specialist (PML; Appendix S2). Patients were considered to have concomitant use with a sedating medication if they took a medication on the list within the same day as taking their hydrocodone-acetaminophen as it was beyond the scope of this study to adjust for other factors that would influence the likelihood of an adverse event from concomitant use (e.g., duration of medication action, chronicity of use, half-life of individual drugs).

The study was conducted as a pragmatic trial to assess how the intervention would operate in the real world if it were “turned on” and left to run without interference or repeated instruction. We measured the rate of successful printing of the MedSheet, the prescription requisition printing with the Take-Wait-Stop instructions, commercial pharmacies filling the pill bottles per the Take-Wait-Stop directions, and successful enrollment in the texting platform.

**Data Analysis**

Descriptive statistics were calculated for all sociodemographic, ED visit, and opioid prescription characteristics. Chi-square, one-way analysis of variance, and Wilcoxon rank-sum tests were used, as appropriate, to test for balanced randomization. An intercluster correlation assessment was conducted to determine the degree of independence among individuals in the same cluster. We used generalized linear mixed models on all outcomes adjusting for physician clustering. Models were run for dichotomous dosing outcomes (adjusted odds ratios [aORs] reported) and for continuous composite knowledge score (adjusted mean differences reported). Examinations for possible associations between patient characteristics and outcome variables were conducted and all models controlled for covariates related to that specific outcome. To isolate the additive benefit of the text messaging, the two intervention arms were compared to each other on the primary and secondary outcomes as well as the individual knowledge questions that comprised the knowledge score. Significance for all analyses was set at p < 0.025 to adjust for multiple testing.

All analyses were first conducted using an intent-to-treat approach. Subsequently, because some patients did not receive one or more pieces of the intervention, the primary outcome was analyzed per protocol, where the same methodology described previously was applied only to patients who successfully received all patient-facing pieces of the intervention. Patients in the EMC\textsuperscript{2} arm were included in the per-protocol analysis.
if they received the MedSheet and the patient-centered TWS prescription wording on their bottle. Those in the EMC\(^2\) + SMS arm were included if they received the MedSheet and TWS prescription wording on bottle, successfully enrolled in SMS texting, and received all seven text messages.

The planned enrollment target was for 816 patients to complete the 1- to 2-week follow-up interval, which would have provided 80% power to detect a difference of 11.8% (from pilot data)\(^3\) between each of the intervention arms and the usual care arm for the primary outcome of any error on the demonstrated dosing task. All analyses were performed using SAS 9.4 (SAS Institute Inc.).

**RESULTS**

**Participant Flow**

Among 126 providers at the study site, 116 (92%) consented and were eligible for their patients to be enrolled. A total of 652 patients were enrolled, for an overall cooperation rate of 57% of those approached (\(n = 1,144\); Figure 3). At the first follow up call (2–4 days) retention rates were 67.3, 74.1, and 69.1% in the usual care, EMC\(^2\), and EMC\(^2\) + SMS groups, respectively. The primary outcome was assessed at the second time point (1–2 weeks postenrollment); at that time the retention rates were 47.0, 58.0, and 51.7%, respectively. By the third follow-up call (1 month...
postenrollment), retention rates were 42.1, 46.5, and 44.9%. A total of 260 (39.8%) medication diaries were returned, including 223 diaries from patients who also completed the primary outcome assessment. Attrition rates for follow-up calls and medication diary return did not differ by arm; however, they did differ by other characteristics with participants completing the study being older (mean ± SD age = 45 ± 14.4 years vs. 40 ± 13.1 years among those who dropped out) and higher literacy (48% adequate literacy and 37.9% limited or marginal literacy completed). For medication diaries, those returning diaries were older, with higher educational attainment, literacy, and household earnings, and were less likely to be uninsured or from a racial/ethnic minority (data not shown).

**Baseline Data**
Participant characteristics, overall and by arm, are summarized in Table 1. At baseline, participants had a mean (±SD) age of 42 (±14.0) years and slightly more than half were female. Overall, the sample had a high degree of educational attainment and a similarly high rate of adequate literacy (66.4%). The majority of patients had not been previously prescribed hydrocodone, but did receive opioids in the course of their ED visit. The most common diagnosis was back pain, and the prescriptions provided were of small pill quantity (mean 15 tabs).

**Outcomes**
Overall 76.4% of patients demonstrated safe use of their newly prescribed opioid with the highest rate of safe use in the EMC2 arm (82.0%). Demonstrated safe use occurred more often in the EMC2 group (aOR = 2.46, 95% confidence interval [CI] = 1.19 to 5.06), but not the EMC2 + SMS group (aOR = 1.87, 95% CI = 0.90 to 3.90) compared with usual care.

Less than half (39.8%, n = 260) of patients returned medication diaries. There were no differences between arms in either of the actual use aggregate assessments as measured by medication diary data (Table 2). Notably, among participants who both returned the medication diary and completed the demonstrated dosing task (n = 223), the overall error rate on the demonstrated dosing task was 19.7% (23.4% control, 16.5% EMC2, 20.3% EMC2 + SMS, p = 0.57). In contrast, those who did not return medication diaries (n = 74) had higher demonstrated dosing error rates across all arms (35.1%), but particularly the control arm (66.7% control, 21.6% EMC2, 36.4% EMC2 + SMS, p = 0.01).

Participants in the usual care arm had the highest rates of concomitant use of sedating medications (30.7%) compared to the EMC2 and EMC2 + SMS (21.0 and 25.9%, respectively) yet again this difference was not statistically significant (Table 2). The most frequently used class of sedating medication was benzodiazepines (13.1%; additional results of coingested sedating medications available in Appendix S3).

Patients in the EMC2 + SMS arm had higher composite knowledge scores (mean [±SD] = 6.2 [±1.7]; β [95% CI] = 0.57 [0.09 to 1.06]) than usual care (mean [±SD] = 5.6 [±1.5]) or EMC2 participants (5.6 [±1.8]). Specifically evaluating the strength of the deconstructed components of the intervention (EMC2 vs. EMC2 + SMS) revealed that the text messages were significantly linked to three knowledge items (able to name acetaminophen as ingredient, aware of need to avoid acetaminophen, aware of need to avoid sedating medications; Table 3).

**Process Measures**
The processes that occurred at the time of the ED visit had a high level of successful inclusion in the discharge documents, with 78% of patients in the intervention arms receiving printed MedSheets automatically (91% ultimately received the MedSheet after it was noted to be missing and the discharge documents were reprinted). The printing failure was a computer programming issue wherein the MedSheet was included if the prescription was written through the “orders” interface, but not the “discharge” interface. Sixty-two percent of intervention patients responded they still had their information sheet. Within the EMC2 + SMS arm 93% of patients successfully enrolled in texting. Only 19 patients (10%) opted out of the texting intervention before all messages were delivered. Although the Take-Wait-Stop prescription requisition successfully printed in the ED for 95% of patients in the intervention arms, when those same patients were reassessed at 1- to 2-week follow-up (n = 211), only 38 (18.0%) had a label on their prescription bottle that corresponded with the Take-Wait-Stop (verbatim or near verbatim) instructions as written on the requisition. An additional 93 patients had wording with three action steps that was considered “adequate” implementation of the label, but not protocol. In contrast, 96.4% of control arm patients had labels with traditional PRN wording. A separate
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N = 652)</th>
<th>Usual-care Arm (n = 202)</th>
<th>EMC&lt;sup&gt;2&lt;/sup&gt; Intervention Arm (n = 243)</th>
<th>EMC&lt;sup&gt;2&lt;/sup&gt; + SMS Intervention Arm (n = 207)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (±SD)</td>
<td>42.2 (±14.0)</td>
<td>43.3 (±14.2)</td>
<td>42.3 (±14.4)</td>
<td>41.3 (±13.3)</td>
</tr>
<tr>
<td>Female gender (%)</td>
<td>57.1</td>
<td>55.9</td>
<td>55.6</td>
<td>59.9</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>46.9</td>
<td>47.3</td>
<td>45.5</td>
<td>48.3</td>
</tr>
<tr>
<td>African American</td>
<td>30.8</td>
<td>32.8</td>
<td>29.3</td>
<td>30.4</td>
</tr>
<tr>
<td>Other</td>
<td>22.3</td>
<td>19.9</td>
<td>25.2</td>
<td>21.3</td>
</tr>
<tr>
<td>Education (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school graduate or less</td>
<td>18.0</td>
<td>17.3</td>
<td>18.1</td>
<td>18.4</td>
</tr>
<tr>
<td>Some college</td>
<td>31.8</td>
<td>34.7</td>
<td>31.3</td>
<td>29.6</td>
</tr>
<tr>
<td>College graduate</td>
<td>31.3</td>
<td>26.2</td>
<td>33.7</td>
<td>33.5</td>
</tr>
<tr>
<td>Graduate degree</td>
<td>18.9</td>
<td>21.8</td>
<td>16.9</td>
<td>18.4</td>
</tr>
<tr>
<td>Income level (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤$40,000</td>
<td>30.6</td>
<td>32.6</td>
<td>30.9</td>
<td>28.0</td>
</tr>
<tr>
<td>&gt;$40,000-$100,000</td>
<td>34.7</td>
<td>37.0</td>
<td>35.0</td>
<td>32.0</td>
</tr>
<tr>
<td>&gt;$100,000</td>
<td>34.7</td>
<td>30.4</td>
<td>34.1</td>
<td>40.0</td>
</tr>
<tr>
<td>Health literacy (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low + marginal</td>
<td>33.6</td>
<td>35.1</td>
<td>32.9</td>
<td>32.9</td>
</tr>
<tr>
<td>Adequate</td>
<td>66.4</td>
<td>64.9</td>
<td>67.1</td>
<td>67.1</td>
</tr>
<tr>
<td>Primary insurance (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>18.0</td>
<td>17.9</td>
<td>19.2</td>
<td>16.7</td>
</tr>
<tr>
<td>Medicare</td>
<td>7.6</td>
<td>10.9</td>
<td>6.3</td>
<td>5.9</td>
</tr>
<tr>
<td>Private/managed care</td>
<td>63.5</td>
<td>58.7</td>
<td>65.7</td>
<td>65.5</td>
</tr>
<tr>
<td>Self or no insurance</td>
<td>6.4</td>
<td>6.5</td>
<td>5.9</td>
<td>6.9</td>
</tr>
<tr>
<td>Other</td>
<td>4.5</td>
<td>6.0</td>
<td>2.9</td>
<td>4.9</td>
</tr>
<tr>
<td>Self-reported health status (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>14.9</td>
<td>14.9</td>
<td>16.1</td>
<td>13.6</td>
</tr>
<tr>
<td>Very good</td>
<td>35.9</td>
<td>31.8</td>
<td>38.0</td>
<td>37.4</td>
</tr>
<tr>
<td>Good</td>
<td>31.7</td>
<td>33.3</td>
<td>29.8</td>
<td>32.5</td>
</tr>
<tr>
<td>Fair</td>
<td>15.3</td>
<td>18.9</td>
<td>12.8</td>
<td>14.6</td>
</tr>
<tr>
<td>Poor</td>
<td>2.2</td>
<td>1.0</td>
<td>3.3</td>
<td>1.9</td>
</tr>
<tr>
<td>Previously prescribed hydrocodone (%)</td>
<td>38.9</td>
<td>36.9</td>
<td>39.1</td>
<td>40.6</td>
</tr>
<tr>
<td><strong>ED Visit Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triage acuity (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 and 2</td>
<td>8.3</td>
<td>7.5</td>
<td>7.9</td>
<td>10.0</td>
</tr>
<tr>
<td>4 and 5</td>
<td>35.9</td>
<td>38.8</td>
<td>36.4</td>
<td>33.5</td>
</tr>
<tr>
<td>Triage pain score, mean (±SD)</td>
<td>7.7 (±2.3)</td>
<td>7.6 (±2.2)</td>
<td>7.7 (±2.4)</td>
<td>7.7 (±2.3)</td>
</tr>
<tr>
<td>Total length of stay (hours), median (IQR)</td>
<td>3.9 (2.9-5.2)</td>
<td>3.6 (2.6-5)</td>
<td>3.9 (2.8-5)</td>
<td>4.1 (3.1-5.8)</td>
</tr>
<tr>
<td>Exposure to opioids in the ED (%)</td>
<td>86.4</td>
<td>86.6</td>
<td>84.4</td>
<td>88.2</td>
</tr>
<tr>
<td><strong>Diagnosis category</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>18.9</td>
<td>21.8</td>
<td>16.5</td>
<td>18.8</td>
</tr>
<tr>
<td>Fractures/dislocations</td>
<td>15.5</td>
<td>14.4</td>
<td>17.7</td>
<td>14.0</td>
</tr>
<tr>
<td>Extremity injuries (nonfracture)</td>
<td>16.9</td>
<td>14.4</td>
<td>20.6</td>
<td>15.0</td>
</tr>
<tr>
<td>Kidney stone</td>
<td>14.7</td>
<td>14.9</td>
<td>16.1</td>
<td>13.0</td>
</tr>
<tr>
<td>Other</td>
<td>34.1</td>
<td>34.7</td>
<td>29.2</td>
<td>39.1</td>
</tr>
<tr>
<td><strong>Opioid Prescription Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily MME prescribed, mean (±SD)</td>
<td>30.8 (±13.4)</td>
<td>29.4 (±12.3)</td>
<td>30.2 (±12.2)</td>
<td>32.7 (±15.3)</td>
</tr>
<tr>
<td>Tabs of opioid prescribed, mean (±SD)</td>
<td>15 (±6.9)</td>
<td>14.7 (±6.4)</td>
<td>16 (±7.8)</td>
<td>14 (±5.9)</td>
</tr>
</tbody>
</table>

<sup>4</sup>IQR = interquartile range; MME = morphine milligram equivalents.
manuscript further evaluates the variations in the prescription filling in this sample.\textsuperscript{38}

**Per-protocol Analysis**

The low rates of the prescription being filled per the protocol prompted a per-protocol analysis for the primary outcome. There were no significant differences by arm in baseline demographics for participants when analyzed per protocol (data not shown). Compared to participants in the usual care arm, those who completed EMC\textsuperscript{2} and EMC\textsuperscript{2} + SMS “per protocol” had 1.48 (95% CI = 0.5 to 4.6) and 2.48 (95% CI = 0.6 to 9.6) higher odds of demonstrating proper dosing respectively when adjusting for physician clustering and health literacy level.

**DISCUSSION**

The ED EMC\textsuperscript{2} Opioid Strategy, designed to support patient education and counseling about safe opioid use, while minimizing burden of providers, had some significant, but overall variable, influence on the outcomes studied. We evaluated outcomes in multiple domains, including demonstrated and actual medication safe use and medication knowledge. The EMC\textsuperscript{2} intervention led to higher rates of safe use when patients were asked to objectively demonstrate how they would take medication, yet our strategy did not show any improvement in actual use based on how participants recorded their medication-taking behaviors via daily diaries. In light of the differences on the demonstrated dosing task between those who did/did not return the medication diaries, it is possible that the lack of difference in actual dosing is related to both low power and low rate of return among patients more prone to dosing errors rather than the strength of the intervention. While it is unclear to what extent either of these two measures validly represents a patient’s true opioid use, there is inherent value in ability of the EMC\textsuperscript{2} intervention—and specifically the Take-Wait-Stop label—to assist patients in understanding how to most appropriately dose out their medication.

### Table 2

Outcome Measures by Study Arm

<table>
<thead>
<tr>
<th>Primary Safe Use Outcome</th>
<th>Usual-care Arm (%)</th>
<th>EMC\textsuperscript{2} Arm (%)</th>
<th>EMC\textsuperscript{2} + SMS Arm (%)</th>
<th>EMCh vs. Usual Care Adjusted Model Outcome aOR (95% CI)</th>
<th>EMCh + SMS vs. Usual Care Adjusted Model Outcome aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceeded maximum daily dose</td>
<td>1.2</td>
<td>6.5</td>
<td>3.1</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>More than prescribed pills per dose</td>
<td>3.6</td>
<td>4.0</td>
<td>2.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Shorter interval than prescribed</td>
<td>26.6</td>
<td>15.6</td>
<td>22.9</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Demonstrated safe use (no errors)</td>
<td>68.4</td>
<td>82.0</td>
<td>76.0</td>
<td>2.46 (1.19 to 5.06)</td>
<td>1.87 (0.90 to 3.90)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Safe Use Outcomes</th>
<th>Actual use based on medication diary (n = 260)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceeded maximum daily dose</td>
<td>1.3</td>
<td>2.0</td>
<td>0.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>More than prescribed pills per dose</td>
<td>10.7</td>
<td>8.0</td>
<td>7.4</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Shorter interval than prescribed</td>
<td>9.3</td>
<td>10.0</td>
<td>5.9</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Actual safe dosing (no errors)</td>
<td>84.0</td>
<td>85.0</td>
<td>89.4</td>
<td>1.04 (0.44, 2.44)</td>
<td>1.59 (0.61, 4.15)</td>
</tr>
<tr>
<td>Use with sedating medication</td>
<td>37.3</td>
<td>24.0</td>
<td>28.2</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Actual safe dosing + no sedating medications (no errors)</td>
<td>52.0</td>
<td>67.0</td>
<td>65.9</td>
<td>1.82 (0.95, 3.48)</td>
<td>1.75 (0.89, 3.44)</td>
</tr>
<tr>
<td>Knowledge composite score, mean (±SD)</td>
<td>5.6 (±1.5)</td>
<td>5.6 (±1.8)</td>
<td>6.2 (±1.7)</td>
<td>−0.02 (−0.47 to 0.42)</td>
<td>0.57 (0.09 to 1.06)</td>
</tr>
</tbody>
</table>

aOR = adjusted odds ratio.

*Adjusted for health literacy and clustering.

\(p < 0.025\) compared to usual-care arm.

\(\dagger\)Adjusted for clustering.

\(\ddagger\)Adjusted for race, income, health literacy, and clustering.

p-value for demonstrated safe dose (EMC\textsuperscript{2} vs Usual Care) is 0.015.

p-value for Knowledge Composite Score (SMS vs Usual Care) is 0.021.
Interestingly, patients were able to report more awareness of the need to avoid sedating medicines, but there were no differences in actual concomitant use between the groups. This finding supports the notion that possessing knowledge about medication risks is likely necessary but not sufficient to ensure safe use, as medication-taking behaviors are often influenced by complex factors in addition to knowledge such as health literacy, self-efficacy, and attitudes.\(^4\) Although not influenced by the intervention, the data reveal the prevalence in this population of using opioids with sedating medications. Nearly one-third of the overall sample were taking their newly prescribed opioid during the same day as a sedating medication (both newly prescribed [e.g., cyclobenzaprine] and chronically used [e.g., alprazolam]). Concomitant use of opioids with sedating medications, particularly benzodiazepines, is emerging as a significant contributor to opioid-related mortality.\(^5\) and underscores the need to translate the knowledge gains we achieved with the intervention into action. The physician writing the newly prescribed opioid may be the better target for eliminating this form of “misuse.” Although the data are reported on a patient level, the root cause of the error is more likely on the prescriber side as the physician ordering the opioid should be aware of the risks of concomitant use with both chronically used and newly prescribed sedating medications and consider alternate analgesics.

Patients in the EMC\(^2\) + SMS arm had higher composite knowledge scores than both patients in the usual-care and EMC\(^2\) arms, supporting the use of SMS text message delivery after the visit to increase knowledge. Although the score was higher, it is unclear whether this finding is clinically meaningful.

Table 3
Outcome Measures—By Intervention Component

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Texting vs. EMC(^2)</th>
<th>aOR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary safe use outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrated safe use(^*)</td>
<td>0.81 (0.36–1.82)</td>
<td>0.60</td>
<td></td>
</tr>
<tr>
<td>Secondary safe use outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual safe dosing (no errors)(^1)(^2)</td>
<td>0.96 (0.50–1.85)</td>
<td>0.90</td>
<td></td>
</tr>
<tr>
<td>Actual safe dosing + no sedating medications(^1)(^2)</td>
<td>1.53 (0.63–3.72)</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>Knowledge(^3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge of medication details (n = 459)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Able to identify by brand name</td>
<td>1.70 (0.82–3.49)</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td>Able to name acetaminophen as an active ingredient(^1)</td>
<td>2.46 (1.16–5.22)</td>
<td>0.02(^a)</td>
<td></td>
</tr>
<tr>
<td>Able to name hydrocodone as an active ingredient</td>
<td>1.26 (0.66–2.39)</td>
<td>0.49</td>
<td></td>
</tr>
<tr>
<td>Aware that medication is a narcotic/controlled substance</td>
<td>0.82 (0.38–1.78)</td>
<td>0.62</td>
<td></td>
</tr>
<tr>
<td>Awareness of precautions (n = 343)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aware of safe amount of alcohol to drink(^1)</td>
<td>0.88 (0.38–2.04)</td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td>Aware of need to avoid other sedating medicines(^1)</td>
<td>2.17 (1.20–3.91)</td>
<td>0.01(^a)</td>
<td></td>
</tr>
<tr>
<td>Aware that prescribed medication can be addictive</td>
<td>0.57 (0.25–1.29)</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>Aware that you should avoid acetaminophen(^1)</td>
<td>2.72 (1.49–4.96)</td>
<td>0.001(^a)</td>
<td></td>
</tr>
<tr>
<td>Side effects (n = 343)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recognized at least one GI side effect (vomiting, nausea, constipation)(^3)</td>
<td>1.28 (0.69–2.35)</td>
<td>0.43</td>
<td></td>
</tr>
<tr>
<td>Recognized at least one sedating side effect (sleepy, dizzy, tired) (^3)</td>
<td>1.01 (0.58–1.74)</td>
<td>0.98</td>
<td></td>
</tr>
<tr>
<td>Knowledge composite score(^1)</td>
<td>0.61 (0.13–1.08)</td>
<td>0.014(^a)</td>
<td></td>
</tr>
</tbody>
</table>

\(^*\)Adjusted for health literacy and clustering.
\(^1\)Indicates questions that were part of the text messages.
\(^2\)Adjusted for clustering.
\(^3\)Adjusted for race, income, health literacy, and clustering.

aOR = adjusted odds ratio; GI = gastrointestinal.
education (delivered in the ED), and video discharge instructions. However, the studies have used different knowledge metrics, making it difficult to compare the interventions’ relative strength.

The variable success of the text messages in our trial raises questions as to why some messages changed knowledge and others did not. Effectively communicating risk is challenging, particularly in the ED, and additional research is needed to determine the best way to communicate risk, particularly the risk of addiction—an item on which our intervention was not successful. While SMS texting has been used previously in the setting of medication adherence to encourage routine use from the ED (e.g., diabetes, hypertension, antibiotics), the goal of our text messages was not to encourage routine use, but rather to reinforce the salience of educational messages delivered at the time of the ED visit or provide a cue to action. The success of the SMS texting component is one of several recent examples of extending the reach of emergency care into the postvisit time period through technology (text messaging, mobile applications, telehealth), a growing and promising avenue for behavioral interventions. We believe that technology delivered interventions such EMC + SMS have great potential in the context of pain management, not only because of their reach into the postvisit space wherein the patient is less distracted but also because the interventions are scalable and can be delivered at the time of the behavior being targeted (e.g., medication taking, pill disposal).

LIMITATIONS

Patients were recruited from a single site in an urban area with a patient population that was relatively well educated and earned a high household income, limiting generalizability. Due to the study design and intervention delivery, patients needed to be consented after randomization, introducing selection bias. Additionally, the trial met with several recruitment challenges that we have detailed in Appendix S4 along with steps taken to improve recruitment, retention, and medication diary return. Although overall recruitment and retention did improve, some of the changes, including the switch from in-person to telephone interview, may have influenced measurement. Despite these attempts to improve recruitment, ultimately, the biggest limitation of the study was not reaching the planned enrollment target. In addition to the recruitment and retention challenges noted above, we had a low rate of return of the medication diaries limiting generalizability from that data source.

An additional limitation is the use of dose demonstration and medical diaries. Demonstrated dosing is an abstraction of actual dosing that may overestimate errors by prompting the patient to take the medications maximally for a 24-hour “day.” Medication diaries are subject to patient recall bias and had a low rate of return, particularly in patients who performed more poorly on the demonstrated dosing task and may be at higher risk for label misunderstanding due to lower literacy.

Further, a minority of the intervention patients received the verbatim Take-Wait-Stop label on their pill bottle. The reasons for this low implementation are likely multiple, including pharmacist unfamiliarity with the label and additional time and workflow interruption to manually type the label rather than using preprogramed “quick codes.”

CONCLUSION

We found that the intervention improved demonstrated safe dosing of opioids and increased patient knowledge. However, there was no influence of the intervention on actual safe medication use among the portion of the sample returning medication diaries. While not discounting the importance of bedside communication, future ED interventions may opt to focus on postdischarge communication as the greatest increases in knowledge in this sample were among patients receiving the text-messaging portion of the intervention.

We acknowledge the research assistants, project coordinators, and analysts who assisted with data collection and preliminary analysis.

REFERENCES

4. Hill MV, Stucke RS, McMahon ML, Beeman JL, Barth RJ Jr. An educational intervention decreases opioid


Suffoletto B, Calabria J, Ross A, Callaway C, Yealy DM. A mobile phone text message program to measure oral antibiotic use and provide feedback on adherence to patients discharged from the emergency department. Acad Emerg Med 2012;19:949–58.


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.13860/full Data Supplement S1. Supplemental material.
CME Information: Video Discharge Instructions for Acute Otitis Media in Children: A Randomized Controlled Open-label Trial

CME Editor: Corey Heitz, MD

Authors: James I. Daley, MD, MS, MPH, Kristin H. Dwyer, MD, Zachary Grunwald, MD, Daniel L. Shaw, MD, Michael B. Stone, MD, Alexandra Schick, MD, Michael Vrablik, DO, M. Kennedy Hall, MD, MS, Jane Hall, PhD, Andrew S. Liteplo, MD, Rachel M. Haney, MD, Nancy Hun, MD, Rachel Liu, MD, and Chris L. Moore, MD

If you wish to receive credit for this activity, please refer to the website: www.wileyhealthlearning.com/aem

Educational Objectives
After reading the article, participants should be able to discuss the effectiveness of video discharge instructions for patients diagnosed with acute otitis media.

Activity Disclosures
This activity received no commercial support.

CME Editor Corey Heitz discloses no relevant financial relationships.

This activity underwent peer review in line with standards of editorial integrity and publication ethics. Conflicts of interest have been identified and resolved in accordance with John Wiley and Sons, Inc.’s Policy on Activity Disclosure and Conflict of Interest.

Accreditation
John Wiley and Sons, Inc. designates this journal-based CME activity for a maximum of 1.0 AMA PRA Category 1 Credit™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

For information on applicability and acceptance of continuing medical education credit for this activity, please consult your professional licensing board.

This activity is designed to be completed within 1 hour. To successfully earn credit, participants must complete the activity during the valid credit period, which is up to two years from initial publication. Additionally, up to 3 attempts and a score of 70% or better is needed to pass the post test.
Video Discharge Instructions for Acute Otitis Media in Children: A Randomized Controlled Open-label Trial

Sheena Belisle, MD1, Andrei Dobrin1, Sharlene Elsie1, Samina Ali, MDCM2,3, Shaily Brahmbhatt1, Kriti Kumar1, Hardika Jasani1, Michael Miller, PhD1,4, Frank Ferlisi, MD5, and Naveen Poonai, MSc, MD1,4

ABSTRACT

Background: Thirty percent of children with acute otitis media (AOM) experience symptoms < 7 days after initiating treatment, highlighting the importance of comprehensive discharge instructions.

