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Emergency medicine is a specialty which closely reflects societal challenges and consequences of public policy decisions. The emergency department specifically deals with social injustice, health and economic disparities, violence, substance abuse, and disaster preparedness and response. This journal focuses on how emergency care affects the health of the community and population, and conversely, how these societal challenges affect the composition of the patient population who seek care in the emergency department. The development of better systems to provide emergency care, including technology solutions, is critical to enhancing population health.

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The Incidence of QT Prolongation and Torsades des Pointes in Patients Receiving Droperidol in an Urban Emergency Department

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Introduction: Droperidol carries a boxed warning from the United States Food and Drug Administration for QT prolongation and torsades des pointes (TdP). After a six-year hiatus, droperidol again became widely available in the US in early 2019. With its return, clinicians must again make decisions regarding the boxed warning. Thus, the objective of this study was to report the incidence of QT prolongation or TdP in patients receiving droperidol in the ED.

Methods: Patients receiving droperidol at an urban Level I trauma center from 1997–2001 were identified via electronic health record query. All patients were reviewed for cardiac arrest. We reviewed electrocardiogram (ECG) data for both critically-ill and noncritical patients and recorded Bazett's corrected QT intervals (QTc). ECGs from critically-ill patients undergoing resuscitation were further risk-stratified using the QT nomogram.

Results: Of noncritical patients, 15,374 received 18,020 doses of droperidol; 2,431 had an ECG. In patients with ECGs before and after droperidol, the mean QTc was 424.3 milliseconds (ms) (95% confidence interval [CI], 419.7–428.9) before and 427.6 ms (95% CI, 424.3–430.9), after droperidol (n = 170). Regarding critically-ill patients, 1,172 received droperidol and 396 had an ECG. In the critically-ill group with ECGs before and after droperidol mean QTc was 435.7 ms (95% CI, 426.7–444.7) before and 435.8 ms (95% CI, 427.5–444.1) after droperidol (n = 114). Of 337 ECGs suitable for plotting on the QT nomogram, 13 (3.8%) were above the “at-risk” line; 3/136 (2.2%; 95% CI, 0.05–6.3%) in the before group, and 10/202 (4.9%; 95% CI, 2.4%–8.9%) in the after group. A single case of TdP occurred in a patient with multiple risk factors that did not reoccur after a droperidol rechallenge. Thus, the incidence of TdP was 1/16,546 (0.006%; 95% CI, 0.00015 - 0.03367%).

Conclusion: We found the incidence of QTc prolongation and TdP in ED patients receiving droperidol to be extremely rare. Our data suggest the FDA “black box warning” is overstated, and that close ECG monitoring is useful only in high-risk patients. [West J Emerg Med. 2020;21(4)728–736.]

INTRODUCTION

Droperidol is a butyrophenone first-generation antipsychotic approved by the United States Food and Drug Administration

(FDA) for the treatment of postoperative nausea and vomiting (PONV).¹ Over the past 30 years it has also become a cornerstone therapy for nausea and vomiting,² headache,^{3,4} and agitation^{5–7}

in the emergency department (ED).⁸ On December 4, 2001, the FDA issued a boxed warning (commonly called a “black box warning”) for droperidol, noting an association with QT prolongation and torsades des pointes (TdP), that recommended electrocardiogram (ECG) monitoring before and continued for 2-3 hours after droperidol administration, and that if QT prolongation (> 440 milliseconds [ms] for men, 450 ms for women) was present, droperidol not be administered. Despite the fact that the boxed warning was based primarily on post-marketing surveillance data (49% of which came from outside the US,⁹ including 83% of all the reported fatalities),¹⁰ the use of droperidol in US EDs decreased substantially after the warning was issued.^{11,12} Sales of droperidol fell 90% within one year of the release of the boxed warning.^{10,13}

As the use of droperidol declined sharply in the first decade of the 21st century, the drug also became scarce even for institutions that continued to use droperidol routinely despite the warning. Manufacturing delays and shortages of raw materials were reported by drug companies, and droperidol became effectively unavailable to most hospitals by 2013.¹⁴ In the winter of 2019, droperidol again became widely available in North America as one US manufacturer resumed production.¹ Since the re-introduction of droperidol, many hospitals have been faced with the decision of whether or not to return droperidol to hospital formularies, and how to systematically integrate the FDA warning into practice. This current scenario is reminiscent of the months immediately following the release of the boxed warning, affecting a variety of medical specialties.¹⁵⁻¹⁷

We previously studied the relationship between droperidol administration and QT prolongation in our ED; however, these data were published only in abstract form.¹⁸⁻²⁰ As droperidol has returned to the US market and clinicians again must make decisions about the risk of QT prolongation, our data are relevant once more. Thus, the objective of this study was to report the incidence of prolonged QT interval or TdP in patients who received droperidol in the ED.

METHODS

Study Design

This was a retrospective, observational cohort study of patients presenting to our ED from January 1, 1997–November 30, 2001, who received parenteral droperidol for any indication. A subanalysis of critically ill patients receiving droperidol was also conducted from January 1, 1997–December 31, 2001. Our institutional review board approved this study.

Study Setting and Population

This study was conducted at an urban, Level I trauma center, safety-net hospital with approximately 100,000 ED visits per year. Our patient population includes a large number of patients with substance use disorders; in fact, we have an entire unit within the ED to care for this patient population.²¹ These patients are potentially high risk for either drug-drug interactions (such as cardiotoxicity with cocaine), or drug-disease interactions (such

Population Health Research Capsule

What do we already know about this issue?
Droperidol is again widely available, but still carries a Food and Drug Administration warning for QT prolongation and torsades des pointes (TdP) with restrictive monitoring and dosing recommendations.

What was the research question?
What is the incidence of clinically meaningful QT prolongation and TdP in ED patients receiving droperidol?

What was the major finding of the study?
QT prolongation was uncommon in ED patients receiving droperidol, and only 1 of 16,546 patients (0.006%) had TdP.

How does this improve population health?
The FDA warning is likely over-cautious; cardiac monitoring resources are probably best used only on patients at high risk for TdP.

as an increased risk of hypokalemia in patients with alcohol use disorder that may predispose a patient to a prolonged QT interval that may be synergistic with droperidol), making our study population relatively high risk compared to other patient populations in which droperidol has been studied, such as those with PONV. During the study period approximately 2,500 patients per year received droperidol.²²

The most common indications for droperidol during this period in our ED from most to least common were acute agitation secondary to ethanol intoxication, non-headache pain, vomiting, and headaches.^{3,22-24} Our ED includes a geographically separate critical care unit (CCU) that easily allows for identification of critically ill patients in a retrospective fashion. Determination of critical illness and placement of patients in the geographically separate CCU was at the discretion of the treating emergency physician. Our critical care rooms are never used for non-critically ill patients, making determination of critical illness by geographic location in a retrospective fashion relatively accurate. During the study period, our ED electronic health record (EHR) was EmSTAT (A⁴ Health Systems).

Selection of Participants

We analyzed patients in two separate cohorts: those deemed critically ill, and those deemed not critically ill. Critically ill patients were defined as having undergone resuscitation in our previously described, designated CCU.²¹ The location designation

in the EHR made it simple to retrospectively determine who was considered critically ill at the time of their ED presentation. EmSTAT was queried for all patients who received droperidol in ED non-critical care areas from January 1, 1997–November 30, 2001. We then identified those who had an electrocardiogram (ECG) ordered after administration of droperidol. ECGs were reviewed and the computerized Bazett's corrected QT intervals (QTc) were recorded. We analyzed ECG data for both critically ill and noncritical patients in three groups – patients with an ECG only before droperidol; only after droperidol; and those with ECGs both before and after droperidol.

To further analyze critically ill patients receiving droperidol, in addition to EmSTAT queries the medical records of all critically ill ED patients from January 1, 1997–December 31, 2001 were hand-searched for any patient receiving droperidol who also had an ECG performed during that visit. For critically ill patients, ECGs with bundle branch blocks or paced rhythms were excluded. We analyzed data in three groups: patients with an ECG only before droperidol; only after droperidol; and those with ECGs both before and after droperidol. We included in the analysis any ECG obtained in the ED after the administration of droperidol, regardless of its proximity to the administration of droperidol.

All subjects receiving droperidol were evaluated for the presence of any ventricular dysrhythmias, with the exception of premature ventricular dysrhythmias. Ventricular arrhythmias were identified via review of ECG interpretations that were recorded for usual care, as well as a query of the EHR for the diagnoses of TdP, ventricular fibrillation, or ventricular tachycardia.

Outcome Measures

As a medication-induced, Bazett corrected QT of < 480 ms is generally considered safe,²⁵ we defined long QT by a Bazett corrected QT \geq 480 ms.^{26,27} Medical records of patients with long QT were further reviewed for previous ECGs demonstrating long QT or TdP. Cardiac monitoring and rhythm strips were reviewed during the course of usual care and may have contributed to final diagnoses, but were not specifically reviewed for the purpose of this study.

For critically ill patients, droperidol dose, ECG timing and intervals, and cardiac rhythms were recorded. Heart rates and corresponding raw QT intervals for patients with a heart rate <150 beats per minute (bpm) were measured manually and plotted on the QT nomogram²⁸ to assess the risk of drug-induced TdP.²⁹ The QT nomogram is a tool developed in the early 21st century that has superior sensitivity and specificity to most commonly used QTc cutoff numbers (including 500 ms).^{29,30} As the vast majority of drug-induced TdP cases occur at heart rates between 30-90 bpm,²⁹ we also sought to report the number of patients who were “at-risk” on the nomogram in this heart rate range.

Data Analysis

We analyzed data with descriptive statistics, chi-squared test and Fisher's exact test, where appropriate.

RESULTS

Complete study enrollment is displayed in Figure 1. Of non-critical patients, 15,374 received 18,020 doses of droperidol in the ED; 2,431 of these patients also had an ECG. Of the patients with ECGs, 376 had an ECG before droperidol, 1,518 had an ECG after droperidol, and 170 had an ECG before and after droperidol. The mean QTc in patients with an ECG before droperidol treatment was 421.3 ms (95% confidence interval [CI], 418.0 - 424.6). The mean QTc in patients with an ECG after droperidol was 421.0 ms (95% CI, 419.5 - 422.5). In the group with ECGs before and after droperidol treatment, the mean QTc was 424.3 ms (95% CI, 419.7 - 428.9) and 427.6 ms (95% CI, 424.3 - 430.9), respectively. The mean ratio of the QTc before to after droperidol treatment was 1.009 (95% CI, 0.99 - 1.02).

Regarding critically ill patients, 11,583 charts were reviewed. Of these, 1,172 patients received droperidol and 396 had an ECG performed that did not have a bundle branch block or paced rhythm. In 96 patients an ECG was obtained only before droperidol; mean QTc was 435 ms (95% CI, 428.1–441.9 ms). In 186 patients an ECG was obtained only after droperidol; mean QTc was 433 ms (95% CI, 427.8 to 438.8 ms). In 114 patients ECGs were obtained before and after droperidol; mean QTc was 435.7 ms (95% CI, 426.7– 444.7 ms) before droperidol and 435.8 ms (95% CI, 427.5–444.1ms) after droperidol. The mean ratio of the QTc before and after droperidol was 1.005 (95% CI, 0.985– 1.025). Droperidol dosing data are displayed in the Table. Of the 396 critically ill patients who had ECGs performed, 345 physical images of ECGs were saved in EmSTAT that could be measured for the heart rate and RR interval. Of these 345, 7/138 (5.1%; 95% CI, 2.1 - 10.2%) had a QTc > 480 ms before droperidol, and 8/207 (3.9%; 95% CI, 1.7 - 7.5%) had a QTc > 480 ms after droperidol. Of 345 ECGs 8 were excluded for rates > 150 bpm, leaving 337 ECGs to plot on the nomogram (Figure 2). Of these, 13 patients (3.8%) were above the “at-risk” line; 3/136 (2.2%; 95% CI, 0.05 - 6.3%) in the before group and 10/202 (4.9%; 95% CI, 2.4% - 8.9%) in the after group. Eight patients (2.4%; 95% CI, 1.0 - 4.6%) with a pulse <90 bpm were above the “at-risk” line: two in the before-droperidol group and six in the after-droperidol group.

One patient of the 16,546 patients enrolled suffered cardiac arrest, deemed unrelated to droperidol. This patient, previously reported,²² had a seizure followed by a cardiac arrest 11 hours after a single dose of droperidol in the ED. This patient had “stuffed,” or hastily ingested, an unknown amount of cocaine in an attempt to avoid being jailed and presented with agitation, which was treated with droperidol and lorazepam. The patient was resuscitated and discharged neurologically intact one week later. Given that the half-life of droperidol is 2.3 hours³¹ and the clinical picture was consistent with cocaine toxicity, the treating team and the investigators deemed this cardiac arrest unrelated to droperidol.

Of the remaining patients, five experienced ventricular dysrhythmias, four had bigeminy, and one had TdP. The single case of TdP occurred in a patient with an alcohol use disorder

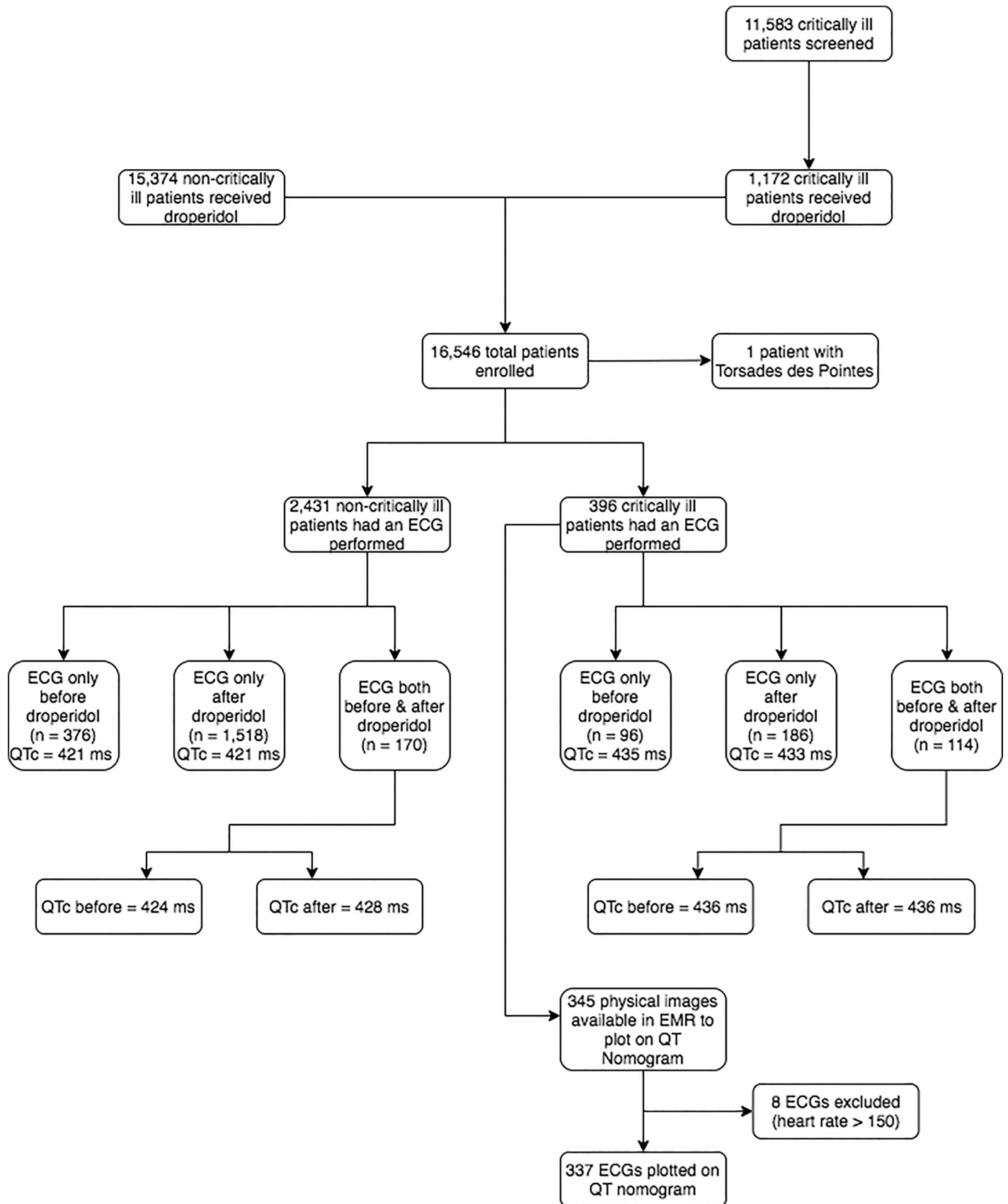


Figure 1. Study enrollment. QTc values, in milliseconds, in each box represent a mean value. ECG, electrocardiogram; EMR, electronic medical record; QTc, corrected QT interval; ms, millisecond.

who presented for nausea and vomiting; symptomatic TdP was observed on cardiac monitoring. The patient was then moved to a critical care room and defibrillated successfully after one shock; intravenous (IV) magnesium was administered. QTc post-defibrillation was 466 ms, and a post-defibrillation ECG was low risk when plotted on the QT nomogram. This patient was found to have hypomagnesemia and subsequently underwent electrophysiology testing including provocation with droperidol, which elicited QTc prolongation but no dysrhythmias. Thus, we found the incidence of TdP in ED patients receiving droperidol to be 1/16,546 (0.006%; 95% CI, 0.00015 - 0.03367%).

DISCUSSION

In this cohort of 16,546 ED patients we found QT prolongation to be extremely rare. We found no clinically significant difference in QT interval among non-critically ill patients who had an ECG performed either before or after droperidol administration. Of a higher risk, critically ill cohort, we found the proportion of patients experiencing a QTc > 480 ms to be similar in patients before they received droperidol (5%) as in patients who had an ECG performed after droperidol (3.9%). When critically ill patients receiving droperidol had their ECGs plotted on the QT nomogram to stratify the risk of TdP, only 3.8% were deemed “at risk” for TdP. We observed a single case of TdP in a high-risk patient that was recognized and corrected before cardiac arrest occurred. Once stabilized, this patient did not have recurrent dysrhythmias after re-exposure to droperidol. Our data suggest that TdP with droperidol is extremely rare, and that when it occurs it does so in patients with multiple risk factors, such as a patient with an alcohol use disorder with an electrolyte disturbance who is actively vomiting, likely triggering a vagal bradycardic response.

Our data contribute to the existing data suggesting the risk of droperidol-induced dysrhythmias is exceedingly rare. Even at the time the FDA boxed warning was issued, peer-reviewed data did not support a solid link between droperidol and TdP, as demonstrated by one review that noted in 67,000 prescriptions for droperidol, not a single cardiac arrest was found.³² In fact,

at the time the FDA boxed warning was issued, the available peer-reviewed, indexed literature demonstrating any evidence regarding an association between droperidol and QT prolongation or TdP was composed of three clinical studies and seven case reports.³³ The FDA specifically cited two of these studies in their decision to add a boxed warning, both of which used larger doses than typically used in EDs.³⁴⁻³⁶ One study randomized 40 head and neck surgical patients to three doses of IV droperidol (0.1, 0.175, and 0.25 milligrams per kilogram [mg/kg]) and observed a dose-dependent increase in the QT interval over a 10-minute study period.³⁶ The other study presented a case report of a patient who suffered TdP after 12.5 mg of IV droperidol, which occurred again after a droperidol re-challenge. The authors then went on to present a prospective observational study of 55 volunteers who received 0.25 mg/kg of IV droperidol prior to elective surgery and noted an increase from baseline in the QT interval in 70% of patients.³⁵ The sentinel patient experiencing TdP, however, later was determined to have bifascicular block needing a pacemaker, and the authors concluded their data was no reason to avoid the use of droperidol.

In addition to these two studies, the FDA also considered approximately 270 post-marketing surveillance reports submitted to MedWatch, the FDA’s Safety Information and Adverse Event Reporting Program. Multiple research groups subsequently submitted Freedom of Information Act requests to obtain and analyze these reports,^{9,10,13,15,33,37} each of which helps clarify unique aspects of these cases. These analyses demonstrate clearly the MedWatch cases used to support the FDA boxed warning do not reflect the use of droperidol in a typical North American ED, nor are the reports of high quality. Several of these cases are duplicate reports (one cardiac arrest case was submitted five different times).⁹ Accounting for duplication there are 232 unique cases.¹⁰ Not all of these cases involved bad outcomes; of 273 reports, 127 involved a serious adverse event (SAE) (death, prolonged hospitalization, or a life-threatening condition)³⁷ including 94 deaths,³³ 65 of which were associated with a cardiac sign or symptom.⁹ Furthermore, not all SAEs were cardiac; of all reports, 97 involved a cardiac symptom,⁹ including 11 patients

Table. Characteristics and electrocardiogram data for critically ill patients receiving droperidol (n = 396).

	ECG before Droperidol (n = 96)	ECG after Droperidol (n = 186)	ECG before and after Droperidol (n = 114)
Median QTc (Bazett’s correction)	424 ms (range, 353 - 526)	424 ms (range, 309 - 533)	Before: 428 ms (range, 353 - 526) After: 423 ms (range, 309 - 533)
Mean time to ECG	33.3 minutes before	25.9 minutes after	Before: 28.2 minutes After: 108.8 minutes
Mean droperidol dose	2.75 mg	3.68 mg	2.21 mg
Ventricular dysrhythmias			
Bigeminy	2	2	-
Torsades de Pointes	-	1	-

ECG, electrocardiogram; QTc, corrected QT intervals; ms, milliseconds; mg, milligrams.

with TdP (six of whom survived).^{9,15}

In addition, these cases do not reflect the use of droperidol in the US. Of these 127 SAEs, 74% came from sources outside the US,³⁷ including 83% of all the fatality reports; only 15 deaths came from within the US.¹⁰ Dosing was also atypically large. Of the foreign-reported deaths that included dosing, 49% of them involved doses ≥ 50 mg, with some patients receiving up to 250 mg.¹⁰ In total, only 14 deaths were reported at doses ≤ 5 mg.³³ Confounding concomitant medications or medical conditions were also extremely common; of the 14 deaths at doses ≤ 5 mg, in only two was droperidol the only medication given,³⁸ and in both cases either an alternative explanation was as likely or droperidol as a cause was not pharmacokinetically plausible.³³ One group conducted an in-depth analysis of all 10 reported deaths at doses ≤ 1.25 mg (only two of which were ED patients) and found that in none of the cases was a cause-and-effect relationship present.¹³ Another used the Naranjo algorithm for adverse drug events to

assign causality to all 65 cardiac deaths, and found no case scored higher than “possible cause” on the algorithm.⁹ Last, the manner in which these cases were submitted to MedWatch was atypical. Of the approximately 270 reports, 71 were submitted on a single day (July 9, 2001), including 53 of the 94 deaths.³³ This large, single-day MedWatch submission came from Janssen-Cilag,³⁸ the company that until March 31, 2001, sold and marketed droperidol in Europe (but not the US).¹⁵ Notably the mean interval from event to report of these cases submitted by Janssen-Cilag was 7.4 years, compared to 1.6 years for the remainder of the reports.¹⁰

Since the issue of the black box warning, several studies have attempted to better quantify the risk of QT prolongation and TdP with droperidol. In a large anesthesia practice, the first-line drug for PONV changed from droperidol (before the boxed warning) to 5HT₃ antagonists (eg, ondansetron) after the boxed warning. They found that out of 291,188 patients (16,791 of whom the authors estimated received droperidol, all in the “before” group), there

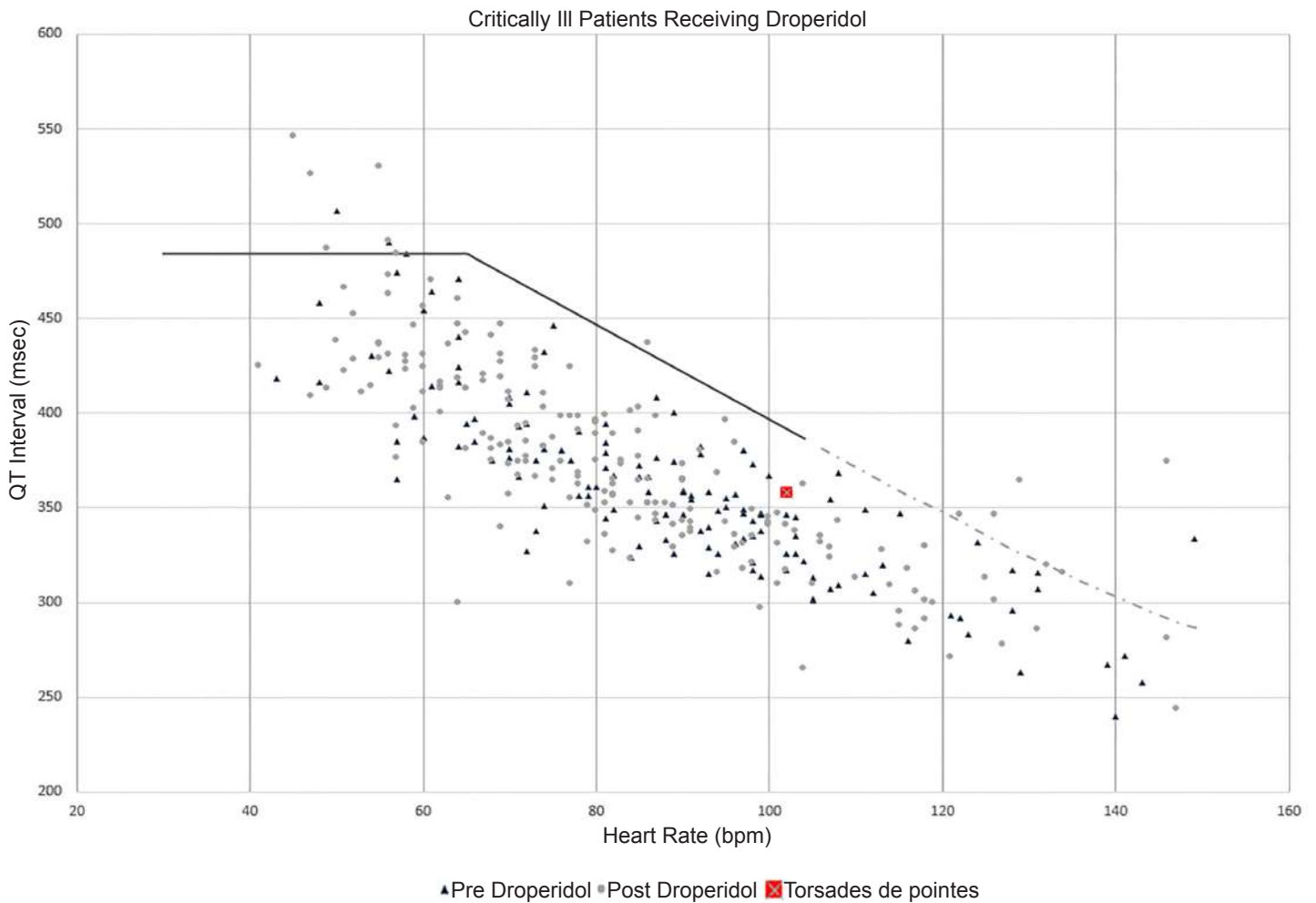


Figure 2. Heart rate and QT interval plotted on the QT nomogram. Data points above the line are considered “at-risk” for drug-induced torsades des pointes (TdP). Triangle represent electrocardiograms (ECG) obtained before patients received droperidol. Circles represent ECGs obtained after patients received droperidol. The lone square is the patient who experienced TdP; however, this ECG was obtained after defibrillation occurred and magnesium was administered. ECG, electrocardiogram; bpm, beats per minute; msec, millisecond.

were three unexplained deaths within 48 hours; one in the before (droperidol) group; and two in the after (mostly ondansetron) group.³⁹ In the single, unexpected fatality case where droperidol was used the patient died over 11 hours after a 1.25 mg dose of droperidol, making it extremely unlikely droperidol was responsible given its 2.3-hour half life. The same group later analyzed another 20,122 surgical patients who received 35,536 doses of droperidol and found no patients developed polymorphic ventricular tachycardia or death due to droperidol.⁴⁰

An Australian group prospectively evaluated 1,403 patients receiving ≥ 10 mg for acute behavioral disturbances in six different EDs, 1,009 of whom had ECGs within two hours of droperidol and found that only 13 patients were “at-risk” on the QT nomogram (seven of whom had other explanations for a long QT); no patients suffered a ventricular dysrhythmia or died.⁴¹ Recently another American group evaluated 6,353 ED encounters where patients received droperidol and found the incidence of a QTc >500 ms was 1.2% in the six months prior to receiving droperidol, and 0.7% after receiving droperidol.⁴² None of these patients suffered TdP or died. We recently published a review that included 4,947 patients who received a median dose of 5 mg intramuscular (IM) droperidol for acute behavioral disturbance from 2012-2013; no patients suffered cardiac arrest.⁴³

Our data align with the findings published since the boxed warning, that the incidence of clinically meaningful adverse cardiac events with droperidol is extremely rare, even in a critically ill, high-risk ED population. Although our data are not recent, they are again relevant as hospitals consider usage restrictions on droperidol now that it is widely available for the first time since 2013. Locally we have noted a substantial variation from institution to institution in terms of restriction of use and required monitoring. Some have not restricted the use of droperidol in any fashion, while some have instituted restrictions even more stringent than the boxed warning, including no use of “as needed” dosing, disallowing the use of droperidol on any order sets in the EHR, and application of the boxed warning’s ECG monitoring parameters for doses less than the FDA-approved 2.5 mg. (The FDA has since clarified that the boxed warning does not apply to doses less than the approved dose.)⁴⁴

Our own institution’s response has been to resume clinical use of droperidol as we once did, with no additional mandatory monitoring requirements. Interestingly, during a recent pharmacy residency accreditation visit from the American Society of Health System pharmacists, our institution was cited for not having measures in place to assure appropriate monitoring of medications with boxed warnings; droperidol was cited as a specific example. In response we have added language from the boxed warning into the medication order itself; however, as peer-reviewed published data do not support routine ECG monitoring this has remained a suggested (but not mandatory) practice. Of note, since the re-introduction of droperidol at our hospital in March 2019, we have administered 3,994 doses of droperidol and have had no adverse events reported to our medication safety committee.

LIMITATIONS

This study has several limitations, including the usual limitations of a retrospective chart review, including convenience sampling and the possibility of unmeasured bias. An example of such a limitation is that because QT monitoring, such as with serial rhythm strips, was not done prospectively, it is possible that events of QT prolongation or even dysrhythmias were missed. Furthermore, we were unable to assess the relative frequency of complications compared to other therapies commonly substituted for droperidol in its absence^{2,14,45,46} because of lack of a comparative group.

The age of our data itself may be a limitation. Although the objective nature of ECG intervals is unlikely to change over time, we have not used the EHR that contained these data since 2007. Many of the patient records in our study are no longer available for review, which limits our ability to conduct additional analysis. The QT nomogram had not been invented at the time our data were collected.²⁹ Once plotted on the nomogram our data suggested 3.8% of critically ill patients receiving droperidol were above the “at-risk” line for TdP. Because the records of these patients are no longer available, we are unable to further analyze these 13 patients to determine whether they had additional risk factors for QT prolongation. Alternatively, the age of our data may carry a unique advantage. All of the patients in the present study received droperidol before the publication of the boxed warning, and as such represent a unique cohort not subject to selection bias that may have pushed emergency physicians to avoid droperidol in at-risk patients, such as those with electrolyte disturbances or underlying cardiac disease. Such bias could make droperidol appear safer than it actually is. A cohort of ED patients receiving droperidol from 1997-2001 may represent a higher risk group than would be seen in a present-day study, and as such may allow for a “worst case” estimate of the incidence of torsades des pointes.

An additional limitation is the use of Bazett’s QT correction. Because the risk of drug-induced TdP is directly proportional to the heart rate (bradycardia prolongs the vulnerable period where a depolarization could trigger TdP) Bazett’s correction over-estimates the risk of the QT interval in tachycardic patients, and under-estimates the risk in bradycardic patients.²⁶ Nevertheless, Bazett’s correction is commonly used in the droperidol literature,⁴² and is the most common formula used by toxicologists to risk stratify patients for TdP.⁴⁷ We attempted to account for this limitation by using the QT nomogram, a tool with greater sensitivity and specificity for detecting drug-induced TdP.²⁹ Last, we studied primarily patients receiving droperidol doses in the 2.5 - 5 mg range. We therefore cannot make generalizations about larger droperidol doses. Calver et al, however, used 10 mg of IM droperidol in a high-risk ED population with acute behavioral disturbance and found no cases of TdP and only six patients above the “at-risk” line on the QT nomogram. Subsequent studies from Australia have found these larger doses to also be safe.^{48,49}

CONCLUSION

We found the incidence of QTc prolongation and torsades des pointes in ED patients receiving droperidol to be extremely rare. The sole case of TdP we found had multiple risk factors for dysrhythmias. Our data suggest the FDA black box warning is overstated, and that close monitoring of patients is useful only in high-risk patients, such as those with critical illness and multiple risk factors for TdP.

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Conflicts of Interest: By the WestJEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. No author has professional or financial relationships with any companies that are relevant to this study. There are no conflicts of interest or sources of funding to declare.

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Remdesivir for the Treatment of COVID-19: A Systematic Review of the Literature

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In March 2020, the World Health Organization declared the spread of SARS-CoV-2 a global pandemic. To date, coronavirus disease-2019 (COVID-19) has spread to over 200 countries, leading to over 1.6 million cases and over 99,000 deaths. Given that there is neither a vaccine nor proven treatment for COVID-19, there is currently an urgent need for effective pharmacotherapy. To address the need for an effective treatment of SARS-CoV-2 during the worldwide pandemic, this systematic review of intravenous (IV) remdesivir was performed. Remdesivir, an anti-viral prodrug originally developed to treat Ebola virus disease, has shown broad spectrum activity against the Coronavirus family. A recent case report reported improvement of clinical symptoms with remdesivir in a patient with COVID-19. After conducting a systematic search of 18 clinical trial registries and three large scientific databases, we identified 86 potentially eligible items. Following removal of duplicates (n = 21), eligible studies were reviewed independently by two authors. After the first round of screening, inter-rater agreement was 98.5% ($\kappa = 0.925$). After the second round of full-text screening, inter-rater agreement was 100%. A total of seven ongoing and recruiting clinical trials of remdesivir (100-200 milligrams, intravenous [IV]) were included. We identified the following primary outcomes: patients discharged (n = 2); time to clinical status improvement (n = 2); improved O₂ saturation (n = 2); body temperature normalization (n = 2); and clinical status (n = 1). Secondary outcomes in all identified studies included documentation of adverse events. Phase 3 trials are expected to be completed between April 2020–2023. Therefore, despite supportive data from in vitro and in vivo studies, the clinical effectiveness of IV remdesivir for treatment of COVID-19 and potential side effects remain incompletely defined in the human population. [West J Emerg Med. 2020;21(4):737–741.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

The novel coronavirus outbreak, which began as an epidemic in Wuhan, China, in December 2019 has been confirmed to

share 79.6% sequence identity with SARS-CoV and 96% genome identity with a coronavirus species in bats, its natural reservoir.¹ Initially referred to as 2019-nCoV, the virus has been renamed SARS-CoV-2, and the disease that results is coronavirus disease-2019 (COVID-19).² At the time of this authorship, there are over 1.6 million confirmed cases and over 99,000 deaths in 205 countries worldwide.³ On March 11, 2020, the World Health Organization responded to the unprecedented spread of COVID-19 and inaction of international governments by

declaring the outbreak a pandemic.⁴

There is currently no safe and proven treatment for COVID-19 and there is no vaccine for SARS-CoV-2; however, vaccines are under development and several treatments have been proposed and are under investigation.⁵⁻⁶ The rapid international spread and severity of COVID-19, which causes symptoms varying from fever, dry cough, and shortness of breath to diarrhea and body aches, has spurred the greater scientific community to quickly identify treatments for the disease.⁴ Potential pharmacological treatments for COVID-19 may be found in one of three categories: broad-spectrum anti-viral drugs; repurposed existing drugs or substances; and novel therapeutic agents.⁷ We chose to analyze remdesivir based on established inhibition of infection by the novel coronavirus in human cell lines (human liver cancer HuH-7 cells).⁸

Remdesivir falls into the first category as an anti-viral prodrug developed to treat infections caused by viruses of the family *Filoviridae*, which includes Ebola virus (*Zaire ebolavirus*).⁹ Discovered in 2016 small molecule GS-5734, remdesivir was used initially to treat Ebola virus disease (EVD) as an adenosine analog that incorporates into viral RNA, leading to premature chain termination and inhibition of viral replication.¹⁰ But in 2019, the first confirmed case of COVID-19 in the United States prompted the use of intravenous (IV) remdesivir for compassionate use, leading to marked improvement of the patient's clinical status within 24 hours.¹¹ The authors suggested that additional clinical studies were needed to complete the safety and efficacy profiles of the anti-viral drug. Given the worldwide urgency for an effective and safe treatment for COVID-19 and the therapeutic potential of remdesivir, this systematic review was performed to determine the outcomes and adverse events associated with this investigational, anti-viral medication.

METHODS

We performed a systematic review of the use of remdesivir for treatment of COVID-19. Eligible articles included human patients with SARS-CoV-2 infection, remdesivir administration, patient outcomes, and adverse events. A search strategy was developed for each database without restrictions for language or years considered. The search parameters for Embase were as follows:

- (1) remdesivir OR GS-5734
- (2) coronavirus OR coronaviruses OR 2019-nCoV OR COVID-19 OR SARS-CoV-2 OR SARS-COV2
- (3) #1 AND #2

Clinical trial registries that were searched included the following: clinicaltrials.gov; Chinese Clinical Trial Registry (ChiCTR); Australian New Zealand Trial Registry; Brazilian Clinical Trials Registry; Chinese Research Information Service Republic of Korea; Clinical Trials Registry India; Cuban Public Registry of Clinical Trials; German Clinical Trials Register; Iranian Registry of Clinical Trials; International Standard Randomised Controlled Trials Number Registry; Japan Primary Registries Network; Lebanese Clinical Trials Registry; Thai Clinical Trials Registry; The Netherlands National Trial Register; Pan African Clinical Trial Registry; Peruvian Clinical Trial Registry; and Sri Lanka Clinical Trials Registry. The following databases were searched: Embase, PubMed, and Web of Science. The search was last updated on March 17, 2020. Study coordinators were contacted for additional information if appropriate.

Eligible studies were identified and screened according to inclusion-exclusion criteria that were established a priori (Table 1). Two authors independently screened the search results, and a third author resolved the disputes. Inter-rater agreement

Table 1. Inclusion-exclusion criteria for systematic review of studies regarding the use of remdesivir for treatment of COVID-19.

Inclusion	Exclusion
1. Human study	1. (a) In vitro study or (b) In vivo study (e.g. animal model) or (c) Other non-human study (unless can be isolated)
2. Remdesivir (GS-5734) included	2. Remdesivir (GS-5734) not included in the article
3. (a) Case report or (b) Case series or (c) Letter of correspondence or (d) Observational study or (e) Clinical trial or (f) Randomized controlled trial	3. (a) Literature review or (b) Systematic review or (c) Meta-analysis or
4. (a) Novel coronavirus or (b) 2019-nCov or (c) SARS-COV-2 or (d) COVID-19	4. (a) Other pathogen or virus included (e.g. Marburg)

Studies that meet all the inclusion criteria may be included in the systematic review. Studies that meet any of the exclusion criteria should be excluded from the systematic review.

was quantified by Cohen's kappa scores as well as percentage agreement as recommended by McHugh.¹² Studies were first screened by title and abstract and then by full-text review. Data were extracted by one author and included the following items: type of study; intervention; number of participants; patient outcomes; adverse events; and study characteristics. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement as an aid in this report.¹³ There is no online review protocol for this study.

RESULTS

The database search yielded a total of 86 items from the following databases: Embase ($n = 21$), PubMed ($n = 20$), Web of Science ($n = 28$), European Union Clinical Trials Register ($n = 2$), and clinicaltrials.gov ($n = 8$). After removal of duplicates ($n = 21$), the first round of screening yielded eight potentially eligible items. Studies were excluded for meeting any of the following criteria: non-human study ($n = 3$); review or meta-analysis ($n = 15$); not including SARS-CoV-2 ($n = 16$); or multiple criteria met ($n = 23$). Inter-rater agreement following the first round of screening was 98.5% ($\kappa = 0.925$). After the second round of screening, seven items were included. Inter-rater agreement was 100%. Study characteristics are described in Table 2.

This review of remdesivir identified ongoing and recruiting trials in 11 countries, including the United States, China, Taiwan, France, and Italy. The average number of participants was 450 (range = 308-600). Selection criteria for each trial varied according to the severity of symptoms (based on peripheral capillary oxygen saturation). Five trials involved a 200-milligram (mg) intravenous (IV) loading dose following by maintenance dose of 100 mg for nine days. Two trials involved a single, 100-mg IV infusion. The primary outcomes for each trial were as follows: proportion of patients discharged ($n = 2$); time to clinical improvement ($n = 2$); improved oxygen saturation ($n = 2$); normalization of body temperature ($n = 2$); and percentage of each severity rating on a 7-point ordinal scale to assess clinical status ($n = 1$). Secondary outcomes included adverse events ($n = 7$); length of stay ($n = 2$); mortality ($n = 3$); duration of ventilation or supplemental oxygen use ($n = 3$); and reduction in viral load ($n = 2$). Results are expected in April 2020 ($n = 2$), May 2020 ($n = 2$), and April 2023 ($n = 1$).

DISCUSSION

Our systematic search identified a total of 86 studies eligible for inclusion, of which seven were incorporated into a qualitative synthesis. All seven of the included studies were Phase 3 clinical trials that were either recruiting patients or considered ongoing. In each trial, IV remdesivir (100-200 mg) was the primary intervention. The predominant treatment protocol described a 200 mg dose administered on the first day followed by subsequent doses of 100 mg each following day (for a total of 5 or 10 days depending on the treatment arm).