Methods: We randomized caregivers of children 6 months to 17 years presenting to the emergency department (ED) with AOM to discharge instructions using a video on management of pain and fever to a paper handout. The primary outcome was the AOM Severity of Symptom (AOM-SOS) score at 72 hours postdischarge. Secondary outcomes included caregiver knowledge (10-item survey), absenteeism, recidivism, and satisfaction (5-item Likert scale).

Results: A total of 219 caregivers were randomized and 149 completed the 72-hour follow-up (72 paper and 77 video). The median (IQR) AOM-SOS score for the video was significantly lower than paper, even after adjusting for preintervention AOM-SOS score and medication at home (8 [7–11] vs. 10 [7–13], respectively; p = 0.004). There were no significant differences between video and paper in mean (±SD) knowledge score (9.2 [±1.3] vs. 8.8 [±1.8], respectively; p = 0.07), mean (±SD) number of children that returned to a health care provider (8/77 vs. 10/72, respectively; p = 0.49), mean (±SD) number of daycare/school days missed by child (1.2 [±1.5] vs. 1.1 [±2.1], respectively; p = 0.62), mean (±SD) number of workdays missed by caregiver (0.5 [±1] vs. 0.8 [±2], respectively; p = 0.05), or median (IQR) satisfaction score (5 [4–5] vs. 5 [4–5], respectively; p = 0.3).

Conclusions: Video discharge instructions in the ED are associated with less perceived AOM symptomatology compared to a paper handout.

From the 1Department of Pediatrics, Division of Paediatric Emergency Medicine, Schulich School of Medicine & Dentistry, Western University, London, Ontario; the 2Department of Pediatrics, Division of Paediatric Emergency Medicine, University of Alberta, Edmonton, Alberta; the 3Children’s Health Research Institute, London Health Sciences Centre, London, Ontario; and the 4Children’s Health Research Institute, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada. Received February 19, 2019; revision received June 27, 2019; accepted July 12, 2019. Presented at the American Academy of Pediatrics Annual Meeting, Orlando, FL, November 2018; the Canadian Paediatric Society Annual Conference, Quebec City, Quebec, May 2018; Canadian Association of Emergency Physicians Conference, Calgary, Alberta, May 2018; the Society for Academic Emergency Medicine Annual Meeting, Indianapolis, IN, May 2018; and the Pediatric Academic Societies Annual Meeting, Toronto, Ontario, May 2018. Funded by a Western University Resident research grant (2017). The authors have no potential conflicts to disclose.

Clinical Trials registration: www.clinicaltrials.gov, NCT02788422.

Author contributions: SB assisted in the conceptualization and design of the trial, monitored data collection, and interpreted the results; NP was the senior, supervising author and drafted the initial manuscript, conceptualized and designed the trial, monitored data collection, and interpreted the results; SA aided in the interpretation of the results, critically reviewed and revised the manuscript; SE assisted in designing the trial, coordinated and supervised data collection, and revised the manuscript; AD, KK, HJ, and SB performed data collection, assisted in interpretation of the results and creation of the data analysis plan, and revised the manuscript; MM assisted in the conceptualization and design of the trial, devised the statistical plan, analyzed the data, and revised the manuscript; FF assisted in the design of the trial, designed the data collection tool, and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Supervising Editor: Michelle L. Macy, MD, MS.

Address for correspondence and reprints: Naveen Poonai, MSc, MD, FRCPC; e-mail: naveen.poonai@lhsc.on.ca.

ACADEMIC EMERGENCY MEDICINE 2019;26:1327–1335.

© 2019 by the Society for Academic Emergency Medicine
doi: 10.1111/acem.13839
Acute otitis media (AOM) is the most commonly diagnosed illness in children after viral upper respiratory tract infections and is the most common indication for antibiotic prescription. Despite the introduction of the pneumococcal conjugate vaccine, 60% of children have experienced at least one episode of AOM by age 3. Costs associated with AOM remain substantial, and parents often visit health care providers for pain and fever. Children less than 5 years have the highest incidence of AOM, and more than one-third experience pain, fever, or both 3 to 7 days following treatment. Almost three-quarters of parents report a significant impact on their work attendance and identify pain and disturbed sleep as the most important sources of AOM-related burden. Survey data suggest high levels of parental uncertainty regarding the treatment of AOM. Moreover, less than 30% of U.S. parents with children with AOM receive instructions on pain management, and only a minority of parents report reading discharge instructions. It has become abundantly clear there is an urgent need to improve the delivery of discharge instructions for AOM.

The Seamless Transitions and Re (Admission) Network (STARNet) initiative has focused on improving the transition of care from health care setting to home and adequate discharge instructions are an essential component of optimal transition. Unfortunately, discharge instructions are often complex, and inadequate parental comprehension has been linked to medication errors, suboptimal postdischarge care, and unnecessary return visits. Among parents who receive discharge instructions in the emergency department (ED), 30% to 50% commit dosing errors and up to 40% fail to administer medications. Standardized discharge instructions are preferred to verbal summaries by parents, are associated with decreased medication error rates, and may be facilitated by video technology. Video technology has been used in pediatric lacerations, sprains, fever, and head injury and is preferred over paper instructions. However, no study has explored the effectiveness of video technology for discharge instruction in AOM. We sought to examine the effectiveness of video discharge instructions in the ED among parents of children with AOM.

**METHODS**

**Study Design and Setting**

We conducted an open-label, parallel group, randomized, two-arm superiority trial to test the hypothesis that video discharge instructions were superior to a paper handout with respect to the AOM Symptom Severity Score (AOM-SOS). We recruited participants from the pediatric ED of the Children’s Hospital, London Health Sciences Center in London, Ontario, Canada, from March 2017 to June 2018. Our institution is a tertiary care pediatric center with an average annual census of 35,000 visits, including approximately 400 patients with AOM. The study received approval from Western University’s Health Sciences Research Ethics Board.

**Participants**

We included parents of children age 6 months to 17 years who had a chief complaint of otalgia in the setting of an upper respiratory tract infection and where the treating physician was at least 50% certain of a clinical diagnosis of AOM. The physician reported diagnostic certainty along a 100-mm visual analog scale and based his/her rating on color photographs of AOM from published diagnostic criteria. We excluded parents who were not the primary care provider, had poor English proficiency, lacked Internet or telephone access, and whose children had a preexisting diagnosis of AOM (≤72 hours old), other concomitant diagnoses (pneumonia, urinary tract infection, gastroenteritis, sinusitis, or any other condition requiring antibiotics and/or admission to hospital), tympanostomy tubes, or acute tympanic membrane perforation. Parents were offered a $5 gift card as compensation for study participation.

A research assistant (RA), unaware of the study hypothesis, assessed eligibility, obtained informed consent, and performed all correspondence with participants. Participants were recruited consecutively for 7 days a week between 10 AM and 10 PM (based on RA availability) following the initial physician assessment.

**Tool Development**

Development of the study materials (knowledge questionnaire, paper, and video instructions) followed published guidelines and were in keeping with a grade 8 literacy level. Information in the video included signs and symptoms, analgesia, and when to seek medical help. The video can be accessed at https://vimeo.com/334292365. The video’s content was informed by a focus group of two pediatric residents, a pediatric emergency nurse, and a pediatric emergency physician. It was pretested among three pediatric emergency physicians and pilot tested among seven parents with
no health care background who were asked to rate it for length, ease of comprehension, and face validity.\textsuperscript{27} The video was created using Easy Sketch Pro3 and administered using a Wi-Fi–enabled iPad. The development, pretesting, and pilot testing of the paper instructions was performed by the identical focus group. Information in the paper instructions (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.13839/full) was identical to the video.

To assess information acquisition, we used a novel 10-item multiple-choice knowledge questionnaire scored out of 10. Each item had one correct answer, an unsure option, and no penalty for guessing (Data Supplement S1, Appendix S2). Questions were limited to information presented in the paper and video instructions. The development, pretesting, and pilot testing of the knowledge questionnaire was performed by the identical focus group.

**Protocol**

Following informed consent, participants were randomized and allocated through a centralized computer-based service (Research Randomizer) to either video or paper-based discharge instructions using permuted block sizes of 4 or 6. Prior to receiving the interventions, participants completed the knowledge questionnaire and baseline AOM-SOS. The AOM-SOS is a validated parent-reported measure of AOM symptomatology\textsuperscript{28} in children as young as 6 months.\textsuperscript{28} Scores range from 0 to 14, with higher scores indicative of greater symptom severity (Data Supplement S1, Appendix S3). The internal consistency of the AOM-SOS is good, with a Cronbach’s alpha of 0.84. The mean scores were significantly different in children with and without a diagnosis of AOM, suggesting good discriminant validity. In addition, scores increased significantly in children who developed AOM and decreased significantly in children whose infection resolved, suggesting good responsiveness.\textsuperscript{25} The interventions were administered by the RA immediately prior to discharge. Immediately after the video had ended and the parents indicated to the RA they had read the handout, the identical knowledge questionnaire was administered. Participants then completed the both subscales of the State-Trait Anxiety Inventory (STAI).\textsuperscript{29} The STAI State and Trait subscales are scored out of 80 and have been used to assess baseline (trait) and illness-related (state) parental distress related to childhood illness.\textsuperscript{30} The internal consistency of the STAI is high, ranging from 0.86 in high school students to 0.95 in military recruits. In terms of content validity, the STAI correlates well with other measures of anxiety.\textsuperscript{31} Participants were permitted to take the paper instructions home or were provided with a unique link to access the video online to accurately track the number of times the video was accessed. Participants in the video group did not receive paper instructions. All participants were asked to refrain from accessing other educational materials. Parents’ questions were answered by the treating physician or RA. However, the bedside nurse and treating physician were asked not to provide any other type of discharge instructions. The RA was present to ensure protocol adherence.

Following discharge, all parents received a daily phone call for 3 consecutive days to complete the AOM-SOS. They were also asked to recall in the past 24 hours any medications administered and doses. On the third day, parents completed a survey assessing their satisfaction with the intervention using a 5-item Likert scale (very unsatisfied = 1, unsatisfied = 2, neutral = 3, satisfied = 4, very satisfied = 5). They were also asked to report the number of missed days of daycare, school, or work; the number of return visits to a health care provider; whether or not analgesia was administered; and any resources used to learn about AOM since discharge. Additionally, they were asked to confirm that they were the only individual who watched the video.

**Outcomes and Analysis**

The primary outcome was the AOM-SOS score on day 3 postdischarge, aligning with the Canadian Institutes of Health Research Strategy for Patient Oriented Research framework that specifies the integration of new knowledge about analgesia into clinical practice, i.e., managing symptoms postdischarge.\textsuperscript{32} The primary outcome was analyzed using ordinal logistic regression adjusted for preintervention AOM-SOS score and analgesia and antibiotic use at home. We believed day 3 would reflect an optimal balance between follow-up adherence and expected resolution of symptoms, as a previous study found that antipyretics and analgesics were used, on average, for 3.6 days in children receiving antibiotics for AOM.\textsuperscript{33} Secondary outcomes included knowledge questionnaire scores, STAI scores, parental satisfaction with the intervention, number of days missed of school or daycare (child) and work (parent), proportion of children with at least one return visit to a healthcare provider, and
proportion of children who received analgesia. Postintervention knowledge questionnaire scores were analyzed using ANCOVA adjusted for preintervention scores. Parent satisfaction was analyzed using ordinal logistic regression. STAI scores were analyzed using independent-samples t-tests. Absenteeism was analyzed using negative binomial regression to account for minor overdispersion in the data. Observations were independent and the data were tested for normality and whether linearity existed. Collinearity was examined with tolerance values and all were sufficient. Categorical outcomes were analyzed using the Pearson chi-square. We performed three post-hoc analyses: the proportion of participants who achieved a >55% reduction in AOM-SOS scores within three days, subgroup analyses for the primary outcome using a test of interaction based on type of AOM (unilateral vs. bilateral) and age (<2 vs. >2 years). For each ordinal logistic regression analysis, we first verified that the omnibus test was significant before looking further at the model predictors. Analyses were by intention to treat.

We calculated a sample size based on a minimal clinically important reduction in AOM-SOS score of 55%. Assuming a standard deviation (SD) of 3.43, a type I error rate of 5% and 90% power, 60 individuals/group were required. Based on previous work requiring a 72-hour follow-up, the sample size was increased by 65% for loss to follow-up and 10% for dropouts, giving a rounded sample size of 105 individuals per group. All data were recorded using the Research Electronic Data Capture (REDCap) platform and analyzed using SPSS (version 24, IBM SPSS). P-values of <0.05 were used to reject the null hypothesis of no difference between groups.

RESULTS

Participants

Of 5,334 parents screened for eligibility, 219 were randomized and analyzed and 149 completed the primary outcome (77 video, 72 paper instructions; Figure 1). Children included 107 of 219 (48.9%) females with an overall mean (±SD) age of 2.9 (±2.8) years and 41 of 219 (18.7%) were not offered analgesia prior to arrival (Table 1). There were no crossovers. Additional resources (Internet, paper documents, advice from a health care provider) were reportedly accessed by 15 of 77 (19.5%) and 13 of 72 (18.1%) in video and paper groups, respectively.

Primary Outcome

Only six of 109 (5.5%) of participants watched the video again, following discharge. Despite this, the median (interquartile range [IQR]) AOM-SOS score in the video group was significantly lower than the paper group on day 3, even after adjusting for preintervention AOM-SOS and medication use (analgesics and antibiotics) (1 [4] vs. 3 [6], respectively; p = 0.004; unadjusted for medication use, p = 0.007; Table 2). There was no significant effect of type of AOM (unilateral versus bilateral, p = 0.93) or age of child (<2 or >2 years, p = 0.15) on the between group difference in AOM-SOS score on day 3. The proportion of participants in the video versus paper groups that achieved at least a 55% reduction in AOM-SOS score within 3 days of discharge was 63/79 (79.7%) versus 50/73 (68.5%; p = 0.11), respectively.

Secondary Outcomes

There were no significant differences in knowledge gain. Parents in the video group had a significantly lower mean (±SD) STAI State (32.3 [±10.7] vs. 35.5 [±12.1], respectively; delta = 3.2; 95% confidence interval [CI] = -6.3 to -0.1; p = 0.04) but not Trait score (33.5 [±8.9] vs. 35.8 [±10.6], respectively; delta = 2.33; 95% CI = -4.9 to 0.3; p = 0.09). There were no significant differences in functional outcomes (return visits to a health care provider, absenteeism from daycare/school or work) or the number of children receiving antibiotics or analgesics following discharge (Table 3). The level of satisfaction was high in both groups (Table 4).

DISCUSSION

We found that discharge instructions delivered using a video was well received and superior to a paper handout in reducing AOM symptomatology but not functional outcomes. Given the logistic advantages of using a video to provide discharge instructions in a busy ED, this approach should be strongly considered, particularly when time and space constraints hamper efforts to engage in a dialogue.

Although AOM symptomatology appeared to be significantly better in the video group, the majority of children in both groups achieved a clinically meaningful reduction (≥55%) in AOM-SOS scores (Table 2). This was not unexpected because the identical discharge instructions were provided to both groups, differing only by the educational format. In addition, our
sample was composed of a relatively educated group of parents where more than two-thirds had a postsecondary degree and had previously cared for children with AOM. As a possible consequence, both groups scored below the STAI threshold for clinically significant situational anxiety and scored high on the postintervention knowledge questionnaire (Table 4). We surmise that participants in both groups were quite capable, at baseline, of managing their child’s symptoms.

The clinical resolution observed in both groups occurred sooner than has been previously described, particularly in the video group (day 2 vs. day 3). Rovers et al. found that 37% of 824 children across six randomized trials experienced a “prolonged” course of AOM, defined as “pain and/or fever at 3 to 7 days.” The authors identified 1) age less than 2 years and 2) bilateral AOM as independent risk factors for a prolonged course. We did not find a significant subgroup effect of these variables but our study was likely not powered to detect differences in AOM-SOS scores based on these covariates. The AOM-SOS incorporates both pain and fever, and in our study, which included 108 of 219 (49.8%) children less than 2 years and 33 of 219 (15.1%) children with bilateral AOM, almost 80% in the video group experienced near complete symptom resolution by day 3. The median AOM-SOS score in the video group on day 3 was 1, consistent with that reported for children without AOM.

Although the majority of parents (178/219, 81.3%) across groups offered analgesia to their children prior to arrival, analgesic use was not universal. In comparison, across groups, a lower proportion of children received analgesia at home for days 1 (135/178, 75.8%) and 2 (98/167, 58.7%), despite high AOM-SOS scores. This may reflect a misconception that antibiotics have analgesic benefits or that analgesia is no longer a priority once antibiotic therapy has been initiated. Almost 57% of parents in a recent German study believed that antibiotics “rapidly relieve earache.” To ensure compliance with the American Academy of Pediatrics guidelines, our findings underscore that health care providers should emphasize to parents the importance of providing appropriate analgesia in the first 3 days of treating AOM, whether or not antibiotics are prescribed.

Our study design lacked a negative control group that received no discharge instructions as this would have been below the standard of care at our institution. This makes it difficult to draw conclusions about the absolute benefit of providing any form of discharge instructions (video or paper). Although not specific to AOM, video discharge instructions provided to parents in the ED setting have consistently been associated with improved knowledge.
contrast, much fewer studies have explored the effectiveness of video discharge instructions on disease-specific health outcomes and compliance. In our sample, recidivism and work/school/daycare absenteeism was uncommon. Absenteeism is likely dependent not only on the disease but on regional economic policies. Greater absenteeism from work has been described, ranging from 16% among Finnish parents of children on amoxicillin-clavulanate to as high as 67% in an international sample.

Although we found a clinical and statistical benefit of video over paper instructions, there were no differences accessing additional sources of information. Therefore, it is unclear if and how the video produced an improvement in symptom scores. One possibility is that the open-label design may have introduced bias such that parents who watched the video simply perceived a relatively greater improvement in AOM symptoms. It is also possible that parents in the video group may have been more likely to utilize

### Table 1
Demographic Characteristics of Participants and Children

<table>
<thead>
<tr>
<th></th>
<th>Paper Instructions (n = 110)</th>
<th>Educational Video (n = 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex of child</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>55 (50)</td>
<td>52 (47.7)</td>
</tr>
<tr>
<td>Male</td>
<td>55 (50)</td>
<td>57 (52.3)</td>
</tr>
<tr>
<td>Child age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2</td>
<td>56 (±50.9)</td>
<td>52 (±47.7)</td>
</tr>
<tr>
<td>&gt;2</td>
<td>54 (±49.1)</td>
<td>57 (±52.3)</td>
</tr>
<tr>
<td>Child offered analgesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prior to arrival</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>86 (78.2)</td>
<td>92 (84.4)</td>
</tr>
<tr>
<td>No</td>
<td>24 (21.8)</td>
<td>17 (15.6)</td>
</tr>
<tr>
<td>Caregiver identity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>84 (76.4)</td>
<td>91 (82.7)</td>
</tr>
<tr>
<td>Father</td>
<td>22 (20)</td>
<td>15 (13.6)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (3.6)</td>
<td>4 (3.6)</td>
</tr>
<tr>
<td>Degree of physician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>certainty in AOM diagnosis</td>
<td>92.1 (14.8)</td>
<td>92.8 (11.2)</td>
</tr>
<tr>
<td>diagnosis using 100 mm VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0 = least certain; 100 =</td>
<td></td>
<td></td>
</tr>
<tr>
<td>most certain)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of AOM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unilateral</td>
<td>94 (85.5)</td>
<td>92 (84.4)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>16 (14.5)</td>
<td>17 (15.6)</td>
</tr>
<tr>
<td>Previous AOM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>71 (64.5)</td>
<td>76 (69.7)</td>
</tr>
<tr>
<td>No</td>
<td>39 (35.5)</td>
<td>33 (30.3)</td>
</tr>
<tr>
<td>Caregiver highest education level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University or greater</td>
<td>37 (33.6)</td>
<td>38 (34.9)</td>
</tr>
<tr>
<td>College</td>
<td>38 (34.5)</td>
<td>46 (42.2)</td>
</tr>
<tr>
<td>Vocational</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>High school</td>
<td>27 (24.5)</td>
<td>24 (22)</td>
</tr>
<tr>
<td>Elementary school</td>
<td>6 (5.5)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Employment in a health care field (previous or current)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>28 (25.5)</td>
<td>33 (30.3)</td>
</tr>
<tr>
<td>No</td>
<td>82 (74.5)</td>
<td>76 (69.7)</td>
</tr>
<tr>
<td>Medication prescribed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>86 (78.2)</td>
<td>89 (81.7)</td>
</tr>
<tr>
<td>Amoxicillin-clavulanate</td>
<td>6 (5.5)</td>
<td>5 (4.6)</td>
</tr>
<tr>
<td>Cefprozil</td>
<td>9 (8.2)</td>
<td>8 (7.3)</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>4 (3.6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (4.5)</td>
<td>7 (6.4)</td>
</tr>
</tbody>
</table>

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

AOM = acute otitis media; VAS = visual analog scale.

*Percentage of total in column.

*Bachelor’s degree, master’s degree, or professional school.

### Table 2
AOM-SOS Scores

<table>
<thead>
<tr>
<th></th>
<th>Paper Instructions (n = 110)</th>
<th>Educational Video (n = 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preintervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (5)</td>
<td>8 (4)</td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 (5.5)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Day 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.5 (6)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Day 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 (6)</td>
<td>1 (4)</td>
</tr>
</tbody>
</table>

Data are reported as median (IQR).

AOM-SOS = acute otitis media Severity of Symptom score; IQR = interquartile range.

*The AOM-SOS scores range from 0 to 14 with higher scores indicative of greater symptom severity.

### Table 3
Provision of Analgesia and Antibiotics by Caregiver Following Discharge

<table>
<thead>
<tr>
<th></th>
<th>Paper Instructions (n = 110)</th>
<th>Educational Video (n = 109)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>69 (77.5)</td>
<td>66 (74.2)</td>
<td>0.59</td>
</tr>
<tr>
<td>Day 2</td>
<td>53 (66.3)</td>
<td>45 (51.7)</td>
<td>0.05</td>
</tr>
<tr>
<td>Day 3</td>
<td>34 (47.2)</td>
<td>27 (35.1)</td>
<td>0.16</td>
</tr>
<tr>
<td>Antibiotics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>80 (89.9)</td>
<td>83 (93.3)</td>
<td>0.42</td>
</tr>
<tr>
<td>Day 2</td>
<td>72 (90)</td>
<td>80 (92)</td>
<td>0.68</td>
</tr>
<tr>
<td>Day 3</td>
<td>63 (87.5)</td>
<td>72 (93.5)</td>
<td>0.33</td>
</tr>
</tbody>
</table>

Data are reported as n (%).

*Analgesics consisted of either ibuprofen or acetaminophen.

*Antibiotics were prescribed to all children of enrolled participants.
nonpharmacologic therapies (rocking, holding, nonnutritive sucking), all of which have been found to reduce pain. Although a greater proportion of parents who received written instructions provided analgesia, we did not assess whether or not it was optimally dosed. However, we expect that the process of randomization would have accounted for both known and unknown sources of potential bias. Although this was not formally tested postdischarge, a more likely possibility is that there may have been greater retention of information in the video group. There is ample evidence that written discharge instructions are often poorly understood or altogether not read. Retention of knowledge has been found to be greater with verbal reinforcement of written discharge instructions, and the video used both verbal and written communication. Cartoon illustrations were also featured in the video; this format has been associated with greater parental comprehension and compliance with ED discharge instructions. A final possibility is that the instruments used to measure knowledge and medication may not have been granular enough to detect between-group differences that may have subtly influenced AOM symptoms. Using video as an adjunct to written instructions has been found to improve parental knowledge of fever, gastroenteritis, and asthma. Although a multimodal approach was not used in our study, a combination may have led to greater knowledge retention.

LIMITATIONS

Low health literacy and limited English proficiency have been cited as risk factors for errors in management of discharge instructions among parents. Our sampling frame included a relatively large proportion of middle-income-class parents with higher education. Therefore, our results cannot be reliably generalized to the demographic that are most at risk from poor comprehension of discharge instructions. We used paper discharge instructions as the comparator because it was the standard of care at our center. The effect sizes cannot be generalized to other settings where verbal instructions are predominantly used. However, written instructions have been shown to impart superior knowledge acquisition to verbal instructions, and the effect size we observed may have been larger if our comparator group received verbal instructions. Finally, the diagnosis of AOM was not definitively confirmed (via tympanograms, for example) but rather was based on the clinical assessment of the treating physician. However, we felt that this was the most pragmatic approach and physicians in both groups were certain enough of the diagnosis of AOM to prescribe antibiotics.

CONCLUSIONS

Children of parents with acute otitis media who watched a 5-minute video in the ED detailing the identification and management of pain and fever experienced a clinically important and statistically significant decrease in symptomatology compared to a paper handout. Both interventions were associated with high parental knowledge and satisfaction and were associated with clinically important reductions in symptoms within 3 days. Our findings suggest that video discharge instructions are beneficial for ED use among parents of children with acute otitis media. Further study is required to examine if video discharge instructions may be related to improved symptomatology of other illnesses.

**Table 4**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Paper Handout</th>
<th>Educational Video</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of correct preintervention knowledge questionnaire answers (maximum 10) (n = 110)</td>
<td>6.9 (±1.7) (n = 109)</td>
<td>7.1 (±1.2) (n = 109)</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of correct postintervention knowledge questionnaire answers (maximum 10) (n = 110)</td>
<td>9.2 (±1.3) (n = 109)</td>
<td>8.8 (±1.8) (n = 108)</td>
<td>0.07</td>
</tr>
<tr>
<td>Children with at least one healthcare visit within 3 days of discharge (n = 72)</td>
<td>10 (13.9)</td>
<td>8 (10.4)</td>
<td>0.49</td>
</tr>
<tr>
<td>Number of days missed of activities/daycare/schoola (n = 72)</td>
<td>1.1 (±2.1) (n = 72)</td>
<td>1.2 (±1.5) (n = 77)</td>
<td>0.62</td>
</tr>
<tr>
<td>Number of workdays missed by parentb (n = 68)</td>
<td>0.8 (±1.9) (n = 72)</td>
<td>0.5 (±1) (n = 77)</td>
<td>0.05</td>
</tr>
<tr>
<td>Parent satisfaction score (maximum 5), median (IQR) (n = 72)</td>
<td>5 (1) (n = 72)</td>
<td>5 (1) (n = 77)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

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

IQR = interquartile range.

aAll children attended a daytime activity, nursery school, elementary school, or daycare.

bIncludes only parents who worked outside the home.


31. Julian LJ. Measures of anxiety: State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), and Hospital Anxiety and Depression Scale-Anxiety (HADS-A). Arthritis Care Res 2011;63:S467–72.


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.13839/full

Data Supplement S1. Supplemental material.
ABSTRACT

Objectives: Repeat visits (revisits) to emergency departments (EDs) for psychiatric care reflect poor continuity of care and impose a high financial cost. We test whether rapid expansion of community health centers (CHCs)—which provide regional, low-cost primary care—correspond with fewer repeat psychiatric-related ED visits (PREDVs).

Methods: We obtained repeated cross-sectional time-series data for 7.8 million PREDVs from the State Emergency Department Database for four populous U.S. states (California, Florida, North Carolina, and New York) from 2006 to 2011. We specified as the outcome variable the count of repeat visits per ED visitor with a psychiatric diagnosis. We retrieved aggregate-level mental health visits at CHCs from the Uniform Data System. Negative binomial regression methods controlled for individual-level confounders, county health system and sociodemographic attributes, year fixed effects, and county fixed effects.

Results: The risk of a repeat PREDV decreased with a county-level increase in mental health patients seen at CHCs (incidence rate ratio = 0.986, 95% confidence interval = 0.98 to 0.99). Conversion of this rate ratio to the number of revisits averted indicated 34,000 fewer repeat PREDVs in these four states statistically associated with a 1% expansion in CHC mental health visits. Exploratory analyses found that revisits decline for relatively mild/moderate illnesses (e.g., mood, anxiety disorders) but not for severe illnesses (e.g., schizophrenia/psychoses).