However, none of the included studies have reported completed or partial data. As a result, the clinical utility of remdesivir for the treatment of COVID-19 remains to be seen, and any adverse events have yet to be reported.

As early as 2017, Sheahan et al reported GS-5734 activity against MERS-CoV and SARS-CoV in human lung cells, suggesting that remdesivir may prove effective against endemic and emerging coronaviruses.¹⁴ Agostini et al later reported that GS-5734 effectively inhibited coronavirus replication in vivo despite intact exoribonuclease proofreading, indicating that remdesivir may have utility against resistant coronavirus strains.¹⁵ Further research has demonstrated the broad-spectrum activity of remdesivir for the purpose of treating endemic coronavirus infections.¹⁶

In December 2019, the first case of SARS-CoV-2 in the United States was successfully treated by IV remdesivir without adverse effects.¹¹ The patient was treated with remdesivir on hospital day 7, and on day 8 the patient experienced symptomatic and clinical improvement significant enough to discontinue supplemental oxygenation with improved saturation in room air, as well as resolution of rales and anorexia. Remdesivir was first reported for treatment of EVD in 2016 with subsequent studies indicating mixed results.^{10, 17-18} Ko et al argued that the findings from previous studies of remdesivir for EVD support testing of remdesivir for treatment of COVID-19.¹⁹ Concurrent in vitro research has supported the use of the drug to treat SARS-CoV-2 infections.²⁰ In contrast, Zhang et al have raised concerns about the possibility of unknown adverse reactions.⁸

LIMITATIONS

The primary limitation of this systematic review stems from the lack of reported patient outcomes from human trials, which are in varying phases of completion. Although some clinical trial registries display preliminary reports of ongoing trials, these partial data are not available for quantitative analysis. Trials are scheduled to be completed as early as April-May 2020.

CONCLUSION

There is both in vitro and limited clinical evidence that supports the use of remdesivir to treat SARS-CoV-2. However, Phase 3 clinical trials have not yet been completed and partial data has not yet been reported. The side-effects profile of remdesivir remains similarly not well defined. Until high-quality studies report significant improvements with administration of IV remdesivir, the use of this experimental drug should be limited to randomized controlled trials. Therefore, the potential of remdesivir as a standard of care therapy for COVID-19 remains to be determined.

NOTE: An addendum to this article has been written by the author AM.²⁰

Table 2. Study characteristics regarding the use of remdesivir for treatment of COVID-19.

ID	Trial Status	Country	Number of Sites	Phase of Trial	Intervention	Number of Participants	Primary Outcome(s)
NCT04292899	Recruiting	Hong Kong Republic of Korea Singapore United States	10	3	Intravenous RDV 200 mg on Day 1 followed by Intravenous RDV 100 mg for 4 days	400	Improved oxygen saturation; Normalization of body temperature
NCT04292730	Recruiting	Hong Kong Republic of Korea Singapore United States	10	3	Intravenous RDV 200 mg on Day 1 followed by Intravenous RDV 100 mg for 4 days	600	Proportion of discharged patients
NCT04257656	Recruiting	China	1	3	Intravenous RDV 200 mg on Day 1 followed by Intravenous RDV 100 mg for 9 days	453	Time to clinical improvement (restricted to 28 days)
NCT04252664	Recruiting	China	1	3	Intravenous RDV 200 mg on Day 1 followed by Intravenous RDV 100 mg for 9 days	308	Time to clinical improvement (restricted to 28 days)
NCT04280705	Recruiting	Republic of Korea Singapore United States	20	3	Intravenous RDV 200 mg on Day 1 followed by Intravenous RDV 100 mg for 9 days	394	Percentage of each severity rating on 7-point ordinal scale with a 15 day time frame
2020-000841-15	Ongoing*	China France Germany Hong Kong Italy Japan Republic of Korea Singapore Spain Taiwan United States	15	3	Intravenous RDV 100 mg	400	Improved oxygen saturation; Normalization of body temperature (restricted to 14 days)
2020-000842-32	Ongoing*	China France Germany Hong Kong Italy Japan Republic of Korea Singapore Spain Taiwan United States	15	3	Intravenous RDV 100 mg	600	Proportion of discharged participants (restricted to 14 days)

*Trial status (as defined by ClinicalTrials.gov) regards a trial as 'ongoing' if it had one of these statuses: 'Active, not recruiting', 'Available', 'Enrolling by invitation', 'Not yet recruiting', 'Recruiting', or 'Suspended'.

RDV, Remdesivir; mg, milligrams.

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Addendum to Systematic Review of Remdesivir for the Treatment of COVID-19

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To the Editor:

We are honored to have our systematic review of remdesivir for the treatment of COVID-19 published in the *Western Journal of Emergency Medicine*.¹ Recently, new studies regarding the use of remdesivir have prompted us to submit this letter. On April 10, Grein et al reported that most patients given remdesivir in an open-label program exhibited observable clinical improvement.² However, Wang et al did not find a statistically significant benefit with remdesivir in a randomized, double-blind, placebo-controlled trial of 237 patients that was published on April 29.³ On the same day, a press release by the National Institute of Allergy and Infectious Diseases (NIAID) regarding the Adaptive COVID-19 Treatment Trial (ACTT) reported significantly reduced time to recovery and mortality with remdesivir.⁴ Therefore, the purpose of our letter is to briefly analyze these new findings and determine whether additional conclusions in remdesivir's treatment of COVID-19 can be drawn.

Grein et al analyzed open-label data from 61 patients who were treated with remdesivir between January–March 2020. Patients were administered a loading dose of 200

milligrams (mg) on the first day followed by nine days of 100 mg infusions. Clinical improvement was based on a six-point scale: 1 = not hospitalized; 2 = hospitalized but not requiring supplemental oxygen; 3 = hospitalized and requiring supplemental oxygen; 4 = hospitalized and requiring nasal high-flow oxygen therapy, noninvasive mechanical ventilation or both; 5 = hospitalized requiring mechanical ventilation, extracorporeal membrane oxygen, or both. Most patients (68%) exhibited clinical improvement and 84% were discharged or showed a decrease of two points or more at follow-up. In total, 13% died and 60% exhibited adverse events, most commonly hepatic and renal dysfunction. Although these findings are encouraging, the small sample size, lack of a comparison group, case-by-case variation in supportive care, and missing data make it difficult to draw robust conclusions.

The first randomized, controlled clinical trial of remdesivir for treatment of COVID-19 was published in *The Lancet* on April 29. This study analyzed treatment of 237 patients (158 given remdesivir and 79 given placebo). Although the remdesivir group showed a reduced time to clinical improvement (18 vs 23 days), this was statistically insignificant. Neither mortality (14% vs 13%) nor adverse events (66% vs 64%) were commonly associated with remdesivir. The most common complications included constipation, hypoalbuminemia, hypokalemia, and anemia. However, there are several limitations to these results. Firstly, patients in the remdesivir and placebo groups

received interferon alfa (29% vs 38%), lopinavir-ritonavir (28% vs 29%), antibiotics (90% vs 94%), and corticosteroids (65% vs 68%) before and after enrollment. These additional drugs make it difficult to differentiate between the effects of remdesivir and other treatments. Moreover, the placebo group received a higher percentage of these drugs. Secondly, 36 patients discontinued treatment due to adverse events, reducing the sample size. Since the trial was terminated early on March 29, the statistical power was reduced from 80% to 58%. Though these findings do not support remdesivir to treat COVID-19, the methodological limitations, missing data, and early termination moderate the results.

The ACTT is an ongoing randomized, double-blinded controlled trial of remdesivir that began enrolling on February 21.⁵ After, the data and safety monitoring board performed a preliminary analysis of 1063 patients, the NIAID reported on April 29 that remdesivir statistically significantly reduced time to recovery compared to placebo (11 vs 15 days, $p < 0.001$). There was also a modest increase in survival (8.0% vs 11.6%), which approached statistical significance ($p = 0.059$). Although preliminary findings released by NIAID are supportive, it remains possible that the final results may differ at the conclusion of the trial. Also, the press release did not reveal any data about adverse events, loss to follow-up, or other complications. Nevertheless, on May 1, based on the ACTT and Gilead open-label trial, the US Food and Drug Administration issued an Emergency Use Authorization (EUA) for use of remdesivir for COVID-19.^{2,4,6} Physicians may find it difficult to make informed decisions regarding treatment of patients with COVID-19. Given the recent EUA, we recommend making the decision to administer remdesivir based on the highest quality of evidence in the literature, which suggests decreased time to recovery and the possibility of increased survival.

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Emergency Department Admissions During COVID-19: Implications from the 2002-2004 SARS Epidemic

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Dear Editor:

The emergency department (ED) represents a frontline in the response to the COVID-19 (coronavirus disease 2019) pandemic. This is similar to the 2002-2004 SARS-CoV-1 (severe acute respiratory syndrome coronavirus) epidemic, where EDs played an important role in triage and screening of patients presenting to hospitals. In this letter, we review the impact of the SARS epidemic on hospital ED admissions, and discuss implications for COVID-19 to enable healthcare systems to better anticipate and manage the effects of the current pandemic on the ED.

During the peak of the SARS outbreak, studies from affected countries (predominantly high-income countries such as Taiwan, Singapore, Hong Kong, and Canada) reported overall declining ED visits, especially for high-acuity and non-respiratory emergencies.¹⁻⁹ Rates of acute myocardial infarction, pulmonary embolism, and gastrointestinal bleeding presenting to EDs declined, indicating that some seriously ill patients did not get access to appropriate medical care.¹ Possible reasons for declining ED visits included patient fear of contracting SARS from EDs, official announcements deterring ED visits, and the media's portrayal of the disease.^{2,3,10} However, some EDs reported an increase in patients harboring concerns of SARS infection, occasionally even without any respiratory symptoms.⁶ Symptomless patients posed a challenge to EDs, as overburdened healthcare workers often delayed the full assessment of these patients although they could represent asymptomatic but infective sources of SARS. Moreover, the increase in potential SARS patients visiting EDs deterred not only healthcare-seeking behavior, but also healthcare-providing

behavior due to fear of nosocomial transmission and insufficient isolation facilities.³ However, despite a decline in number of visits, ED staff were increasingly overburdened with the triage and management of the influx of potential SARS patients.³ As a result, EDs also saw a drop in performance and quality of care indicators, such as length of stay and early return to the ED.⁴ Moreover, although expenses in the ED fell, the increased per patient expenditures (up to 35.9%), decreased reimbursements (up to 21.7%), operational disruptions, and decreased surgical procedures placed hospitals under major financial stress.^{3,7} Hospital recovery time, in terms of ED visits, ranged from months to years.⁵

Despite most SARS data discussed in this letter originating from high-income countries, we expect the COVID-19 pandemic to produce similar – though perhaps more augmented – effects on ED trends worldwide. The public's fear of COVID-19 resulting in decreased ED visits for emergencies risks serious health consequences that must not be overlooked. Hospitals must explore ways to reduce these unfortunate consequences, such as the use of telephone helplines encouraging the use of hospital services when appropriate. Telehealth also enables hospitals to continue providing consultations for other medical specialties, thereby reducing financial losses. Reducing the likelihood of a nosocomial COVID-19 outbreak, while also alleviating the public's fear of visiting an ED, may be achieved through better infection control measures and availability of appropriate personal protective equipment. Where possible, the construction of isolation centers (away from existing EDs), and designation of specific public hospitals for the testing and management of COVID-19 patients, could also offer potential solutions. Additionally, it is also important for public health systems to maintain constant, positive, yet transparent, communication with patients and families through the pandemic. Lastly, decreased revenue from declining visits to EDs may cripple a hospital financially and quickly render it incapable of continuing health provision

during the pandemic. To negate this, it is important for governments to mobilize financial resources to compensate hospitals and healthcare workers, ensuring their ability and motivation to continue fighting COVID-19.

In conclusion, the 2002-2004 SARS outbreak showed how the current COVID-19 pandemic may lead to considerable ramifications for emergency care in the population, as well as hospitals' long-term operational and financial capabilities. Lessons learned from the SARS outbreak show the need for extensive telehealth services, designated COVID-19 management facilities, higher sanitary and infection control standards, and better communication with the general population. This letter aims to guide public health officials to prevent avoidable, yet potentially dire, consequences of the COVID-19 pandemic on ED accessibility and utilization.

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First Do No Harm With COVID-19: *Corona Collateral Damage Syndrome*

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Communication is complex in that what we say is not always what is heard. Communication that is intended to help can sometimes result in doing harm. The COVID-19 pandemic is a public health emergency. While we rapidly learn of the scientific and healthcare aspects of this disease, there is an opportunity to better understand the consequences of well-intentioned communication by experts.

Given the nature of the rapid global spread of the virus and the high fatality rate of those sick enough to require intensive care, public health and elected-leader messaging of “Stay at Home” was appropriate. With no vaccine or cure, the public health tools of social distancing, respiratory and hand hygiene, and stay-at-home orders were both appropriate and effective at flattening the curve and delaying the peak caseload of COVID-19. Most locations in the US were successful in avoiding overwhelming hospital resources including intensive care units.

However, there are increasing reports from the US and other countries that outside of high-demand hot spots like New York City, most emergency departments (ED) and hospitals have experienced a steep decline in their patient census. ED visits declining 50% or more through the end of April have been widely reported.¹ Emergency physicians, cardiologists, neurologists, and acute care surgeons wondered, where did all the acute, non-COVID-19 patients go?^{2,3} While the number of trauma incidents may have dropped off due to stay-at-home orders, it is unlikely that heart attacks, strokes, and acute surgical emergencies had stopped occurring.

Then we started seeing *delayed presentations* of many diseases with their resulting complications: appendicitis with rupture; completed heart attacks; and strokes with significant deficits, to name a few.^{4,5} These are *time-sensitive* conditions in patients who were coming in past the optimal window for

treatment. Why did this occur, what role did our messaging play, and how can we correct this in the future?

Corona collateral damage syndrome (CCDS) is the clinical condition resulting from a delay or failure to seek or receive care for acute emergencies for non-COVID-19 medical conditions.³ The key cause of CCDS is the fear of catching the virus by coming for care to hospital EDs or other healthcare facilities. This fear appears to have been principally associated with the strong but important message: “Stay at Home.”

This message was said repeatedly by authority figures and amplified by news networks over the past few months. This barrage of messages was effective in getting the public to social distance and stay home. However, the unanticipated collateral damage was the fear of seeking help for *other* concerning symptoms.⁶ We have the opportunity now to course correct and nuance the message:

“If you are having an emergency, go to the Emergency Room. *Hospitals have taken dramatic steps to protect emergency patients from contracting COVID-19.*”

We are reminded that language matters and communication has consequences, some unforeseen. Always best to ask the listener what they heard.

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Electronic Health Record-Based Surveillance for Community Transmitted COVID-19 in the Emergency Department

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Introduction: SARS-CoV-2, a novel coronavirus, manifests as a respiratory syndrome (COVID-19) and is the cause of an ongoing pandemic. The response to COVID-19 in the United States has been hampered by an overall lack of diagnostic testing capacity. To address uncertainty about ongoing levels of SARS-CoV-2 community transmission early in the pandemic, we aimed to develop a surveillance tool using readily available emergency department (ED) operations data extracted from the electronic health record (EHR). This involved optimizing the identification of acute respiratory infection (ARI)-related encounters and then comparing metrics for these encounters before and after the confirmation of SARS-CoV-2 community transmission.

Methods: We performed an observational study using operational EHR data from two Midwest EDs with a combined annual census of over 80,000. Data were collected three weeks before and after the first confirmed case of local SARS-CoV-2 community transmission. To optimize capture of ARI cases, we compared various metrics including chief complaint, discharge diagnoses, and ARI-related orders. Operational metrics for ARI cases, including volume, pathogen identification, and illness severity, were compared between the pre- and post-community transmission timeframes using chi-square tests of independence.

Results: Compared to our combined definition of ARI, chief complaint, discharge diagnoses, and isolation orders individually identified less than half of the cases. Respiratory pathogen testing was the top performing individual ARI definition but still only identified 72.2% of cases. From the pre to post periods, we observed significant increases in ED volumes due to ARI and ARI cases without identified pathogen.

Conclusion: Certain methods for identifying ARI cases in the ED may be inadequate and multiple criteria should be used to optimize capture. In the absence of widely available SARS-CoV-2 testing, operational metrics for ARI-related encounters, especially the proportion of cases involving negative pathogen testing, are useful indicators for active surveillance of potential COVID-19 related ED visits. [West J Emerg Med. 2020;21(4)748–751.]

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INTRODUCTION

SARS-CoV-2, a novel coronavirus, is the cause of an ongoing global pandemic. It can cause a serious respiratory illness, termed COVID-19, with comorbid and older adults at increased risk of death.^{1,2} While other affected countries instituted widespread testing for SARS-CoV-2 as part of early and successful mitigation efforts, due to a variety of factors, diagnostic testing efforts in the United States (US) during early phases of community spread continue to be significantly hampered.^{3,4} The lack of testing capacity resulted in stringent testing recommendations from the Centers for Diseases Control and Prevention, which specifically excluded asymptomatic or mildly symptomatic individuals. The delay in community-based surveillance has generated substantial uncertainty among health systems attempting to prepare for a surge in cases and severely limited a primary tool of pandemic mitigation: source identification and contact tracing. Early detection of a surge in emergency department (ED) COVID-19 cases is essential to guide response plans if hospitals hope to avoid overwhelmed systems.

Therefore, faced with the absence of a readily available rapid diagnostic assay, we developed a simple, electronic health record (EHR)-based tracking tool to detect variations in encounters due to acute respiratory infections (ARI), organism identification for ARIs, or ARI acuity related to potential unrecognized COVID-19 community transmission. The first step was to develop a process for identifying ARI using available EHR data. The second step was to determine whether we could detect a significant change in ARI case without identified pathogen as a metric of potential COVID-19 community transmission.

METHODS

We conducted this project using combined EHR data from an academic medical center ED with over 60,000 patient visits per year and an affiliated community ED with over 20,000 annual visits. Data were collected for ED arrivals from February 17-March 30, 2020, which included three weeks before and after confirmed local SARS-CoV-2 transmission. All ED visits during this time period were included in our dataset and examined for potential ARI. SARS-CoV-2 testing was available via the state department of health and later in-house during the post three-week time period but for select patient groups only.⁵ All data were electronically extracted from the EHR by an experienced data analyst. This project was considered quality improvement and did not meet the federal definition of human subject research pursuant to 45 CFR 46 as assessed using a self-certification tool provided by

our institutional health sciences institutional review board.

Using the consensus of our departmental COVID-19 response team, including ED operations, informatics, and infectious diseases experts, we identified four potential EHR-based criteria to identify ARI encounters and a series of operational metrics for inclusion in an ARI outbreak tracking tool. Each selected metric needed to satisfy two basic criteria: 1) readily extractable electronically from existing EHR data; 2) involve only simple calculations for ease of interpretation and translation to other EHR platforms. For the first metric, overall ARI volume, we applied four criteria to all ED encounters to determine what would provide the most comprehensive capture of potential cases: 1) chief complaints specific to ARI (cough, flu-like symptoms, sore throat, upper respiratory symptoms, sinus symptoms); 2) discharge diagnoses specific to ARI (ICD-10 codes J00-J06, J09-J18, J20-J22, J40); 3) respiratory pathogen isolation order; and 4) respiratory pathogen test order (influenza/respiratory syncytial virus assay, group A streptococcus swab, expanded viral polymerase chain reaction [PCR] panel).

Given the disproportionate rate of critical illness among patients with COVID-19 as compared to other ARI (e.g., seasonal influenza), we then included three metrics of severity: 1) percentage of patients with ARI requiring admission; 2) percentage of patients with ARI admitted to intermediate care or intensive care units (IMC/ICU); and 3) percentage of patients with ARI receiving antibacterial therapy. The antibiotic metric was included to capture any increase in ARI patients being treated with empiric antibiotics (e.g., met sepsis criteria). Finally, given the restricted testing criteria in place and ongoing uncertainty about the SARS-CoV-2 RNA PCR assay's sensitivity and specificity⁶ to identify ARI encounters, potentially due to undiagnosed COVID-19, we selected a metric of percent ARI without an identified pathogen on any organism identification assay. This was selected due to the lack of discriminating clinical features between influenza and COVID-19 and the ongoing routine use of influenza/respiratory syncytial virus (RSV), expanded viral panel and group A strep assays for ARIs in our ED. Data were extracted from the EHR and analyzed using R 3.6.2 (The R Project for Statistical Computing, CRAN). We compared proportions of encounters before and after community transmission using a chi-square test.

RESULTS

The combined overall ED census in our two departments decreased from 5213 to 3550 (-1663 encounters) from the pre- to post-time period, but the proportion of ED visits due to ARI increased significantly (6.6%, 95% confidence interval 4.6-8.5%, $p < .001$). When identifying ARI cases, we first created a combination definition using the union of all four individual criteria and applied it to all ED encounters. This identified 2540 total ARI encounters over the six-week period. When examined individually, each of the four criteria identified

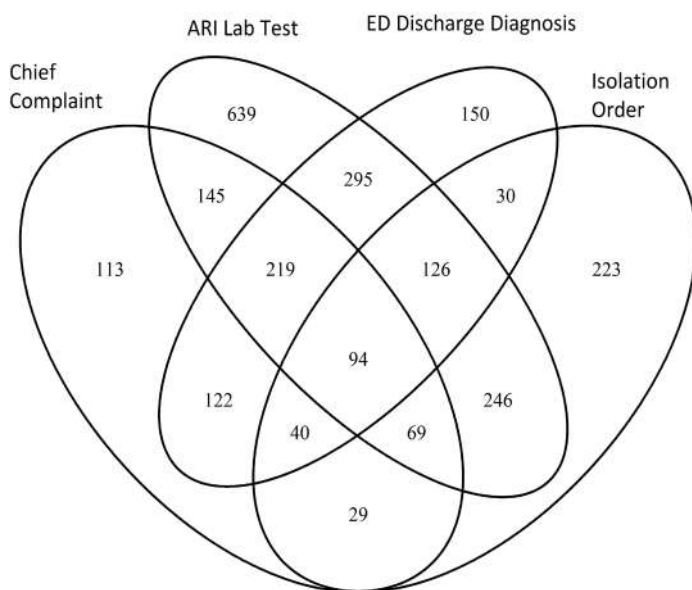


Figure. Number of acute respiratory infection encounters identified by different criteria.

ARI, acute respiratory infections; *ED*, emergency department.

unique ARI cases (Figure). Specifically, when compared to the combined definition, chief complaint specific to ARI identified 32.7% of cases while discharge diagnosis related to ARI identified 42.4% of cases. Orders for respiratory pathogen isolation or respiratory pathogen testing identified 33.7% and 72.2% of cases, respectively.

The Table compares our selected ED ARI metrics from three weeks before and three weeks after the local onset of community SARS-CoV-2 transmission. ARI encounters without an identified pathogen increased despite no change in the proportion of ARI encounters receiving pathogen testing. Of note, only 40% of ARI encounters received SARS-CoV-2 testing in the post period with a positivity rate of 6% (27/462 tested). In terms of acuity metrics, we did not detect a statistically significant change in overall ARI admissions or those requiring IMC/ICU care. There was a statistically significant decline in the proportion of ARI cases receiving antibiotics.

DISCUSSION

In the early stages of the COVID-19 pandemic, we developed an ED surveillance tool for ARI encounters potentially related to undiagnosed community transmitted SARS-CoV-2 using readily available EHR data and simple calculations. As such, this tool could be easily implemented at other institutions. This approach to surveillance would especially benefit hospitals that do not currently have access to rapid SARS-CoV-2 identification assays or those adhering to restricted COVID-19 testing criteria as part of efforts to

preserve personal protective equipment (PPE) or testing capacity. Despite rapid progress in available diagnostics, ongoing concerns over PPE and reagent shortages will continue to hamper widespread community surveillance testing in the US.⁷

Our approach expands upon more basic methods for ED-based seasonal influenza surveillance efforts by evaluating a multi-component definition of ARI that combines chief complaints and discharge diagnoses with actual orders for respiratory isolation and pathogen testing. Our results suggest the traditional approach of using chief complaint (e.g., influenza-like illness [ILI]) and/or discharge diagnoses alone may be inadequate for comprehensive identification of ARI encounters.⁸ Of note, we did exclude fever alone in our chief complaint definition as it is not specific to ARI and would result in capture of many infections unrelated to COVID-19 (e.g., urinary tract and skin infections).

In the case of a respiratory pandemic due to a novel pathogen, traditional, laboratory-based surveillance will also be ineffective. Based on ongoing influenza activity during the study time period and its similar clinical presentation to COVID-19, we selected percentage of ARI cases receiving pathogen testing with negative results as our metric for potential cases of undiagnosed COVID-19. The observed significant increase in overall ARI encounters and those without identified pathogen mirrors national observations of increased encounters for ILI without identified pathogen over the same time periods.⁹⁻¹¹ This late-season spike in ILI cases, which did not occur in previous years, was confirmed in one report from Los Angeles to partially represent community transmission of COVID-19. Among patients with ILI who were tested for SARS-CoV-2, they observed a 5% positivity rate which is similar to our findings (6% positivity), suggesting a similar community transmission burden in disparate geographic locations around the same time period.¹¹ Although we did not demonstrate a difference in our markers of ARI severity, we attribute this to continued low volumes of COVID-19 cases in our community. We anticipate these metrics will become increasingly valuable for early identification of a need for additional intensive care resources should ongoing mitigation efforts not succeed in flattening the outbreak curve locally.

LIMITATIONS

For ARI case identification, it is possible that cases that would have been identified with manual chart review were excluded. Given the dynamic nature of the ongoing COVID-19 pandemic and limited post-community spread data available for analysis, we did not perform a formal, interrupted time series analysis to account for temporal effects. ARI volumes and percentage of ARI cases without identified pathogen must be interpreted based on local outbreak dynamics. As population-level surveillance metrics, these indicators should not be used to inform diagnosis or treatment decisions for individual patients.

Table. Acute respiratory infection-related emergency department encounter metrics before and after community transmission of SARS-CoV-2.

	Pre-Community Transmission (n = 1372)	Post-Community Transmission (n = 1168)	Difference in Proportions (% , 95% CI)	P value
Pathogen Testing	998 (72.7%)	835 (71.5%)	-1.2% (-4.8%,2.2%)	0.512
Negative Pathogen Test	578 (42.1%)	642 (55.0%)	12.9% (9%,16.7%)	<0.001
Admitted	412 (30.0%)	374 (32.0%)	2% (-1.6%,5.6%)	0.299
Admitted to IMC/ICU	79 (5.8%)	83 (7.1%)	1.3% (-0.6%,3.3%)	0.192
Antibiotic Use	245 (17.9%)	165 (14.1%)	-3.8% (-6.6%,-0.9%)	0.001

CI, confidence interval; IMC, intermediate care unit; ICU, intensive care unit.

CONCLUSION

In this project, we evaluated a strategy for using EHR data to identify ARI-related ED encounters and demonstrated significant changes in metrics related to these encounters during the onset of local community SARS-CoV-2 transmission. ARI without identified pathogen encounters may serve as a lead population-level surveillance indicator for ARI outbreaks related to novel pathogens, such as the ongoing COVID-19 pandemic.

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In Young Adults with COVID-19, Obesity Is Associated with Adverse Outcomes

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Introduction: For patients with COVID-19, several characteristics have been identified that may be associated with adverse outcomes. However, there is a paucity of data regarding the effect of obesity on young adult patients with COVID-19. We sought to identify whether adverse outcomes are associated with obesity, particularly in COVID-19 patients 45 years and younger.

Methods: This was a two-center, retrospective cohort study that included 210 patients. Eligible patients were between the ages of 18-45 years old, had tested positive for SARS-CoV-2 on real-time reverse transcription polymerase chain reaction via nasopharyngeal swab, and were not pregnant. Primary outcomes were defined as follows: 1) in-hospital mortality during the study period; 2) need for mechanical ventilation; and 3) admission to the hospital. We analyzed baseline characteristics of the cohort using descriptive statistics. Odds ratios (OR) were calculated to assess associations between outcomes and obesity, defined as body mass index (BMI) >30.

Results: Of those patients who tested positive, 18 died during hospitalization (9%), 36 (17%) required mechanical ventilation, and 94 (45%) were admitted. Each of the primary outcomes was significantly associated with a BMI >30 (mortality OR = 6.29, 95% confidence interval [CI], 1.76-22.46, $p = 0.0046$; mechanical ventilation OR = 6.01, 95% CI, 2.5-14.48, $p = 0.0001$; admission OR 2.61, 95% CI, 1.49-4.58, $p = .0008$).

Conclusion: Obesity appears to be an independent risk factor for poor outcomes in young patients with COVID-19. Future studies examining the clinical characteristics and risk factors of COVID-19 patients across large, diverse populations will strengthen our understanding of this novel and complex disease. [West J Emerg Med. 2020;21(4)752–755.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

BACKGROUND

In December 2019, a novel coronavirus was identified that has since changed the world as we know it. SARS-CoV-2 began infecting people in the Hubei Province in China and

has since affected people on almost every continent. Experts identified the clinical syndrome caused by this virus as COVID-19, which primarily manifests as a respiratory illness that has high transmissibility, pathogenicity, morbidity, and mortality. Clusters of outbreaks continue to appear, most recently affecting the United States. Studies have identified comorbidities that may be associated with worse outcomes, including diabetes, hypertension, cardiovascular disease, chronic obstructive pulmonary disease, malignancy, and chronic liver disease.¹⁻² Clinicians in the US are taking notice

of another trend – younger patients who are obese (defined as body mass index [BMI] equal to or greater than 30) appear to be at greater risk for adverse outcomes when contracting the virus. Two recently published articles identified obesity as a risk factor for COVID-19.^{3,4} This may not have been broadcasted as a known risk factor from the Chinese, South Korean, and Italian cohorts, as their obesity rates are significantly lower than US rates: 6.2%, 4.7%, 19.9%, respectively, compared to 36.2% in the US.⁵

The devastation that SARS-CoV-2 is causing is simply unprecedented in our lifetime. There is building evidence that identifies the clinical characteristics and features of this disease.¹⁻⁴ High case-fatality rates have been reported in both China and Italy: 2.3% and 7.2%, respectively.⁶⁻⁷ More data is being reported on a daily basis that changes our approach to this growing pandemic. This highlights the need to identify any and all potential risk factors and/or clinical outcomes that may alter future clinical practice.

Obesity has been previously identified as a risk factor for disease severity in viral illnesses. During the H1N1 outbreak in 2009, numerous investigations identified a greater number of subjects with obesity admitted for in-patient care, those requiring mechanical ventilation, and overall mortality.⁸ This disproportionate effect of viral illnesses on obese patients identifies a potential risk factor that needs to be further investigated given the COVID-19 outbreak. We sought to identify whether adverse outcomes such as mortality, need for mechanical ventilation, or hospitalization are associated with obesity, particularly in COVID-19 patients 45 years and younger.

METHODS

This retrospective cohort study was conducted at two sites: a high-volume, urban, academic, tertiary-care medical center and an affiliated suburban community hospital. Each chart was reviewed by at least two investigators. Sample charts were reviewed by all three principal investigators to assess interrater agreement. Although none of the three investigators were blinded to the study hypothesis, the chart elements of interest were clearly defined and objective, mitigating the need for interpretation of ambiguous elements.

Patient information was de-identified to secure patient confidentiality. The study was reviewed and approved by a single institutional review board that reviews research for the health system.

Eligible patients were between the age of 18 and 45 years old who had presented to one of two emergency departments between March 8–April 4, 2020, and tested positive for SARS-CoV-2 on real-time reverse transcription polymerase chain reaction via nasopharyngeal swab. Patients who were pregnant (upon history or laboratory investigation) were excluded from the study. Although the decision to test a patient for SARS-CoV-2 was at each physician's discretion on a case-by-case basis, they were expected to follow institutional policy in accordance with the Centers for Disease Control and Prevention's "Priorities for Testing Patients with Suspected COVID-19 Infection."⁹ Patients who were discharged from the hospital before test results returned were followed up via phone call by an emergency provider. Patients who were discharged and had not returned to the hospital system after the follow-up period were assumed to be alive and not admitted elsewhere.

A total of 210 patient charts were included in the study. Demographic data (age, gender, BMI) and the presence or absence of three primary outcomes (in-hospital mortality, need for invasive mechanical ventilation, and admission to hospital) were recorded. We analyzed baseline characteristics of the cohort using descriptive statistics. Odds ratios were calculated to assess associations between outcomes and BMI.

RESULTS

Of 210 eligible patients, 18 died during hospitalization (9%), 35 (17%) required mechanical ventilation, and 94 (45%) were admitted to the hospital. Of 116 discharged patients, 103 (89%) were successfully followed up and confirmed to be alive in home-quarantine within one week of ED presentation. Of this group, one patient was reported to be admitted to another hospital.

Descriptive statistics by outcome are shown in the Table. Patients who died had a mean BMI of 37.97 (+/- 7.27) compared to 29.75 (+/- 6.21) for those who were alive at the end of the study period. Patients who required mechanical

Table. Descriptive statistics by outcome.

Group	Mean BMI	SD	Sample size	Range
In-hospital mortality	37.97	7.27	18	24.98-58.48
Alive at end of study period	29.74	6.21	192	19.28-55.32
Required mechanical ventilation	35.72	6.98	36	23.94-58.48
Did not require mechanical ventilation	29.82	6.95	174	19.38-47.48
Admitted to hospital	32.47	7.28	94	20.76-58.48
Discharged from ED	29.3	6.49	116	19.38-47.48

BMI, body mass index; *SD*, standard deviation; *ED*, emergency department.

In-Hospital Mortality			Mechanical Ventilation			Admission		
	Yes	No		Yes	No		Yes	No
BMI >30	15	85	BMI >30	29	71	BMI >30	57	43
BMI <30	3	107	BMI <30	7	103	BMI <30	37	73
OR: 6.29 95% CI: 1.76 to 22.46 p = 0.0046			OR: 6.01 95% CI: 2.5-14.48 p = 0.0001			OR: 2.62 95% CI: 1.49-4.58 p = 0.0008		

Figure. Odds ratio for BMI and primary outcomes. BMI, body mass index; OR, odds ratio; CI, confidence interval.

ventilation had a mean BMI of 35.72 (+/- 6.98) compared to 29.82 (+/- 6.95) for those who did not. Patients who were admitted to the hospital had a mean BMI of 32.47 (+/- 7.48) compared to 29.3 (+/- 6.49) for those who were discharged.

Each of the three primary outcomes were significantly associated with a BMI >30 as shown in the Figure (mortality OR = 6.29, 95% CI, 1.76-22.46, p = 0.0046; mechanical ventilation OR = 6.01, 95% CI, 2.5-14.48, p = 0.0001; admission OR 2.61, 95% CI, 1.49-4.58, p = .0008).

At the end of our study period, two patients who required mechanical ventilation (both with BMI >30) remain admitted to an intensive care unit. One was transferred to another hospital for extracorporeal membrane oxygenation. Therefore, that patient's final disposition (i.e., discharge or death) is not known.

DISCUSSION

Although previous studies representing different cohorts address obesity when describing clinical characteristics of COVID-19 patients, we are the first to address obesity as a potential independent risk factor for adverse outcomes specific to adults 45 years old and under with COVID-19. A recent, single-center study from New York University concluded that obesity in adults under 60 is a risk factor for hospital admission and need for intensive care but did not investigate mortality or need for mechanical ventilation.¹⁰ Until recently, obesity may have been overlooked as a meaningful risk factor, as countries such as China, South Korea, and Italy have far lower rates of obesity than the US. Our findings agree with evidence from the H1N1 outbreak in 2009, in which the presence of obesity was associated with poor outcomes including mechanical ventilation requirement and mortality.

LIMITATIONS

As a two-center, retrospective case-control study, our study has limitations. The patient sample from this relatively small geographic area may not be representative of all other populations, and therefore may limit generalizability. In addition, co-morbid conditions such as diabetes or hypertension were not accounted for, which may have an impact on the clinical course of COVID-19. It is worth noting, however, that a substantial number of (43%) these young patients did not have a primary care physician

and therefore were likely unaware of the presence of any co-morbid conditions. Of note, such comorbidities are often encompassed under the umbrella term "metabolic syndrome," which many obese patients possess. Next, although we had a relatively high follow-up rate, it was assumed that discharged patients who did not return to the hospital system were alive and not admitted elsewhere, potentially impacting the accuracy of our results. Finally, this cohort likely represented a sicker group than the general population, as only patients who were selected for testing and tested positive were included in the study.

CONCLUSION

Obesity appears to be an independent risk factor for poor outcomes in young patients with COVID-19. Future studies examining the clinical characteristics and risk factors of COVID-19 patients across large, diverse populations will strengthen our understanding of this novel and complex disease.

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The Next Pandemic: Prepare for “Disease X”

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The COVID-19 pandemic will, slowly, and with some hiccups and many tragedies, pass into memory. This coronavirus may disappear and later recur, continue endemically under vaccine control, or simply attenuate and vanish.¹ The economy and healthcare systems will return to a new normal, some parts more quickly than others. Like the multiple plagues humanity has endured since our ancestors gathered into cities, it will generate recriminations for slow and misguided responses, profiteering, and over- or underreacting to economic, social, and healthcare events that will, retrospectively, be obvious.² The individuals and organizations most culpable for exacerbating the disaster (e.g., many national and some state political leaders) will escape responsibility while they scapegoat others and try to re-write history. Heroes, whether individuals who helped provide clear risk communication and leadership (e.g., Anthony Fauci, MD, of the National Institutes of Health; Sanjay Gupta, MD, of CNN; and Li Wenliang, MD, who died while trying to notify the world about the pandemic) or groups that persevered in the face of fear and life-threatening danger (e.g., emergency department, intensive care unit, emergency medical services, and other critical healthcare staff and first responders) will emerge. Without fanfare, most will return to their normal jobs, scarred but proud of their efforts. As they have before, pundits and scholars will write endlessly about the pandemic’s cause, effects, and ways to ameliorate the next pandemic’s brutal destruction of lives and ways of life. The problem is, we have done all this before and seem not to have learned the lessons our predecessors taught.

To most people, COVID-19 appears to be an anomaly; it isn’t. The 20th century began with devastating waves of Spanish flu that killed from 50 million to 100 million people

worldwide. About one new disease is emerging each year.¹ Not all have human-to-human transmission, but enough do (e.g., severe acute respiratory syndrome, Middle East respiratory syndrome coronavirus, Ebola virus disease) to scare those tasked with monitoring the world’s health. To highlight the danger and to prioritize research, each year the World Health Organization (WHO) commissions an expert committee to update its list of the most threatening infectious diseases that lack effective treatments or vaccines. The current list (Table 1) contains COVID-19.³ That is no surprise, given that the entire world is now focused on that pathogen. What should act as a wake-up call to seriously fund the surveillance of, research into, and treatment of the wide variety of potential pandemic agents is the entity at the end of the short list: Disease X. Since 2015, the WHO has used this designation for a disease that could cause a pandemic due to a pathogen currently unknown to cause human illness. Last year’s Disease X now has a name, COVID-19. The next unknown and unnamed entity may already be lurking.

One might ask: Why don’t we devise a plan to identify such pathogens early and mobilize scientists, the healthcare community, politicians, and the populace to fight these scourges? The answer is, we already have. We know what steps to take to limit a pandemic. WHO, the Centers for Disease Control and Prevention (CDC), and the Departments

Table 1. World Health Organization list of emerging diseases for research prioritization.³

- COVID-19
- Crimean-Congo hemorrhagic fever
- Ebola virus disease and Marburg virus disease
- Lassa fever
- Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome (SARS)
- Nipah and henipaviral diseases
- Rift Valley fever
- Zika
- Disease X

Table 2. Lessons learned after SARS: preparation, management, and risk communication.^{1,6,7,11}

1. **More pandemics will appear.** Be prepared. COVID-19 will not be the last new disease to take advantage of modern global conditions. Continued vigilance is vital. Preparation includes enhancing the integration and effectiveness of the public health, healthcare, and emergency management systems through education, supplying adequate provisions, and drills as well as developing incentives (eg, tax credits, identified cost savings) that increase the number of nongovernmental entities engaged in actions that enhance their communities' health security.
2. **Report cases early.** Global health security requires promptly identifying and reporting cases of any disease with the potential for international spread. Concealing these cases or denying that they exist carries the potential for enormous human suffering and death, loss of international credibility, negative domestic and regional economic impact, and a very real risk the outbreak will spiral out of control.
3. **Alert the world.** As soon as an emerging and transmissible infection is confirmed, international bodies, such as WHO, must issue a global alert through all available communication modalities.
4. **Promote international scientific collaboration.** The world's scientists, clinicians, and public health experts must act collaboratively to investigate, control, and, if possible, eliminate the disease.
5. **Provide leadership and consistency.** Coordinating messages and policy among federal, state, and local health officials and affected institutions is critical to avoiding contradictions and confusion that can undermine public trust and impede containment measures. To build public trust and cooperation, provide continuous, accurate, and science-based information on what is known and not known about the disease. Information should be technically correct and sufficiently complete to support policies and actions without being patronizing. Minimize duplication of, and ensure coordination between federal, state, local, and tribal authorities.
6. **Avoid speculation.** During an outbreak, limit officially disseminated information to specific data and results; messages should omit speculation, over-interpretation of data, overly confident assessments of investigations and control measures, and comments related to other jurisdictions. Rumors, misinformation, misperceptions, and stigmatization of affected groups must be addressed promptly and definitively.
7. **Provide safety guidelines.** It is essential to provide guidance to the public on actions to take to protect themselves and their family members and colleagues. Assess healthcare system cybersecurity and develop alternative plans for any cyberincident.
8. **Institute travel limitations and screening.** Implement appropriate travel restrictions and airport screening to contain the international spread of an emerging infection. Airport screening may include passive passenger screening using questionnaires or sophisticated infrared equipment to screen all passengers for fever and indications of possible exposure, as well as health worker-conducted interviews.
9. **Implement early and consistently support containment, testing, and aggressive contact tracing.** In the absence of a curative drug or preventive vaccine, well-known public health interventions can effectively contain an outbreak. The methods include active surveillance of suspected contacts, self-surveillance by contacts who voluntarily isolated themselves, and widespread testing, social distancing, and quarantine.
10. **Stockpile necessary medications and equipment.** Enhance the national capability to produce and effectively use both medical countermeasures and nonpharmaceutical interventions, including those needed for both the acute and the chronic conditions.
11. **Bolster national healthcare infrastructures.** A high priority is improving existing healthcare systems' weaknesses that permit emerging infections to amplify and spread and that can compromise patient care. This includes having adequate materials and capacity for expected surges of infected patients, including hospitals and other healthcare facilities.
12. **Protect healthcare workers.** The people at greatest risk for contracting the disease are health workers, including first responders. This requires working with professional societies to improve strategies (including PPE use) to protect healthcare workers. Special vigilance must be paid to women, who staff the lower ranks of health personnel in many countries.
13. **Do just-in-time professional education.** Educate healthcare workers and public health staff on appropriate strategies to recognize the disease and to implement control measures.
14. **Prepare the public.** Recognize that preparation for and control of pandemics are extremely disruptive and consume enormous resources at levels that might not be sustainable over time.