Conclusion: An increase in mental health services at CHCs corresponds with a modest decline in repeat PREDVs. This decline concentrates among those with less severe mental illnesses.
reducing repeat psychiatric-related ED visits (PREDVs) while also strengthening mental health care delivery in nonurgent settings.\textsuperscript{7}

Previous literature on repeat PREDVs focuses on patient and ED characteristics that affect the likelihood of revisits. Less work, however, examines whether system-level health care factors affect repeat visits.\textsuperscript{8} System-level services may affect the likelihood of repeat PREDVs in three ways. First, expansion of health insurance may lower barriers to help-seeking in all settings including the ED.\textsuperscript{9} Second, distance from health care providers, rural/urban location, neighborhood level socioeconomic attributes (e.g., racial/ethnic composition, poverty) and less tolerant societal attitudes toward mental illness could lead patients and caregivers to avoid regular psychiatric treatment from primary care providers and delay care until emergency care is needed.\textsuperscript{3,10} Third, regional health care system capacity may determine availability or supply of specialist and primary care mental health resources that may serve as a viable alternative to ED care.\textsuperscript{11} Community-based mental health services may ensure regular follow-up, thereby reducing repeat PREDVs for a subset of cases not requiring urgent care.\textsuperscript{12}

A cross-sectional analysis of adults in the United States finds that community-level health care resources (such as federally qualified health centers) correlate positively with psychiatric help-seeking, particularly among racial/ethnic minorities.\textsuperscript{13} Federally qualified health centers, also known as community health centers (CHCs), have expanded dramatically over the past decade in the United States. CHCs now serve one in 12 persons in the country.\textsuperscript{14} These centers target low-income, disadvantaged neighborhoods. About 75\% of CHCs provide mental health services.\textsuperscript{15}

The number of patients seen at CHCs for mental health and substance use has increased markedly over the past decades.\textsuperscript{16} This substantial increase in regional mental health care supply may affect the risk of repeat PREDVs. CHCs provide case management, routine follow-up visits, and preventive care regardless of a person’s ability to pay. We know of no research that evaluates whether the expansion of mental health services at CHCs corresponds with a reduced rate of repeat PREDVs.

We tested the hypothesis that county-level increases in mental health visits at CHCs correspond with a reduction in the risk of repeat PREDVs. We examined 7.8 million outpatient psychiatric patients from 109 U.S. counties from 2006 to 2011, a period that underwent rapid expansion of mental health services at CHCs. The literature on utilization of emergency services following increases in health care access and supply shows both increases and decreases in ED visits.\textsuperscript{9,11,12} We therefore specify our tests as two-tailed.

Our work contributes to the literature in that we provide the first large-scale, longitudinal evaluation of CHCs’ impact on repeat PREDVs. Results from our study hold particular relevance given an Affordable Care Act–funded increase in CHCs and the possibility that growth might reduce—or, in light of the Oregon experience, increase—expensive, clinically disadvantageous repeat visits.

METHODS

Data, Variables, and Study Population

Outcome: Patient-level Data on PREDVs. We obtained psychiatric outpatient ED data from the State Emergency Department Database (SEDD). The Agency for Healthcare Research and Quality makes available the SEDD under their Healthcare Cost Utilization Project (HCUP).\textsuperscript{17} SEDD contains visit-level data on all outpatient treat-and-release PREDVs from over 99\% hospitals in participating states in the United States.\textsuperscript{18} We identified repeat users of the ED for psychiatric care through a unique identifier called “visitlink” (details provided in Data Supplement S1, Appendix A.1, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13812/full).\textsuperscript{19} Prior research utilizes this variable to examine high users of EDs for psychiatric and somatic conditions.\textsuperscript{20,21}

Researchers using administrative data such as the SEDD typically code an ED visit as “psychiatric-related” if a mental health diagnosis appears on any of the ICD-9 diagnostic codes recorded for the visit.\textsuperscript{22} This decision arises from observations that an underlying mental health condition may present to the ED with other complaints or stated reasons for the visit (e.g., stomachache). We, consistent with this logic, classified psychiatric-related visits as ED encounters assigned an ICD-9 diagnostic code—anywhere in the ED record—for mental health–related conditions contained in the Clinical Classification Software (CCS).\textsuperscript{23} CCS classifications compile ICD-9 codes into clinically meaningful categories and enjoy wide utilization in mental health literature on ED visits and inpatient admissions.\textsuperscript{22–26} These mental health conditions
include mood, anxiety, psychoses, and substance use disorders, among others (please refer to Appendix Table A.1 for full list of ICD-9 codes). Institutional review board review by the University of California deemed that our study did not qualify as human subjects research; no human subjects protocol number was assigned.

**Study Population.** We included in our analysis states that report the visitlink variable and race, age, gender, county, and health insurance information. Four states—California, Florida, North Carolina, and New York—met these conditions. The most populous state in this group, California, does not report race after 2011. Hence, we restricted our analysis to the time period of 2006 to 2011. Our final analytic sample comprises 7.8 million patients with an outpatient PREDV.

**Exposure: County-level Mental Health Visits at CHCs.** We retrieved data on our independent variable, mental health visits/patients at CHCs, from the Uniform Data system (UDS). As a condition of receiving federal funding under section 330 of the Public Health Service Act, CHCs report aggregated information on patient demographics and service volume. Over 99% of CHCs completed these reports over our study period. The Health Resource and Service Administration oversees the UDS data collection and verification through state-level data trainings, data screening for discrepancies, communication with CHC directors for outliers, and a clinical consultation helpline for data entry and compilation. We acquired the UDS data via a Freedom of Information Act Request (#17F167).

We used aggregated county-level CHC mental health indicators to measure the system-level reach of CHC mental health services in a county-year. We used three indicators of mental health services in CHCs: 1) mental health visits at CHCs, 2) mental health patients seen at CHCs, and 3) number of mental health visits per mental health patient at CHCs. Whereas the first two measures gauge the volume of services, the third measure may assess the extent of continuity of care or the severity of a condition.

**Data Analysis**

We defined the outcome variable of revisit (i.e., repeat PREDV) as greater than one occurrence of a patient's unique identifier within a state-year. We assigned a revisit value of zero for patients with only one PREDV within a year. Patients with more than one visit received a revisit score equal to the total occurrence of ED visits less the first visit. Because our outcome variable is a count of repeat visits, we employed a negative binomial regression approach. The negative binomial specification enjoys widespread use in literature concerning psychiatric ED visits. Based on the episodic and rare nature of repeat PREDVs, a count regression model provides a more consistent estimate than does a traditional ordinary-least-squares approach. We also examined a Poisson structure for count data, but the negative binomial approach provided a much better model fit given the discovered overdispersion of the count of revisits.

We estimated the change in the count of repeat PREDVs per unit change in county-level CHC mental health services. The base count or incidence of repeat PREDVs may vary substantially across counties and across years for reasons unrelated to CHC mental health service capacity. We selected our empirical model to control for this possibility. We fitted a two-way fixed-effects model where county indicator variables capture all time-invariant county heterogeneity (such as the underlying prevalence of mental disorders specific to each county) and year indicators control for secular annual trends in psychiatric ED revisits that impact all regions within a year.

In addition, we controlled for county attributes that may affect repeat PREDVs and correlate positively with expansion of CHC mental health services. These variables, aggregated to the county-year level, include percentage of population below the poverty line, percent without health insurance, physicians per 100,000 population, total hospital beds available, and percentage of population reporting African American race/ethnicity. All CHCs serve medically underserved areas and populations, but caution dictates that we also control for residual health care, socioeconomic status, and ethnicity-related variation. We obtained these data from U.S. Census Bureau's Population Estimates and Small Area Estimates programs. We retrieved data on number of physicians and hospital beds per county-year from the area health resource files. We linked these variables to SEDD using county Federal Information Processing Standards (FIPS) codes. We specified clustered, robust standard errors to adjust for nonconstant variance across counties. We repeated this analysis for youths (age < 25 years) and adults (age ≥ 25 years) separately, in keeping with literature that suggests
differential psychiatric help-seeking patterns in these age groups. For hypothesis tests that reject the null, we estimated the number of repeat PREDVs statistically averted with increase in exposure.

Although not central to our test, we then explored whether mental health visits at CHCs reduced repeat PREDVs to a greater extent for relatively less-severe illnesses (e.g., anxiety disorders) versus more serious conditions such as schizophrenia. To understand the extent of variation in repeat PREDVs by disease severity, we first plotted the cumulative probability of an ED revisit using nonparametric Kaplan-Meier survival graphs. Kaplan-Meier estimates provide cumulative probabilities by multiplying the probability of event occurrence (i.e., a revisit to the ED) at successive time points with revisit probabilities computed for earlier time points. These estimates yield revisit likelihood curves by disorder groups, and the difference in slopes of these curves for separate disorders helps compare repeat PREDV probabilities for severe versus mild/moderate psychiatric diagnoses. Next, we conducted negative binomial regression analyses (using identical formulation as described above), separately for each illness group contained within CCS classifications. We conducted all analyses in Stata version 14.3.

RESULTS

Descriptive Results

During our study period, over 21% of outpatient ED visitors with a psychiatric-related diagnosis had a repeat visit (Figure 1). Most persons with repeat PREDVs had only one additional visit in a year. A small fraction of individuals, however, reported more than 10 revisits. The variance of repeat visits (1.26) was nearly three times its mean (0.42), which indicates that a negative binomial count model better fits the data than a Poisson count model (Table 1). Whites comprised the majority of psychiatric-related ED patients. Consistent with previous research, the majority of psychiatric-related ED visitors had public insurance.

Figure 2 graphs the rate of growth in repeat PREDVs over our test period. By 2011, average repeat visits per patient increased by over 33% relative to 2006 levels. The upward trend cohered with previous findings on psychiatric ED utilization rates. Mental health visits at CHCs also showed a sharp rise over the study period (Figure 3) and increased by approximately 50% from 2006 to 2011. Data Supplement S1, Appendix Figures A.1 and A.2, show trends in average number of CHC mental health patients per 100 population (Data Supplement S1, Figure A.1), average number of mental health visits per mental health patient at CHCs (Data Supplement S1, Figure A.2), as well as state-specific trends (Data Supplement S1, Appendix Figures A.3–A.5). Overall, we observed a positive slope for both exposures, with slight decline in years 2007 and 2008 for CHC mental health patients and CHC visits per mental health patient, respectively.

Figure 4 graphs the probability of a repeat visit within 1 calendar year of first ED encounter for anxiety, mood, and psychotic disorders (including schizophrenia) based on the diagnosis at index PREDV. We focused on these three illness groups to permit comparisons to previous research and given that these comprise about 50% of all ED repeat visits in our data. Consistent with past research, the highest probability of a revisit within 1 year of index ED visit occurred for schizophrenia/psychotic disorders, followed by mood and anxiety disorders.

On average, CHCs reported 2.3 mental health visits and 0.75 mental health patients per 100 population in a county. This rate, however, varied widely across county-years (Table 2). Mental health patients averaged about three CHC visits, with some counties averaging as high as eight visits per patient. The large standard deviation of county-level socioeconomic and health system indicators such as percentage of population in poverty, physician concentration, and others indicated wide variation in socioeconomic characteristics and health system indicators across county-years.
Table 1

<table>
<thead>
<tr>
<th>Attributes</th>
<th>N</th>
<th>% of Total Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total sample size</td>
<td>7,797,308</td>
<td>100</td>
</tr>
<tr>
<td>Psychiatric-related ED patients with zero repeat visits</td>
<td>6,133,451</td>
<td>78.66</td>
</tr>
<tr>
<td>Psychiatric-related ED patients with one or more repeat visits</td>
<td>1,663,857</td>
<td>21.34</td>
</tr>
<tr>
<td>Mean repeat psychiatric-related ED visits (per capita)</td>
<td>0.42</td>
<td></td>
</tr>
<tr>
<td>Standard deviation of repeat psychiatric-related ED visits (per capita)</td>
<td>1.26</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>4,468,732</td>
<td>57.31</td>
</tr>
<tr>
<td>African American</td>
<td>1,295,359</td>
<td>16.61</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1,220,219</td>
<td>15.65</td>
</tr>
<tr>
<td>Other</td>
<td>812,998</td>
<td>10.43</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3,702,315</td>
<td>47.48</td>
</tr>
<tr>
<td>Female</td>
<td>4,051,058</td>
<td>51.95</td>
</tr>
<tr>
<td>Insurance status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>2,999,354</td>
<td>38.56</td>
</tr>
<tr>
<td>Private</td>
<td>2,353,721</td>
<td>30.21</td>
</tr>
<tr>
<td>Uninsured</td>
<td>2,437,703</td>
<td>31.29</td>
</tr>
<tr>
<td>Age group (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25 (youth)</td>
<td>1,479,753</td>
<td>18.98</td>
</tr>
<tr>
<td>≥25 (adults)</td>
<td>6,301,792</td>
<td>80.82</td>
</tr>
</tbody>
</table>

Figure 2 Average number of repeat PREDVs per patient in 109 counties in California, Florida, North Carolina, and New York from 2006 to 2011 (n = 7.8 million). PREDVs = psychiatric-related ED visits. [Color figure can be viewed at wileyonlinelibrary.com]

Figure 3 Average number of mental health visits at CHCs per county in California, Florida, North Carolina, and New York from 2006 to 2011. CHCs = community health centers.

Analytic Results

Negative binomial regression results (Table 3) indicated a reduction in repeat PREDV rate ratio with a one-unit increase in CHC mental health visits per 100 population (Model 1, incidence rate ratio [IRR] = 0.986, p < 0.001). Put another way, we observed 1.4 fewer repeat PREDVs for every additional 100 mental health visits at CHCs. An increase in mental health patients seen at CHCs also correlated with a 2.6% reduction in repeat PREDVs, although this relation fell just outside conventional levels of statistical detection (Model 2, IRR = 0.974, p = 0.09). Intensity of CHC mental health service utilization, modeled as mental health visits per mental health patient at CHCs (Model 3), showed no association with repeat PREDVs.

Previous research indicated that children seek psychiatric ED care via fundamentally different pathways than do adults.37 In light of this work, expansion of mental health services at CHCs may affect adults’ and children’s rate of repeat PREDVs differently. To
explore this possibility, we divided our sample into youth (age < 25 years) and adults (age ≥ 25 years) and repeated the analysis. Results for adults remained essentially unchanged from the original test (Data Supplement S1, Appendix Table A.2). However, the inverse association between CHC mental health visits and repeat PREDVs appeared slightly stronger for youth (Data Supplement S1, Appendix Table A.2).

Exploratory Results by Disorder Subgroups

Exploratory analyses by psychiatric disorder subgroups showed that increases in mental health visits at CHCs correspond with a lower risk of repeat PREDVs for adjustment, anxiety, ADD/conduct, cognitive, impulse control, mood, alcohol disorders, and suicidal ideation/self-harm. We, by contrast, found no association with CHC visits and repeat PREDVs for developmental, personality, substance use, and psychotic disorders (Data Supplement S1, Appendix Table A.3).

Statistical Estimation of Revisits Averted

To gauge the magnitude of repeat PREDVs averted with CHC expansion of mental health services, we estimated the net absolute reduction in repeat PREDVs following increases in mental health visits at CHCs. We obtained the predicted number of events for each unit increment in mental health visits at CHCs (average marginal effect, all other covariates held constant) using Stata’s “margins” command (Data Supplement S1, Appendix Figure A.6). We then multiplied the predicted events by the total sample size to obtain number of predicted repeat PREDVs. For our study of 7.8 million PREDV cases, we estimated approximately 34,000 fewer repeat PREDVs statistically attributable to a 1% expansion (i.e., 1-unit increase per 100 population) in CHC mental health visits.

DISCUSSION

We used a large population-based data set of psychiatric-related outpatient ED visits to test the novel hypothesis that expanding primary mental health care at CHCs corresponds with a reduced incidence of repeat PREDVs. We examined four geographically dispersed states, covering 7.8 million visits, over a dynamic time period. The results supported our hypothesis in that an increase in mental health visits at CHCs corresponds with a reduction in the risk of repeat PREDVs. We viewed the modest magnitude of the result as reasonable given the relatively low average penetration rate of CHCs in many counties (i.e., 8% in 2015).14,40 Subgroup analyses indicated that this inference holds for both adults and youth and for less severe disorders.

Emergency services largely focus on crisis-oriented care. Aftercare following a psychiatric ED visit plays a major role in reducing repeat emergency visits. However, a large proportion of emergency physicians do not use or have access to coordinated systems for identifying, tracking, and following up on high utilizers of psychiatric EDs.51 CHCs may plausibly reduce revisits.
by overcoming these drawbacks in many ways. First, continuous follow-up, combined with routine preventive care at community centers may detect changes in mental health status in a timely manner and reduce the need of emergency interventions. Second, CHCs may promote patient involvement during psychiatric consultations to foster trusting patient-provider relationships, reduce the likelihood of a misdiagnosis, and ensure adherence to medication. Third, routine interaction with psychiatric patients may enhance the knowledge, skills, and capacity of CHCs primary health providers in delivering care.

Strengths of our study include the use of 7.8 million patient records with information on annual revisits per patient, which help control for individual-level attributes and allow precise estimation. The time-series nature of our data, combined with a county-level fixed-effects strategy, also controls for regional and temporal patterns that could confound associations. In addition, we analyzed some of the most populous and diverse states in the United States over a 6-year time period, which lends external validity to our results. Furthermore, exploratory analyses of multiple subgroups (by age, illness) show that trends in our data cohere with observations from small-sample studies of characteristics of repeat psychiatric ED users, which supports the reliability of the SEDD data set.

Exploratory analyses reveal differential revisit responses to increases in community-level mental health care at CHCs depending on the type of mental disorder diagnosis at initial ED admission. Improved access to primary care at CHCs may reduce the demand for EDs among patients with psychiatric disorders of relatively mild/medium acuity but not among the severely mentally ill who require comprehensive and specialized services. We, however, note the exploratory nature of this diagnosis-specific analysis. We encourage more refinement and testing of our speculative claim.

Over our test period, societal factors such as reduced stigma against psychiatric help-seeking, or reduction in the patient out-of-pocket costs for mental health care at CHCs may reduce the demand for EDs among patients with psychiatric disorders of relatively mild/medium acuity but not among the severely mentally ill who require comprehensive and specialized services. We, however, note the exploratory nature of this diagnosis-specific analysis. We encourage more refinement and testing of our speculative claim.

Table 3
Negative Binomial Regression Results Predicting IRR of a Revisit to Outpatient Psychiatric ED as a Function of 1) CHC Mental Health Visits (Model 1), 2) CHC Mental Health Patients (Model 2), and 3) CHC Mental Health Visits per Mental Health Patient (Model 3)

<table>
<thead>
<tr>
<th>Covariates</th>
<th>Model 1</th>
<th></th>
<th>Model 2</th>
<th></th>
<th>Model 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CHC mental health visits per 100 population</td>
<td>0.986***</td>
<td>0.981-0.992</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>CHC mental health patients per 100 population</td>
<td>—</td>
<td>—</td>
<td>0.974</td>
<td>0.944-1.004</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>CHC mental health visits per patient</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.984</td>
<td>0.962-1.005</td>
<td>—</td>
</tr>
<tr>
<td>Age (years)</td>
<td>0.993***</td>
<td>0.981-0.992</td>
<td>0.993***</td>
<td>0.992-0.995</td>
<td>0.993***</td>
<td>0.992-0.995</td>
</tr>
<tr>
<td>Females (reference = male)</td>
<td>0.950</td>
<td>0.992-0.995</td>
<td>0.950</td>
<td>0.898-1.006</td>
<td>0.950</td>
<td>0.897-1.006</td>
</tr>
<tr>
<td>Race (reference = white)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>African American</td>
<td>0.945</td>
<td>0.898-1.006</td>
<td>0.945</td>
<td>0.886-1.009</td>
<td>0.945</td>
<td>0.885-1.009</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.780***</td>
<td>0.744-0.817</td>
<td>0.780***</td>
<td>0.744-0.817</td>
<td>0.780***</td>
<td>0.743-0.816</td>
</tr>
<tr>
<td>Other</td>
<td>0.684***</td>
<td>0.630-0.743</td>
<td>0.684***</td>
<td>0.630-0.743</td>
<td>0.685***</td>
<td>0.630-0.745</td>
</tr>
<tr>
<td>Public insurance (reference = all other insurance groups)</td>
<td>1.371***</td>
<td>1.294-1.454</td>
<td>1.371***</td>
<td>1.294-1.454</td>
<td>1.373***</td>
<td>1.294-1.456</td>
</tr>
<tr>
<td>Private insurance (reference = all other insurance groups)</td>
<td>0.581***</td>
<td>0.537-0.630</td>
<td>0.582***</td>
<td>0.537-0.630</td>
<td>0.581***</td>
<td>0.536-0.629</td>
</tr>
<tr>
<td>Percentage of poverty</td>
<td>1.009</td>
<td>0.998-1.020</td>
<td>1.009</td>
<td>0.998-1.020</td>
<td>1.007</td>
<td>0.996-1.018</td>
</tr>
<tr>
<td>Percent uninsured</td>
<td>1.004</td>
<td>0.997-1.011</td>
<td>1.004</td>
<td>0.997-1.012</td>
<td>1.004</td>
<td>0.997-1.011</td>
</tr>
<tr>
<td>Physicians per 100,000 population</td>
<td>1.001</td>
<td>0.999-1.003</td>
<td>1.001</td>
<td>1.000-1.003</td>
<td>1.001</td>
<td>1.000-1.003</td>
</tr>
<tr>
<td>Hospital beds per 100,000 population</td>
<td>1.000</td>
<td>1.000-1.001</td>
<td>1.000</td>
<td>1.000-1.001</td>
<td>1.000</td>
<td>1.000-1.001</td>
</tr>
<tr>
<td>Percent African American</td>
<td>0.924**</td>
<td>0.876-0.974</td>
<td>0.929**</td>
<td>0.882-0.979</td>
<td>0.929*</td>
<td>0.876-0.986</td>
</tr>
<tr>
<td>Year fixed effects (reference = 2006)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>2007</td>
<td>1.037**</td>
<td>1.010-1.064</td>
<td>1.032*</td>
<td>1.006-1.059</td>
<td>1.029*</td>
<td>1.002-1.057</td>
</tr>
<tr>
<td>2008</td>
<td>1.089***</td>
<td>1.054-1.125</td>
<td>1.085***</td>
<td>1.051-1.120</td>
<td>1.081***</td>
<td>1.048-1.116</td>
</tr>
<tr>
<td>2009</td>
<td>1.136***</td>
<td>1.088-1.186</td>
<td>1.130***</td>
<td>1.083-1.180</td>
<td>1.122**</td>
<td>1.074-1.173</td>
</tr>
<tr>
<td>2010</td>
<td>1.132***</td>
<td>1.065-1.204</td>
<td>1.123***</td>
<td>1.055-1.195</td>
<td>1.119**</td>
<td>1.050-1.193</td>
</tr>
<tr>
<td>2011</td>
<td>1.215***</td>
<td>1.153-1.280</td>
<td>1.206***</td>
<td>1.143-1.272</td>
<td>1.201**</td>
<td>1.136-1.269</td>
</tr>
</tbody>
</table>

**IRR = incident rate ratio.**

*p < 0.05.

**p < 0.01.

***p < 0.001.
health care, could account for the upward trend in psychiatric care both at CHCs and in EDs. Furthermore, these factors may differ across state- or county-level settings. We encourage future research that investigates this general upward trend as well as geographic variation in this trend.

Prior research finds that the health care charge for frequent psychiatric ED users is six times greater than infrequent visitors’ median charge (i.e., $19,500 vs. $3,300). In contrast, the care charge for a psychiatric or behavioral health-related CHC visit ranges from $67 to $146 per visit, which represents a small fraction of that incurred per mental health–related ED visit. A rigorous cost-effectiveness analyses of the influence of CHC expansion on the system of care may further inform the debate regarding the value of continued CHC expansion as a strategy to reduce medically unnecessary ED visits.

LIMITATIONS

We cannot know whether individuals who initially sought care in an ED setting subsequently sought care at CHCs rather than via an ED revisit. Our results, rather, pertain to system-level drivers of repeat PREDVs. Regional expansion of low-cost health systems may increase psychiatric help-seeking for regular rather than episodic urgent care. In such a circumstance, it remains plausible that health system expansions may prompt patients to seek CHCs as an alternative to EDs.

The visitlink algorithm used to define ED revisits may not capture all revisits. Researchers at HCUP cannot link visits which span across 2 calendar years. This circumstance, combined with the strict inclusion criteria for labeling an ED visit as a “revisit,” indicates that our estimates of the total number of repeat PREDVs represent a lower bound of the true level. Although the careful process for creating visitlink promotes strong internal validity of results, we caution the reader against using our estimates of the count of repeat PREDVs to approximate the population-level frequency of revisits.

Recent research finds that an increase in geographic density of CHCs per county coincides with a reduction in ED usage among uninsured adults but not among publicly insured patients. We could not directly test differential revisits by insurance group because CHCs currently do not report data on insurance group for mental health visits. We also have limited information on precise indicators of quality and continuity of mental health care provided at CHCs. As of 2014, CHCs must report the prevalence of the use of a depression screener for all patients. This quality control measure may assist future examination of “high-performing” CHCs, which serve as exemplars for integration of behavioral health into the primary care setting.

CONCLUSIONS

We observed a modest relation between a rise in community health center mental health visits and a reduction in the risk of repeat psychiatric-related ED visits. If replication of our work in other places and times supports 34,000 fewer repeat psychiatric-related ED visits for each 1% expansion in community health center mental health visits, this reduction in psychiatric-related ED visits could yield substantial benefit on the overcrowded yet underfunded ED setting.

We acknowledge Dr. Lisa Abdishoo and Dr. Ana Wong McDonald at Los Angeles Christian Health Centers (LACHC) for providing insight into mental health services at community health centers.

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.13812/full Data Supplement S1. Supplemental material.
Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluid in Sepsis: The PRoMPT BOLUS Randomized Controlled Trial Pilot Feasibility Study

Fran Balamuth, MD, PhD, MSCE, Marlena Kittick, MPH, Peter McBride, Ashley L. Woodford, Nicole Vestal, Mary Kate Abbadessa, MSN, RN, T. Charles Casper, PhD, Melissa Metheney, RN, Katherine Smith, MPH, BSN, RN, Natalie J. Atkin, Jill M. Baren, MD, J. Michael Dean, MD, Nathan Kuppermann, MD, MPH, and Scott L. Weiss, MD, MSCE

ABSTRACT

Background: Resuscitation with crystalloid fluid is a cornerstone of pediatric septic shock treatment. However, the optimal type of crystalloid fluid is unknown. We aimed to determine the feasibility of conducting a pragmatic randomized trial to compare balanced (lactated Ringer's [LR]) with 0.9% normal saline (NS) fluid resuscitation in children with suspected septic shock.

Methods: Open-label pragmatic randomized controlled trial at a single academic children’s hospital from January to August 2018. Eligible patients were >6 months to <18 years old who were treated in the emergency department for suspected septic shock, operationalized as blood culture, parenteral antibiotics, and fluid resuscitation for abnormal perfusion. Screening, enrollment, and randomization were carried out by the clinical team as part of routine care. Patients were randomized to receive either LR or NS for up to 48 hours following randomization. Other than fluid type, all treatment decisions were at the clinical team’s discretion. Feasibility outcomes included proportion of eligible patients enrolled, acceptability of enrollment via the U.S. federal exception from informed consent (EFIC) regulations, and adherence to randomized study fluid administration.