WHO, World Health Organization; SARS, severe acute respiratory syndrome; PPE, protective personal equipment.

of Homeland Security and Health and Human Services have produced and disseminated detailed plans.⁴⁻⁷ After the SARS pandemic, for example, WHO itemized the steps needed to control a pandemic (Table 2). These vital steps were ignored during the initial period of the COVID-19 pandemic.¹ WHO, chronically underfunded, is saddled with a bloated, slow, and uncoordinated bureaucracy that has to answer to 194 countries. It has been condemned for both overreacting (2009 H1N1 pandemic) and severely underreacting (2014 Ebola epidemic and the COVID-19 pandemic) and for failing

to act.⁸⁻¹¹ The CDC is chronically underfunded and has no political power. Academics are voices in the wilderness whose advice is usually sought too late in the process for it to have much effect.

As the COVID-19 threat lessens, politicians will make grand promises to implement plans to stop, or at least to prepare for, the next pandemic. The recovering economy will be too weak at first to support the effort, although more funding will be promised in the future. Politicians will ultimately make changes that are politically expedient and

will fail to authorize the changes necessary to produce faster, more flexible responses. The memories of angst and societal disruption during COVID-19 will recede. Our bulwarks against pandemic diseases will remain underfunded and inadequate to the task. Even so, multiple Disease Xs are clearly in our future; we need to be prepared.

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Closure in the Time of COVID-19

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“I was able to tell him that I am naming my son after him,” she confessed. I found myself more emotional than anticipated by this stranger’s news. I met Sarah (name has been changed) a week prior to this phone call, because, as a doctor in the emergency department, I had treated her in our “COVID tent.” Like the majority of patients battling COVID-19, she was medically stable and safely discharged home to endure the path toward physical recovery.

However, before her discharge, Sarah pulled two Ziploc bags out of her purse. Each was neatly labeled with a name, holding a cell phone and charger inside. One bag had the name of her father; the other bag had the name of her grandfather. They were not as lucky in their battles against the COVID-19 virus, as they were currently fighting for their lives in our hospital. Sarah’s only request was to find a way to get these phones to them, so that she and the rest of her family could hear their voices again.

Our hospital, like most facing this pandemic, has a very restricted visitor policy in order to “flatten the curve.” Families are unable to sit at the bedside of their sick loved ones. Time that is often spent comforting one another, sharing information, or even “getting affairs in order” is now stolen away by the intensely isolating conditions required for managing this contagion. I was at the end of my shift, and therefore a bit more free to deliver these phones to her family’s nurses. This was a small and simple act, compared to other acts of heroism performed at the hospital each day, yet I could not predict how important this technological connection would be to the family at large.

I called Sarah a week after our ED visit to check on her, since she was six months pregnant and fighting her own COVID infection. She relayed that she was recovering well. She then expressed her gratitude for the delivery of the cell phones. With them, she was able to have many deep conversations with her father over the subsequent three days. “I got to tell him that I love him. I got to tell him that I and my [unborn] baby are okay. And I got to tell him that I will be naming my son after him.”

Sarah went on to tell me that her father died that morning.

She lost her father, but her last memories of him are filled with meaningful conversations. Sarah expressed how much that meant for her to have closure.

Even after her father died, her grandfather remained in the hospital, slowly losing his battle against COVID. As his body continued to falter, they were able to bring him home on hospice, to be with the family before his death. He was able to come home because a phone was plugged in and voices connected.

This simple act of delivering these cell phones allowed Sarah to bring some sort of closure during these tragic and sudden losses. As healthcare workers, we are on the front lines fighting with our patients against COVID-19. Most of our patients do well. Unfortunately, many do not survive. However, we can help every patient and family to retain their humanity in this overwhelming time. Every little thing we do makes a difference in the lives of our patients and their families.

The COVID-19 pandemic has forced clinical providers to adapt nearly every part of our practice to provide medical care for patients, and we also need to evolve how we support their loved ones coping with the multiple levels of separation. As frontline providers, when we treat family members in the ED then we have the chance to help them make connections with their family upstairs. While we do not always see the downstream effects, even the small acts can make a major positive impact for our patients. We need to focus on helping our patients and families to connect in these dire times. That connection can allow the patients, families, and even providers, to find closure and meaning, even if cure and simple physical proximity are unattainable.

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Brief Review of Chloroquine and Hydroxychloroquine Toxicity and Management

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As of April 21, 2020, more than 2.5 million cases of coronavirus disease 2019 (COVID-19), caused by the SARS-CoV-2 virus, have been reported in 210 countries and territories, with the death toll at 171,810. Both chloroquine and hydroxychloroquine have gained considerable media attention as possible therapies, resulting in a significant surge in demand. In overdose, both medications can cause severe, potentially life-threatening effects. Here, we present a brief overview of the pharmacology of chloroquine and hydroxychloroquine, manifestations of toxicity, and treatment considerations. [West J Emerg Med. 2020;21(4)760–763.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

As of April 21, 2020, more than 2.5 million cases of coronavirus disease 2019 (COVID-19), caused by the SARS-CoV-2 virus, have been reported in 210 countries and territories, with the death toll at 171,810.¹ While extensive research is underway to evaluate the efficacy of numerous antiviral and other immunomodulatory medications against COVID-19, chloroquine (CQ) and hydroxychloroquine (HCQ), in particular, have gained considerable attention. Data to support the use of CQ and HCQ for COVID-19 are limited and inconclusive, as its use against SARS-CoV-2 has been demonstrated in vitro and in small, poorly controlled, or uncontrolled clinical trials.²⁻⁴

Since being prominently featured in the press as a potential COVID-19 therapy, demand for CQ and HCQ has exploded. On March 31, 2020, the United States Food and Drug Administration added both medications to its drug shortages webpage due to a significant surge in demand.⁵ Soon after, the California Department of Consumer Affairs reported that healthcare providers were wrongfully hoarding and prescribing CQ or HCQ for themselves and family members for COVID-19 prophylaxis despite a lack of evidence to support this use.⁶ In

response, several states have issued emergency restrictions on how CQ and HCQ can be dispensed.

Unfortunately, the media attention and the increase in usage of CQ and HCQ do not come without significant consequences. Both medications, when taken in overdose, can cause severe, potentially life-threatening effects. On March 23, 2020, an Arizona man died after an overdose of chloroquine phosphate, formulated as an aquarium cleaner.⁷ In light of recent events, we anticipate emergency departments may see a rise in cases of acute and chronic toxicity from CQ and/or HCQ. Here, we present a brief overview of the pharmacology of CQ and HCQ, manifestations of toxicity, and treatment considerations.

PHARMACOLOGY & PATHOPHYSIOLOGY

The structurally related compounds CQ and HCQ have historically been used for the prophylaxis or treatment of malaria and share many therapeutic and pharmacokinetic properties. HCQ differs from CQ only by a hydroxyl group, but is considered less potent and is 40% less toxic than CQ in animal models (Figure 1).⁸ Both CQ and HCQ interfere with multiple intracellular processes, resulting in antimalarial, anti-inflammatory, and immunomodulating effects. The anti-inflammatory effects are more pronounced in HCQ, making it useful for the treatment of rheumatoid arthritis and systemic lupus erythematosus.⁹

Oral CQ and HCQ are rapidly and completely absorbed from the gastrointestinal tract with peak whole blood levels

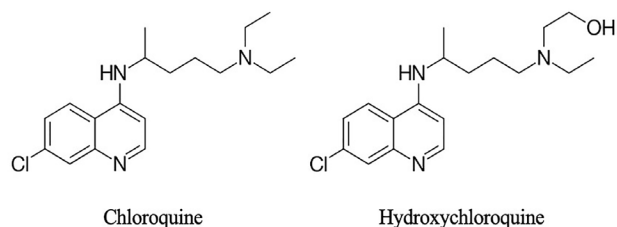


Figure 1. Structural comparison of chloroquine and hydroxychloroquine.¹⁰

reached 1-3 hours after ingestion.¹⁰ It is this peak level that is responsible for the rapid onset of severe symptoms and most correlates with mortality risk in acute overdose.¹¹ Both CQ and HCQ are metabolized by cytochrome (CYP) P450 enzymes. Therefore, concomitant use of CYP2C8 (clopidogrel, gemfibrozil), and CYP3A4/5 (azole antifungals, ciprofloxacin, diltiazem, macrolides, verapamil) inhibitors may raise CQ and HCQ blood levels.¹² Due to the large volume of distribution and strong tissue-binding properties of these drugs, the terminal half-life is 5-12 days for CQ and 1-2 months for HCQ.¹⁰ Severe symptoms generally occur over several hours, but patients can have evidence of ongoing toxicity for days following ingestion.

CQ and HCQ are structural derivatives of quinine and share pathophysiologic mechanisms of toxicity. These drugs have direct cardiovascular toxicity through blockade of voltage-dependent sodium and potassium channels.¹³ This provides the cellular mechanism for the observed QRS and QT interval prolongation (Figure 2). Hypotension and cardiogenic shock are due to direct cardiodepressant effect rather than peripheral vasodilation.¹⁴ Hypokalemia is common, especially in acute CQ overdoses, and is likely due to an intracellular shift in potassium and not a true, total-body potassium deficit.¹⁵

CLINICAL MANIFESTATIONS

CQ and HCQ toxicity is rapid in onset and potentially life-threatening. Severe effects have been associated with ingestion of 5 grams or more of CQ, including systolic blood pressure less than 80 millimeters of mercury, QRS complex duration of 120 milliseconds or more, and hypokalemia (less than 3 millimoles [mmol] per liter [L]). Serum concentrations of CQ greater than 8 micrograms (mcg) per milliliter (mL) have also been associated with severe poisoning, but CQ or HCQ concentrations are unlikely to be readily available during initial assessment and management.¹⁶ Respiratory depression, central nervous system depression, and seizures have also been described in acute poisoning.¹⁷

The cardiovascular effects of CQ and HCQ may be precipitous and are frequently the primary cause of mortality. Both drugs act as Vaughan-Williams Class IA antidysrhythmics with “quinidine-like” effect. Electrocardiogram (ECG) changes due to sodium and potassium channel blockade are evident with QRS interval widening, QT prolongation, ST segment

Population Health Research Capsule

What do we already know about this issue?
Chloroquine and hydroxychloroquine have gained media attention as possible therapies for coronavirus disease 2019, but both can cause potentially life-threatening effects.

What was the research question?
We present an overview of the pharmacology, toxicity, and treatment of chloroquine and hydroxychloroquine overdose.

What was the major finding of the study?
Acute toxicity is characterized by direct cardiotoxicity. Supportive care is the mainstay of treatment.

How does this improve population health?
Clinicians may see a rise in cases of acute and chronic toxicity from chloroquine and hydroxychloroquine and should be familiar with management strategies.

depressions, atrioventricular block, and the appearance of U waves.¹⁰ Cardiac dysrhythmias, including ventricular tachycardia, ventricular fibrillation, and torsade de pointes may result. Hypotension occurs early, is often severe, and progresses rapidly to cardiogenic shock.¹⁷

Despite severe effects in large, acute ingestions, CQ and HCQ are generally well tolerated at therapeutic doses with mild adverse effects. Common effects are nausea, diarrhea, anorexia, abdominal cramps, rash, and alopecia.¹² Rarely, sensorineural deafness, visual disturbances, corneal opacities, and irreversible retinopathy can occur with cumulative doses exceeding 100 grams, which usually occurs when CQ and HCQ are dosed as anti-inflammatories.⁹ In addition, agranulocytosis, aplastic anemia, hypersensitivity reactions, hepatitis, myopathy, neuropathy, and cardiomyopathy have been reported with chronic use. CQ and HCQ can act as oxidant stressors, resulting in hemolysis in patients with G6PD deficiency.¹⁰

CLINICAL MANAGEMENT

Aggressive symptomatic and supportive care is the mainstay of treatment for both CQ and HCQ overdose. In addition to stabilization of the airway, breathing, and circulation, the patient should receive intravenous (IV) access as well as continuous cardiac monitoring. Serial ECGs should be obtained to monitor for QRS and QT interval prolongation. CQ and HCQ are well absorbed by activated charcoal, and thus should be administered

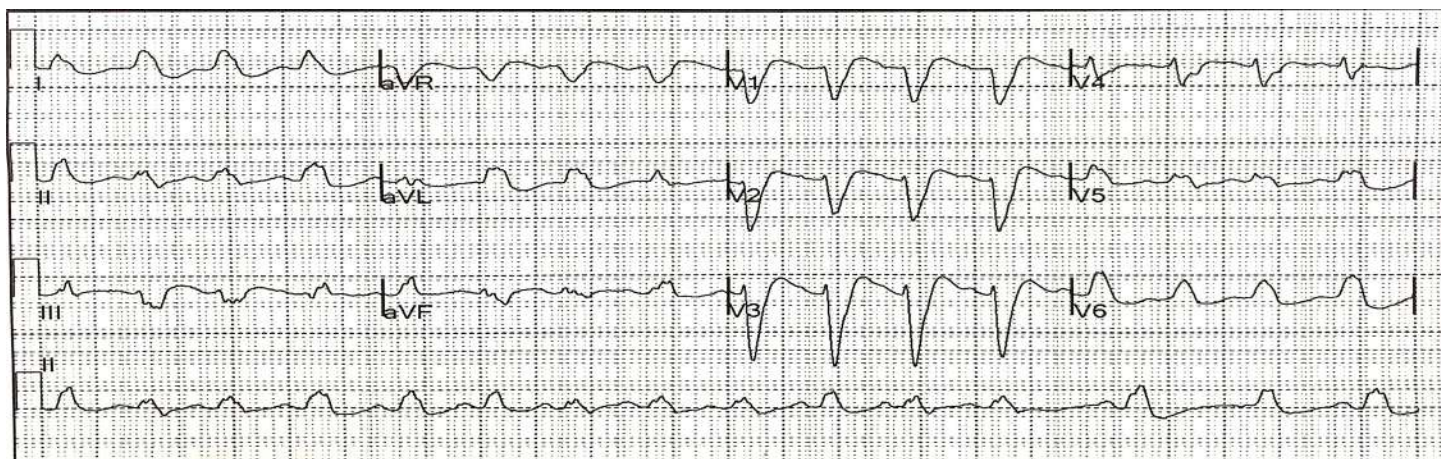


Figure 2. Electrocardiogram from patient with acute hydroxychloroquine overdose demonstrating QRS interval widening (QRS interval = 254 milliseconds).

if the risk for aspiration is low. Additionally, given the life-threatening nature of CQ and HCQ poisoning, decontamination with gastric lavage can be considered in cases of a large overdose and if the patient presents soon after ingestion. A medical toxicologist or poison control center should be contacted to assist with management.

Boluses of sodium bicarbonate (1-2 milliequivalents per kilogram [kg] IV) should be provided for QRS interval prolongation to counteract the effects of sodium channel blockade. Of note, the serum alkalinization that results from sodium bicarbonate administration may exacerbate the pre-existing hypokalemia seen from toxicity, which can contribute to further dysrhythmias. However, several reports have suggested that hypokalemia may be protective in severe CQ poisoning.¹⁸⁻²⁰ Therefore, replacement of potassium is controversial in the setting of acute toxicity, although we believe it would be reasonable to treat severe hypokalemia (i.e., < 2 mmol/L). Cases of rebound hyperkalemia have been reported once toxicity resolves; therefore, serial potassium levels should be obtained.^{8,19}

Both diazepam and epinephrine have been suggested as specific treatments for CQ and HCQ toxicity. In observational studies, patients with mixed overdoses of diazepam and chloroquine had less toxic effects than those who ingested chloroquine alone.^{11,19} Diazepam is believed to decrease CQ and HCQ induced-vasodilation and have central antagonistic, anticonvulsant, and antidysrhythmic effects.¹⁰ We recommend that patients with severe CQ and HCQ symptoms receive high-dose diazepam therapy (2 milligrams/kg IV over 30 minutes). Because high-dose IV epinephrine (0.25 micrograms/kg per minutes [mcg/kg/min], increasing by 0.25mcg/kg/min until adequate systolic blood pressure) has been the most extensively studied in cases of CQ- and HCQ-induced hypotension, epinephrine is the vasopressor of choice in these specific ingestions.^{16,21} Additionally, combining high-dose diazepam and high-dose epinephrine has shown a potential mortality benefit when compared to controls.¹⁶ Like sodium bicarbonate,

high-dose epinephrine may worsen pre-existing hypokalemia. Finally, a trial of 20% IV fat emulsion (Intralipid) may be indicated in refractory cases, but extracorporeal membrane oxygenation will provide greater benefit if available.^{22,23}

SUMMARY

Poisoning from CQ or HCQ can be life-threatening and may become more frequent with increased media attention and use during the COVID-19 pandemic. Acute toxicity is characterized by direct cardiotoxicity, hypokalemia, and precipitous cardiovascular collapse. Treatment includes aggressive gastrointestinal decontamination, sodium bicarbonate for QRS interval widening, and high-dose diazepam and epinephrine in patients with severe toxicity and evidence of shock.

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A Multidisciplinary Intubation Algorithm for Suspected COVID-19 Patients in the Emergency Department

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Introduction: Intubation of patients suspected of having coronavirus disease 2019 (COVID-19) is considered to be a high-risk procedure due to the aerosolization of viral particles. In an effort to minimize the risk of exposure and optimize patient care, we sought to develop, test, provide training, and implement a standardized algorithm for intubating these high-risk patients at our institution.

Methods: We developed an initial intubation algorithm, incorporating strategic use of equipment and incorporating emerging best practices. By combining simulation-based training sessions and rapid-cycle improvement methodology with physicians, nurses, and respiratory therapists, and incorporating their feedback into the development, we were able to optimize the process prior to implementation. Training sessions also enabled the participants to practice the algorithm as a team. Upon completion of each training session, participants were invited to complete a brief online survey about their overall experience.

Results: An algorithm and training system vetted by simulation and actual practice were developed. A training video and dissemination package were made available for other emergency departments to adopt. Survey results were overall positive, with 97.92% of participants feeling confident in their role in the intubation process, and many participants citing the usefulness of the multidisciplinary approach to the training.

Conclusion: A multidisciplinary, team-based approach to the development and training of a standardized intubation algorithm combining simulation and rapid-cycle improvement methodology is a useful, effective process to respond to rapidly evolving clinical information and experiences during a global pandemic. [West J Emerg Med. 2020;21(4)764-770.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

The 2019 novel coronavirus first emerged in Wuhan,

China, in December 2019 and was declared a pandemic by the World Health Organization (WHO) on March 11, 2020.¹ As the disease spread rapidly across the globe, healthcare providers who have traditionally been responsible for airway management, including emergency physicians, intensivists, and anesthesiologists, had to quickly adjust routine practices to account for concerns of exposure to, and spreading of, the virus as it was postulated to have stability in aerosolized form.²

Airway management with endotracheal intubation is a high-risk and time-sensitive medical task. It is standard practice in emergency medicine training programs to teach a systematic approach to airway management, often enlisting the use of checklists or algorithms.³ The multimodal training focuses on motor skills, assessment skills, and decision-making. However, it is uncommon to introduce education simultaneously with a systematic evaluation of iterative process changes associated with what is normally considered routine airway management care. Evaluating necessary process changes that included the complexity involved with standardizing airway, communications, and team-based skills in order to minimize aerosolization of highly infectious viral particles during intubation proved challenging.

Early data from China estimate that 3.2% of confirmed coronavirus disease 2019 (COVID-19) cases developed severe disease requiring endotracheal intubation and positive pressure ventilation at some point in their clinical course.⁴ Due to the potential for aerosolization of patient secretions during this invasive procedure, endotracheal intubation is recognized to be a high-risk procedure in terms of potential exposure and transmission to healthcare providers.⁵

As more cases emerged in the United States, process recommendations regarding intubation were made by various groups.⁶⁻⁹ Major themes of these recommendations include the use of an N95 respirator or powered air-purifying respirator (PAPR) as part of personal protective equipment (PPE) by all members of the healthcare team with direct patient contact during the procedure. Environmental considerations include the recommended utilization of a negative pressure isolation room for the procedure when possible, as well as minimizing risk by having the fewest number of providers with direct patient contact. Procedural recommendations included having the most experienced provider perform the intubation using video laryngoscopy, rapid sequence induction (RSI), and avoiding the use of non-invasive positive pressure ventilation and bag-valve-mask ventilation (BVM).