Results: Of 59 eligible patients, 50 (85%) were enrolled and randomized. Twenty-four were randomized to LR and 26 to NS. Only one (2%) of 44 patients enrolled using EFIC withdrew before study completion. Total median (interquartile range [IQR]) crystalloid fluid volume received during the intervention window was 107 (60 to 155) mL/kg and 98 (63 to 128) mL/kg in the LR and NS arms, respectively (p = 0.50). Patients randomized to LR received a median (IQR) of only 20% (13 to 32) of all study fluid as NS compared to 99% (64% to 100%) of study fluid as NS in the NS arm (absolute difference = 79%, 95% CI = 48% to 85%).

Conclusions: A pragmatic study design proved feasible to study comparative effectiveness of LR versus NS fluid resuscitation for pediatric septic shock.

From the 1Department of Pediatrics, Division of Emergency Medicine; the 2Pediatric Sepsis Program; the 4Department of Anesthesiology and Critical Care, Children’s Hospital of Philadelphia, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA; the 3Department of Pediatrics, University of Utah School of Medicine, Salt Lake City, UT; the 5Department of Emergency Medicine, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA; and the 6Department of Emergency Medicine, University of California, Davis Health, Sacramento, CA.

Received April 5, 2019; revision received May 17, 2019; accepted May 26, 2019.

This study was performed at the Children’s Hospital of Philadelphia.

Financial support was provided by 5K12HL109009-04 and U24 TR001597. Dr. Balamuth received support from K23 HD082368. Dr. Weiss was also supported by K23GM110496.

The authors have no relevant financial information or potential conflicts to disclose.

Supervising Editor: Michelle L. Macy, MD, MS.

Address for correspondence and reprints: Fran Balamuth, MD, PhD, MSCE; e-mail: balamuthf@email.chop.edu.

ACADEMIC EMERGENCY MEDICINE 2019;26:1346–1356.

doi: 10.1111/acem.13815
Crystalloid fluid resuscitation is a key component of treatment for septic shock, but uncertainty remains about the optimal type of fluid. Crystallloid fluids are categorized as unbalanced/unbuffered (i.e., 0.9% “normal” saline [NS]) or balanced/buffered (i.e., lactated Ringer’s [LR], Hartmann’s solution, or PlasmaLyte). Currently, NS is the most common choice for initial fluid resuscitation worldwide. However, NS contains a supraphysiologic concentration of chloride and a low strong ion difference that can lead to hyperchloremia, metabolic acidosis, and decreased renal blood flow. In both adults and children, hyperchloremia, often associated with NS administration, has been associated with increased acute kidney injury, multiple organ dysfunction syndrome, vascular permeability, coagulopathy, fluid overload, and death compared to balanced fluids in surgery, trauma, and sepsis. In contrast, other studies have suggested either no benefit or even harm from balanced fluid resuscitation.

Two recent large pragmatic trials provide the most compelling clinical evidence of benefit for balanced fluid resuscitation in both critically ill and non–critically ill adults, with a small, but meaningful, reduction in major adverse kidney events and hospital mortality. The largest benefit was observed in adults with sepsis. However, no trial has compared the effectiveness of different crystallloid fluid types for resuscitation in children with sepsis, and the two largest observational pediatric studies reported conflicting results. Consequently, there is insufficient evidence to strongly recommend a specific crystallloid fluid type for resuscitation of children with septic shock.

A large, prospective, randomized trial is needed to determine the comparative effectiveness of different crystallloid fluid types for the initial resuscitation and ongoing hydration of children with septic shock. Such a trial would require enrollment near onset of resuscitation, consistent adherence to a single fluid type, and a sample size large enough to detect small, but clinically meaningful, differences in risks and benefits. A pragmatic study design could enable efficient and affordable enrollment of a large number of children across multiple sites, as such designs are often used to compare two efficacious therapies in a heterogeneous population as part of routine clinical care. The established efficacy, strong safety profile, near-universal availability, familiarity of use, and comparable cost of LR and NS lend well to a pragmatic pediatric trial. Given the complexities of implementing such a trial, we first conducted a single-center feasibility study to 1) test whether emergency department (ED) clinicians could screen, randomize, and administer study fluids to children with suspected septic shock during the course of routine clinical care; 2) ensure acceptability to patients and providers of enrollment through the U.S. federal exception from informed consent (EFIC) regulations; and 3) determine whether clinicians would adhere to a randomized fluid type with minimal study team oversight.

**METHODS**

**Study Design**

We conducted a pragmatic, two-arm, open-label, randomized controlled trial of LR versus NS for fluid resuscitation in children presenting to the ED with suspected septic shock at a single academic children’s hospital from January 25, 2018, to August 31, 2018. The trial was approved by the institutional review board (IRB) at the Children’s Hospital of Philadelphia with provisions for EFIC under the U.S. Food and Drug Administration (FDA) IND #13698 and was registered at ClinicalTrials.gov/NCT03340805. The trial was monitored by an independent data and safety monitoring board. We have included both the CONSORT extension for reporting pragmatic trials (adapted from Zwarenstein et al.) and the PRECIS2 tool for assessing the pragmatic score of the trial in Data Supplement S1, Appendixes 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.13815/full).

**Study Population**

All patients >6 months and <18 years of age with suspected septic shock treated in the ED were eligible for enrollment. Suspected septic shock was defined by clinician decision to treat suspected bacterial infection with parenteral antibiotics, collection of a blood culture, and intent to administer at least two fluid boluses for abnormal perfusion (defined as the treating clinician’s determination that either hypotension or flash/delayed capillary refill was present). Enrollment was open at all times during the 6-month study period. We leveraged activation of our institution’s sepsis clinical pathway to identify eligible patients, although patients with suspected septic shock not identified by this pathway were also eligible. Reliance on clinician judgment of suitability for enrollment best approximates “usual care” and is commonly employed in pragmatic trials. Patients were excluded if they had...
received either >40 mL/kg or an indeterminate amount of resuscitation fluid, the clinician judged it unsafe to administer either LR or NS (including for suspected brain herniation, known serum potassium > 6 mEq/L or total serum calcium > 12 mg/dL, known fulminant hepatic failure, end-stage kidney disease on dialysis, mitochondrial disease, inborn errors of metabolism, or allergy to LR or NS), known to be pregnant or incarcerated, or had opted out of the study (see below for details). Given pragmatic eligibility criteria designed to mimic “real-world” practice, prior enrollment during a previous sepsis episode was not an exclusion criteria.

Consent
Patients were enrolled with prospective informed consent if a legally authorized representative (LAR) was present at the bedside and the patient’s condition allowed sufficient time to conduct an informed consent discussion. When a LAR was not present or if fluid administration was deemed emergent, patients were enrolled under EFIC after having the opportunity to “opt-out” during a brief, focused bedside discussion about the study. Patients enrolled under EFIC were approached as soon as feasible by the study team to inform them of study participation, educate about study details, and offer the opportunity to withdraw from study procedures.

In accordance with requirements for EFIC under 21 CFR 50.24 within the United States, we conducted several community consultation and public disclosure activities prior to beginning study enrollment. Community consultation included surveys and focus groups of patients and families at risk for sepsis who were being treated in the ED or pediatric intensive care unit (PICU) and face-to-face meetings with physicians and staff about the study. Public disclosure of the study intent included dissemination of a study website (https://promptbolus.research.chop.edu), posters and brochures made visible and available within inpatient care and family waiting areas, and direct notification of all attending physicians at the Children’s Hospital of Philadelphia. Individuals who opposed future enrollment into the study under EFIC (should they become eligible) were encouraged to contact the study team through the study website. These individuals were asked to wear a bracelet provided by the study team indicating their desire not to be enrolled. We also maintained an “opt-out” list with the study screening forms. Data and feedback from community consultation and public disclosure activities were summarized and reported to the FDA and IRB and submitted to the FDA public docket prior to commencing enrollment. Following completion of patient enrollment and data analysis, results were publicly disclosed via this publication, via our study website, and at ClinicalTrials.gov.

Intervention
Because NS was the overwhelmingly predominant crystalloid fluid used for resuscitation in the ED prior to this study, NS was considered the control group. Although LR was used in several settings within the hospital (e.g., PICU, operating room), LR fluid resuscitation was rarely used in the ED and thus was considered the intervention group. Because use of other balanced fluids, such as PlasmaLyte, were not available for clinical use, only NS and LR were included in this study. The study was conducted using fluids contained in an existing cart that was utilized in the ED to expedite sepsis care. Prior to the study, the cart contained only 0.9% saline as resuscitative fluid. LR was added to the cart as a second option during the study period.

The randomization sequence was generated prior to the start of the study using permuted blocks and equal allocation into two groups. Patients were enrolled after eligibility was confirmed by a treating attending ED physician or pediatric emergency medicine fellow physician who had received specific training and IRB approval to confirm eligibility. We had a “wash-in” period of research coordinator support for enrolling clinicians, with independence expected after 4 weeks. For the first 2 weeks of enrollment, research coordinators were available in person to assist with enrollment. For the second 2 weeks, they were available via text message. Following this wash-in period, clinicians enrolled independently. In the rare instance that the treating physician had not received training about study eligibility and procedures, a second trained clinician/investigator was required to confirm eligibility and conduct randomization. Treatment allocation was then revealed by a member of the clinical team opening the next serially numbered manila opaque envelope located in the top drawer of a sepsis resuscitation cart at the patient’s bedside. The number on each envelope (and thus the sequence of randomization) was recorded in a log at time of enrollment and tracked on a daily basis by the study team to ensure that all subjects were randomized in appropriate numerical sequence. Fluid administration was by open
label, with neither the patient nor the care team blinded to the treatment assignment. Blinding of study fluid was deemed not to be pragmatic based on a prior study demonstrating that electrolyte profiles unintentionally revealed crystalloid fluid allocation in two-thirds of patients.9

After allocation was revealed, the clinical team was instructed to administer all subsequent bolus and maintenance fluids as the assigned crystalloid from the time of randomization until 11:59 PM on the following calendar day. An order set within the computerized ordering system was made available to facilitate correct fluid administration. Only the fluid type was determined by the study protocol. All decisions about timing, volume, and rate of fluid administration were at the discretion of the clinical team. An alternative fluid could be substituted if clinically indicated in the judgment of the treating attending physician. All other therapies were recommended in accordance with the institution’s sepsis clinical pathway, but remained at the discretion of the clinical team. For maintenance fluids, the base NS or LR fluid could be supplemented with dextrose or additional electrolytes as determined clinically by the treating attending physician. Research staff were available for questions and support but did not directly oversee screening, enrollment, randomization, or study fluid administration.

Data Collection
Clinical data were recorded onto a secure, standardized electronic case report form developed with input from all study investigators and the Trial Innovation Center at the University of Utah. A data dictionary defining each variable was developed prior to medical record abstraction. In keeping with the pragmatic design, a parsimonious list of data elements included patient demographics, comorbid conditions, amount and type of study and nonstudy fluid administration, source of infection, and sepsis-related therapies, including time to antibiotics, vasoactive agents, mechanical ventilation, renal replacement therapies, and extracorporeal membrane oxygenation. In addition, specified laboratory values measured as part of routine clinical care were collected (e.g., electrolytes, creatinine). Potential adverse events were collected at two time points—once during the period of study fluid administration and again 5 to 7 days after randomization. Although this pilot and feasibility study was not powered for effectiveness endpoints, we monitored all-cause hospital mortality capped at 90 days, hospital length of stay, and hospital-free days out of 28. In addition, because two large adult trials published after starting enrollment for this trial demonstrated differences in major adverse kidney events at 30 days with balanced fluid treatment,11,12 we added this endpoint post hoc (see Table 1). Safety endpoints included brain herniation, electrolyte abnormalities, and treatment for thromboembolism.

Outcomes
We assessed three outcomes related to the feasibility of conducting this pragmatic trial that would inform a subsequent multicenter clinical trial: 1) the proportion of eligible patients randomized, 2) acceptability to patients/families and clinicians of using EFIC for enrollment, and 3) adherence to study group assignment with demonstrable separation between the groups in the type of fluid used. We a priori established criteria to determine feasibility for each outcome measure (Table 1). In addition, we tracked processes for data collection using medical record review and collected data on potential effectiveness and safety endpoints to be used in a future multicenter trial (Table 1).

Statistical Analysis
We report subject characteristics, clinical features, and outcomes using counts and relative frequencies for categorical variables and median with interquartile range (IQR) for numeric variables. We compared outcomes between treatment groups using chi-square tests or Wilcoxon rank-sum tests, with confidence intervals (CIs) for proportions calculated by the Wilson score method. CIs for differences in medians were obtained using the nonparametric bootstrap. The study was powered to detect an absolute difference in the mean use of NS between arms of at least 65% with a lower 95% CI border of >60%. Analyses were conducted using R Language and Environment, version 3.3.2.21

RESULTS
Of 184 patients who presented with suspected septic shock during the study period, 174 (95%) were screened for eligibility. Ten patients had opted out of consideration for study participation and were therefore not considered to be eligible. Of the 59 eligible patients, 50 (85%) unique patients were randomized (Figure 1), with 24 subjects randomized to LR and 26 to NS. Patient characteristics by study group are
presented in Table 2. Nineteen patients (38%) had identified bacterial or fungal pathogens, and only two (4%) had final diagnoses other than septic shock. Site of infection is listed in Table 2 and pathogens isolated are listed in Data Supplement S1, Table S1. All patients were admitted to the hospital.

Forty-four (88%) patients were enrolled under EFIC. The LAR of each patient enrolled under EFIC was notified of enrollment by a study team member as soon as feasible and offered the opportunity to withdraw from further study procedures. Contact with the LAR was successful for all but two patients, one of whom had died shortly after PICU admission (unrelated to study fluid administration). One patient (2% of EFIC subjects) withdrew from further study fluid administration but allowed data to be included in the analysis. We are aware of at least two additional patients who were not enrolled because the ED physician was concerned about enrollment via EFIC despite otherwise meeting eligibility criteria. Thus, of the 46 total patients who we can confirm met the specified conditions for EFIC, this method of enrollment was acceptable to 43 (93%).

Total median (IQR) crystalloid fluid volume administered during the intervention window was 107 (60 to 155) mL/kg and 98 (63 to 128) mL/kg in the LR and NS arms, respectively ($p = 0.50$, Table 3). Approximately one-half of the total crystalloid fluid administered during the intervention window was as bolus fluids and one-half as maintenance fluids in both study groups. Thirty-eight percent of subjects in the LR group and 42% in the NS group received $\geq 60$ mL/kg of bolus crystalloid fluid ($p = 0.73$).

Overall, there was strong adherence to study arm assignment (Table 3) with appropriate separation of

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Study Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome</strong></td>
<td><strong>Definition</strong></td>
</tr>
<tr>
<td><strong>Feasibility outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Proportion of eligible patients enrolled</td>
<td>$&gt;65%$ of eligible patients enrolled</td>
</tr>
<tr>
<td>Acceptability of EFIC</td>
<td>$\leq 10%$ of patients withdrawing from study after enrollment under EFIC or $&gt;90%$ of EFIC-eligible patients enrolled with completion of study activities</td>
</tr>
<tr>
<td>Adherence to group assignment</td>
<td>Absolute difference in proportion of total isotonic fluids administered as NS between groups of $\geq 65%$ or $\geq 85%$ of subjects in NS arm received $\geq 90%$ of study fluid as NS and $\geq 80%$ of subjects in LR arm received $\geq 75%$ of study fluid as LR(^a)</td>
</tr>
<tr>
<td><strong>Effectiveness outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>MAKE30</td>
<td>Major adverse kidney events at 30 days (defined as at least one of the following): Death</td>
</tr>
<tr>
<td>All-cause hospital mortality</td>
<td>Censored at 90 days</td>
</tr>
<tr>
<td>Hospital length of stay</td>
<td>Days from hospital admission until discharge</td>
</tr>
<tr>
<td>Hospital-free days out of 28 days</td>
<td>Days between enrollment and day 28 in which patient was alive and out of the hospital</td>
</tr>
<tr>
<td>New inpatient RRT</td>
<td>New continuous renal replacement therapy, hemodialysis, or peritoneal dialysis</td>
</tr>
<tr>
<td>Safety outcomes</td>
<td>All within 4 calendar days of randomization except thrombosis which was within 7 days</td>
</tr>
<tr>
<td>Hyperlactatemia</td>
<td>$\geq 4$ mMol/L</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>$&gt;6$ mEq/L</td>
</tr>
<tr>
<td>Hypercalcemia</td>
<td>Ionized calcium $&gt; 1.35$ mmol/L or total serum calcium $&gt; 12$ mg/dL</td>
</tr>
<tr>
<td>Hypernatremia</td>
<td>$&gt;155$ mEq/L</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>$&lt; 128$ mEq/L</td>
</tr>
<tr>
<td>Hyperchloremia</td>
<td>$&gt;110$ mEq/L</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Therapy for new arterial or venous thrombus with systemic anticoagulant or Clotting of intravenous catheter in subjects receiving ceftriaxone and LR</td>
</tr>
<tr>
<td>Cerebral edema</td>
<td>Therapy with hyperosmolar therapy (hypertonic saline and/or mannitol) for radiographic and clinical determination of new impending or present brain herniation</td>
</tr>
</tbody>
</table>

EFIC = exception from informed consent; LR = lactated Ringer’s; MAKE30 = major adverse kidney events within 30 days; NS = 0.9% normal saline; RRT = renal replacement therapy

\(^a\)Patients were eligible for enrollment after an initial 20 mL/kg fluid bolus, which was most commonly expected to be 0.9% saline. Thus, it was anticipated that patients randomized to lactated Ringer’s would receive at least one 0.9% saline bolus.
fluid type administered between study groups (Figure 2). Patients randomized to LR received a median (IQR) of only 20% (13% to 35%) of all (including preand postrandomization) isotonic fluids as NS compared to 100% (100% to 100%) of fluid as NS in the NS arm (difference = 80%, 95% CI = 65% to 89%), which met our prespecified feasibility goal of an absolute difference in the proportion of total isotonic fluids administered as NS between groups of ≥65%. When only postrandomization fluids were considered, patients randomized to the LR arm received a median (IQR) of 0% (0% to 0%) of isotonic fluids as NS and 100% (100% to 100%) as LR, while patients in the NS arm received a median (IQR) of 100% (100% to 100%) of isotonic fluids as NS and 0% (0% to 0%) as LR. Sixty-three percent of patients in the LR arm received ≥75% of their isotonic fluid as LR, which fell slightly short of our second a priori established feasibility goal. Eighty-eight percent of patients in the NS arm received ≥90% of their isotonic fluid as NS, which met our feasibility goal. Of note, there were two patients in the LR arm who were randomized based on intent to give ≥40 mL/kg resuscitative fluids who ultimately did not receive any study fluids. These patients are included in the analysis based on intention-to-treat principles. Additional details regarding fluid administration can be found in Data Supplement S1, Table S2.

Median (IQR) time per patient for data extraction from the medical record was 105 (90 to 165) minutes. Data were available for all specified variables from each enrolled patient. Potential effectiveness and safety endpoints to be used for a multicenter trial are shown in Table 4. All endpoints were able to be ascertained from routine clinical data collection. Rates laboratory testing sent are shown in Data Supplement S1, Table S3. Adverse events by group are also listed in Table 4. There were no unexpected serious adverse events related to study fluid administration.

**DISCUSSION**

We have demonstrated feasibility to use a pragmatic study design to randomize children with suspected septic shock to LR versus NS fluid resuscitation. Specifically, we enrolled 85% of eligible subjects and enrollment under EFIC had 93% acceptability overall among patients and providers, with only one postenrollment withdrawal. We also demonstrated adherence to study group assignment with acceptable separation between the two arms. Finally, we established that collection of a parsimonious set of variables about patient characteristics, fluid administration and other sepsis therapies, and clinical outcomes was efficient to abstract from the medical record with minimal missing data. The results of our pilot study support use of this pragmatic study design in a larger multicenter trial to test the comparative effectiveness of balanced/buffered fluids versus NS resuscitation for pediatric septic shock.

Pragmatic trials are intended to help clinicians choose among efficacious therapies, while explanatory trials test causal research hypotheses. In reality, however, the degree of trial “pragmatism” exists along a
Our ultimate aim is to determine the comparative effectiveness of different types of crystalloid fluids for resuscitation of pediatric septic shock with maximal generalizability of trial results across usual care practices. We therefore tested whether our study design was sufficiently pragmatic for busy emergency physicians to expeditiously enroll a large number of children with a heterogeneous, life-threatening condition concurrent with their clinical care. Although conducted at a single center, we included more than 50 pediatric emergency medicine attending and fellow physicians and screened 184 patients. We utilized an existing systematic sepsis recognition program\textsuperscript{19} to assist screening, but accurate enrollment ultimately relied on clinician judgment of key elements that defined septic shock, i.e., suspicion of bacterial infection and abnormal perfusion. With this approach, only 15% of eligible patients were missed and only 4% of enrolled patients did not have septic shock. Notably, we purposely did not utilize the comprehensive research support services available within our ED to simulate future enrollment at other sites where research infrastructure may differ. In addition, the case mix of enrolled children in terms of presence of comorbid conditions was similar to published estimates in U.S. children’s hospitals.\textsuperscript{24,25} Moreover, we anticipate that the proliferation of sepsis screening and recognition programs will help to facilitate enrollment in a future multicenter trial in a similar manner as in our pilot study.

Although there is debate about the appropriate volume and rate of fluid administration in children with septic shock, crystalloid fluid resuscitation is recommended as a critical, early intervention to address hypovolemia.\textsuperscript{15,16} Most fluid resuscitation of children with septic shock occurs within the initial hours after sepsis recognition. Delaying enrollment until after admission to an intensive care unit or even after several hours of ED resuscitation may ensure septic shock as the correct diagnosis and concentrate enrollment of patients most likely to have the study outcome, but risks substantial volume of prestudy fluid resuscitation that may dilute the main effect of the fluid intervention. Such contamination with prestudy fluid resuscitation has been noted in previous trials in adults, in which receipt of fluid volumes of $\geq 2000$ mL prior to study enrollment was common.\textsuperscript{26–28}

To enroll patients as early as possible after eligibility, we conducted the study under the U.S. exception from informed consent (EFIC) regulations for emergency research in the United States. EFIC studies are justified under the following strict conditions: 1) patients are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of a therapy; 2) obtaining prospective informed consent is not feasible; 3) patients may directly benefit from the research; and
Table 3
Fluid Administration During Intervention Window

<table>
<thead>
<tr>
<th>Variable</th>
<th>LR Group</th>
<th>NS Group</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total crystalloid volumes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>administered</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crystalloid fluid volume (mL/kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total fluid</td>
<td>107 (60 to 155)</td>
<td>98 (63 to 128)</td>
<td>-9 (-57 to 35)</td>
</tr>
<tr>
<td>Bolus fluid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prerandomization</td>
<td>20 (19 to 23)</td>
<td>20 (17 to 27)</td>
<td>0 (-1 to 4)</td>
</tr>
<tr>
<td>Postrandomization</td>
<td>38 (20 to 60)</td>
<td>33 (20 to 40)</td>
<td>-5 (-28 to 18)</td>
</tr>
<tr>
<td>Maintenance fluid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>49 (18 to 88)</td>
<td>35 (24 to 78)</td>
<td>-14 (-50 to 18)</td>
</tr>
<tr>
<td>NS</td>
<td>0 (0 to 0)</td>
<td>21 (2 to 41)</td>
<td>21 (4 to 39)</td>
</tr>
<tr>
<td>LR</td>
<td>40 (9 to 78)</td>
<td>0 (0 to 0)</td>
<td>-40 (-68 to -11)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0 to 0)</td>
<td>0 (0 to 21)</td>
<td>0 (0 to 17)</td>
</tr>
<tr>
<td>Proportion of patients receiving ≥60 mL/kg as bolus fluid</td>
<td>9 (38)</td>
<td>11 (42)</td>
<td></td>
</tr>
</tbody>
</table>

Adherence to study arm

<table>
<thead>
<tr>
<th>Variable</th>
<th>LR Group</th>
<th>NS Group</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid compliance among isotonic fluids&lt;sup&gt;a,b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre- and postrandomization fluid</td>
<td>15 (63)</td>
<td>23 (88)</td>
<td></td>
</tr>
<tr>
<td>Postrandomization fluid</td>
<td>20 (83)</td>
<td>24 (92)</td>
<td></td>
</tr>
<tr>
<td>Proportion of isotonic fluid as NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre- and postrandomization&lt;sup&gt;c&lt;/sup&gt;</td>
<td>20 (13 to 35)</td>
<td>100 (100 to 100)</td>
<td>80 (69 to 85)</td>
</tr>
<tr>
<td>Postrandomization</td>
<td>0 (0 to 0)</td>
<td>100 (100 to 100)</td>
<td>100 (100 to 100)</td>
</tr>
<tr>
<td>Proportion of isotonic fluid as LR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre- and postrandomization</td>
<td>80 (65 to 87)</td>
<td>0 (0 to 0)</td>
<td>-80 (-85 to -69)</td>
</tr>
<tr>
<td>Postrandomization</td>
<td>100 (100 to 100)</td>
<td>0 (0 to 0)</td>
<td>-100 (-100 to -100)</td>
</tr>
</tbody>
</table>

Data are reported as n (%) or median (IQR).
IQR = interquartile range; LR = lactated Ringer’s; NS = 0.9% normal saline.
<sup>a</sup>Fluid compliance was defined as receipt of ≥75% of study fluid as LR in LR group and ≥90% of study fluid as NS in NS group.
<sup>b</sup>Isotonic fluids included LR, NS, D5 LR, or D5 NS with additional electrolytes permitted as per clinical team.
<sup>c</sup>Elements that were determined a priori as feasibility metrics.

Figure 2 Histograms depicting distribution of fluid type including (A) both pre- and postrandomization and (B) postrandomization only.
research could not be practicably be carried out without using EFIC. Additional safeguards include pretrial community consultation among potential subjects and their families and pre- and posttrial public disclosure to promote awareness and transparency. These criteria set an appropriately high bar and, thus, EFIC studies have been uncommon to date in children. However, several EFIC-based studies have been successfully carried out in the United States and, using a related ethical design, in Europe, Canada, and Australia. For this study of two efficacious resuscitation fluids, enrollment with EFIC was approved by our IRB, endorsed by the FDA through our IND application, and proved acceptable to patients/families and clinicians.

Pragmatic trials are conducted in typical care settings without intense efforts to standardize interventions beyond the intervention being studied and with the expectation that care will vary between subjects as a matter of chance, clinician preference, and institutional policies. Ideally, the intervention and comparator (in this case, LR and NS, respectively) are already widely used, such that clinicians feel comfortable with either treatment arm. In the United States, emergency clinicians caring for children rarely use fluids other than NS, while hospitalists and intensive care clinicians may be more familiar with LR. We therefore provided a brief educational overview to our emergency staff prior to commencing study enrollment, but otherwise relied on established institutional protocols to support safe administration of both fluids. For example, routine protocol is to avoid concurrent administration of LR with ceftriaxone and blood products. The SMART11 and SALT-ED12 trials used a bioinformatics approach to guide fluid administration. Although we considered a similar approach, this was deemed unlikely to be reproducible across multiple centers. Instead, with prestudy education and study team assistance offered remotely as needed, we were able to successfully and safely implement randomized allocation to LR or NS beginning in the ED and continuing on through hospital and/or PICU with adequate separation of study arms. In addition, we made available a single-page screening form, paper envelope randomization, and access to both study fluids within a "sepsis cart" that could be wheeled to the patient’s bedside. We also instructed ED providers to "hand off" study group assignment to inpatient physicians and nurses. We believe that these simple study procedures would be generally reproducible across multiple centers with varying resources. Finally, we confirmed that maintenance fluids comprised a large proportion of fluid administration within the first 24 to 48 hours, supporting the importance of including maintenance fluids in a larger trial, as previously noted.

LIMITATIONS

There are several limitations to this study. First, despite attempts to minimize site-specific features in screening, enrollment, study interventions, and data collection, it is unlikely that multiple sites would have the exact experience as we found in this pilot study. Second, acceptability of enrollment with EFIC may vary across regions or sites and attention to local culture and values will be important. In addition, it is possible that there were additional patients who were considered not to be safe for administration of study fluids because of unstated concerns about EFIC, thus

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Effectiveness and Safety Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes</td>
<td>LR Group</td>
</tr>
<tr>
<td>Effectiveness outcomes</td>
<td></td>
</tr>
<tr>
<td>MAKE30</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Total cause hospital mortality, censored at 30 days</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hospital length of stay (days)</td>
<td>5 (3–8)</td>
</tr>
<tr>
<td>Hospital-free days out of 28 (days)</td>
<td>23 (20–25)</td>
</tr>
<tr>
<td>Additional adverse events</td>
<td></td>
</tr>
<tr>
<td>Vasoactive infusion</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>7 (29)</td>
</tr>
<tr>
<td>Seizure</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hepatic dysfunction</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Rash</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Pressure injury</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Safety outcomes</td>
<td></td>
</tr>
<tr>
<td>Hyperlactatemia</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Hypercalcemia</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hypernatremia</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hypoventilation</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hyperchloremia</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Cerebral edema</td>
<td>1 (4)</td>
</tr>
</tbody>
</table>
| Categorical variables are listed as n (%); continuous outcomes are listed as median (IQR). Shock was defined as need for vasoactive medication; respiratory failure was defined as need for invasive or noninvasive mechanical ventilation. LR = lactated Ringer’s; MAKE30 = major adverse kidney events within 30 days; NS = 0.9% normal saline; RRT = renal replacement therapy.

LR = lactated Ringer’s; MAKE30 = major adverse kidney events within 30 days; NS = 0.9% normal saline; RRT = renal replacement therapy.
resulting in an overestimate of acceptability of EFIC. However, withdrawal of only one subject after EFIC is reassuring that families found this mode of enrollment acceptable for this study. Fourth, the pragmatic nature of our inclusion criteria necessitated clinician determination of “suspected shock,” which resulted in enrollment of patients with a spectrum of illness severity. Fifth, the intervention window ranged from 24 to 48 hours to ensure that all subjects were exposed to at least 24 hours of study fluid resuscitation while providing a straightforward and clear stopping point for clinicians. Although such variability could have affected the volume of study fluid between subjects, this variable should be balanced by randomization and previous studies have demonstrated that the majority of fluid was administered within the initial 24 hours.11,17 Sixth, this pilot study was not able to inform sample size or endpoint selection for a multicenter trial. However, we have pursued other efforts for this purpose.28 Finally, our pilot study was conducted for a short time period. For a larger multicenter trial, enrollment will occur over several years and we can expect that adherence may wax and wane over time and vary by site. Efforts to maintain study adherence and ensure enrollment of eligible patients will likely need to be more extensive than in our pilot study.

CONCLUSIONS

In conclusion, we demonstrated feasibility to use a pragmatic study design to study the comparative effectiveness of lactated Ringer’s versus normal saline fluid resuscitation for pediatric septic shock. This pilot trial supports using a similar pragmatic study design for a definitive multicenter comparative effectiveness trial.

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.13815/full

Data Supplement S1. Supplemental material.
ABSTRACT

Objective: The objective was to identify key questions for emergency medicine (EM)-based adolescent sexual and reproductive health and to develop an evidence-based research agenda.

Methods: We recruited national content experts to serve as advisory group members and used a modified Delphi technique to develop consensus around actionable research questions related to EM-based adolescent reproductive and sexual health care. Author subgroups conducted literature reviews and developed the initial list of research questions, which were iteratively refined with advisory members. External stakeholders then independently rated each item for its importance in expanding the evidence base (1 = not important to 5 = very important) via electronic survey.

Results: Our final list of 24 research questions included items that intersected all sexual and reproductive health topics as well as questions specific to human immunodeficiency virus/sexually transmitted infections (HIV/STIs), pregnancy prevention, confidentiality/consent, public health, and barriers and facilitators to care. External stakeholders rated items related to HIV/STI, cost-effectiveness, brief intervention for sexual risk reduction, and implementation and dissemination as most important.

Conclusions: We identified critical questions to inform EM-based adolescent sexual and reproductive health research. Because evidence-based care has potential to improve health outcomes while reducing costs associated with HIV/STI and unintended pregnancy, funders and researchers should consider increasing attention to these key questions.

Although preventable, sexually transmitted infections (STIs), human immunodeficiency virus (HIV) infection, and unintended pregnancy are significant and costly public health problems in the United States that disproportionately impact adolescents, especially racial and ethnic minorities and those
without commercial insurance. Appropriate and timely care can mitigate or prevent these outcomes, but many adolescents do not receive preventive, evidence-based care. Access to care also may be limited due to insurance barriers or geography. This limited access results in reliance on emergency departments (EDs), with those at highest risk for HIV/STIs and pregnancy—minority and uninsured adolescents—now overrepresented in this setting.

Adolescents account for almost 19 million annual ED visits, most of which are nonurgent and many of which are related to sexual health complaints. Furthermore, several million high-risk adolescents use the ED as their only or primary contact with health care. Adolescents in the ED frequently report behaviors that increase their risk for HIV/STI and unintended pregnancy. Among adolescent ED patients, rates of infection with chlamydia and gonorrhea are up to seven times higher than those in the general adolescent population. Furthermore, female adolescents accessing the ED for care have a risk of pregnancy within the next 12 months that is three times greater than that in adolescents in the general population.

The Society for Academic Medicine recognizes the ED as an “effective site for preventive care,” evidenced by organizational conferences, consensus statements, and specialized training opportunities to reduce disparities stemming from social determinants of health. Further, national organizations recommend that all clinicians capitalize on any health visits to provide key preventive sexual health services. While the ED represents an important location for reaching large numbers of sexually at-risk adolescents, it is underutilized as a setting to improve adolescent sexual health outcomes. Achieving behavior change among providers or adolescents is complex and generally requires comprehensive, multilevel approaches. As such, we need research to guide diverse efforts to achieve optimal outcomes. Some interventions to improve HIV screening have been successful, but these are mostly designed for adults. ED-based interventions to address adolescent-specific needs are central to increasing access to 1) contraception, 2) HIV/STI detection and treatment, 3) behavioral risk reduction counseling, and 4) linkage to ongoing care.

Goals of This Work
Despite the significant individual, societal, and public health costs of HIV/STIs and unintended pregnancy, only a limited body of rigorous ED-focused adolescent sexual health research exists. More evidence is needed to inform best clinical practices and quality initiatives, shape support for policy decisions, and foster EM-based educational guidelines. To develop prioritized research recommendations to fill this void, we aimed to establish an expert working group to review the existing literature, identify knowledge gaps, and use consensus techniques to develop a research agenda for adolescent sexual and reproductive health in the ED setting.

METHODS

Study Design
All consensus processes were conducted between May 2017 and October 2018. We recruited an advisory group of content experts and used a modified Delphi technique to identify the most pressing emergency medicine (EM)-focused adolescent sexual and reproductive health research questions. We obtained institutional review board approval from the lead author’s institution to conduct this work.

Authorship Group Formation
In 2015, a pediatric EM-based Adolescent Sexual Health Working Group was formed to expand the breadth of adolescent sexual and reproductive health research in the acute care setting. Working group membership included 23 volunteers from 12 institutions who regularly participated in scheduled meetings. The group discussed development of a research agenda as one of multiple projects and in May 2017, nine members volunteered to form the authorship group conducting this work. Three authorship chairs (MKM, LC, and CJM) moderated authorship team meetings, led data analysis, and recorded detailed notes.

Selection of Expert Advisory Group Members
We recruited individuals with expertise in adolescent health, EM, public health, infectious disease, and/or health services research to serve as advisory group members for the consensus process. Between November 1 and December 1, 2017, we identified experts by reviewing previously published peer-reviewed adolescent sexual health research, leadership/membership rosters for related research and/or medical professional societies (e.g., Society for Adolescent Health and Medicine), and personal recommendations from
leading investigators in the field. Potential members (N = 42) were recruited via e-mail. The final group consisted of 18 members (see 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.13809/full).

Selection of External Stakeholders
We introduced this work at a quarterly meeting of the Pediatric Emergency Care Applied Research Network (PECARN), the first federally funded multi-institutional network for pediatric EM research in the United States. We sent e-mail requests to solicit feedback from all members serving as leaders at the local or regional level (i.e., principal investigators).

Consensus Methods
We used a modified Delphi technique to develop consensus around actionable research questions. This technique involves a systematic method for collecting and analyzing data and developing consensus among a small group of content experts.35 The process consists of successive rounds of questionnaires and summarized responses to attain consensus on an issue.36,37 The initial steps are designed to elicit a wide range of responses. A common and acceptable modification of the Delphi process is to use a structured questionnaire in the first round that is based on current literature. The Delphi process is considered complete when there is convergence of opinion or when a point of diminishing returns is reached. The process can include between three to five rounds of iteration.

These consensus methods are particularly useful as a means of synthesizing information where unanimity of opinion does not exist, often owing to insufficient evidence. Strengths of this method include avoidance of individual dominance by using private survey responses and providing controlled feedback to the group’s responses and using the round-robin process that allows individuals to change their opinions. To address potential limitations associated with the technique, we utilized an experienced team leader (CJM) and ensured consistent participation from advisory members and authors.

For Phase 1, the authorship group met in person and via conference calls. We e-mailed survey links to advisory members and nonchair authors (Phase 2) and to external stakeholders (Phase 3). Reminder e-mails were sent at 1 and 2 weeks after the initial e-mail for those who had not yet responded.

Phase 1 (May–October 2017): Structuring the Process and Generating Initial Questions With Authorship Team. The authorship team met in May 2017 to begin structuring the process. We selected two overarching questions to guide this work: “What are the current knowledge gaps related to improving adolescent sexual health outcomes in the emergency department setting?” and “What are the highest priority research questions related to improving adolescent sexual health outcomes in the emergency department setting?” Among the nine authors, we formed three subgroups to review the literature on broad EM-based research categories (i.e., pregnancy prevention, HIV/STI, and other topics) to facilitate participation and thinking around a more refined area. Each subgroup then generated a brief summary of the literature (with key references) and an initial list of research questions. Literature summaries and initial lists were shared among the authorship team. Authors then provided edits and suggestions to all items in written format and during a conference call. Authorship chairs then consolidated all suggestions into a first draft that included revised items.

Phase 2: Iterative Refinement and Establishing Priority. Round 1 (November–December 2017): Revisions and New Questions. Advisory members received the literature summaries generated in Phase 1 and were informed about project goals and the two overarching questions driving the process. They were provided with the initial questions generated in Phase 1 and asked to suggest revisions for each item. Advisory members were also asked to provide additional questions to be included in the research agenda. Authorship chairs discussed all suggestions for revisions to initial items as well as all new items generated by advisory members. Based on advisory member feedback, the chairs then edited, deleted, added, and consolidated items to achieve a revised list of questions. During this phase, the chairs noted that additional research categories were needed and certain questions were common across categories; thus, we added new categories, including a category for “intersecting” questions that were relevant across categories.

Round 2 (February–June 2018): Revisions and Ratings. Advisory members received a summary of changes, including new categories, as well as the newly
generated list of questions. They were asked to suggest revisions to each item and rate the importance of each question as it relates to EM-based sexual and reproductive health research overall (1 = unimportant to 5 = very important). Authorship chairs discussed all suggested revisions and achieved consensus around final changes to items. All authors reviewed priority ratings and achieved consensus by eliminating questions that met predetermined criteria. Specifically, items with mean scores < 3 or those with mean scores < 4 but with significant variability (standard deviation ≥ 1) were dropped.

**Phase 3 (July–September 2018): Feedback From External Stakeholders.** These stakeholders were asked to rate each item for its importance in expanding the evidence base for EM-based adolescent sexual and reproductive health research via electronic survey (1 = not important to 5 = very important). Stakeholders were not asked to edit, delete, or suggest new items. All authors then reviewed these priority ratings and achieved consensus on final items.

**RESULTS**

In Phase 1, we generated 50 research questions. In Phase 2 (round 1), advisory members (n = 18) suggested nine new questions. After refinement, consolidation, and separation of intersecting questions, a list of 30 potential questions remained. In Phase 2 (round 2), advisory members (n = 19) and nonchair authors (n = 6) provided final suggestions for revisions and priority ratings. Based on values established a priori, we removed six questions and retained a total of 24. These final questions were presented to external stakeholders in Phase 3 (n = 22, response rate = 92%). The questions receiving the 10 highest mean values from external stakeholders are indicated with an asterisk (Tables 1–5).

**DISCUSSION**

To improve adolescent health outcomes and reduce the burden of HIV/STIs and unintended pregnancy, high-quality research is needed to develop the evidence for best practices, especially in EDs, where high-risk adolescents frequently seek care. We used rigorous methodology to identify key ED-based research questions that address HIV/STI screening and diagnosis, promote unintended pregnancy prevention, and support adolescent confidentiality, as well as intersecting questions that address broader concerns such as dating violence and specific medicolegal issues. With

---

**Table 1**

<table>
<thead>
<tr>
<th>Intersecting EM-related Adolescent Sexual and Reproductive Health Research Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How can we optimize referral and follow-up care for reproductive or sexual health needs among adolescents treated in the ED?</td>
</tr>
<tr>
<td>2. How can we optimize evidence-based care for adolescents with genitalious complaints in the ED?</td>
</tr>
<tr>
<td>3. Which sexual risk-reduction interventions (e.g., STI, HIV, pregnancy prevention) are cost-effective in the ED setting?</td>
</tr>
<tr>
<td>4. How can efforts to reduce sexual risk behaviors be optimally delivered as part of ED care?</td>
</tr>
<tr>
<td>5. What is the role of the ED in identifying, preventing, and intervening with adolescent dating violence?</td>
</tr>
<tr>
<td>6. What are the legal considerations (e.g., local, federal) surrounding provision of sexual and reproductive health care in the ED?</td>
</tr>
<tr>
<td>7. How can we optimize parental involvement to promote healthy sexual behaviors for adolescents in the ED?</td>
</tr>
<tr>
<td>8. How can we disseminate and implement effective sexual health interventions in the ED?</td>
</tr>
</tbody>
</table>

HIV = human immunodeficiency virus; STI = sexually transmitted infection.
*Question was ranked as one of the top 10 most important items by external stakeholders.

**Table 2**

<table>
<thead>
<tr>
<th>HIV/STI-related EM-relevant Adolescent Sexual and Reproductive Health Research Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How do we optimize STI screening for the asymptomatic adolescents across different ED settings?</td>
</tr>
<tr>
<td>2. How can we facilitate implementation and dissemination of best STI screening practices?</td>
</tr>
<tr>
<td>3. How can we optimize HIV screening for the asymptomatic adolescent ED population across different ED settings?</td>
</tr>
<tr>
<td>4. What is the feasibility and acceptability of providing partner-based interventions (e.g., expedited partner therapy, notification) when adolescents are diagnosed with an STI in the ED?</td>
</tr>
</tbody>
</table>

HIV = human immunodeficiency virus; STI = sexually transmitted infection.
*Question was ranked as one of the top 10 most important items by external stakeholders.

**Table 3**

<table>
<thead>
<tr>
<th>Pregnancy Prevention-related EM-relevant Adolescent Sexual and Reproductive Health Research Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How can health care providers in the ED optimize contraception provision for adolescents?</td>
</tr>
<tr>
<td>2. How can we most effectively identify females with recent unprotected intercourse to discuss pregnancy intentions and need for pregnancy prophylaxis (e.g., emergency contraception)?</td>
</tr>
<tr>
<td>3. What are the facilitators and barriers to ensuring reproductive justice (i.e., ability of any woman to determine her own reproductive destiny) when offering contraception?</td>
</tr>
</tbody>
</table>

*Question was ranked as one of the top 10 most important items by external stakeholders.
the input of multidisciplinary stakeholders, we propose these research questions as a guide for future investigators and funders. Given the national priority of reducing HIV/STIs and adolescent pregnancy as stated by the Centers for Disease Control and Prevention (CDC) and defined in the objectives of Healthy People 2020, increased funding is needed via research networks, federal research institutes, and philanthropy to address these urgent public health issues and research questions.

As an introduction to this agenda, we present these overarching themes. Barriers to accessing and providing sexual health care to adolescents in the ED have been fairly well described. However, our understanding of parental perspectives on this care could be expanded. We lack knowledge on facilitators to adolescent sexual health care and also lack studies that are multicentered or represent geographically diverse populations. For research involving aspects of confidentiality and consent, we advise that these topics are investigated together, as they are difficult to separate both clinically and within research. We encourage investigators to consider inclusion of cost-effectiveness assessment with any intervention, especially those outside of HIV screening where some of this work has been published. Further, we lack research describing the effect of policies on health care provision and best practices for implementation and dissemination once effective ED-based interventions are identified.

Because we lack high-quality evidence for many areas of sexual and reproductive health, we chose to keep many of the research questions broad to reflect the need for a wide breadth of work. In some instances, published evidence supported more focused questions. In addition to research exploring these specific questions, multipronged approaches that include quality improvement, legislative advocacy, and community engagement are needed to improve health outcomes. These approaches can be integrated and included as part of the systematic investigations to develop evidence for best practices.

### Intersecting Themes

While it is well established that adolescent ED patients are a high-risk population, how to provide evidence-based sexual and reproductive health care in the unique ED setting is less clear. Genitourinary (GU) complaints are common among adolescents presenting to the ED, but providers often lack the knowledge, comfort, time, and skills to provide evidence-based sexual health care. Many ED providers do not follow evidence-based STI testing and treatment guidelines; further, they lack accuracy in identifying which patients tested for STIs need empiric treatment, contributing to under- and overtreatment for STIs. Many sexually active females in the ED report recent unprotected intercourse, making them eligible for pregnancy prophylaxis with emergency contraception (EC). However, this opportunity to provide intervention is often missed as many adolescents are not routinely asked about recent unprotected sex or offered timely EC, except in cases of sexual assault. Research is needed on how ED providers can better deliver evidence-based care to adolescents with increased risk for STIs and pregnancy.

Central to the feasibility of providing sexual and reproductive health care in the ED is defining how this care should be delivered and which patients may benefit most. Tailoring approaches that identify,

---

### Table 4
Confidentiality/Consent-related EM-relevant Adolescent Sexual and Reproductive Health Research Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What are best practices in the ED for maintaining adolescent confidentiality for sexual and reproductive health care (e.g., communication with parents/guardians, documentation on gender identity and risk behaviors)?</td>
<td></td>
</tr>
<tr>
<td>2. How do adolescents and parents/guardians view issues of confidentiality with respect to participation in sexual and reproductive health research?</td>
<td></td>
</tr>
<tr>
<td>3. How do adolescents and parents/guardians view issues of confidentiality with respect to clinical care for sexual and reproductive health?</td>
<td></td>
</tr>
<tr>
<td>4. What are best practices for consenting minor adolescents to participate in sexual and reproductive health research?</td>
<td></td>
</tr>
</tbody>
</table>

### Table 5
Emergency Medicine-relevant Adolescent Sexual and Reproductive Health Research Questions Related to Public Health and Barriers and Facilitators

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public health:</td>
<td></td>
</tr>
<tr>
<td>1. What are the short- and long-term effects of evidence-based sexual health interventions on key outcomes (e.g., HIV/STI identification, prevention of unintended pregnancy, ED visits for care)?</td>
<td></td>
</tr>
<tr>
<td>2. How can partnerships with other clinical settings and community-based organizations be used to improve health outcomes and extend positive effects from evidence-based intervention?</td>
<td></td>
</tr>
<tr>
<td>3. How can we assess the impact of evidence-based interventions on health outcomes at a community, regional, or national levels?</td>
<td></td>
</tr>
<tr>
<td>Barriers and facilitators:</td>
<td></td>
</tr>
<tr>
<td>4. What are the parental attitudes, beliefs, and practices regarding adolescent participation in sexual and reproductive health care?</td>
<td></td>
</tr>
<tr>
<td>5. What are the parental attitudes, beliefs, and practices and associations regarding adolescent participation in receiving sexual and reproductive health care?</td>
<td></td>
</tr>
</tbody>
</table>

*Question was ranked as one of the top 10 most important items by external stakeholders.*
diagnose, treat, and refer high-risk patients, such as those presenting with complaints related to the GU system, may be more feasible than providing key aspects of sexual health care routinely to all patients. However, many adolescent patients presenting with complaints not clearly related to the GU system also participate in high-risk sexual behaviors and could benefit from interventions to reduce their risk of STIs and pregnancy. We lack understanding of best practices to reduce sexual risk behaviors for these patients, and more attention needs to be given to the cost-effectiveness of interventions to develop our understanding for effective and scalable implementation.

For all patients presenting to the ED, especially those with complaints related to sexual health, referral to outpatient adolescent-tailored care is essential to health maintenance. While referral to care may occur through multiple efforts during the ED visit (e.g., discharge instructions, verbal communication), limited data demonstrate that adolescents often do not complete such referrals when advised. Efforts are needed to improve referral and follow-up from the ED, ensuring adolescents’ access to comprehensive sexual and reproductive care for needs unlikely to be addressed during the routine ED visit (e.g., vaccination) or that require ongoing management (e.g., contraception).

Variations in care can be influenced by state statutes, political influences, and/or differences in opinions between administrators and providers at the ED level. Specific for contraception, some states explicitly allow all minors to consent for these services, while many other states allow consent only in specific circumstances (e.g., minors who are parents). In addition, regional and professional differences in attitudes toward EC have been documented among ED staff and may limit access to care. A deeper understanding of how these considerations impact care provision is essential to achieve sustained improvements in health outcomes. Further, once effective interventions or best practices are identified, little is known about best methods for dissemination and implementation across EDs that may vary widely in regard to state statues, institutional resources, setting type, and expected practices.

Finally, adolescent relationship abuse (ARA), also known as teen dating violence, is a major public health concern with wide-reaching and lifelong negative health outcomes. While one in 10 high school students report dating violence victimization, prevalence of physical or sexual violence in dating relationships among ED adolescent patients may be as high 50%. Despite guidelines to provide universal education to reduce ARA during clinical interactions, little work describes effective interventions or best models for use in the ED. Rare ED-based interventions, such as SaferTeen and Project U-Connect, show promise for reducing dating victimization and perpetration following a single ED visit but have yet to be widely disseminated.

**HIV and STIs**

Adolescents account for nearly half of the 19 million new cases of STIs each year. STIs contribute to reproductive morbidity such as ectopic pregnancy, pelvic inflammatory disease, and infertility. Adolescents in the ED have especially high rates of STIs: 22% to 26% among those with symptoms and 5% to 10% among those without symptoms. Since the ED visit may be the only contact with a medical clinician for many adolescents, EDs represent a key site for STI prevention and treatment. However, while adolescent patients and their parents have repeatedly demonstrated acceptance of sexual health discussion and HIV/STI testing, clinicians have reported less acceptance of directly providing this care. Further, racial disparities have been demonstrated in ED-based STI testing, with black females nearly four times more likely to be tested than nonblack females. With CDC recommendations to expand HIV screening to the ED environment, more consideration has been given to development of optimal screening strategies across unique EDs. For common STIs like chlamydia, use of computerized surveys to assess risk and provide decision support to clinicians has shown promise to increase testing among high-risk adolescents. We also need research to eliminate barriers to timely treatment including development of novel technologies that could provide rapid (e.g., point of care) and accurate test results and evaluation of system-level changes to facilitate patient contact to share test results.

Rapid HIV screening is well described in the adult literature, although many ED clinicians still report poor knowledge of adolescent HIV screening recommendations. Some efforts have been shown to increase ED-based HIV testing among all ages including use of opt-out testing practices and educational interventions to increase parental involvement and improve adolescent and parental HIV knowledge.
Additional research is needed to determine best practices for cost-effective and feasible HIV/STI screening of asymptomatic adolescent patients and to facilitate the implementation and dissemination of identified practices.

Provision of partner-based interventions for adolescents diagnosed with an STI has been largely unexplored in the ED setting. Partner notification involves identifying and informing partners of exposure, ensuring that partners receive evaluation and treatment, and providing prevention counseling. Expedited partner therapy, which is permissible in most states, is the practice of providing treatment to patients’ sexual partners without a medical evaluation or clinical assessment. Specific gaps include stakeholder knowledge, attitudes, and beliefs toward partner-based intervention as well as intervention feasibility and acceptability.

### Pregnancy Prevention

Despite declines in adolescent pregnancy rates over the past several decades, the United States has one of the highest rates in the industrialized world, and reduction of adolescent pregnancy remains a top priority for both the CDC and the U.S. Department of Health and Human Services. The risk of unintended pregnancy among adolescent females seeking care in the pediatric ED setting is more than three times greater than the national average. Frequent ED utilization and lacking a primary provider or private insurance are associated with higher risk for unintended pregnancy. Thus, interventions that identify females in EDs at high risk for unintended pregnancy are critically needed.

While adolescents are receptive to learning about and initiating contraception in the ED, research on best practices to reduce pregnancy risk and optimize contraceptive provision remains unclear. Small, single-site studies have demonstrated feasibility and acceptability of brief interventions for text messaging and personalized counseling to reduce pregnancy risk and improve access to both point-of-care and referral-based contraception.

Large studies to evaluate the efficacy and cost-effectiveness of such interventions have not been conducted. And ED-based research regarding patient-centered counseling and reproductive justice (i.e., the ability of any woman to determine her own reproductive destiny) is lacking. Virtually no ED-based work describes how to engage males and parents or trusted adults in pregnancy prevention efforts, although there is rich literature from other settings describing the important role these referents play in reducing sexual risk taking. Additional knowledge gaps involve understanding provider- and system-level issues such as how this work may fit into various provider roles, intervention to improve completion of reproductive health referral, and impact on ED work flow.

Emergency contraception is used by women within 120 hours following unprotected intercourse to prevent pregnancy. Many adolescents may be eligible for pregnancy prophylaxis as 10% to 14% of sexually active females reported unprotected intercourse within 120 hours preceding the ED visit. Barriers to EC in the ED are well described and include provider lack of knowledge and adolescent concerns about privacy. Adolescents in the ED are accepting of EC education and prefer to receive education from clinicians. While many ED directors report support for ED-based pregnancy prevention intervention, many ED clinicians do not support screening for recent unprotected intercourse and rarely provide EC outside of sexual assault. More research is needed that improves our ability to identify eligible patients who may be interested in EC and also targets elimination of barriers to provision while connecting these adolescents to regular, and more effective, contraception.

### Confidentiality and Consent

Multiple national medical societies consider confidential care for minor adolescents to be essential and most states allow minors to independently consent for evaluation and treatment of specific conditions. This varies from state to state but generally includes mental health services, treatment for substance abuse and addiction, pregnancy-related care, contraceptive services, and STI testing and treatment. While adolescents report that confidentiality is critically important in their decision to seek reproductive care, the best practices for maintaining confidentiality in the ED are not well defined.

Barriers to confidentiality in the ED include provider lack of knowledge, unique work environments, and patient flow patterns that make private interviews challenging to conduct. ED clinicians must also manage sensitive conversations within newly formed relationships. Adolescent privacy may also be breached inadvertently by electronic health records and billing documents. In most states, parents have access to their minor children’s medical records, which may
include sensitive information about gender identity, risk behaviors, and test results. Parents are highly accepting of sexual health discussions and services when their adolescent children receive ED care, but also express desire to understand the details of the visit, including testing results.66,67 ED clinicians are challenged to balance the interests of both adolescents and parents, while adhering to state statutes and institutional expectations. More research is needed to understand how to best facilitate confidential care in accordance with expert guidelines.