While these recommendations provide general guidance and strategies for intubating patients with either confirmed or suspected COVID-19, there is still a need to incorporate these changes at the local level. The risk of aerosolization of viral particles during the procedure requires adaptations to standard airway management algorithms and procedures, based on resources available. Without experience and training with these new methods, and without an established protocol for their implementation, there is potential for suboptimal patient care and increased risk of exposure to the healthcare team. Therefore, training healthcare providers on the new changes will help to avoid uncertainty and confusion, reduce risks of healthcare provider infection, and lead to increased first-pass success for the intubation procedure.

To implement such change, there is a need to develop and implement a stepwise process for intubation of high-risk COVID-19 patients that incorporates the newly published

Population Health Research Capsule

What do we already know about this issue?
The coronavirus disease 2019 (COVID-19) pandemic has forced healthcare providers to make adaptations to the procedure of intubation to minimize exposure risk.

What was the research question?
We sought to develop, test, and implement a standardized intubation algorithm for suspected COVID-19 patients.

What was the major finding of the study?
A simulation-vetted algorithm and training system were developed and disseminated across our healthcare system.

How does this improve population health?
Our standardized approach to intubation minimizes exposure risk, increases the quality of patient care, and can easily be adapted at other institutions.

recommendations. Changes to existing emergency department (ED) airway management routines require a multidisciplinary approach, attention to detail, and a rapid-cycle improvement process to guide the development of a new algorithm. Each cycle of testing and training needs to inform necessary changes to the developing algorithm based on the successes and identified areas that did not perform optimally.

Simulation has previously been identified as a successful tool to educate and serve as a useful framework to evaluate system change to clinical processes,^{10,11} as well as teamwork and systems-related training in critical care environments.¹² Simulation has also been described by our institution and others as a useful modality for rapid development of necessary curriculum and process validation during pandemic preparedness.¹³⁻¹⁵

The primary goal of this project was to develop and implement a standard process for intubation of all patients with suspicion for COVID-19 for the ED at our institution, employing a multidisciplinary approach using simulation and a rapid-cycle improvement methodology. We designed our revised approach to incorporate the emerging best practices including 1) minimization of exposure risk to aerosolized patient secretions; 2) optimization of the strategic use of equipment; 3) maximization of first-pass intubation success; 4) enhanced teamwork, communications and patient safety principles; and 5) incorporation of quick access to backup, emergency equipment in case of a difficult airway.

Our primary outcome was to conduct training sessions, develop a modified airway algorithm that had been tested for functional use, and create a deployable training package for dissemination across the EDs of our health system.

METHODS

Team and Equipment Deployment

Our algorithm development process was developed around a four-member team that included a physician (DR), two registered nurses (RN1 and RN2), and a respiratory therapist (RT). Three members of the team (DR, RN2, and RT) would participate in the actual procedure while RN1 would serve as logistics support outside the zone of potential contamination. A fifth person, a patient care technician (PCT), could assist RN1 as needed if available.

The first step in development of our procedural algorithm was to compile a list of standard equipment needed for intubations of infected or suspected COVID-19 patients. We first identified the minimum standard equipment and medications that would need to be prepared to enter the procedural area. The equipment is prepared on a standard bedside tray and minimized to prevent confusion and unnecessary contamination or equipment waste. The equipment to be prepared on the tray was organized into a bag labeled “Inside Bag” to indicate the contents were to go into the procedure room. Inside items included standard intubating equipment, listed in Figure 1.

A second bag, designated as the “Outside Bag,” contained items that were to be staged immediately

outside the room in which the procedure was to occur and contained what would be historically considered backup equipment for difficult airways. Outside items consisted of a cricothyrotomy kit, I-gel (Intersurgical, Berkshire UK), and gum elastic bougie. The I-gel was selected as the primary rescue device mainly due to its ease of insertion compared to other supraglottic devices. The Outside Bag is designed to remain outside of the room with the belief that it would be uncommonly needed and could remain unopened to avoid unnecessary equipment waste.

A third bag, designated the “Vent Bag,” contains items needed to initially confirm tube placement and would be carried into the treatment area along with the ventilator, and then assembled by the RT. Equipment in this bag included BVM, viral filter, PEEP (positive end expiratory pressure) valve, and colorimetric carbon dioxide (CO₂) detector. These bags were attached to each ventilator to ensure easy access and availability.

The bags of equipment were pre-assembled and stored in the designated treatment area in our ED for intubating patients suspicious of COVID-19, ensuring that they were readily available and easy to access.

Algorithm Development and Team Roles

The initiation of our procedure is triggered when the physician decides that a patient’s clinical condition requires intubation. The core management team for the patient is quickly established and the DR, RT, and RN2 don appropriate PPE. Simultaneously, RN1 begins following a checklist to accomplish STEP 1 in our procedure (Figure 1). STEP 1 focuses on preparing medications for rapid sequence induction (RSI) and post-intubation sedation, verifying that “inside items” are present, preparing the endotracheal tube (ETT) selected by the physician, and anticipating any additional procedures to be completed after intubation, such as central line placement.

Once STEP 1 is completed, the DR, RN2, and RT proceed inside the room. The DR is responsible for transporting the video laryngoscope and blades and setting up the equipment. The “inside items” (that had been prepared by RN1) are rolled in by RN2, and the ventilator and Vent Bag are transported in and set up by the RT. Our final idealized placement of equipment and providers is in Figure 2.

The RN2 then reads the pre-intubation checklist, which begins STEP 2 (Figure 3). The checklist serves as a time-out to ensure necessary equipment is present and functioning. After the initial checklist is completed, RN2 then reads the script (Figure 3), which serves as a reminder to the team about the backup plan and equipment that is immediately available, should intubation prove difficult.

The DR then performs the intubation. To minimize aerosolization of secretions, pre-oxygenation is delivered by face mask oxygen at 10-12 liters (L) per minute (min) with an additional 5-6 L/min of oxygen delivered via nasal

STEP 1 - INITIAL CHECKLIST

Team:
 Inside room: DR, RT, RN2
 Outside room: RN1, PCT (prn)

OUTSIDE THE ROOM CHECKLIST

- Confirm with DR:
 - RSI meds
 - ETT (Initial size and back-up size)
 - Sedation med plan
 - Post-intubation vascular access needs
- Inside team dons appropriate PPE
- Establish communication plan for when door to room closes
- Prepare Inside Room Tray:
 - One ETT (size per DR),
 - Stylet
 - Syringe
 - Balloon check
 - Lubricant
 - OG/NG tube
 - Stethoscope
 - Inside room checklist on tray
 - Yankauer + suction tubing (if not in room)
- Prepare sedation meds (pump if needed)
- Crash cart near room
- Line cart, IO (PRN)
- Confirm Outside Room Bag is present
- Confirm RT present + vent + vent bag

Figure 1. Step 1 of COVID-19 intubation algorithm. DR, physician; RT, respiratory therapist; RN, registered nurse; PCT, patient care technician; RSI, rapid sequence intubation; ETT, endotracheal tube; PPE, personal protective equipment; OG/NG, orogastric, nasogastric; IO, Intraosseous infusion; PRN, as necessary.

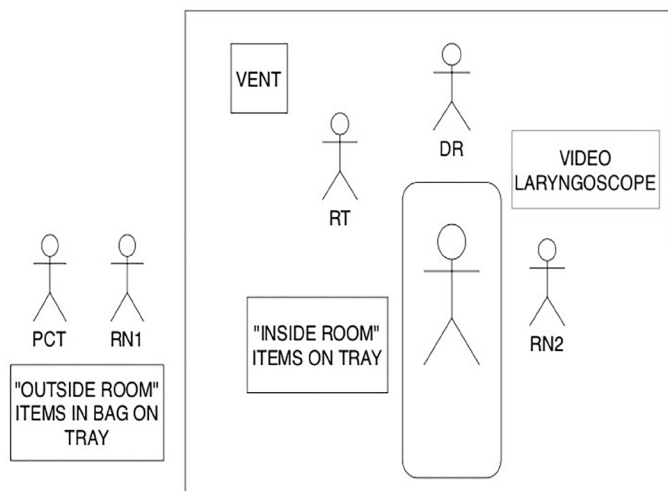


Figure 2. Layout of core management team and equipment for intubation.

RT, respiratory therapist; DR, physician; RN, registered nurse; PCT, patient care technician.

cannula, which remains in place upon removal of face mask. This method provides apneic oxygenation, reducing the potential need for BVM or positive pressure ventilations. If the intubation is successful the BVM, pre-fitted with a viral filter and a CO₂ detector, is connected and up to five shallow breaths are given to confirm tube placement with the colorimetric device.

The BVM is then disconnected, and the DR quickly covers the disconnected ETT with his or her thumb while the patient is hooked up to the vent circuit. The RT then holds the ETT while the DR places an orogastric or nasogastric tube. The DR then holds the tube while the RT places the tube-holder and secures the ETT. Once the tube has been secured, RN2 will then read the script (Figure 3), prompting the DR to place any additional lines or other invasive procedures before doffing PPE. This ensures that all lines will be placed prior to radiograph confirmation, attempting to minimize exposure to radiology technicians and conserve PPE. The pre-identified, post-intubation sedation plan will then be implemented.

In the event of a difficult airway or failed first attempt, we incorporated an early activation of a backup plan (that is appropriate for the given facility) into our algorithm. Thus, if the DR requests the Outside Bag, RN1 would also call for additional help. If the airway proved difficult and intubation is not successful within a reasonable time, or if the patient decompensated, we encouraged placement of the I-gel backup device and ventilation through the I-gel until additional resources arrived. This is based upon previous studies demonstrating the I-gel to be the quickest device to be used to secure the airway while wearing PPE.¹⁶ The DR also has the option to perform a cricothyrotomy if clinically indicated.

Training, Refinement and Implementation

Upon completion of the initial version of the intubation algorithm, we partnered with the Winter Institute for Simulation, Education and Research (WISER) to conduct simulation-based training sessions. WISER is the simulation institute of the University of Pittsburgh and the UPMC Health System and is accredited by the Society for Simulation in Healthcare in the areas of Teaching/Education, Assessment, Research, and Systems Design. The simulation training sessions were strategically designed to teach a refresher of airway management as modified for the pandemic, but also to study our new processes, incorporating the necessary teamwork and communications to allow for rapid optimization. In addition to standard simulation-based training, we employed the Plan-Do-Study-Act (PDSA) rapid-cycle improvement process to evaluate the need for refinements of our process changes as well as our educational content.

We held seven days of multiple one-hour sessions for multidisciplinary training, deliberate practice, and process refinement. Participation was voluntary. DRs were recruited via email and could select a convenient time over the available training days. RNs and RTs were recruited from those working in the department, as identified by nursing and RT leadership as the most convenient way to maximize both availability and participation. The training sessions were conducted in situ within our ED.

Primary goals of the training sessions were to have participants practice their roles associated with the new process while working as a team, to recognize some difficulties associated with PPE that may not be routinely used, and to recognize the effectiveness of checklist and standardized processes. The secondary goal of the training sessions was to identify process changes that could be implemented successfully, as well as those requiring revisions or removal from the redesigned intubation process. Participants were allowed to practice as many times as desired, using actual equipment and an intubating mannequin.

Following each training session, a debriefing was held to help to ensure participant understanding of the material as well as to solicit their professional input into the redesigned system. Based on the observations and feedback of participants comprising the core team, numerous changes were made over a short period of time to enhance the algorithm. By the fourth day of training and study, there were no major changes identified for the algorithm and it was then trialed in our department.

Upon completion of the training session, participants were invited to complete an online (SurveyMonkey), seven-question survey focusing on reaction (Appendix A). The course evaluation was approved by our institution's institutional review board (approval #PRO13040395). The link to the survey was emailed to participants. The survey consisted of basic information including role (physician, RT, RN), and prior use of PAPR for intubation, followed by four 5-point Likert-scale items (scored from strongly disagree to

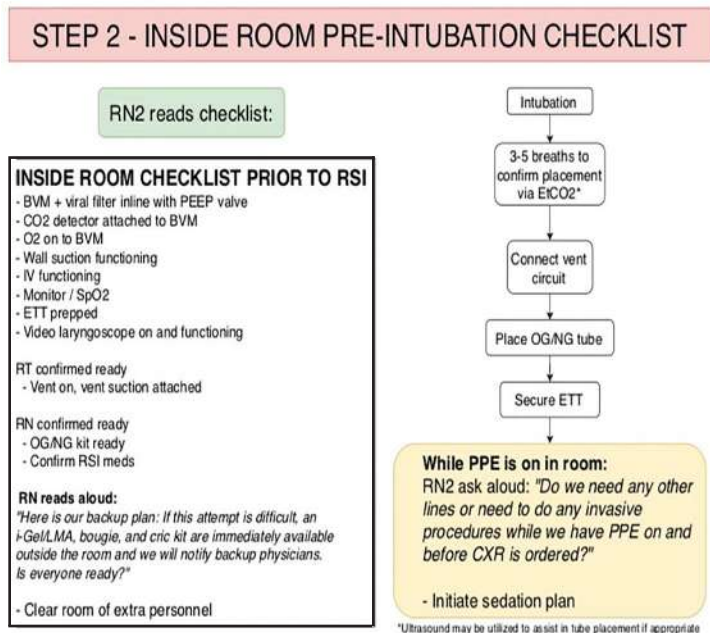


Figure 3. Step 2 of COVID-19 intubation algorithm.

BVM, bag-valve mask; PEEP, positive end expiratory pressure; CO₂, carbon dioxide; O₂, oxygen; SpO₂, peripheral capillary oxygen saturation; RT, respiratory therapist; RN, registered nurse; LMA, laryngeal mask airway; RSI, rapid sequence intubation; ETT, endotracheal tube; EtCO₂, end-tidal carbon dioxide; PPE, personal protective equipment; OG/NG, orogastric/nasogastric; CXR, chest radiograph.

strongly agree with a neutral option) to assess the educational objectives of the session. Finally, there was one final, open-text item asking for any additional feedback or suggestions. To increase response rates, we sent another email five days later as a reminder to participants.

RESULTS

Two intubations of real patients were carried out using the new system by two of us on the core team. (PP and GS). A post-procedural multidisciplinary debriefing was held and resulted in several more changes to the algorithm. The algorithm underwent a total of 17 iterations of substantial change. Following the live patient validation and subsequent adjustments, an online video training overview was created and bundled with a package of PDFs to create print materials. This allowed for dissemination across our health system to facilitate rapid implementation at facilities that had a perceived need for such a systematic change.

A total of 54 participants completed the training course over the initial seven sessions. We received 48 total responses (19 DRs, 28 RNs, and one RT), for a response rate of 88.8%. Survey results were largely positive. Specifically, there was a positive improvement in level of confidence with one's role in the intubation process. Prior to the course, only 32.33%

selected either "agree" or "strongly agree" to the item, "Prior to taking this course, I felt confident with my role in the intubation process of high-risk COVID patients." However, after completing the course, 95.74% selected either "agree" or "strongly agree" to the item, "After completing this course, I feel confident with my role in the intubation process of high-risk COVID patients." Further, 97.92% selected either "agree" or "strongly agree" to the item "I would recommend this course to other healthcare providers." Most participants (93.75%) also felt that the course enhanced their team communication skills (question 6).

We received 18 responses for the open-ended item, with feedback overall positive. Many of the responses highlighted the usefulness of the training overall, expressing gratitude for the dedicated time to physically practice. One major theme, however, was the effectiveness of the multidisciplinary, team-based approach, which was highlighted by the following comments:

Very educational. There was a lot of open discussion and suggestions were bounced back and forth which was nice.

The Intubation Simulation was excellent! It was very helpful to have staff with different areas of expertise providing input from their experiences & suggesting ways to improve our performance & decrease our risk for an exposure. Thank you for taking the time to facilitate this!

This was high yield, manageable length, and extremely team based. I'm glad we were able to do it within the clinical setting in which we work.

Areas of improvement suggested from the open-ended feedback included using different scenarios to allow for more practice and providing a finalized list of the algorithm for those who participated early in the course before the final changes were implemented, the latter of which was satisfied with the online materials distributed across the health system.

DISCUSSION

What is unique to our algorithm and training sessions is that we combined training with evaluation and iterative practice improvement into a rapid cycle re-design of traditional airway practices. We incorporated multidisciplinary practice and were able to incorporate the suggestions of practicing professionals near-real time for system optimization. Through the first four sessions, we made multiple revisions to the algorithm.

Examples of major revisions included methods for covering the tube after the intubation while the ventilator circuit was being attached. A number of other revisions were also made, addressing specific placement of equipment in the room and adding equipment to the "inside items" (marker for labeling RSI medications), as suggested by nurses. Finally, different methods of communication between the team inside

the room and the nurse and PCT outside the room were also tested, with the final decision to use readily available baby monitors. The original solution of using Spectralink phones was found to be unsuccessful during the first of the trials involving an actual patient.

Although we did want to standardize the intubation process for patients with suspicion for COVID-19 as much as possible, the algorithm still allows some room for incorporating individual physician clinical decision-making. Recognizing different physician preferences in medications for RSI as well as post-intubation sedation, for example, we did not mandate the exact drug regimen in our algorithm. Selection of ETT size, method of backup plan, and placement of central or arterial line access were similarly addressed. Due to different approaches to management of a patient's respiratory status, especially within the setting of rapidly evolving understanding of COVID-19 and its optimal management, we did not feel as though any criteria for intubation would follow a "one size fits all" mentality and should instead be considered on a case-by-case basis. Therefore, our algorithm begins after the need for intubation has been established. Our focus was on optimization of the process once the clinical decision to intubate was made.

We recognize that there have been many other proposed methods for minimizing the aerosolization of viral particles during intubation, in addition to other preferences for intubation techniques and use of backup devices. Some institutions have even incorporated specific intubation teams that intubate all high-risk patients in the hospital. We recognize that these are all acceptable strategies for addressing the common problem. We believe that the adoption of any one system is based upon the resources, experiences, and situations that are unique to the individual ED.

While we designed the details of our algorithm based on the resources available at our institution and what we determined to be the most feasible through feedback received during our training sessions, we tried to identify and include flexibility in areas we thought would have the most implementation variability. Therefore, our revised airway process recommendations could be easily adapted for use at other EDs. The basic structure and overall process are easily transferable, while specific materials and details could be adapted based on availability and preferences at other institutions. Implementation of our streamlined process could have profound effects on efficiency of patient care, patient safety, and safety of the healthcare team.

Lastly, our extensive process validation that included simulation training sessions along with debriefings after our first two experiences with actual patients allowed for the development of materials to facilitate deployment of our recommended new approach to airway management to the 19 EDs across our health system that see over 400,000 patients per year. In addition to our asynchronous training and print materials, we will be conducting train-the-trainer sessions in

collaboration with WISER to help local champions adopt our methods for their institution efficiently and effectively.

LIMITATIONS

One limitation of our work is the inability to evaluate our algorithm in a large number of actual patients. The formidable challenges imposed upon the delivery of healthcare during the pandemic combined with the need to maximize the safety of healthcare providers necessitated a rapid roll-out of our revised processes based on our findings from our rapid-cycle improvement methodology. However, we do intend to collect further feedback from real-time use. Another limitation to our report is that the analysis of our training sessions is limited to Kirkpatrick Level 1 reaction data. Given the demands of our team during the pandemic, combined with the changing details of our training sessions based on the iterative feedback, a more formal assessment was not feasible.

Future studies could address a more formal effectiveness of the training program, focusing on team-based, non-technical skills acquisition. A formal review of patient outcomes associated with the new airway management recommendations after implementation in the ED would also be appropriate.

CONCLUSION

A multidisciplinary, team-based approach to the development and training of a standardized intubation algorithm combining simulation and a rapid-cycle improvement methodology is a useful, effective process to respond to rapidly evolving clinical information and experiences during a global pandemic.

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Point-of-care Lung Ultrasound Is More Sensitive than Chest Radiograph for Evaluation of COVID-19

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Introduction: Current recommendations for diagnostic imaging for moderately to severely ill patients with suspected coronavirus disease 2019 (COVID-19) include chest radiograph (CXR). Our primary objective was to determine whether lung ultrasound (LUS) B-lines, when excluding patients with alternative etiologies for B-lines, are more sensitive for the associated diagnosis of COVID-19 than CXR.

Methods: This was a retrospective cohort study of all patients who presented to a single, academic emergency department in the United States between March 20 and April 6, 2020, and received LUS, CXR, and viral testing for COVID-19 as part of their diagnostic evaluation. The primary objective was to estimate the test characteristics of both LUS B-lines and CXR for the associated diagnosis of COVID-19. Our secondary objective was to evaluate the proportion of patients with COVID-19 that have secondary LUS findings of pleural abnormalities and subpleural consolidations.