Research has potential to advance care and improve outcomes for both individual participants and for the larger population. These potential benefits cannot be achieved without research participation. However, adolescents have often been excluded from participation, in part because of unique challenges involving informed consent, institutional review board requirements, and parental involvement.93 Among adolescents in the ED, requiring parental consent appears to preclude participation in minimal risk STI research, especially for younger nonblack females.94 Further, although variation in development occurs, many adolescents and younger children are capable of meaningful participation in complex decision making95–97 and for mid- and late adolescents the cognitive abilities to understand research and to make decisions about participation are similar to these abilities in adults.95

Research with adolescents must balance respect for their emerging capacity for independent decision making with the need for special protections in the context of contemplating risks and benefits.98 There is a paucity of ED-based literature and studies that describe parental and adolescent views on research participation are needed.

Public Health and Barriers and Facilitators

As reported in the 2009 Academic Emergency Medicine Consensus Conference focused on ED-based public health efforts, integrating proven public health interventions into routine ED care requires “disseminating the information, developing then implementing a plan, evaluating the success of the initial attempt, and then modifying procedures and processes to create sustainability.”99 Further, we must demonstrate that ED-based sexual health interventions lead to short- and long-term effects on key outcomes at the patient, community, regional, and national levels. To successfully integrate public health practices into the ED, a multipronged approach is needed that includes rigorous research; updated educational curriculum for health professional trainees; enhanced delivery of preventive services through various personnel including public health professionals; and use of clinical information systems and digital technology to facilitate screening, intervention, and referral.100

Social EM is an approach to care that recognizes the ED’s unique position within the community and strives to address the social determinants driving medical illness, in addition to providing illness-related care.26 Because there is growing support for a broader, ecologic perspective to amplify and extend efficacy of sexual risk reduction interventions, we should consider how to partner with community-based organizations when developing or implementing ED-based interventions. Advancing research that considers larger public health problems including social determinants may create opportunities to reduce adolescent sexual risk taking on a large scale and lead to improved population health.

As described, barriers to care have been fairly well described, although our understanding of facilitators could be broadened. Developing a deeper understanding of parental perspectives for both clinical care and research participation may facilitate improved outcomes and warrants investigation.

LIMITATIONS

Although work utilizing consensus techniques is subject to selection and collective expert bias, we attempted to reduce this risk by inviting advisory members with varied expertise and by sharing only deidentified data to minimize influence from one or more members. External stakeholders were limited to pediatric EM physician researchers and our work may lack generalizability outside of the academic setting. Because the established processes for developing consensus involves the use of small groups of experts, some relevant topics may not have been identified as highest priority for research. We intentionally did not examine the feasibility of conducting any research needed to address these agenda items.

CONCLUSION

Using validated consensus-building processes, we identified critical questions to inform ED-based adolescent sexual and reproductive health research. The evidence generated from these priority items has potential to inform a multipronged approach needed to improve
References


32. Miller MK, Pickett ML, Reed JL. Adolescents at risk for sexually transmitted infection need more than the right medicine. J Pediatr 2017;189:23–5.


82. Miller MK, Champsassak S, DeLurgio S, et al. An emergency department intervention to increase adolescent

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.13809/full
Data Supplement S1. Supplemental material.
Does Shared Decision Making Actually Occur in the Emergency Department? Looking at It from the Patients’ Perspective

Elizabeth M. Schoenfeld, MD, MS1,2, Marc A. Probst, MD, MS3, Denise D. Quigley, PhD4, Peter St. Marie5, Nikita Nayyar, DO6, Sarah H. Sabbagh, MPH7, Tanesha Beckford8, and Hemal K. Kanzaria, MD, MS7

ABSTRACT

Objective: We sought to assess the frequency, content, and quality of shared decision making (SDM) in the emergency department (ED), from patients’ perspectives.

Methods: Utilizing a cross-sectional, multisite approach, we administered an instrument, consisting of two validated SDM assessment tools—the CollaboRATE and the SDM-Q-9—and one newly developed tool to a sample of ED patients. Our primary outcome was the occurrence of SDM in the clinical encounter, as defined by participants giving “top-box” scores on the CollaboRATE measure, and the ability of patients to identify the topic of their SDM conversation. Secondary outcomes included the content of the SDM conversations, as judged by patients, and whether patients were able to complete each of the two validated scales included in the instrument.

Results: After exclusions, 285 participants from two sites completed the composite instrument. Just under half identified as female (47%) or as white (47%). Roughly half gave top-box scores (i.e., indicating optimal SDM) on the CollaboRATE scale (49%). Less than half of the participants were able to indicate a decision they were involved in (44%), although those who did gave high scores for such conversations (73/100 via the SDM-Q-9 tool). The most frequently identified decisions discussed were admission versus discharge (19%), medication options (17%), and options for follow-up care (15%).

Conclusions: Fewer than half of ED patients surveyed reported they were involved in SDM. The most common decision for which SDM was used was around ED disposition (admission vs. discharge). When SDM was employed, patients generally rated the discussion highly.
Many emergency department (ED) patients want to be part of medical decision making when multiple, reasonable options are available. Shared decision making (SDM)—the conversation between patients and clinicians where clinicians describe options and share their expertise and patients contribute their values and preferences—has been gaining increased recognition in emergency medicine. Emergency physicians (EPs) report using SDM in about half of the encounters where they believe it appropriate, but cite multiple barriers to widespread use. A framework exists to encourage physicians to recognize opportunities to use this patient-centered method of decision making, but little is known about the actual frequency, content, or quality of SDM in the ED from the patient perspective.

Shared decision making has the potential to decrease resource utilization and improve patients’ knowledge, understanding of risk, trust in physician, and experience of care. Despite increased attention to SDM in the ED, few rigorously tested decision aids exist for use in the ED. It is likely that the majority of SDM in the ED takes place without the use of a formal decision aid, and measuring the frequency and quality of these interactions is challenging. To increase adoption of SDM, a better understanding of the current usage of SDM is needed. To facilitate the widespread implementation of SDM in the ED, we need a better understanding of how SDM is currently being used and whether existing scales are feasible for assessing SDM in the ED.

We sought to use currently available, validated scales to measure the content, frequency, and quality of SDM in ED encounters from the patient perspective and to determine if patient- and visit-level factors were associated with the use of SDM. Additionally, we sought to assess the feasibility of two commonly used scales (the CollaboRATE scale and the SDM-Q-9) in the ED setting, to guide future SDM implementation efforts. Finally, we hypothesized that a newly developed question about “choice awareness” and involvement in decision making would be feasible and would correlate with other markers of patient experience.

METHODS

Study Design and Setting
We administered an instrument that included three different SDM-related scales (two validated and one newly developed) to a cross-section of alert, stable adult patients at two academic EDs. The composite instrument described here was the 17-item second section of a two-part (total 36-item) instrument regarding patient’s preferences in decision making. The entire instrument is available in the 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.13850/full). Patients only received this second section, evaluating the occurrence of SDM, if the ED portion of the care was complete (i.e., the decision regarding admission or discharge had been made, and the patient was aware of the plan). Instrument design and testing are described below. The study was approved by each hospital’s institutional review board.

The two hospitals are both urban, teaching, safety-net hospitals and level one trauma centers with 80,000 to 115,000 annual visits. One hospital is in New England and the other in California.

Selection of Participants
Participants were eligible for inclusion if they were English-speaking ED patients, age 18 and older, alert, oriented, and hemodynamically stable. Exclusion criteria were altered mental status; intoxication; presenting for hallucinations or suicidal or homicidal ideation; or other cognitive, hearing, or linguistic barriers to the administration of an English-language survey. To assess whether SDM happened during the visit, only subjects whose ED care was considered completed were included—that is, patients only received the instrument when they were aware of their disposition (admission vs. discharge). Patients awaiting discharge paperwork from their nurse, or awaiting inpatient bed placement, were approached. Once a patient had been admitted for over 4 hours, they were not eligible for the study both to avoid oversampling admitted patients and because patients may have difficulty distinguishing ED care from inpatient care provided in the ED. Verbal informed consent was used to maintain confidentiality, and trained research assistants (RAs) administered the survey either in verbal or in written form. Screening logs were maintained to record reasons for exclusions and refusals and to ensure that patients with multiple ED visits were only enrolled once; these data have been published previously. Overall sampling was based on RA availability (i.e., convenience sampling) but RAs attempted to enroll a consecutive sample of patients available during their shifts across various days and time spans.
Methods and Measurements
To determine the best tool to measure the occurrence of SDM from the patients’ perspectives, the research team assessed several validated options. We determined that two published and publicly available scales were potentially appropriate for general use in the ED setting: the CollaboRATE scale (Data Supplement S1, Box 1) and the SDM-Q-9 (Data Supplement S1, Box 2).

CollaboRATE (Data Supplement S1, Box 1)
The CollaboRATE scale was developed to guide SDM implementation efforts. It was meant to be not only valid but practical, having only three questions, and the original development showed concurrent validity with the SDM-Q-9. (The concurrent validity with the SDM-Q-9, as measured by Pearson product moment correlation was \( r = 0.80 \) \([95\% CI = 0.78 \text{ to } 0.82], p < 0.001; \text{relationship: strong, positive}\) for mean scores and as measured by point-biserial correlation was \( r_{pb} = 0.50 \) \([95\% CI = 0.46 \text{ to } 0.54], p < 0.001; \text{relationship: strong, positive}\) for top-box scores.)

CollaboRATE has been used as a general measure across several settings—primary care, surgery, anesthesia, and others.

SDM-Q-9 (Data Supplement S1, Box 2)
The SDM-Q-9 was developed by taking the theoretical key steps of SDM and translating them into actionable items. The SDM-Q-9 was developed by taking the theoretical key steps of SDM and translating them into actionable items. Considerable refinements led to the final nine-item tool, which has since undergone psychometric testing in different populations, such as oncology, neurology, and behavioral health, with generally favorable properties (for example, in the oncology population, total sum scores derived from the general factor showed good reliability in terms of omega coefficient = 0.90).

We used cognitive interviewing prior to survey deployment to assess the understandability and feasibility of using these scales in the ED. For cognitive interviewing, we approached stable ED patients and explored both scales with open-ended questions regarding their interpretation of the questions. We discovered that patients were willing to give favorable responses to questions like, “My doctor precisely explained the advantages and disadvantages of the options” (item from SDM-Q-9) even in scenarios when no decisions had been discussed with the patient. We decided that prior to presenting the SDM-Q-9 questions we would ask about choice awareness.

Choice awareness is the understanding that more than one reasonable option exists and thus that a decision needed to be made. This concept does not currently have a validated patient-reported metric. The use of a choice awareness question prior to the use of the SDM-Q-9 forced respondents to report what decision conversation they were rating—as was also suggested by the original SDM-Q-9 scale development team.

To assess choice awareness, we asked two additional questions. The first question was to categorize any decision-making conversations participants had with their clinician (e.g., admission vs. discharge, one medication vs. another), including a response option for “We did not discuss any decisions.” Second, we asked whether respondents were “as involved in today’s decisions as you would have liked to be” with three response options “Yes, I was as involved as I wanted to be,” “No, I would have liked to be more involved,” and “Not applicable, there were no decisions for me to be involved in today.” These questions were developed from the study team’s qualitative work and were subject to multiple rounds of cognitive interviewing and piloting (Data Supplement S1, Box 3).

Additionally, two Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) ratings were included to assess the patients’ experience of overall care.

The final instrument contained 17 items, 15 of which were drawn from validated scales. It was administered as a section of a 36-item instrument assessing preferences (Control Preferences Scale), experiences of care, and demographics (see Data Supplement S1, Appendix S1). Some patients responded to both sections at the same time, if their ED care was complete, while others responded to the longer first section (that included 10 demographics items) while waiting for tests and then completed the instrument described here only when a disposition decision had been made and communicated.

Outcomes
Our primary outcome was the degree to which SDM occurred, from the patients’ perspective, as measured by the CollaboRATE scale, the SDM-Q-9 scale, and the final choice awareness question derived from the qualitative work: “Were you as involved as you wanted to be?” We measured the association between choice awareness (i.e., being able to recognize that decisions were being made) on the primary outcomes and other measures of patient experience. Secondary outcomes
included the proportion of patients willing and able to answer each scale (feasibility). We also reported findings from an exploratory analysis of whether any of the collected covariates were associated with the occurrence of SDM.

Data Analysis
Data were compiled using REDCap electronic data capture tools. Based on physician-reported estimates that SDM is appropriate about 50% of the time, and used in 50% of those instances,4 we sought to determine if patients reported the use of SDM approximately 25% of the time. A sample size of 300 would give a power of 0.80, with an alpha of 0.05, to detect reported SDM at 25%, with a 95% CI of ±2%. Our study was not powered to detect which covariates (such as demographics) were significantly associated with the occurrence of SDM; therefore, our regression analyses should be considered exploratory and hypothesis generating only and is not intended to be generalizable. Factors used for adjustment in the regression models were selected based on clinical relevance. Descriptive statistics were expressed as means and proportions. Differences in measures were presented with 95% CIs.

As per the authors’ suggestions in the original article, we dichotomized CollaboRATE responses using the “top-box” scoring approach, which means that respondents are categorized by whether or not they rated all three statements as “10 out of 10,” as this is considered to represent optimum SDM. We report SDM-Q-9 scores after rescaling from 0 to 100.11 Feasibility is reported as the proportion of patients able to fill out individual scales.

For our exploratory analysis, we used logistic regression to assess whether collected patient- and visit- characteristics were associated with a top-box score.24 We used linear regression to evaluate associations between these covariates and the CollaboRATE and SDM-Q-9 numerical scores, scaled to 0 to 100. We also modeled the response to our one developed question, “Were you as involved as you would have liked to be?” We used logistic regression with the 0/1 outcome, 1 = yes and 0 combining “no” and “not applicable”—there were no decisions for me to be involved with today.”

Regarding covariates examined, we included demographics, a summary score of 15 items on “barriers to SDM,” and the Control Preferences Scale, to assess whether any of these were associated with the occurrence of SDM from the patients’ perspectives.25 Additional details on the scaling of these covariates is available in Data Supplement S1, Appendix S2. No clinical covariates (i.e., variables regarding testing, results, or provider) were collected.

For our newly developed measure, “Were you as involved in today’s decisions as you would have liked to be?” we examined the association of the three response options with the other measures of SDM and patient experience measured by HCAHPS overall ratings. All analyses were performed with R version 3.5.

RESULTS
Participant Characteristics
Of the participants who completed the first section of the instrument (response rate = 83%),2 were asked to complete the second section of the instrument that included the measures described above, and 285 were included (eight excluded because of incomplete CollaboRATE scores; Figure 1). The mean age of participants was 49 years old with 47% (n = 135) female (Table 1). The mean (±SD) CollaboRATE score was 84 (±23)/100 and 49% of participants had a top-box

![Figure 1 Patients screened, approached, and consented for Sections I and II of the instrument.](image-url)
score (i.e., the highest response option for all three questions). Table 2 shows patient experience scores. Ninety-nine patients completed the SDM-Q-9 items with a rescaled mean score of 73/100.

When asked explicitly about involvement in decision making, the most frequently discussed decision was regarding “admission versus discharge” (19%), followed by “treatment options like medications” (17%), “different options for follow-up care after you leave the ED” (15%), and “one test versus another test or no test” (13%). The majority of participants, 56% (n = 159) reported that they “did not discuss any decisions” (Table 3). When queried regarding “were you as involved as you wanted to be,” results reflected a similar trend: 47% (n = 133) reported “yes,” 6% (n = 18) reported “no,” and the remaining 46% (n = 131) reported “Not applicable, there were no decisions for me to be involved in today,” with 1% (n = 3) not responding.

To assess the association between patient and visit characteristics and the frequency and quality of SDM, we modeled the outcome of SDM using the different instruments. Our four models examined top-box CollaboRATE scores, raw CollaboRATE scores, scaled SDM-Q-9 scores, and our newly developed question. The final models are found in Data Supplement S1, Appendix S3. The following characteristics were associated with a lower likelihood of giving a top-box CollaboRATE score: higher agreement with barriers, being admitted, younger age, and identifying as white. When the score was modeled based on its raw numeric value using linear regression, no covariates were statistically significant. The model of the SDM-Q-9 scores showed an association only between being male and a higher SDM-Q-9 score. Finally, when we modeled “were you as involved in today’s decisions as you wanted to be” (using a 0/1 outcomes with “yes” vs. both “no” and “not
applicable"), no covariate factors were significantly associated with a “yes” answer (i.e., “Yes, I was involved in today’s decisions as I wanted to be”).

Regarding feasibility, of the initial 293 participants, 285 (97%) answered all three of the CollaboRATE questions. However, after the addition of the question asking about choice awareness, only 99 (34%) completed the SDM-Q-9 questions. This is because, based on piloting and the original SDM-9 publication, we asked patients to explicitly identify the specific conversation/decision they were rating before they answered the SDM-Q-9 questions. If a patient was unable to identify a specific conversation/decision, they were not asked to complete the questions about SDM in the SDM-Q-9.

Regarding associations between whether participants could identify a decision being made (i.e., choice awareness) and measures of quality of SDM and patient experience, those who were unable to identify a decision they were involved in, had only a 6 points lower mean CollaboRATE score compared to those who were able to identify a decision (82 vs. 88, 95% CI of difference = 1 to 11). For participants who reported “Yes, I was as involved as I wanted to be” (n = 133), the mean CollaboRATE score was 32 points higher than for those (n = 18) who said “No, I would have liked to be more involved” (90 vs. 58, 95% CI of difference = 22 to 42). These two groups also showed significant differences in ratings of overall patient experience of care, using a 0 to 10 rating with 0 as the worst care possible and 10 as the best care possible. Those reporting adequate involvement rated their overall experience of care higher than those who reported wanting more involvement, with a median (IQR) of 10 (9–10) versus 7 (6–8; Table 4).

**Table 2**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>285</td>
</tr>
<tr>
<td>Completed all three parts of CollaboRATE (%)</td>
<td>285 (97% of 293)</td>
</tr>
<tr>
<td>No (excluded from further analysis)</td>
<td>8 (3% of 293)</td>
</tr>
<tr>
<td>CollaboRATE top-box score (%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>139 (48.8)</td>
</tr>
<tr>
<td>No</td>
<td>146 (51.2)</td>
</tr>
<tr>
<td>CollaboRATE score, mean (±SD)</td>
<td>84.5 (±22.8)</td>
</tr>
<tr>
<td>SDM-Q-9 completed (%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>99 (34.7)</td>
</tr>
<tr>
<td>No</td>
<td>186 (65.3)</td>
</tr>
<tr>
<td>SDM-Q-9, mean (±SD) (n = 99)</td>
<td>73.23 (±21.7)</td>
</tr>
<tr>
<td>Were you as involved in today’s decisions as you would have liked to be? (%)</td>
<td></td>
</tr>
<tr>
<td>Yes, I was as involved as I wanted to be.</td>
<td>133 (46.7)</td>
</tr>
<tr>
<td>No, I would have liked to be more involved.</td>
<td>18 (6.3)</td>
</tr>
<tr>
<td>Not applicable, there were no decisions for me to be involved in today.</td>
<td>131 (46.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Would you recommend this ED to friends/family (%)</td>
<td></td>
</tr>
<tr>
<td>Definitely no</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Probably no</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Probably yes</td>
<td>52 (18.2)</td>
</tr>
<tr>
<td>Definitely yes</td>
<td>223 (78.2)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Overall rating of care received (%)</td>
<td></td>
</tr>
<tr>
<td>0 (worst)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>1</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>2</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>3</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>4</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>5</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>6</td>
<td>8 (2.8)</td>
</tr>
<tr>
<td>7</td>
<td>23 (8.1)</td>
</tr>
<tr>
<td>8</td>
<td>38 (13.3)</td>
</tr>
<tr>
<td>9</td>
<td>46 (16.1)</td>
</tr>
<tr>
<td>10 (best)</td>
<td>155 (54.4)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Overall rating of care received from 1 to 10, mean (±SD)</td>
<td>8.92 (±1.6)</td>
</tr>
</tbody>
</table>

SDM = shared decision making.

**DISCUSSION**

To our knowledge, this is the first study to assess the occurrence of SDM in the ED from the patient perspective. Our results suggest that the areas where SDM is being used most frequently include admission/discharge, treatments/medications, follow-up planning, and testing. Future efforts aimed at increasing SDM should focus on the development of decision aids and clinician training around discussing the disposition decision (i.e., admission vs. discharge) with patients, when clinically appropriate. For example, SDM is potentially appropriate for conditions such as intermediate-risk chest pain, pneumonia, pyelonephritis, cellulitis, and intermediate-risk syncope, among others. Supporting physicians in how best to engage in SDM for these clinical scenarios would have the highest potential for impact.

Although approximately half of patients were able to report a decision they discussed, it is notable that 46% of participants felt that “there were no decisions for me to be involved with today.” Being “as involved
as I would like to be” was associated with better overall experiences of care, as measured by HCAHPS ratings; however, it was less clear how failing to recognize an opportunity for involvement influenced patients’ overall experience of care. This is consistent with our prior research that found that ED patients often do not expect SDM and are not aware of decisions being made with or without their involvement.1

Our results mirrored prior patient experience research—that involvement in decision making, as a component of communication, is clearly correlated with overall ratings of the patient experience of care.26 When we compared those who responded “yes” to “Were you as involved as you wanted to be?” to those who responded with a “no” (i.e., omitting those who did not see opportunities for involvement), we found very large differences across all measures: CollaboRATE top-box scores decreased from 52% to 6% and “definitely yes” on the “would recommend” question decreased from 82% to 33%. This provides evidence for the importance of helping patients feel involved in decision making; patients who feel involved in clinical decisions report a better overall experience of care.

Regarding the feasibility of the two previously validated measures, a number of important questions are clarified by our results. The CollaboRATE was, as advertised, “fast and frugal;” 97% of participants provided answers to all three questions. However, those who reported “there were no decisions for me to be involved in” had similar CollaboRATE scores to those who reported they were “as involved as they wanted to be” in a decision, raising the question of whether patients may offer high scores on the CollaboRATE scale without actually experiencing SDM, as defined for research purposes. This has been seen in other studies as well: Bakhit et al.27 found that the use of a decision aid increased OPTION scores (a SDM measure scored by a third-party observers) but that CollaboRATE scores were unchanged. Stubenrouch et al.14 sought to determine current levels of SDM within preoperative visits with anesthesiology and

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Participants’ Responses to “Did You and Your Doctor Discuss Any of the Following Decisions Today?” a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response Options</td>
<td></td>
</tr>
<tr>
<td>Being admitted to the hospital versus going home</td>
<td>54 (19.1)</td>
</tr>
<tr>
<td>Medications (one medication vs. another or vs. no medication)</td>
<td>47 (16.6)</td>
</tr>
<tr>
<td>Different options for follow-up care after you leave the ED</td>
<td>43 (15.2)</td>
</tr>
<tr>
<td>One test versus another test or no test (like CT scan, blood tests, or ultrasound)</td>
<td>38 (13.4)</td>
</tr>
<tr>
<td>Surgery or a procedure</td>
<td>16 (5.7)</td>
</tr>
<tr>
<td>Going to an observation unit or physical rehabilitation versus going home or being admitted</td>
<td>15 (5.3)</td>
</tr>
<tr>
<td>Antibiotics versus no antibiotics or another option</td>
<td>13 (4.6)</td>
</tr>
<tr>
<td>Breathing tubes, ventilators, or life support (e.g., “What would you want done if you stopped breathing on your own?”)</td>
<td>8 (2.8)</td>
</tr>
<tr>
<td>CPR and aggressive care versus comfort care</td>
<td>6 (2.1)</td>
</tr>
<tr>
<td>No, I did not discuss any decisions with my ED doctors today.</td>
<td>159 (56.2)</td>
</tr>
</tbody>
</table>

aData are reported as total n (%). Percentages do not equal 100 as participants could select more than one response, unless “No, I did not discuss any decisions with my emergency department doctors today” was selected.

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Differences in Validated Measures Based on Newly Developed Question, “Were You As Involved in Today’s Decisions As You Would Have Liked to Be?” (Statistical Comparison Is Between “Yes” and “No” Groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Yes, I Was as Involved as I Wanted to Be”</td>
</tr>
<tr>
<td>Total</td>
<td>133</td>
</tr>
<tr>
<td>CollaboRATE top-box score (%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>69 (51.9)</td>
</tr>
<tr>
<td>No</td>
<td>64 (48.1)</td>
</tr>
<tr>
<td>CollaboRATE score, mean (±SD)</td>
<td>90.4 (±15.2)</td>
</tr>
<tr>
<td>Overall rating of ED, mean (±SD)</td>
<td>9.1 (±1.5)</td>
</tr>
<tr>
<td>Willingness to recommend (%)</td>
<td></td>
</tr>
<tr>
<td>Definitely no</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Probably no</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Probably yes</td>
<td>23 (17.3)</td>
</tr>
<tr>
<td>Definitely yes</td>
<td>109 (82.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>
found that while third-party observers, again using the OPTION score, gave conversations low marks for the presence of SDM, patients gave these same conversations high scores on the CollaboRATE and SDM-Q-9 scales. It appears that patients often do not recognize that there are decisions that they could be involved in and, as a result, provide high scores for good communication, without actual involvement in decision-making. Nonetheless, the concepts CollaboRATE attempts to assess are valid measures of patient-centered communication and may be more appropriate, from patients’ perspectives, than whether SDM, as defined by a researcher or clinician, has actually happened. Additionally, with an overall top-box score of 49%, this metric may be appropriate for measuring implementation of SDM interventions aimed at improving patient experience, as our study suggests that there is room for improvement, at least in the studied EDs.

A potential shortcoming of the SDM-Q-9 scale emerged during cognitive testing, as patients were often willing to give positive ratings to SDM when in fact no discussion of a decision had taken place. Patients would check “agree” to “The doctor made clear to me that a decision needed to be made;” however, when research staff would ask for more detail about that decision, patients would clarify that they were not thinking about anything specifically. The SDM-Q-9 is clearly only meant for use when the participant can reflect on a specific conversation about a decision, and we found that in the evaluation of ED clinical decision making, this did not happen most of the time. The SDM-Q-9 did have the distinct advantage of giving specific feedback regarding aspects of SDM. From our data, we could easily note which of the nine domains were rated best and worst. For example, while only 7% disagreed with, “My doctor made clear that a decision needs to be made,” 24% disagreed with, “My doctor told me that there are different options for my medical condition.”

Despite the respective advantages of these two scales, as noted, patients usually rate interactions higher than third-party observers do.14,27 Based on previous studies, we should assume that the actual number of decisions discussed was lower than these scores suggest. For example, in the analogous study by Stubenrouch et al. in anesthesiology, when all scores were rescaled to 0 to 100, mean scores were 92/100 for both CollaboRATE and SDM-Q-9, but only 31/100 as judged by a third party (as measured by the OPTION score).14 Therefore, while CollaboRATE and SDM-Q-9 are intended to be patient-centered measures of SDM, they may be simply measuring the general interpersonal and communication skills of the clinician.

**LIMITATIONS**

Our study has several limitations. The current tools measuring SDM are new, inexact, and evolving, and SDM can be measured (inexactly) from multiple perspectives. No current measurement tools have been developed specifically for the context of ED care, although the tools we employed were created to be implemented in a variety of clinical scenarios. The tool that is most commonly used in SDM research, the OPTION scale, is time- and resource-intensive, as it requires audio or video recording of the patient–provider conversation and an adequately trained third-party observer(s) to rate the conversation. We instead chose two easy-to-score, patient-centered tools to incorporate the patients’ perspectives. However, most patients are not familiar with the concept of SDM and do not expect it.1,2 Therefore, patients may be judging provider–patient communication in general and not specifically SDM.1,2

Our study is also limited in generalizability for two main reasons. First, the instruments were only available in English. Second, we included only two locations, both of which were urban, academic, safety-net hospitals. It is unknown if we would find similar results with non-English speakers or at different types of EDs. Finally, as the instrument followed earlier questions about the desirability of involvement with decisions, we may have influenced responses by asking about preferences and barriers, and survey fatigue may have affected the responses to the final questions.

**CONCLUSIONS**

In conclusion, fewer than half of stable, cognitively intact, English-speaking adult ED patients recognized that decisions were being made that they could have been involved in. The most frequent decision discussed was admission versus discharge, but fewer than half of participants reported that they were involved to the degree they wanted. While in the context of busy ED care this could be considered reasonable, there is certainly room for improvement. The appropriate use of shared decision making could be increased by providing training and education for clinicians, by the development of more evidence-based decision aids for commonly encountered clinical scenarios, and by the
development of patient experience measures related to shared decision making. Further research on the implementation of shared decision making in this setting is warranted since even a small degree of involvement in decision making appears to be quite meaningful to ED patients.

The authors acknowledge the assistance of the research associates program at Baystate Medical Center as well as Athena Sofides, Shelby Mader, Kye Poronsky, Kyle Gress, and Daniela Garcia.

References

27. Bakhit M, Del Mar C, Gibson E, Hoffmann T. Shared decision making and antibiotic benefit-harm conversations: an observational study of consultations between general practitioners and patients with acute respiratory infections. BMC Fam Pract 2018;19:165

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.13850/full

Data Supplement S1. Supplemental material.
Prehospital Care of Pediatric Hypoglycemic Seizure Patients in the State of North Carolina: A Retrospective Cohort Study

Zachary T. Burroughs, MD1, Michael S. Mitchell, MD2, Brian Hiestand, MD, MPH3, and James Winslow, MD, MPH3,4

ABSTRACT

Background: Pediatric seizures are commonly encountered in emergency medical services (EMS). Evidence is accumulating that the rate of hypoglycemia in this setting is low, challenging the concept of routine prehospital glucose measurement.

Objective: We studied factors associated with EMS protocol compliance for glucose testing in children < 18 years of age with a 9-1-1 call for seizure as well as rates of hypoglycemia in the prehospital setting.

Methods: We performed a retrospective analysis of data from the North Carolina EMS registry from 2013 to 2014. North Carolina EMS protocols require glucose measurement prior to seizure treatment. Scene calls for patients ≤ 17 years with a complaint of seizure were included. We calculated incidence of testing, hypoglycemia, and the relative risk of compliance with glucose measurement.

Results: There were 13,182 calls for seizure, of which 6,262 (47.5%, 95% confidence interval [CI] = 46.6% to 48.3%) had a glucose obtained. Hypoglycemia (glucose < 60 mg/dL) was present in 78 of 6,262 (1.25%, 95% CI = 0.97% to 1.5%) patients. Glucose was supplemented in 61 patients (median glucose 61 mg/dL, interquartile range = 51 to 67 mg/dL). Testing rates increased with age (relative risk [RR] = 1.04 per year, 95% CI = 1.03–1.04 per year), emergency medical technician–paramedic (EMT-P) presence (RR = 1.2, 95% CI = 1.1–1.3) and with antiepileptic medication use (RR = 1.24, 95% CI = 1.1 to 1.2). Testing was less likely in nonwhite patients (RR = 0.95, 95% CI = 0.92 to 0.98).

Conclusions: Compliance is suboptimal, varying with patient age, race, and EMT-P presence. Testing increases when antiepileptic drugs are used. Hypoglycemia in tested patients was infrequent; however, proper treatment for hypoglycemic seizures will not be delivered if testing does not occur. It is worthwhile examining the utility of routine testing in this setting; however, until such time as protocols are revised, regional EMS administration should focus on education and uniform compliance with state protocols.

Pediatric seizures are commonly encountered in emergency medical services (EMS).1 One study found that seizures were the second most common chief complaint when requesting EMS transport to a pediatric emergency department,1 and seizures account for 4% to 8% of all EMS calls.2 The majority of pediatric patients undergoing blood glucose monitoring and receiving treatment for hypoglycemia in the prehospital setting have a chief complaint of seizure.3 In contrast, Beskind et al.4 found that hypoglycemia was...
a rare event in EMS calls for seizures (1.2%) when examining a combined adult and pediatric population. The majority of EMS protocols require blood glucose testing prior to seizure treatment with respect to children. Two recent studies have suggested that hypoglycemia is a rare cause of seizure in pediatric patients and challenged the concept of routine glucose measurement in the pediatric seizure patient.

Goals of This Investigation
This study aims to assess the rate of hypoglycemia in pediatric patients with chief complaint of seizure in the prehospital setting by North Carolina EMS providers. This study also aims to assess factors associated with protocol compliance with regard to pediatric seizure patients by EMS providers in the state of North Carolina. EMS protocols are in place to promote best practice and are implemented to ensure standardized care across multiple settings and locations. We feel that protocol compliance is important to study to understand how well these instructions are being implemented and utilized.

We hypothesize that hypoglycemia is not commonly associated with seizures in the prehospital setting within the pediatric population in the state of North Carolina. We further hypothesize that compliance with EMS protocol is low with regard to obtaining a point-of-care blood glucose in the setting of seizures in pediatric patients.

METHODS

Study Design and Setting
We performed a retrospective analysis of data from the North Carolina Office of Emergency Medical Services (NCOEMS) Prehospital Medical Information System (PreMIS) database. The database contains information from all private and public EMS operations within the state of North Carolina and is compliant with the National EMS Information System (NEMSIS) format. The NC EMS protocol requires glucose testing as one of the first steps in the evaluation of suspected seizure, regardless of the presence or absence of active seizures (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.13834/full). Treatment thresholds for hypoglycemia are not defined and are governed by county protocols. There is heterogeneity at the county level as to treatment thresholds, ranging between 60 and 70 mg/dL. However, as no county protocol used a threshold less than 60 mg/dL, that was chosen as our threshold for our study—below this point, all counties are in agreement that treatment should occur. However, we also report the prevalence of results between 60 and 70 mg/dL. This study was approved by the Wake Forest University Biomedical Institutional Review Board. We conducted the study and prepared the manuscript in concordance with the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines.

Selection of Participants
Data were provided for all 9-1-1 EMS calls recorded in PreMIS from January 1, 2013, through December 31, 2014, for patients ≤17 years identified as having a patient chief complaint containing “seizure” or provider primary impression listed as “seizure.” Any call other than a primary scene run was excluded, such as interfacility transfers or prescheduled transports.

Measurements
We extracted the following covariates from the PreMIS data set: age, race, ethnicity, sex, highest crew member credential, and administration of an antiepileptic medication (inclusive of benzodiazepines, barbiturates, and seizure disorder–specific medications such as phenytoin, valproic acid, or levetiracetam). Crew member credential was broken down into the subcategories of emergency medical technician–paramedic (EMT-P), emergency medical technician–intermediate (EMT-I), emergency medical technician–basic (EMT-B), and other (predominantly nurse or physician). Race and ethnicity data were combined into a single variable (termed “race” for the purposes of the analysis) and dichotomized as white (specifically non-Hispanic ethnicity) or nonwhite, which included Hispanic ethnicity as well as all racial categories that were not white. We also obtained EMS transport disposition, dichotomizing into transport or no transport. The first blood glucose documented was utilized for purposes of defining hypoglycemia. All EMT levels were allowed to carry glucometers, all levels could administer oral glucose, and EMT-I and EMT-P could administer parenteral glucose. The treatment of hypoglycemia could include oral (glucose) or IV (dextrose) routes.

Data Analysis
We calculated the relative risk of compliance with glucose measurement using a multivariable generalized
RESULTS

There were 13,182 calls for seizures for patients \( \leq \) 17 years who met inclusion criteria. There were 6,488 calls in 2013 (49.2%) and 6,694 calls in 2014 (50.8%). Table 1 provides basic characteristics of the cohort. Of the 13,182 calls included, 10,649 (80.8%) were transported by EMS to a facility for further care leaving 2,533 calls (19.2%) in which the patient was not transported by EMS, including 1,121 calls (8.5%) where the patient/family refused EMS transport.

Glucose testing was performed in 6,262 (47.5%, 95% confidence interval [CI] = 46.7% to 48.4%) patients and was not performed in 6,920 (52.5%, 95% CI = 51.6% to 53.3%) patients. Hypoglycemia (blood glucose \( \leq 60 \) mg/dL) was present in 78/6,262 (1.25%, 95% CI = 0.97% to 1.5%) patients in which glucose was obtained. The blood glucose was between 60 and 70 mg/dL in 137 (2.2%, 95% CI = 1.8% to 2.6%) additional patients.

There were a total of 70/13,182 (0.53%, CI = 0.41% to 0.67%) patients in the entire cohort who received treatment for hypoglycemia. Of patients in whom testing occurred, treatment was provided in 61/6,262 (0.97%, 95% CI = 0.75% to 1.25%), with a median glucose level of 61 mg/dL (interquartile range [IQR] = 51–67 mg/dL) and not given in 6,201 (median glucose = 105 mg/dL, IQR = 90–124 mg/dL; \( p < 0.0001 \)). Of the patients who received glucose or dextrose, there were 29 with documented hypoglycemia (<60 mg/dL), 22 with blood sugars of 61 to 69 mg/dL, 10 with blood sugars \( \geq 70 \) mg/dL, and nine patients who did not have a glucose check documented. There were 1,324 patients who received an antiepileptic drug (10%, 95% CI = 9.5% to 10.6%). Of these, 809 (61%, 95% CI = 58.5% to 63.7%) had a glucose checked, and eight had hypoglycemia (1%, 95% CI = 0.3% to 1.7%).

There were a total of 12,070 records with complete data available for model building. Sex was not recorded on 55 encounters, EMT certification level was not recorded in 277, and race/ethnicity was not documented on 797, resulting in 1,112 records being excluded (some records had multiple missing data elements). The relative risk of having a blood glucose checked in compliance with state EMS protocol was calculated, adjusting for age, race/ethnicity composite (as defined under Methods), highest crewmember credential, sex, and whether or not an antiepileptic drug was given. Table 2 provides the full model results. In summary, increasing age, EMT-P presence, and antiepileptic drug administration all increased the likelihood of glucose testing compliance, while the composite variable nonwhite race or Hispanic ethnicity was associated with a decreased likelihood of testing. We found no association with testing likelihood and the sex of the child.

Table 1: Characteristics of the Cohort, With Delineation by Testing/No Testing

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total Cohort ((N = 13,182))</th>
<th>Glucose Testing Performed ((n = 6,262))</th>
<th>Testing Not Performed ((n = 6,920))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>6.6 (±5.3)</td>
<td>7.9 (±5.4)</td>
<td>5.5 (±4.9)</td>
</tr>
<tr>
<td>Nonwhite race/ethnicity</td>
<td>6,103 (46.3%, 45.4%–47.1%)</td>
<td>2,879 (46.1%, 44.9%–47.4%)</td>
<td>3,224 (46.6%, 45.4%–47.8%)</td>
</tr>
<tr>
<td>Male sex</td>
<td>7,207 (54.7%, 53.8%–55.5%)</td>
<td>3,390 (54.1%, 52.9%–55.4%)</td>
<td>3,817 (55.1%, 54%–56.3%)</td>
</tr>
<tr>
<td>EMT-P present</td>
<td>12,139 (92.1%, 91.6%–92.5%)</td>
<td>5,839 (93.2%, 92.6%–93.9%)</td>
<td>6,300 (91%, 90.3%–91.7%)</td>
</tr>
<tr>
<td>AED given</td>
<td>1,324 (10%, 9.5%–10.6%)</td>
<td>809 (12.9%, 12.1%–13.8%)</td>
<td>515 (7.4%, 6.8%–8.1%)</td>
</tr>
<tr>
<td>Transported</td>
<td>10,649 (80.8%, 80.4%–81.8%)</td>
<td>5,316 (84.9%, 84%–85.8%)</td>
<td>5,333 (77.1%, 76.1%–78.1%)</td>
</tr>
</tbody>
</table>

Continuous variables are presented as mean (±SD). Categorical variables are presented as counts (proportion, 95% CI) for the proportion. Sex was not recorded on 55 encounters, EMT certification level was not recorded in 277, and race/ethnicity was not documented on 797. AED = antiepileptic drug; EMT-P = emergency medical technician-paramedic.
DISCUSSION

This study supports both of our hypotheses. The first hypothesis was that hypoglycemia is not commonly associated with seizures in the prehospital setting within the pediatric population in the state of North Carolina. In our study, hypoglycemia (<60 mg/dL) was present in only 1.25% of patients in which glucose was obtained. This is a similar range to that reported by both Beskind et al. and Remick et al. In Remick’s single-center study, they recommend changing protocol so that testing is not performed routinely in prehospital pediatric seizure/postseizure care, based on 771 subjects and four hypoglycemic events. Although our data reflected data found in the study by Remick et al., further validation in multicenter studies may be needed prior to implementation in protocol change.

In our study, of those patients with glucose checked, only 1% of patients were given glucose. Beskind et al. reported a similar rate of glucose administration with 1.75% of patients with a glucose obtained receiving glucose; however, this was again examining adult and pediatric patients combined. We further found that of patients with documented hypoglycemia (<60 mg/dL) only 37% were given glucose. The median glucose was 61 mg/dL for those who had a glucose checked and were given glucose. This is also similar to Beskind et al. who reported a median blood glucose measurement of 59 mg/dL for patients given a glucose product when examining pediatric and adult patients combined. Although the NC state level EMS protocol provides guidance on testing (see Data Supplement S1), the threshold for treatment varies at the county level between 60 and 70 mg/dL, resulting in a distribution of treated hypoglycemia that ranges above the absolute minimum threshold of 60 mg/dL. As we do not have data on the specific county of origin for each encounter, this does limit our ability to provide conclusions regarding the actual treatment of lower blood glucose levels.

Our second hypothesis was that compliance with state protocol in the pediatric seizure population would be suboptimal. This hypothesis was supported by our finding that of the 13,182 calls for seizure patients that met inclusion criteria, glucose testing was performed in only 47.5% of patients.

Our study found that compliance varied based on age, race, paramedic presence, and administration of an antiepileptic drug. We interpret this as paramedic presence is more likely to increase compliance with protocol due to more extensive training. In addition, if seizure-terminating medications were administered, it may be that the EMS crew were going to be certain that the correct intervention was going to be applied, resulting in more testing. We do not have access to final diagnoses from this database; however, there may have been a presumption of febrile seizure in the younger patients, resulting in a decreased likelihood of testing in the younger patients. We do not have a presumption as to the root cause for decreased testing in nonwhite children, but this may be due to implicit bias, which has previously been demonstrated in other pediatric care settings. We feel that this requires further, targeted research.

LIMITATIONS

We acknowledge that our study has several limitations given its retrospective nature. Our study only represents the state of North Carolina, and it is possible that our data are not reflective of other populations. One possible limitation is that our study may have underestimated pediatric seizure patients with hypoglycemia due to overall poor compliance with protocol with only 47.5% of patients reported to have undergone glucose testing. In addition, a patient encounter may have been included in the data set due to a chief complaint of “seizure,” but the EMS primary impression would be one of a different pathologic state. In that setting, the EMS team may have pursued a different evaluation pathway. Our treatment of race and ethnicity as a composite variable is distinctly a simplification of a very complex issue; however, we utilize this concatenation in light of the demographics of the population in our region and our cohort. Finally, data were not available regarding whether seizures had resolved by the time EMS arrived on scene. However, the NC EMS protocol directs glucose assessment

### Table 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>RR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.04</td>
<td>1.036–1.042</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nonwhite</td>
<td>0.95</td>
<td>0.92–0.99</td>
<td>0.008</td>
</tr>
<tr>
<td>EMT-P present</td>
<td>1.21</td>
<td>1.10–1.32</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AED given</td>
<td>1.24</td>
<td>1.19–1.30</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male</td>
<td>1.01</td>
<td>0.98–1.05</td>
<td>0.43</td>
</tr>
</tbody>
</table>

AED = antiepileptic drug; EMT-P = emergency medical technician – paramedic.
regardless of the presence or absence of active seizure; therefore, even if seizure activity had resolved, testing was indicated by protocol.

CONCLUSION

Compliance with protocol is suboptimal and is affected by patient age and race. Compliance increases with paramedic presence and the use of antiepileptic drugs, suggesting that active seizure treatment is associated with an increased chance of testing glucose. The overall rate of hypoglycemia in those patients with glucose checked was low. However, proper treatment for hypoglycemic seizures will not be given if testing does not occur. It is unknown how many cases of hypoglycemia were missed in those not tested. It is worthwhile examining the utility of routine testing in this setting; however, until such time as protocols are revised, regional emergency medical services administration should focus on education and compliance with state protocols.

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.13834/full

Data Supplement S1. Pediatric seizure.
Clinical Gestalt for Early Prediction of Delayed Functional and Symptomatic Recovery From Mild Traumatic Brain Injury Is Inadequate

Frederick K. Korley, MD, PhD, W. Frank Peacock, MD, James T. Eckner, MD, Ronald Maio, DO, MS, Scott Levin, PhD, Kathleen T. Bechtold, PhD, Matthew Peters, MD, Durga Roy, MD, Hayley J. Falk, ScM, Anna J. Hall, Timothy E. Van Meter, PhD, Richard Gonzalez, PhD, and Ramon Diaz-Arrastia, MD, PhD

There are limited prognostic tools to guide clinicians in acute risk stratification of adult mild traumatic brain injury patients (mTBI). While the majority of mTBI patients achieve full recovery within 7 to 14 days, approximately 25% to 30% remain symptomatic for 3 or more months postinjury. Early identification of the subset of mTBI patients at high risk for protracted recovery will: 1) facilitate administering the right discharge instructions and subspecialty referral to the right at-risk mTBI patients; 2) enable individualized education of patients regarding their expected course of recovery; 3) allow targeted administration of cognitive and behavioral therapy that has been found to be efficacious when implemented during the acute phase of injury; and 4) enable enrichment of study populations of mTBI clinical trials with patients who are at risk for protracted recovery and therefore decrease the sample size required for demonstrating therapeutic efficacy.

We performed a substudy of participants who were enrolled in the Head Injury Serum Markers for Assessing Response to Trauma (HeadSMART) study, an observational prospective cohort study. HeadSMART study design and methods have been previously published. Briefly, we included ED patients 18 years or older, who presented to an urban academic medical center within 24 hours of injury, met the American College of Emergency Physicians’ criteria for evaluation of TBI with a head CT scan, received head CT imaging, and provided written informed consent. The study was approved by the local institutional review board.

Demographic and injury characteristics were based on participants’ self-report obtained by trained research coordinators and a review of the electronic medical record. The resident physician or midlevel provider responsible for the clinical care of an enrolled participant was interviewed regarding the participant’s prognosis. The treating attending physician was also interviewed independently. Interviews occurred after results of diagnostic tests were available. The text of the prognosis questions asked is presented...
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.13844/full).

Follow-up was conducted either via telephone or an in-person assessment at 1, 3 and 6 months postinjury. Functional recovery was ascertained using the Glasgow Outcome Scale Extended (GOSE) and symptomatic recovery was ascertained using the Rivermead Post-Concussion Questionnaire (RPQ). Delayed functional recovery was defined as GOSE score < 8 at 3 months postinjury. Delayed symptom recovery was defined as having three or more postconcussive symptoms (PCS) at 3 months postinjury that were graded as mild or more severe problems compared to their preinjury status. Outcome assessments were performed by trained research coordinators and reviewed by a board-certified neuropsychologist for accuracy.

Head CT scans were reread by one board-certified neuroradiologist and classified as having either a traumatic intracranial abnormality/skull fracture or not. The professional experience of clinicians was quantified based on the number of years since graduating from professional school into: 0 to 1, 1 to 2, 3 to 4, and more than 4 years for resident physicians and midlevel providers and 0 to 9, 10 to 19, and 20 years or more for attending physicians. Clinicians were asked to rate the certainty of their prediction on a scale of 0% to 100%. These ratings were then categorized into three groups: low (0%–49%), moderate (50%–89%), and high (90% or greater).

The accuracy of clinician gestalt was determined by comparing clinical prediction to participant outcome. The discriminative ability of clinical gestalt was quantified with the area under the receiver operator curve (AUC). We tested for differences in the predictive accuracy of clinical gestalt according to professional experience and certainty of prediction, using the chi-square test. Accuracy was defined as the number of correct predictions (true positives + true negatives) divided by the total number of predictions. A two-tailed p-value of <0.05 was considered statistically significant.

A total of 217 subjects met the inclusion criteria for this analysis. Included subjects were predominantly male (59.6%), and Caucasian (50.7%) and had a median age of 43 years. The most common mechanism of injury was falls (31.8%). At presentation, 192 (88.5%), 23 (10.6%), and two (0.9%) subjects had a Glasgow Coma Scale of 15, 14, and 13, respectively. Traumatic intracranial injuries were identified on the head CTs of 32 (17.1%) subjects. The distribution of GOSE scores at 3 months were as follows: among the 217 subjects studied, 115 (53.0%) had delayed functional recovery and 105 (49.3%) had delayed symptom recovery. At 3 months, five, one, three, 17, 33, 56, and 102 subjects had GOSE scores of 1 to 8, respectively. A total of 80 residents and midlevel providers were interviewed at least once. Among these clinicians, 23 (28.8%), 27 (33.8%), 28 (35.0%), 13 (16.2%), and 19 (23.8%) had 0 to 1, 1 to 2, 3 to 4, and >4 years of professional experience, respectively. A total of 32 attending physicians were interviewed at least once. Among attending physicians, 13 (40.6%), 13 (40.6%), and six (18.8%) had 0 to 9, 10 to 19, and 20 years or greater of professional experience.

Resident physicians and midlevel providers predicted that nine (4.2%) subjects will have delayed functional recovery at 3 months postinjury (Table 1), yielding an accuracy of 48.4% (95% confidence interval [CI] = 41.7% to 55.1%) and an AUC of 0.51 (95% CI = 0.48 to 0.54). Among resident/midlevel providers, three (1.4%), 67 (31.0%), and 146 (67.6%) had low, moderate, and high certainty of the accuracy of their prediction of functional recovery, respectively. The accuracy of predicted functional recovery was 33.3, 31.3, and 56.8% (p = 0.003) among those with low, moderate, and high certainty, respectively.

Residents and midlevel providers predicted that 55 (25.3%) participants will have persistent PCS at 3 months postinjury, yielding an accuracy of 59.6% (95% CI = 53.0% to 66.3%) and an AUC of 0.60 (95% CI = 0.54 to 0.65). Among resident/midlevel providers, nine (4.2%), 100 (46.3%), and 107 (49.5%) had low, moderate, and high certainty of the accuracy

<table>
<thead>
<tr>
<th>Resident/midlevel</th>
<th>Delayed Functional Recovery (%)</th>
<th>Delayed Symptom Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>5.2</td>
<td>34.3</td>
</tr>
<tr>
<td>Specificity</td>
<td>97.1</td>
<td>84.3</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>66.7</td>
<td>67.9</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>52.4</td>
<td>43.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attending</th>
<th>Delayed Functional Recovery (%)</th>
<th>Delayed Symptom Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>8.1</td>
<td>54.5</td>
</tr>
<tr>
<td>Specificity</td>
<td>92.5</td>
<td>82.5</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>50.0</td>
<td>63.2</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>52.1</td>
<td>60.0</td>
</tr>
</tbody>
</table>
of their prediction of symptom recovery, respectively. The accuracy of predicted symptom recovery was 44.4, 58.3, and 62.0% (p = 0.52) among those with low, moderate, and high certainty, respectively.

Attending physicians provided their clinical gestalt in 77 (36.3%) cases. Attending physicians predicted that six (7.8%) of participants will have complete functional recovery at 3 months postinjury, yielding an accuracy of 51.9% (95% CI = 40.5% to 63.4%) and an AUC of 0.50 (95% CI = 0.44 to 0.56). Among attending physicians, 0 (0%), 24 (31.6%), and 52 (68.4%) had low, moderate, and high certainty of the accuracy of their prediction of functional recovery, respectively. The accuracy of predicted functional recovery was 33.3 and 59.6% (p = 0.03) among those with moderate and high certainty, respectively.

Attending physicians also predicted that 19 (25.0%) of participants will have persistent PCS at 3 months postinjury, yielding an accuracy of 60.8% (95% CI = 49.4% to 72.2%) and an AUC of 0.59 (95% CI = 0.49 to 0.69). Among attending physicians, four (5.6%), 33 (43.4%), and 39 (51.3%) had low, moderate, and high certainty of the accuracy of their prediction of symptom recovery, respectively. The accuracy of predicted symptom recovery was 50, 53.1, and 68.4% (p = 0.38) among those with low, moderate, and high certainty, respectively. The accuracy of clinical gestalt did not vary according to the number of year of clinical experience.

To our knowledge this is the first study of the accuracy of emergency physicians’ clinical gestalt for predicting mTBI outcome in adult participants on the day of injury. We report four major findings. First, clinicians studied had an optimistic view regarding the prognosis of mTBI, despite the fact that the study cohort consisted of significantly injured subjects (17% positive CT and a high rate of delayed recovery). They expected more than 90% of subjects to have complete functional recovery whereas in reality, approximately 50% of the cohort studied had delayed functional recovery and persistent PCS. Second, ED resident/midlevel provider accuracy for predicting functional recovery and persistent PCS are low (48.2 and 59.8%, respectively). The accuracy of resident/midlevel providers’ gestalt was low even among residents/midlevel providers who were more than 90% certain of the accuracy of their prediction. However, there was a trend toward higher accuracy with higher degree of certainty of prediction. Third, the accuracy of attending clinician gestalt for functional recovery and PCS is also low (51.9 and 60.8%, respectively). Similar to residents/midlevel providers, there was a trend toward higher accuracy with higher degree of certainty of prediction. Fourth, clinician experience did not influence the accuracy of predicting mTBI outcome.

Despite its strengths, our study also has a number of limitations. First, the observed prevalence of poor outcomes following mTBI in our cohort was higher than the prevalence reported in other mTBI studies (approximately 50%1,2,8 vs. 30%), but similar to a recently published large observational study.9 Thus our population may be more severely injured than others. However, this should not affect the sensitivity or specificity of clinical gestalt. Second, our study was performed at two hospitals that are part of one health system, and therefore it is possible that findings may not be generalizable. A prior multicenter study reported similar findings in a pediatric population.10 Third, although the RPQ is one of the most commonly used tools for ascertaining mTBI outcomes, it is limited in its ability to distinguish between concussion- and non–concussion-related symptoms.

The accuracy of clinical gestalt for predicting mTBI outcomes on the day of injury is poor. Data-driven strategies are needed to provide clinical decision support for mTBI risk stratification in acute care settings.

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.13844/full
Data Supplement S1. Interview Questions for Clinicians.
Hot Off the Press: Assessing Risk of Future Suicidality in Emergency Department Patients

Justin Morgenstern, MD1, Corey Heitz, MD2, Chris Bond, MD3, and William K. Milne, MD4

BACKGROUND
Suicidal ideation is common, accounting for about 1% of emergency department (ED) visits or about 1.4 million visits a year in the United States.1 Although there are numerous validated screening tools, such as the PHQ9, the ED-Safe Patient Safety Screener, and the Suicide Behaviors Questionnaire–Revised (SBQ-R), none have been tested against physician gestalt, and none are widely used in clinical practice.2–4 The Convergent Functional Information for Suicidality (CFI-S) is a validated screening tool for suicidal ideation, but it has not been tested in an ED setting.5,6 The current trial aimed at assessing the accuracy of the CFI-S in the ED, while comparing it to a screening tool already in use and physician gestalt.7

ARTICLE SUMMARY
This is a prospective observational study assessing the prognostic accuracy of a screening tool (the CFI-S) and physician gestalt in predicting future suicidality spectrum events. They included a convenience sample of 338 patients. A total of 9.5% of the cohort had a suicidality spectrum event in the 6-month follow-up period. The two-question screening tool currently used at this hospital missed half of these patients. Both the CFI-S and physician gestalt were moderately accurate in this cohort. The CFI-S was neither statistically nor clinically better than physician gestalt.