Results: We identified 43 patients who underwent both LUS and CXR and were tested for COVID-19. Of these, 27/43 (63%) tested positive. LUS was more sensitive (88.9%, 95% confidence interval (CI), 71.1-97.0) for the associated diagnosis of COVID-19 than CXR (51.9%, 95% CI, 34.0-69.3; $p = 0.013$). LUS and CXR specificity were 56.3% (95% CI, 33.2-76.9) and 75.0% (95% CI, 50.0-90.3), respectively ($p = 0.453$). Secondary LUS findings of patients with COVID-19 demonstrated 21/27 (77.8%) had pleural abnormalities and 10/27 (37%) had subpleural consolidations.

Conclusion: Among patients who underwent LUS and CXR, LUS was found to have a higher sensitivity than CXR for the evaluation of COVID-19. This data could have important implications as an aid in the diagnostic evaluation of COVID-19, particularly where viral testing is not available or restricted. If generalizable, future directions would include defining how to incorporate LUS into clinical management and its role in screening lower-risk populations. [West J Emerg Med. 2020;21(4)771-778.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

Novel coronavirus, SARS-CoV-2, is responsible for causing the coronavirus disease 2019 (COVID-19). With an estimated case fatality rate of 1%, COVID-19 has resulted in over 305,000 deaths worldwide to date.¹ COVID-19's mortality

is primarily due to lung injury resulting in acute respiratory distress syndrome (ARDS).² The definition of ARDS has changed over time; however, using the 2012 Berlin definition it would include acute bilateral lung injury in the absence of fluid overload, causing hypoxemia and respiratory failure.³ Physicians evaluating patients may wish to order radiographic imaging to screen for findings of COVID-19, evaluate severity of pulmonary involvement, or assess for alternative etiologies of illness. Radiographic results may alter the treating physician's concern for COVID-19 thereby guiding patient counseling, or supporting clinical choices such as hospitalization, the need for closer follow-up, or anticipating complications of the disease. The American College of Radiology (ACR) recommended the use of portable chest radiograph (CXR) when medically necessary for patients with suspected or known COVID-19, which does not include screening purposes.⁴ However, it is estimated that portable CXR is only 69% sensitive for findings of COVID-19.⁵

When compared to CXR, lung ultrasound (LUS) may offer improved diagnostic accuracy in the evaluation of patients with suspected COVID-19 pneumonia. LUS has a high sensitivity and often out-performs CXR in the diagnosis of other pulmonary infections.⁶ LUS findings for COVID-19 have been reported in the literature and include B-lines, pleural abnormalities, and subpleural consolidations.⁷⁻⁹ Evaluation of B-lines is already within the scope of practice for emergency physicians (EP), and instruction in interpreting LUS is part of current residency education standards.¹⁰

Importance

LUS is a safe, readily available tool that can be employed by EPs to provide real-time clinical assessment for COVID-19. Lab testing utility is hampered by delays in results, accuracy, and availability. CXR may miss pulmonary disease, and the ACR has cautioned against routine screening with chest computed tomography (CT), citing concerns of poor specificity of ground-glass opacities for COVID-19 as well as infection control procedures necessary to decontaminate the CT scanner.⁴ Regarding infection control procedures, we expect that portable (or hand-held) ultrasounds would be easier to decontaminate than portable CXR machines or CT suites.

Goals of This Investigation

Our primary aim was to determine whether detection of B-lines on LUS, among patients without alternative etiologies for their presence, is more sensitive for the diagnosis of COVID-19 than CXR. Our secondary aim was to evaluate the proportion of patients with COVID-19 that have secondary LUS findings of pleural abnormalities and subpleural consolidations.

METHODS

Study Design and Setting

This was a retrospective, observational, cohort study of patients undergoing COVID-19 testing (based on real-time

Population Health Research Capsule

What do we already know about this issue?
Lung ultrasound (LUS) has been shown to outperform chest radiograph (CXR) in its ability to detect abnormalities with non-coronavirus disease 2019 (COVID-19) pulmonary infections.

What was the research question?
To determine if B-lines detected by LUS are more sensitive for the associated diagnosis of COVID-19 than an abnormal CXR.

What was the major finding of the study?
B-lines detected by LUS were more sensitive for the associated diagnosis of COVID-19 than an abnormal CXR.

How does this improve population health?
In locations where viral testing is not available or has significant delays, LUS may provide important information for the evaluation of suspected COVID-19.

reverse transcriptase-polymerase chain reaction [RT-PCR] of nasopharyngeal sampling performed on an assay developed by the Center for Regenerative Medicine at Boston University, operating under an Emergency Use Authorization], who also had both diagnostic LUS and CXR for the evaluation of COVID-19 in the emergency department (ED). This study had institutional review board approval and was conducted based on Standards for Reporting of Diagnostic Accuracy Studies (STARD) guidelines and best practices for retrospective reviews.¹¹

This investigation was performed at a large urban academic ED in the United States with >140,000 visits per year. The ED is associated with an emergency medicine residency and clinical ultrasound fellowship, and has six dedicated portable ultrasound machines (Philips SPARQ, Wayne, PA; and MINDRAY TE7, Arnold, MD). All ultrasound studies are transferred wirelessly and stored in QPATH (Telexy, Blaine, WA). There was no formal education for LUS specific to COVID-19; however, all physicians have had structured training in LUS. All physicians were provided literature from a small study of 20 patients with COVID-19 that had 12 lung zones evaluated with ultrasound, which found 75% of patients had abnormal LUS findings at the posterior lung bases.⁹ When performing point-of-care ultrasound in the clinical setting, all EPs at our institution are required to archive at least one image that is representative of their findings.

Selection of Participants

All ultrasound studies completed in the ED between March 20, 2020–April 6, 2020, were reviewed for LUS imaging. We reviewed the electronic health record (EHR), EPIC (Verona, WI) to determine whether COVID-19 testing was performed. Subjects were included for evaluation if they had a COVID-19 test performed during the index hospitalization or within two weeks of the LUS examination. At the hospital during this time period, COVID-19 testing was performed only on people with symptoms concerning for disease, and no routine screening practices were in place. However, performance of viral testing was at physician discretion, and those without viral testing were excluded from analysis. We also excluded subjects if they did not have a CXR. Lastly, based on EHR review from patient history or physician documentation, patients were excluded if they had reasons for alternative causes of B-lines (congestive heart failure, renal disease leading to volume overload, or underlying lung disease), as it would not be possible to determine the etiology of the abnormal ultrasound results.

Test Methods

All lung ultrasounds were reviewed by two expert EPs, both with clinical ultrasound fellowship training (JRP and KCM), who were blinded to COVID-19 results. When disagreements occurred, a third ultrasound fellowship-trained, blinded independent expert reviewer adjudicated (MML). LUS were scored as positive or negative after review of all images. Subjects were considered to have a positive LUS if any B-lines were detected. The reviewers further graded positive ultrasounds as having 1-2 B-lines or ≥ 3 B-lines.¹² If B-lines coalesced, the score was graded as ≥ 3 B-lines if the area of B-lines took up $\geq 30\%$ of the intercostal space. Although ground-glass opacities can manifest as thinner B-lines < 3 mm apart, we allowed for percentage grading to account for coalescing in addition to “light beam” artifact, which is a broader, band-shaped artifact described in COVID-19.¹³ Because COVID-19 is reported to cause focal and diffuse lung disease, we chose the image with the most B-lines detected at one intercostal space to score each patient.

The images were subsequently evaluated for subpleural consolidations and pleural abnormalities (Figure 1 and Online Supplemental Videos A-E). We defined subpleural consolidations as an area of hypoechoic focus at the pleural line. These areas may be associated with increased B-lines originating from this area of hypoechoic focus. For pleural abnormalities we defined this as a) loss of pleural line echogenicity; b) irregular contour of the pleural line; or c) areas that appeared > 3 millimeters in thickness by visual estimation.¹⁴ Secondary LUS findings were determined by a consensus of all reviewers. Finalized CXR reports were recorded. We classified CXRs as positive if the report included infection in the differential, as defined by words such as opacity, consolidation, or airspace disease. CXRs

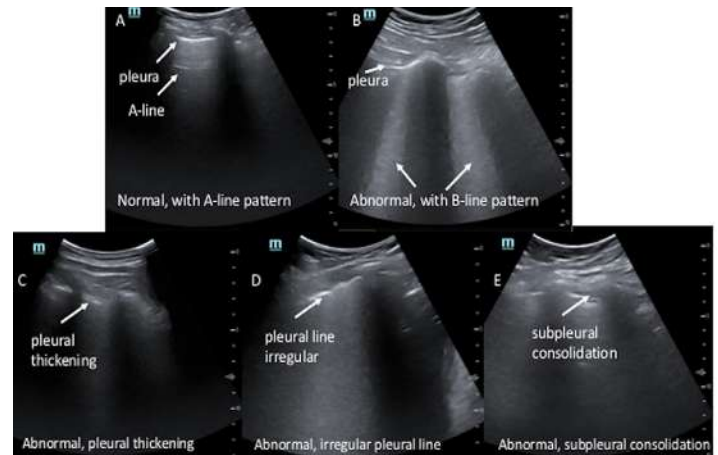


Figure 1. Lung ultrasounds. (A) Normal lung ultrasound. A-lines are horizontal lines that can be seen in the absence of pathology. (B) Abnormal lung ultrasound. The pleura is noted at the top of the lung. This is an example of coalescing B-lines shown as what appear to be headlights coming down from the pleura. (C) Abnormal lung ultrasound. Demonstrated is pleural thickening, > 3 millimeters by visual estimate was considered abnormal. (D) Abnormal lung ultrasound. Demonstrated is an irregular pleural line seen in viral infections. (E) Abnormal lung ultrasound. Shown is a subpleural consolidation that appears black between the pleura above the pleural line.

were classified as negative if no abnormality was noted, an abnormality was noted but attributed to a non-infectious etiology, or was inconclusive for infectious process.

After LUS scoring and data collection, clinical data including demographics, co-morbidities, vital signs, and laboratory values, was collected from the EHR by two investigators (JRP and FS) using a standardized abstraction technique and entered into REDCap.

Outcome Measures

The primary outcome measure was the sensitivity of LUS compared to CXR for the detection of COVID-19, using the RT-PCR laboratory test as the reference standard. Secondary outcome measures were the proportion of additional secondary LUS findings (pleural abnormalities or subpleural consolidation) detected.

Analysis

A sample size of 43 patients with an estimated sensitivity of 40% for CXR and 70% for LUS yields 81% power with an alpha of 0.05 assuming 70% disease prevalence. We used an estimated sensitivity of 40% based on results of CXR findings in influenza, as the referenced paper of 69% was not available at the time this study was designed.^{5,15} We compared sensitivities of LUS and CXR using a two-sided McNemar’s test. Patient demographics were evaluated with descriptive statistics, Fisher’s exact tests, Wilcoxon sum-ranked test, chi-squared tests, and Welch’s t-test. Inter-rater reliability for

the primary outcome between the two primary reviewers was assessed by Cohen's kappa.¹⁶ In addition, 95% Agresti-Coull confidence intervals (CI) were calculated for CXR and LUS test characteristics. We performed all analyses using SAS v9.4 (SAS Institute Inc., Cary, NC). Sample size calculations were conducted using PASS 19 (PASS 2019 Power Analysis and Sample Size Software (2019). NCSS, LLC. Kaysville, UT).

RESULTS

Characteristics of Study Subjects

A total of 304 ultrasound studies were completed over the 18-day study period (Figure 2). Of these, 81 had LUS performed. Among these, 43 met inclusion criteria, and 27/43 tested positive for COVID-19 by RT-PCR (63%). Four patients admitted with initial negative results were retested, and two were found to be positive. These two subjects were classified in the 27 total patients with COVID-19. Table 1 describes the demographic and clinical information of the included patients.

Main Results

The sensitivity and specificity of B-lines on LUS associated with COVID-19 were 88.9% (95% CI, 71.1-97.0) and 56.3% (95% CI, 33.2-76.9), respectively. The association between CXR and COVID-19 results had a sensitivity and specificity (Appendix) of 51.9% (95% CI, 34.0-69.3) and 75.0% (95% CI, 50.0-90.3). LUS was more sensitive than CXR for the association of pulmonary findings of COVID-19 ($p = 0.013$). While there was a trend for CXR to be more specific for the

associated diagnosis of COVID-19, this was not found to be statistically significant ($p = 0.453$). Additional LUS test characteristics are provided in Table 2. Cohen's kappa for inter-rater agreement between the two expert LUS reviewers for the primary outcome was strong ($\kappa = 0.83$, 95% CI, 0.65-1.00). There were only three cases out of 43 where there was disagreement on the primary outcome between the two reviewers. These involved cases where B-lines were more subtle.

B-lines were more frequently detected in patients with COVID-19 (24/27 patients with COVID-19 and 7/16 patients without, $p < 0.001$). Of the 27 patients with confirmed COVID-19 infection, 21 had pleural abnormalities (77.8%) and 10 had subpleural consolidations (37%). Of the 16 subjects without COVID-19, three had pleural irregularities (18.8%) and two had subpleural consolidations (12.5%).

There was a mean of 6.2 LUS images recorded per patient, which was not significantly different between COVID-19 results, and a median of 6 LUS images taken per patient. Images were more frequently obtained with a curvilinear probe 37/43, (86%), than the phased array probe, 6/43 (14.0%). Of the LUS studies, 8/43 (18.6%) were completed by residents or physician assistants, 4/43 (9.3%) by an ultrasound fellow, 17/43 (39.5%) by ultrasound faculty, and 14/43 (32.6%) by non-fellowship trained EPs. Of the CXRs performed, 42/43 (97.7%) were performed as portable examinations. The one 2-view CXR was a false negative.

DISCUSSION

To our knowledge this is the first study to evaluate the test characteristics of LUS for COVID-19. We also are the first to compare the diagnostic performance of LUS to the more conventional use of CXR. Although preliminary, this work provides important results for the application of LUS for detection of COVID-19. This investigation offers compelling evidence that B-lines detected by LUS are more frequently associated with COVID-19 than an abnormal CXR. This finding is in line with the performance of LUS in other pulmonary disease entities.^{6,10}

We used RT-PCR as the reference standard for diagnosis of COVID-19. However, it is known that the test characteristics of RT-PCR are dependent on collection technique, timing in disease process, and processing technique. In our population there were two negative RT-PCR tests that were positive on repeat testing. Both patients with initially negative RT-PCR tests had positive LUS findings; thus, it is possible LUS is more sensitive than RT-PCR for COVID-19. Further research would be necessary to substantiate this theory.

Our study reports a sensitivity of 52% for CXR, which is lower than the reported 69% for portable CXR. It is unknown whether the radiologists in that previous study were blinded, and it is also unclear how body mass index or other variables may have resulted in our reported lower sensitivity for CXR. It is unknown how two-view CXRs would perform for the detection of lung involvement from COVID-19, as it might

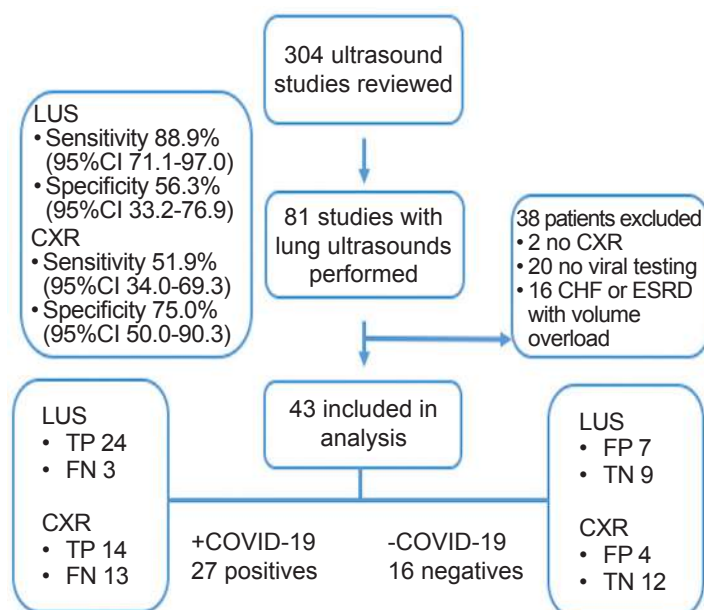


Figure 2. Flow chart of enrollment in lung ultrasound study. CI, confidence interval; CXR, chest radiograph; LUS, lung ultrasound; CHF, congestive heart failure; ESRD, end-stage renal disease; TP, true positive; FP, false positive; TN, true negative; FN, false negative.

Table 1. Demographic and clinical variables of patients enrolled in study to evaluate test characteristics of lung ultrasound for coronavirus disease 2019 (COVID-19).

	Overall (N=43)	COVID-19 (+) (N=27)	COVID-19 (-) (N=16)	P-value
Demographics				
Age (years), median (IQR)	52.0 (25.0)	53.0 (20.0)	50.0 (28.5)	0.880*
Race, n (%)				< 0.001†
White	12 (27.9)	3 (11.1)	9 (56.3)	
Black	15 (34.9)	8 (29.6)	7 (43.8)	
Asian	0 (0.0)	0 (0.0)	0 (0.0)	
Other/unknown	16 (37.2)	16 (59.3)	0 (0.0)	
Ethnicity, n (%)				< 0.001‡
Hispanic	12 (27.9)	12 (44.4)	0 (0.0)	
Non-Hispanic	27 (62.8)	11 (40.7)	16 (100.0)	
Unknown	4 (9.3)	4 (14.8)	0 (0.00)	
Gender, n (%)				0.076†
Male	21 (48.8)	16 (59.3)	5 (31.3)	
Female	22 (51.2)	11 (40.7)	11 (68.8)	
BMI (kg/m ²), mean (SD)	31.6 (8.4)	31.7 (9.0)	31.3 (7.5)	0.891§
Symptom duration at time of LUS (days), mean (SD)	5.4 (4.8)	6.0 (4.9)	4.4 (4.6)	0.311§
Diabetes, n (%)	11 (25.6)	10 (37.0)	1 (6.3)	0.033‡
Asthma, n (%)	9 (20.9)	4 (14.8)	5 (31.3)	0.257‡
Obesity, n (%)	19 (44.2)	12 (44.4)	7 (43.8)	1.000‡
Coronary artery disease, n (%)	2 (4.7)	0 (0.0)	2 (12.5)	0.133‡
COPD, n (%)	3 (7.0)	1 (3.7)	2 (12.5)	0.545‡
Vital Signs				
SpO ₂ (%), median (IQR)	96.0 (3.0)	95.0 (2.0)	96.5 (3.0)	0.082*
Temperature (°F), median (IQR)	99.1 (2.1)	99.9 (2.1)	98.3 (0.9)	0.001*
Systolic blood pressure (mmHg), mean (SD)	128.7 (20.3)	126.2 (15.5)	132.8 (26.6)	0.376§
Diastolic blood pressure (mmHg), mean (SD)	76.8 (13.3)	75.0 (12.0)	79.9 (15.3)	0.255§
Initial heart rate (bpm), mean (SD)	91.2 (18.3)	96.2 (18.4)	82.8 (15.2)	0.018§
Respiratory rate (rpm), mean (SD)	21.0 (5.5)	22.0 (6.7)	19.4 (1.6)	0.070§
Diagnostic testing				
Abnormal WBC K/ μ L (<4 or >11), n (%)	16 (43.2)	10 (41.7)	6 (46.2)	1.000‡
Abnormal polys K/ μ L (<1.8 or >7.0), n (%)	13 (35.1)	9 (37.5)	4 (30.8)	0.734‡
Abnormal lymphocytes K/ μ L (<1.1 or >3.5), n (%)	15 (40.5)	12 (50.0)	3 (23.1)	0.166‡
Abnormal platelets K/ μ L (<150 or >400), n (%)	5 (13.5)	2 (8.3)	3 (23.1)	0.321‡
Abnormal sodium mmol/L (<135 or >145), n (%)	8 (21.6)	7 (29.2)	1 (7.7)	0.216‡
Abnormal ferritin ng/ml (>109), n (%)	24 (80.0)	20 (90.9)	4 (50.0)	0.029‡
Abnormal LDH U/L (>308), n (%)	16 (51.6)	14 (63.6)	2 (22.2)	0.054‡
Abnormal D-dimer ng/mL DDU (>243), n (%)	17 (54.8)	13 (61.9)	4 (40.0)	0.441‡
Abnormal Fibrinogen mg/dL (>460), n (%)	20 (66.7)	15 (71.4)	5 (55.6)	0.431‡

*Wilcoxon rank-sum test

†Chi-squared test of independence

‡Fisher's exact test

§Two-independent samples t-test

IQR, interquartile range; BMI, body mass index; kg, kilogram; m², meter squared; SD, standard deviation; LUS, lung ultrasound; COPD, chronic obstructive pulmonary disease; SpO₂, oxygen saturation; °F, Fahrenheit; mmHg, millimeters of mercury; WBC, white blood cell count; K/ μ L, thousands per microliter; mmol, millimoles; L, liter; ng, nanograms; ml, milliliter; LDH, lactate dehydrogenase; U, units; DDU, D-dimer units; mg, milligram; dl, deciliter; polys, polymorphonuclear leukocytes.

Table 1. Continued.