QUALITY ASSESSMENT
This study asks an important question and provides some valuable information, but there are a number of weaknesses that have to be considered when interpreting the results. Although the authors aimed to recruit consecutive patients, practical considerations meant that a convenience sample was obtained, potentially introducing selection bias. Because a large number of patients are boarded in this ED, the initial treating physician was not available, meaning that physician gestalt was only available for about half of the patients. Furthermore, this is a single-center study, looking at a patient population with a very high risk of suicide spectrum events, which potentially limits external validity.

The primary outcome was a composite, which can combine very important outcomes, like suicide attempts, with less important outcomes, like ED return visits. In fact, ED return visits could be seen as a positive outcome, considering that the patient was comfortable with the care received at the initial encounter and knew where to turn when things got worse. On the other hand, we should not overlook the underlying suffering that drives a patient to...
return to the ED with suicidal ideation and the care those patients require. Similarly, looking at outcomes over 6 months seems like a very long time for emergency providers, especially considering how much a patient’s mental status can change in that time frame. It might be unrealistic to expect a screening tool to be accurate over such a long time frame. On the other hand, suicidality spectrum events are rare but very important outcomes, and accurate prediction is important whether the events occur weeks or even years after the initial ED visit.

KEY RESULTS
A total of 367 patients were approached and 338 agreed to participate in the study. The mean age was around 40 years with about 50/50 male/female split. The majority of the patients were nonwhite. Physician gestalt data was only available for 190 of the patients.

Thirty-two patients (9.5%) had a suicidality spectrum event in the 6-month follow-up period. These events included 10 suicide attempts, 11 aborted or interrupted attempts, 13 preparatory acts, 16 psychiatric hospitalizations, and 29 repeat ED visits for suicidal thoughts. There were no completed suicides.

The accuracy of the CFI-S score and physician gestalt were not clinically nor statistically different in the group of patients who had both tests, with an area under the curve of 0.77 and 0.75, respectively. The CFI-S took a median of 3 minutes to complete.

AUTHORS’ COMMENTS
We were surprised that 10% of unselected ED patients experienced an event related to suicidality in the 6 months after their ED visit in this cohort. Although that number will vary in different contexts, it is an important reminder for physicians about the suffering our patients experience. Unfortunately, neither the CFI-S screening tool nor the physician gestalt were very accurate at detecting these patients. This is an important area for future research.

TOP SOCIAL MEDIA COMMENTARY

Casey Parker (@broomedocs)
Suicide risk assessment is like searching for a needle in a needle-factory. . . . I suspect that until AI is much smarter we will rely on humans reading humans to predict risk. Risk is often transient and just needs a safe place to pass.

Alison Hayward MD (@Alisonation)
Current methods of #suicide screening inadequate to catch many patients who will go on to try to harm themselves. This 3 min screen = improved accuracy!

Joshua (@reverendofdoubt)
Seems oddly high? If national estimates are 1% and Indiana is reporting 10%, is this more a reflection of the prevalence around the hospital as opposed to what the screening tool captures? are we missing something by not knowing primary / secondary diagnoses @ visit?

Do you think we should be screening all adult ED patients for suicidality?
onlinelibrary.wiley.com/doi/full/10.1111/sem.13562
#sgemhop @SAEMOnline @CAEP_Docs @ACEPNow @First10EM @KirstyChallen @AliRaja_MD

<table>
<thead>
<tr>
<th>Yes</th>
<th>16%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>84%</td>
</tr>
</tbody>
</table>

121 votes - Final results
TAKE-TO-WORK POINTS

This screening tool is no more accurate than clinician gestalt, so it is unlikely to improve patient care in the ED. Suicide is a very important topic that requires careful consideration in all our patients.

References

Intensive Glucose Control for Critically Ill Patients

John Conway1, and Benjamin Friedman, MD2

NARRATIVE

In the past decade, emergency department (ED) to intensive care unit (ICU) admissions increased by 79% to 2.2 million admissions annually, reflecting the increasing role of emergency medicine physicians in providing care for critically ill patients.1 Optimal glucose control in critical care patients has been a topic of contention for decades. In 2001 a single-center trial of mechanically ventilated surgical patients found intensive glucose control (maintaining glucose at 80–110 mg/dL) reduced mortality compared to conventional control (180–200 mg/dL only if glucose exceeded 215).2 Subsequent studies provided conflicting data, and in 2009, the multicenter NICE-SUGAR trial, the largest trial yet, demonstrated increased mortality with intensive glucose control.3 Current American Diabetes Association (ADA) guidelines, reflecting concern about harms associated with intensive glucose control, recommend conventional glucose control with a target glucose range of 140 to 180 mg/dL for critically ill patients who experience persistent hyperglycemia.4

The meta-analysis summarized here provides an updated review of intensive glucose control effects on critical care patients.5 A total of 27 randomized trials enrolling 17,582 patients compared intensive with conventional glucose control in adult medical, surgical, and mixed critical care settings. Most had similar glucose targets. The primary outcomes were 3- to 6-month and short-term mortality (mainly within 28 days). Secondary outcomes were severe hypoglycemia (defined as serum glucose < 40 mg/dL: associated with increased mortality in multiple studies),6–8 sepsis, and need for dialysis.

There was no significant difference found in any primary outcome, and among secondary outcomes, only severe hypoglycemia in the intensive group was more common (relative risk = 4.9, 95% CI = 3.2–7.5, NNH = 12). Notably, there was no significant difference found in any outcome between patients in medical, surgical, or mixed ICUs.

CAVEATS

This meta-analysis is limited in several ways. There was variation, in glucose targets, type of insulin, dose and mode of administration, duration of follow-up, and concomitant therapy. Additionally, not all trials...
reported on all outcomes of interest, and patient-level data are not available, limiting secondary research.

The quality of evidence included in this meta-analysis is high. For most outcomes, despite the clinical heterogeneity noted above, there was little statistical heterogeneity. The only outcome with significant heterogeneity was severe hypoglycemia ($I^2 = 76.1\%$, $p < 0.001$), suggesting that clinical variation between studies affected this outcome.

Despite these flaws three additional, slightly less recent reviews have pooled these data as well with similar results despite differing numbers of trials, subjects, and point estimates. This consistency across author groups and approaches is reassuring.9–11

This meta-analysis also fails to address some ongoing research that has identified subgroups of patients who may stand to benefit from intensive glucose control. For example, two recent studies from the surgical ICU setting have found that among nondiabetic patients who had undergone major cardiothoracic surgery, intensive glucose control reduced morbidity.12,13 No similar benefit was found for patients with a prior diagnosis of diabetes. Despite these interesting findings and ongoing research, conventional glucose control currently remains the standard of care in hospitalized patients.14

In summary, there was no benefit found with intensive glucose control in critical care patients but there was increased incidence of severe hypoglycemia. With no benefits and increased harms, the most appropriate color rating for intensive glucose control is black (harms > benefits). Current ADA guidelines, citing the findings of prior meta-analyses, recommend conventional glucose control with targeted blood glucose of 140 to 180 mg/dL in critically ill patients who experience persistent hyperglycemia.4

References


Outpatient Treatment for Low-Risk Febrile Neutropenia

Michael Gottlieb, MD1, Alex Koyfman, MD2, and Brit Long, MD3

Summary heading Among low-risk patients with febrile neutropenia, weak evidence suggests outpatient and inpatient treatment are equally safe

NNT color recommendation Yellow (unclear if benefits)

Benefits in NNT NA (No difference in risk of treatment failure or mortality in adults or children)
Shorter hospitalization by 1.64 days in adult patients and 3.9 days in pediatric patients

Benefits in percentages NA (no difference in risk of treatment failure or mortality in adults or children)

Harms in NNH No difference in adverse drug reactions

Harms in percentages No difference in adverse drug reactions

Efficacy endpoints Treatment failure, mortality

Harm endpoints Adverse drug reactions

Who was in the studies 10 trials including 994 low-risk patients (628 adults, 366 children) with cancer, fever, and neutropenia

NARRATIVE

Fever and infection are common in neutropenic cancer patients.1,2 While some become severely ill, most patients have an uneventful course, with 50% to 60% having no life-threatening complication or fatal infection.1,2 Patients with febrile neutropenia have therefore been divided into low-risk and high-risk groups. Those patients at low risk of complications may benefit from outpatient management.1,2 Admission to the hospital has its own risks, including iatrogenic infections and reduced quality of life.1 Guidelines thus recommend risk stratification for potential outpatient treatment.3,4 However, it is important to determine if outpatient management is as safe and effective as inpatient management in low-risk patients.

This systematic review and meta-analysis5 included randomized controlled trials that compared inpatient antimicrobial therapy with outpatient antimicrobial therapy for low-risk febrile neutropenic adults or children with cancer. The primary outcomes were treatment failure (death, nonresolution of signs or symptoms of presenting infection, or change of antibiotic) and mortality at 30 days.

The authors identified 10 relevant studies (n = 994), six in adults (n = 628) and four in children (n = 366). Definitions for low risk were not standardized, but generally required that patients not 1) need hospitalization, 2) have focal or severe infection, 3) have relapse of the disease, and 4) be receiving intensive chemotherapy. Overall, there was no difference in treatment failure (relative risk [RR] = 0.81, 95% confidence interval...
Among pediatric patients, there was also no difference in treatment failure (RR = 1.0, 95% CI = 0.6 to 2.0) or mortality (RR = 0.6, 95% CI = 0.2 to 2.7). Hospitalization duration, a secondary outcome, was 1.64 days lower in the adult outpatient group (95% CI = -2.22 to 1.06) and 3.9 days lower in the pediatric outpatient group (95% CI = -5.37 to -2.43). The risk of adverse drug reactions (harm endpoint) was not statistically significant between the two groups (low quality evidence).

CAVEATS

While this review suggests no significant difference in treatment failure or mortality between inpatient and outpatient management, patients were observed for 24 to 72 hours in the hospital before discharge in six trials and discharged immediately in only two trials. Despite this, there was still a reduction in patient hospitalization and length of stay. The certainty of this estimate was considered low, however, based on potential bias and quality of evidence.

Additionally, low-risk criteria varied between studies with only one utilizing Multinational Association for Supportive Care in Cancer criteria and none using Clinical Index of Stable Febrile Neutropenia criteria, the two currently recommended tools.3–5 There are no existing criteria for low-risk stratification in pediatric patients with neutropenic fever. Moreover, there were differences in types and routes of antibiotic regimens and types of cancers (e.g., blood-borne vs. solid tumors). There was also limited reporting on randomization and allocation concealment. Evidence quality of the included randomized controlled trials was low to moderate based on the GRADE approach, and CIs were wide for main outcome measures. Finally, the studies may have been underpowered for their primary outcomes due to low sample sizes in several trials.

Despite the above limitations, these findings suggest outpatient treatment of selected low-risk patients with cancer and febrile neutropenia was, in these investigations, as safe as inpatient management. We have assigned a color recommendation of yellow (unclear if benefits) both because the only quantifiable benefit was a secondary measure and because of the low certainty of this finding. Clearly, larger, high-quality trials are needed to establish with more certainty the promising benefits suggested by these data.

REFERENCES

While the opioid epidemic rages on killing more than 47,000 Americans in 2017 alone, our emergency departments (EDs) are overflowing with patients who have painful conditions, many of whom respond well—specifically in the acute setting—to opioid therapy.

Although we have mountains of data and plenty of mass media headlines outlining the scope of the opioid tragedy, ED-based studies that develop thoughtful/careful interventions, deliver them reproducibly, and test them rigorously are exceedingly rare.

I commend McCarthy et al. for identifying ED opioid prescribing as an issue in 2014, before it was on many radars. Instead of hand wringing and trotting out one shocking statistic after another and shrugging off responsibility, they asked: how can we—as bedside ED doctors—do better? They went on to ask how combining their bedside improvements in patient education, with postvisit interventions both at the pharmacy and in the primary care setting could help deliver safer opioid pain control for patients.

I am impressed with the time and effort it must have taken to create and deploy the reading level–appropriate informational handout, change the labeling practices of local pharmacies, and automate the notification of primary care doctors of a new opioid prescription. They went on to avoid the temptation—which must have been strong—to implement the changes without the rigor of a randomized control trial demands.

As for the results themselves, they highlight the important point that successful collaboration between the ED doctors, pharmacies, and local primary care providers—however complicated and uncompensated it might be—is a possible and a worthwhile undertaking. Just like we have trauma coordinators, STEMI committees, and dedicated stroke nurses, perhaps every ED should have an opioid committee that works to implement projects aimed at delivering patient-focused improvements in safety and quality.

The data of McCarthy et al. also remind us that a substantial majority (84%–89.4%) of ED patients prescribed an opioid at discharge use them as directed. Recently published data report that 9% of patients who are prescribed opioids for acute pain in the ED continue to use them at 3 months and very few (<1%) report using them for causes other than pain relief. Sadly, when one considers the sheer volume of patients who leave the ED each year with an opioid prescription and the potential life-threatening risk of overdose when medications are used incorrectly or in unsafe combinations, the reported levels of misuse are quite concerning.

Perhaps most concerning in this data set is the fact that 28.2%–37.3% of patients used their opioid medications with another sedating medication. We know that this is a leading risk factor for overdose and mortality. As McCarthy et al. point out, we should take this on ourselves, as prescribers, to improve. I might quibble with their inclusion of all commonly used antidepressants in this calculation but just including their tier I co-ingestions (benzodiazepines and other opioids) the rates of coingestion are still much too high at 14.62%. While there are indeed cases where patients taking sedating medications will also need opioid pain relief, we must be paying closer attention to patients’ medication lists, using alternatives wherever possible, and having a full discussion of risks of coingestions with each individual patient.

The work of McCarthy et al. reminds us that our impact at the bedside, in times of stress and pain for patients, may not be the ideal time for them to understand every risk or piece of information we would like
for them to know. Their work also adds to a great wealth of data in the behavior health literature that demonstrates that knowledge, on its own, does not always lead to behavior change. In fact, one of the defining criteria of a substance use disorder is continued use despite knowledge of harm: “Use of the substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.”\(^5\) However challenging bedside education is, we all have a responsibility to review the risks of these high-risk prescriptions in an accurate, accessible way with patients and should encourage us to build and use tools that help reinforce important information after patients leave the ED.

Just because we may not be able to stem the tide of the opioid epidemic from the bedside of individual patients does not absolve us of the obligation to do what is within our control to make patients safer. So what can we all take from this article to the bedside? How many of us always, every time check to make sure patients are not on sedating medications before prescribing an opioid? How many of us are discussing that risk with patients? How many of us risk stratify patients for their risk of long-term use or development of a substance use disorder? How many of us tell every patient in clear terms that opioids are habit forming and 9% people will still be using them at 30 days and those using at 30 days have a 9% chance of developing a substance use disorder?\(^6\) How many of our departments have a reading level–appropriate handout about the risks and appropriate use of opioids? How many of us even know what the label on the pill bottle reads? How many of us go over, in detail, how we want patients to use their pain medications and how much a maximum daily dose is? How many of us remind patients about safely storing and disposing of their medications?

We, as ED doctors alone, are not going to solve this problem but certainly there is more we can each be doing to help. McCarthy et al. remind us that we need to put forth the effort and give us a sense of where to start, both at the bedside and in our hospital systems and communities at large.

Krista Brucker, MD, MS
(kbrucker@gmail.com)
South Bend Emergency Physicians, South Bend, IN

Supervising Editor: Jeffrey A. Kline, MD

References

5. Use of the substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Washington, DC: American Psychiatric Association, 2013.
Clincians must continually synthesize, integrate, and revise estimates of treatment effectiveness. The “number needed to treat” (NNT)\textsuperscript{1,2} has emerged as a frontrunner among the absolute and relative measures that describe treatment effects.\textsuperscript{3,4} Calculated as the inverse of absolute risk reduction, NNT estimates the average number of patients who need to be treated to positively impact one person with therapeutic benefit:\textsuperscript{1}

\[
\text{NNT} = \frac{1}{\text{Absolute Risk Reduction}}.
\]  

A distinct advantage of NNT is its ability, using a single number, to describe the absolute impact or effectiveness of a particular therapy. Interventions with lower NNT are more efficacious, since one must treat fewer patients to observe an effect. The popularity of NNT is illustrated by an entire Internet domain (www.thennt.com) that extols its virtues to promote the most effective therapies while decrying those with insufficient benefit.

Lost in the populist enthusiasm for NNT is its inherent mathematical complement, which is a more realistic and clinically useful number for the practicing physician. Thus, we propose the “number needed to waste everybody’s time” (NNT-WET):

\[
\text{NNT-WET} = \text{NNT} - 1.
\]

Number needed to waste everybody’s time estimates the average number of patients who need to be treated, but receive no therapeutic benefit, for someone else to benefit. NNT-WET is a direct measure of the inefficiency of clinical practice; it conveys the ineffectiveness of clinical interventions by measuring the effort required to help just one solitary patient. In the postmodern era of limited medical resources and therapeutic nihilism, NNT-WET is the metric that provides the appropriate level of cynicism required by today’s practicing clinician.

Number needed to waste everybody’s time offers several advantages over NNT. First, NNT fails to sufficiently emphasize that most patients do not benefit from treatments routinely used in clinical practice. Since the vast majority of NNT estimates exceed two, a given individual patient is unlikely to benefit from treatment (Figure 1A). NNT-WET also shifts the clinical conversation from the assumption that we must treat the patient (e.g., “This treatment is great—it’s NNT is only ten!”), to a state best described as therapeutic malaise (e.g., “The NNT-WET is nine . . . what’s the point?”). The NNT-WET helps illustrate that for most treatments, the costs, inconvenience, and risks are disproportionately applied to the many, so that only a single person (whom, most importantly, is not you!) can benefit.

When quantifying the harms associated with treatment, the corollary to NNT is “number needed to harm” (NNH), which is calculated as the inverse of absolute risk increase:

\[
\text{NNH} = \frac{1}{\text{Absolute Risk Increase}}.
\]

The NNH estimates the average number of patients who need to be treated before one person is negatively impacted by a harmful side effect caused by the therapy.

Author contributions: MJR first conceived of the NNT-WET; JCR developed the nomenclature NNT-DRI; and both authors contributed equally to drafting and editing the manuscript.

Dr. Reeves has no disclosures, other than being a former member of the anti-Thatcher dries (Wikipedia “Wets and Dries,” https://en.wikipedia.org/wiki/Wets_and_dries). Dr. Reynolds has no disclosures, other than being a resuscitation science enthusiast, which inherently requires dogged optimism despite sizable numbers needed to treat.

Disclaimer: The (mostly) satirical views expressed in this paper are influenced by the authors’ membership in an underground, alt-med society whose central mission is [quote] “therapeutic nihilism through the lens of evidence-based practice.”
Interventions with higher NNH are less risky, since more patients can be treated before an adverse treatment-related event occurs. When combined with NNT, these two numbers convey to patients, in a simple manner, the tradeoffs between risks and benefits of treatment.¹,²

Using similar logic and rationale as used for NNT-WET, we also propose a revised measure for the NNH, the “number needed to divert reckless intervention” (NNT-DRI),

\[ \text{NNT-DRI} = \frac{\text{NNH}}{C_0} + 1 \]

Number needed to divert reckless intervention is the mathematical complement of NNH. It estimates the average number of patients who need to be treated, and who escape the therapy’s adverse effects, for someone else to sustain an adverse event. NNT-DRI is a measure of the recklessness of clinical intervention; a small NNT-DRI indicates that only a few patients escape harm, whereas a large NNT-DRI is reassuring since regardless of whether any patient benefits, many patients are not harmed. A large NNT-DRI is a state of Hippocratic bliss (primum non nocere).

Likewise, NNT-DRI offers advantages over NNH, which insufficiently acknowledges the patients that regularly escape therapeutic maleficence. Clinicians should rejoice in large NNT-DRI estimates that represent the multitudes of patients they have not harmed (Figure 1B). The NNT-DRI helps illustrate that adverse effects of treatments are disproportionately applied to an unfortunate few, while the rest manage to escape them. NNT-DRI shifts the clinical conversation from a serious discussion of risk (e.g., “This treatment is dangerous, the NNH is only five.”), to a state of reassurance best described as willful ignorance (e.g. “Maybe so, but four of them will do just fine!”).

The treatment of acute ischemic stroke with systemic thrombolyis offers a useful scenario to illustrate our proposed measures. Using risk estimates from a meta-analysis of individual patient data,⁵ we estimated the NNT to achieve excellent functional recovery 3 to

---

Figure 1  (A) Tradeoff between the proportion of treated patients who benefit (i.e., the NNT) versus those that do not (i.e., the NNT-WET) as the NNT increases. (B) Tradeoff between the proportion of treated patients who are harmed (i.e., the NNH) versus those who are not (i.e., the NNT-DRI) as the NNH increases.
6 months after treatment ranged from 10 (0–3 hours after symptom onset) to 50 (4.5–6 hours after symptom onset). These estimates translate to NNT-WET values of 9 and 49, respectively. Thus, to impart therapeutic benefit, clinicians must labor to rapidly identify, evaluate, and treat between nine and 49 patients who are exposed to the cost and risks of treatment without any of the corresponding benefits. Likewise, we estimated the NNH for 7-day fatal intracranial hemorrhage after treatment is a mere 40 regardless of the interval after symptom onset.5 Yet with a corresponding NNT-DRI value of 39, clinicians can find solace in knowing that 97% (39/40) of patients they treat with systemic thrombolytics will escape this particular peril. (Note: NNT-WET and NNT-DRI estimates for systemic thrombolyis up to 24 hours after symptom onset are forthcoming.)6

There are several limitations to consider in our work and NNT/NNH in general. Primarily, all “number needed to . . .” values are time-dependent and the choice of the particular time interval is often arbitrary; this problem is exacerbated by incorrectly assuming that the risks and benefits of treatment are constant over time. Other important limitations include the variable duration of clinical trials (primary source of NNT/NNH data), the danger of extrapolating across differing baseline risks (resulting in widely different NNT/NNH estimates), and the inability to predict which individual patient will be the one to sustain benefit or harm.1,7,8 Finally, NNT and NNH foster the misconception that treatment decisions should only be quantified as a binomial probability for a given patient to receive benefit or harm.9 This “lottery” interpretation of treatment effects is only realistic in certain specific clinical scenarios determined by stochastic processes (e.g., true “accidents”). The lottery interpretation of NNT is not suitable for preventive interventions that delay adverse events rather than eliminate them.9

The complement of NNT was alluded to by the original proponents of NNT.1 However, we argue that repackaging this idea is simply a good example of what constitutes “innovation” in modern-day medicine. To our knowledge (limited as this is), we are the first to market these concepts in this fashion, and we will naturally seek to trademark NNT-WET® and NNT-DRI®.

In summary, NNT-WET and NNT-DRI represent a novel and (mostly) satirical tool for clinicians and patients to understand treatment options. They represent true population-based measures that are uniquely patient-centered in that they apply to the vast majority of patients neither benefit nor are harmed (i.e., the “99%” instead of the “1%”). NNT-WET and NNT-DRI serve as reminders of the inefficiency of clinical medicine; clinicians can rest assured that most of their well-intentioned treatments have no effect whatsoever—for good or for ill.

Mathew J. Reeves, BVSc, PhD
Joshua C. Reynolds, MD, MS
(reyno406@msu.edu)

1Department of Epidemiology and Biostatistics, Michigan State University College of Human Medicine, East Lansing, MI
2Department of Emergency Medicine, Michigan State University College of Human Medicine, Grand Rapids, MI

Supervising Editor: John Burton

References
Point of Care Ultrasound for Emergency Medicine and Resuscitation is the latest entry to the current plethora of point-of-care ultrasound (POCUS) books in acute care medicine. The editors are all experienced emergency physicians who were early adopters of bedside ultrasound and have used their expertise to become international leaders in POCUS. This text is a basic introduction to POCUS that is most relevant to emergency physicians, but it will appeal to any physician practicing acute care medicine, including critical care, internal medicine, hospital medicine, and pediatrics.

After an introduction to the concept of POCUS and ultrasound physics and knobology, the subsequent seven chapters are organized into anatomic organ systems: heart (echocardiography), chest (thoracic), abdomen (free fluid, biliary, renal, bowel obstruction, appendicitis), pelvis (early pregnancy), vascular (aorta, inferior vena cava, deep vein thrombosis), musculoskeletal, and small parts (ocular and scrotal). This is followed by a chapter on procedural guidance. The last three chapters cover ultrasound in specialized environments: education and simulation, pediatrics, and lastly, prehospital care. Overall, it is logically and intuitively organized, and it is easy to find the chapter covering the ultrasound application one wants to review. However, the chapter on education and simulation is awkwardly inserted between chapters covering clinical POCUS applications. Grouping all the clinical chapters together would improve the flow of the book; the nonclinical chapters could then round out the end of the text.

The authors do a good job of breaking down POCUS applications into core and advanced, based on difficulty of mastery and clinical utility. Each chapter starts with a brief half-page summary highlighting the clinical indications, important key points, and clinical utility of the scans covered in the chapter. Not only is this an excellent introduction to each chapter, but it’s also a great way to quickly review the chapter afterward. Specific POCUS applications are organized into subsections: image generation, image interpretation, pitfalls, and clinical use. The ultrasound novice will find these sections easy to navigate. This text also attempts to be as evidence based as possible, referring to literature and studies published as recently as 2018. Each chapter concludes with a “further reading” section that lists important studies, guidelines, and review articles. By referencing the evidence base, the reader gains a better understanding of the strengths and limitations of POCUS. One also learns some interesting esoteric details, such as the fact that “the disappearance of lung sliding in pneumothorax was first described in horses.” As a bonus, the education and simulation chapter provides a good review of the current state of POCUS training among different specialty organizations and a framework for POCUS curriculum development.

However, there are some issues with this book. It covers the heart, chest, and abdomen chapters in extensive detail, including advanced echocardiographic topics like regional wall motion abnormality, diastolic function, and stroke volume calculation. Yet other topics like skin and soft tissue infection, joint effusion, scrotal, airway, intussusception, and pyloric stenosis are covered in a superficial manner. The procedures chapter could be improved by including a subsection on indications and contraindications for each procedure. While the first chapter contains clinical vignettes demonstrating the utility of POCUS, it would be helpful for each chapter or application to have its own illustrative clinical case. Stylistically, the writing is in the Queen’s English, using terms like “right iliac fossa” rather than “right lower quadrant.” Finally, the book suffers from a lack of consistency in both its illustrations and ultrasound images. The illustrations and figures seem to be sourced from a variety of different illustrators and publications. Furthermore, while...
most ultrasound images are from actual patients, some ultrasound images are sourced from a Vimedix ultrasound simulator (CAE Healthcare). Ultrasound is a visual modality, so this lack of consistency and cohesiveness in the book’s images is distracting.

Despite these minor issues, Point of Care Ultrasound for Emergency Medicine and Resuscitation is a welcome addition to the POCUS library and a great resource for the beginner. I would recommend this book to residents and physicians who have limited ultrasound experience or knowledge, because it provides a solid foundation and introduction to the broad variety of POCUS applications available to the acute care provider.

Daniel J. Kim, MD
(dkim000@gmail.com)
Department of Emergency Medicine, University of British Columbia, Vancouver General Hospital, Vancouver, BC, Canada

Supervising Editor: Peter E. Sokolove, MD
In Gray et al. (https://onlinelibrary.wiley.com/doi/10.1111/j.1553-2712.2010.00885.x) the third author’s name is misspelled. The correct spelling is Anita Srivastava.