	Overall (N=43)	COVID-19 (+) (N=27)	COVID-19 (-) (N=16)	P-value
Abnormal ESR mm/hr (>30), n (%)	26 (83.9)	21 (91.3)	5 (62.5)	0.093 [‡]
Abnormal CRP mg/L (>5), n (%)	29 (90.6)	21 (91.3)	8 (88.9)	1.000 [‡]
Abnormal Brain-Natriuretic Peptide pg/ml (>72.3), n (%)	2 (6.7)	2 (9.1)	0 (0.0)	1.000 [‡]
Clinical results				
Type of CXR, n (%)				1.000 [‡]
Portable	42 (97.7)	26 (96.3)	16 (100.0)	
Two-view	1 (2.3)	1 (3.7)	0 (0.0)	
Admitted, n (%)				0.092 [‡]
Yes	31 (72.1)	22 (81.5)	9 (56.3)	
No (discharged)	12 (27.9)	5 (18.5)	7 (43.75)	
If admitted, location, n (%)				0.834 [‡]
Floor	22 (71.0)	15 (68.2)	7 (77.8)	
IMCU	3 (9.7)	2 (9.1)	1 (11.1)	
ICU	6 (19.4)	5 (22.7)	1 (11.1)	
If admitted, transferred to ICU within 48 hours, n (%)				0.286 [‡]
Yes	5 (16.1)	5 (22.7)	0 (0.0)	
No	26 (83.9)	17 (77.3)	9 (100.0)	
Required supplemental oxygen in ED, n (%)				0.054 [†]
Yes	16 (37.2)	13 (48.2)	3 (18.8)	
No	27 (62.8)	14 (51.9)	13 (81.3)	
LUS images recorded, mean (SD)	6.21 (3.3)	5.93 (3.7)	6.69 (2.5)	0.472 [§]
Ultrasound probe used, n (%)				0.069 [‡]
Phased array	6 (14.0)	6 (22.2)	0 (0.0)	
Curvilinear	37 (86.1)	21 (77.8)	16 (100.0)	
Linear	0 (0.0)	0 (0.0)	0 (0.0)	
LUS: B-lines, n (%)				< 0.001 [‡]
0	12 (27.9)	3 (11.1)	9 (56.3)	
1-2	4 (9.3)	1 (3.7)	3 (18.8)	
≥3	27 (62.8)	23 (85.2)	4 (25.0)	
LUS: pleural thickening, n (%)	24 (55.8)	21 (77.8)	3 (18.8)	< 0.001 [‡]
LUS: sub-pleural consolidation, n (%)	12 (27.9)	10 (37.0)	2 (12.5)	0.158 [‡]

*Wilcoxon rank-sum test

†Chi-squared test of independence

‡Fisher's exact test

§Two-independent samples t-test

ESR, erythrocyte sedimentation rate; *mm*, millimeter; *hr*, hour; *CRP*, C-reactive protein; *mg*, milligram; *L*, liter; *PG*, picogram; *ml*, milliliter; *CXR*, chest radiograph; *IMCU*, intermediate care unit; *ICU*, intensive care unit; *ED*, emergency department; *LUS*, lung ultrasound; *SD*, standard deviation.

outperform portable CXR. However, given the infectious nature of COVID-19 portable CXR is the recommended diagnostic test for patients with suspected COVID-19, and these results demonstrate a generally low sensitivity.

Evidence that LUS is more sensitive for the associated diagnosis of COVID-19 than CXR has potential global implications. These results may be of particular importance to settings with significant delays in viral RT-PCR testing,

settings in which RT-PCR testing is restricted or not available, or where CXR or CT are not accessible. Further scientific investigation could determine how LUS at the time of initial evaluation may aid the physician in counseling patients with regard to findings suggestive of COVID-19. Our investigation provides important new data for the role of LUS relative to CXR for patients being evaluated for COVID-19.

Conversely, LUS did have a lower specificity than CXR.

Table 2. Association of lung ultrasound and chest radiograph findings of COVID-19.

	Value	95% CI
Sensitivity (%)		
Lung ultrasound	88.9	71.1 - 97.0
Chest radiograph	56.3	33.2 - 76.9
Specificity (%)		
Lung ultrasound	51.9	34.0 - 69.3
Chest radiograph	75.0	50.0 - 90.3
Positive predictive value (%)		
Lung ultrasound	77.4	59.9 - 88.9
Chest radiograph	77.8	54.3 - 91.5
Negative predictive value (%)		
Lung ultrasound	75.0	46.2 - 91.7
Chest radiograph	48.0	30.0 - 66.5
Positive likelihood ratio		
Lung ultrasound	2.03	0.84 - 3.23
Chest radiograph	2.07	0.10 - 4.05
Negative likelihood ratio		
Lung ultrasound	0.20	0 - 0.43
Chest radiograph	0.64	0.32 - 0.96

CI, confidence interval.

As noted, 1-2 B-lines may be non-pathologic; however, only one patient in this study was found to have 1-2 B-lines that did in fact have COVID-19. It is possible that using LUS with only one or two B-lines to direct care for patients suspected of having COVID-19 could lead to unnecessary isolation or further medical testing. Additionally, there are other etiologies for LUS B-lines, and our results will likely be most valuable when interpreted in the clinical context of the medical evaluation.

Physicians should have an estimation of pretest probability when performing and interpreting diagnostic testing, and LUS for COVID-19 is no exception to this rule. In this population with a high prevalence of disease (as judged by RT-PCR results), a positive LUS was a good predictor of disease. Further work is necessary to better delineate how to incorporate these findings into screening for asymptomatic patients, diagnostic algorithms, and clinical management strategies.

LIMITATIONS

Since this was a retrospective study, it is unclear why physicians chose to perform both CXR and LUS. It is also unknown whether the result of either diagnostic test affected the physician's choice to perform the other test. Additionally, the treating physician was not blinded to the patient's history, exam, or CXR. It is possible that knowledge of these data points would change the extent to which the physician performed their LUS. Despite this, there were a similar number of images recorded for patients with and without COVID-19.

Over half of the studies performed were performed by non-fellowship trained EPs. Further work is needed to validate these findings in a population of EPs without fellowship training. Identification of B-lines is a core skill of EPs; therefore, we anticipate the findings would be similar.

Another limitation was the use of RT-PCR for the diagnosis of COVID-19, as it likely misses some cases. Some of the tests classified as false positive may have actually been true positives. RT-PCR was chosen as the reference standard since that is what is currently used at our, and most, institutions nationally, and viral culture is not feasible at this time. Inconclusive CXRs were scored as negative, which might favor the analysis toward LUS. This was done, in accordance with STARD guidelines, because inconclusive CXRs do not provide diagnostic guidance in real time.¹¹

We used B-lines in this study as a reliable marker for COVID-19. It is possible a comprehensive evaluation including pleural abnormalities and subpleural consolidations would improve the test characteristics of LUS. We chose to only include B-lines for our assessment as B-lines are already familiar to EPs and would be easier to implement. We included any number of B-lines (one or more) as abnormal; however, it has been reported 1-2 B-lines may not be pathologic. We selected this approach to maximize the sensitivity of LUS at the cost of specificity.

CONCLUSION

This investigation provides evidence that LUS is more sensitive for the associated diagnosis of COVID-19 than CXR when excluding patients with other expected causes of B-lines. This work could have important implications where viral testing is restricted or alternative diagnostic imaging is not available. Further work may find LUS for the evaluation and care of COVID-19 patients to be of clinical benefit and may also have a role to guide testing as screening and contact tracing are expanded.

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Predictors of Mortality in Adults Admitted with COVID-19: Retrospective Cohort Study from New York City

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Introduction: Rapid spread of coronavirus disease 2019 (COVID-19) in the United States, especially in New York City (NYC), led to a tremendous increase in hospitalizations and mortality. There is very limited data available that associates outcomes during hospitalization in patients with COVID-19.

Methods: In this retrospective cohort study, we reviewed the health records of patients with COVID-19 who were admitted from March 9–April 9, 2020, to a community hospital in NYC. Subjects with confirmed reverse transcriptase-polymerase chain reaction (RT-PCR) of the nasopharyngeal swab for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were included. We collected data related to demographics, laboratory results, and outcome of hospitalization. Outcome was measured based on whether the patient was discharged home or died during hospitalization.

Results: There were 888 consecutive admissions with COVID-19 during the study period, of which 513 were excluded with pending outcome or incomplete information. We included a total of 375 patients in the study, of whom 215 (57%) survived and 160 (43%) died during hospitalization. The majority of patients were male (63%) and of Hispanic origin (66%) followed by Blacks (25%), and others (9%). Hypertension (60%) stands out to be the most common comorbidity followed by diabetes mellitus (47%), cardiovascular disease (17%), chronic kidney disease (17%), and human immunodeficiency virus/acquired immunodeficiency syndrome (9%). On multiple regression analysis, increasing odds of mortality during hospitalization was associated with older age (odds ratio [OR] 1.04; 95% confidence interval [CI], 1.01-1.06 per year increase; $p < 0.0001$), admission D-dimer more than 1000 nanograms per milliliter (ng/mL) (OR 3.16; 95% CI, 1.75-5.73; $p < 0.0001$), admission C-reactive protein (CRP) levels of more than 200 milligrams per liter (mg/L) (OR 2.43; 95% CI, 1.36-4.34; $p = 0.0028$), and admission lymphopenia (OR 2.63; CI, 1.47-4.69; $p 0.0010$).

Conclusion: In this retrospective cohort study originating in NYC, older age, admission levels of D-dimer of more than 1000 ng/mL, CRP of more than 200 mg/L and lymphopenia were associated with mortality in individuals hospitalized for COVID-19. We recommend using these risk factors on admission to triage patients to critical care units or surge units to maximize the use of surge capacity beds. [West J Emerg Med. 2020;21(4)779–784.]

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a viral infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 belongs to the coronaviridae family of viruses, with (SARS-CoV) and Middle East respiratory syndrome coronavirus being other members of the same family.¹ COVID-19 started as a cluster of unknown pneumonia cases in Wuhan, China, in December 2019.² The World Health Organization declared COVID-19 a pandemic on March 11, 2020.³ Since then the number of positive cases has increased exponentially, spreading to scores of countries including the United States.⁴

New York state, especially New York City (NYC) and surrounding boroughs, has experienced the highest infection rate of COVID-19 in the US, leading to significant morbidity and mortality. As of April 12, 2020, there have been more than 110,000 cases diagnosed with 30,000 hospitalizations in NYC. Hospitalizations associated with COVID-19 in NYC have led to significant challenges in human and infrastructure resource allocation for healthcare institutions.⁵ There are few reports related to resource allocation and triaging the patients admitted to hospitals.^{6,7} In the middle of the pandemic we attempted to evaluate our experience in search of any clinical and/or laboratory predictors that would help us to rapidly triage patients to appropriate units.

The borough of the Bronx has a population with a poverty rate double that of the national average.⁸ Healthcare dynamics in this area are complex⁹ due to prevailing socioeconomic and cultural challenges in the community.¹⁰ The Bronxcare Health System (BCHS) hospital in the South Bronx serves this population, which was faced with one of the highest infection rates of COVID-19 in the US.

METHODS

Study Design

We conducted this retrospective cohort study at BCHS, a safety-net hospital located in the Bronx, New York, US. The study was approved by the institutional review board (IRB) at BCHS, and written informed consent was waived by the IRB owing to the observational nature of the study in a rapidly evolving pandemic. The chart abstractors were blinded to the study hypothesis.

Participants and Eligibility Criteria

We retrospectively analyzed consecutive patients who had been admitted to our hospital between March 9, 2020 and April 9, 2020 and who were diagnosed as having COVID-19. Individuals aged 18 years and above were included in the study. Diagnosis of COVID-19 was defined as the patient having a positive result on the nasopharyngeal swab for SARS-CoV-2 by reverse transcriptase polymerase chain reaction (RT-PCR). Nasopharyngeal swab samples were collected at the time

Population Health Research Capsule

What do we already know about this issue?
Coronavirus disease 2019 (COVID-19) has been associated with significant mortality. Few reports identify risk factors for mortality in patients hospitalized with COVID-19.

What was the research question?
What are the risk factors for mortality in hospitalized population with COVID-19 infection?

What was the major finding of the study?
Increased odds of mortality were noted with older age, and admission values of D-dimer, C-reactive protein, and lymphopenia.

How does this improve population health?
Use of these indicators upon admission may help to triage COVID-19 patients in a surge capacity situation.

of admission, and testing was performed by RT-PCR assay. The hospital used test kits from several manufacturers, made available by the New York State Department of Health (DOH) during surge phase.

All patients were admitted to the hospital through the emergency department (ED). Laboratory and radiological tests were performed based on clinical care needs of patients following existing medical and critical care guidelines. Laboratory tests included complete blood count, coagulation profile, liver panel, basic metabolic panel, C-reactive protein (CRP), lactate dehydrogenase (LDH), and other tests as indicated. Common radiological assessment included chest radiograph and computed tomography of the chest based on clinical decision-making. Patients were managed with supportive care and specific pharmacological protocols created by the hospital's COVID-19 management guidelines committee in accordance with the Centers for Diseases Control and Prevention and the NY State DOH. Specific pharmacological treatments included systemic corticosteroids, hydroxychloroquine, colchicine, antiretroviral medications, and Tocilizumab.

A total of 888 patients with laboratory-confirmed SARS-CoV-2 were admitted during the study period to BCHS hospital. We excluded from the final analysis patients who were still receiving care in the hospital at the time

of preparation of this manuscript and those patients with incomplete information

Data Collection

We reviewed electronic health records, nursing records, and laboratory findings of all patients with laboratory-confirmed SARS-CoV-2 infection. Demographic data such as age, gender, and ethnicity were extracted. We also collected information on comorbid conditions including hypertension (HTN), diabetes mellitus (DM), obstructive airway disease (OAD), cardiovascular disease (CVD), chronic kidney disease (CKD), end stage renal disease, and human immunodeficiency syndrome (HIV)/acquired immunodeficiency syndrome (AIDS). Details of hospital course, use of ventilators, and laboratory results were also collected. We divided patients into two groups for final analysis based on survival at the end of hospital course (discharged vs deceased). Collected data were cross-checked by the authors at the end of data collection. Any disagreement between two authors was resolved by consulting with all authors and reaching consensus agreement.

Statistical Analysis

We performed all statistical analyses using JMP 14, Mac version (SAS, Cary, NC).¹¹ Continuous variable was expressed as median with interquartile range (IQR). Categorical variables were represented as counts and percentages. We used Fisher's exact test to compare nominal variables between two groups, and we compared continuous variables using an independent, two-tailed t-test. Relation between risk factors and in-hospital mortality was measured using univariable and multivariable regression. We excluded variables from the univariate analysis if the difference was not significant or number of variables was very small. A two-sided α value of less than 0.05 was considered statistically significant.

RESULTS

A total of 888 consecutive patients were hospitalized in BCHS hospital with COVID-19 between March 9, 2020 and April 9, 2020. In the final analysis, we excluded the following patients: those whose SARS-Cov-2 results were pending or whose definitive outcomes were not available at the time of the study as they were still hospitalized; and those with incomplete information. We excluded 513 patients and included a total of 375 in the final analysis.

Of 375 patients, 215 (57%) were discharged home safely and 160 (43%) died during hospitalization. Median age was 63 years (range 19-97, interquartile range [IQR] 52.0-72.0). The majority of the hospitalized patients were male (63%) with male-to-female ratio of 12:7. Ethnic distribution of the study population was as follows: Hispanic (66%); Black (25%); and other (9%) (Table 1). This ethnic distribution differs from the surrounding Bronx community where Hispanics and Blacks represent 54.4% and 43.6% of the

population, respectively.⁸ Comorbid conditions were present in three out of every four patients (77%) with HTN being the most common (60%) followed by DM (47%), CVD (17%) OAD (17%), CKD (14%), HIV/AIDS (9%), and chronic liver disease, (5%). Admission laboratory findings showed neutrophilia (26%), neutropenia (2%), lymphopenia (62%), and lymphocytosis (1%). Baseline characteristics of the study patients are shown in Table 1. Out of the 375 patients, 320 (85%) received hydroxychloroquine; 9 (2%) received antiretroviral medications; 12 (3%) received colchicine; and 3 (1%) received tocilizumab. Median time from hospitalization to outcome (discharge or death) was five days (IQR 3-8 days).

Male gender (70%), HTN (72%), DM (56%), CVD (24%), CKD (19%) and HIV/AIDS (9%) were noted with high prevalence in the deceased group. We also noted that neutrophilia was more frequent in the deceased group compared to the discharged group (34% vs 19%, $p = 0.0077$). Lymphopenia was predominant in the deceased group with 122 patients (76% vs 51%, $p < 0.0001$) compared to survivors. Admission LDH, CRP, D-dimer, and ferritin levels were higher in the deceased group compared to the survivor group (Table 1).

On multiple regression analyses (Table 2), we observed increasing odds of mortality during hospitalization associated with older age (odds ratio [OR] 1.04, 95% confidence interval [CI], 1.01-1.06 per year increase, $p = 0.0001$), admission D-dimer levels of more than 1000 nanogram/milliliter (ng/mL) (OR 3.16; 95% CI 1.75-5.73; $p < 0.0001$) admission CRP levels of more than 200 milligrams/liter (mg/L) (OR 2.43; 95% CI, 1.36-4.34; $p = 0.0028$) and admission lymphopenia (OR 2.63 [1.47-4.69]; $p = 0.0028$). Mean time from hospital admission to discharge was five days (IQR 3.0-8.0) and to death was five days (IQR 2.3-8.0; $p = 0.91$). There were more Hispanics admitted compared to Blacks (66% vs 25%) with a similar trend observed in the deceased (68% vs 24%) and survived groups (64% vs. 25%) (Table 1).

DISCUSSION

The rapid, ongoing COVID-19 pandemic resulted in an exponential increase in the number of infected individuals in New York, especially NYC. As of April 15, 2020, approximately 30,000 people were hospitalized leading to an enormous burden on the NYC healthcare system and its providers.⁵ This impact was more significant in safety-net hospitals. Very limited data is available to determine risk factors and their association with outcomes in COVID-19 patients, to help hospitals and providers in triaging and managing these patients more efficiently.¹²⁻¹⁵ Considering a higher surge of cases in densely populated cities such as NYC triaging tools would enable the appropriate allocation of resources.

We looked at several risk factors in hospitalized adults with COVID-19 in this study. The higher death (43%) rate in our study

Table 1. Baseline characteristics of patients diagnosed with coronavirus disease 2019 (COVID-19) after hospital admission.

	Total (N = 375)	Deceased (N = 160)	Survived (N = 215)	P-value
Demographic and clinical characteristics				
Age, years	63.0 (52.0-72.0)	68.0 (60.0-75.0)	58.0 (48.0-68.0)	< 0.0001
Gender				0.0173
Female	139 (37%)	48 (30%)	91 (42%)	
Male	236 (63%)	112 (70%)	124 (58%)	
Ethnicity				0.4553
Black	93 (25%)	39 (24%)	54 (25%)	
Hispanic	246 (66%)	109 (68%)	137 (64%)	
Other	36 (9%)	12 (8%)	24 (11%)	
Comorbidity	287 (77%)	142 (89%)	145 (67%)	<0.0001
Hypertension	225 (60%)	115 (72%)	110 (51%)	< 0.0001
Diabetes	175 (47%)	90 (56%)	85 (40%)	0.0017
Cardiovascular disease	62 (17%)	38 (24%)	24 (11%)	0.0018
Obstructive airway disease	62 (17%)	29 (18%)	33 (15%)	0.4854
Chronic kidney disease	51 (14%)	31 (19%)	20 (9%)	0.0060
HIV/AIDS	22 (6%)	14 (9%)	8 (4%)	0.0469
Chronic liver disease	18 (5%)	11 (7%)	7 (3%)	0.1420
Laboratory markers (at the time of admission)				
Neutrophil count (NC) ($\times 10^3/\text{microliter}$)	5.9 (4.0-8.2)	6.25 (4.3-8.8)	5.3 (3.8-7.5)	0.0393
<1.5 $\times 10^3/\text{microliter}$	7 (2%)	3 (2%)	4 (2%)	0.0077
1.5-8.0 $\times 10^3/\text{microliter}$	272 (72%)	103 (64%)	169 (79%)	0.0077
>8.0 $\times 10^3/\text{microliter}$	96 (26%)	54 (34%)	42 (19%)	0.0077
Lymphocyte count (LC) ($\times 10^3/\text{microliter}$)	0.8 (0.6-1.2)	0.7 (0.5-0.9)	0.9 (0.7-1.3)	0.8738
<1.0 $\times 10^3/\text{microliter}$	232 (62%)	122 (76%)	110 (51%)	<0.0001
1.0-4.8 $\times 10^3/\text{microliter}$	139 (37%)	36 (23%)	103 (48%)	<0.0001
>4.8 $\times 10^3/\text{microliter}$	4 (1%)	2 (1%)	2 (1%)	<0.0001
(NC/LC ratio)	6.9 (4.1-11.0)	8.75 (5.13-13.77)	6.0 (3.5-8.8)	< 0.0001
Lactate dehydrogenase (LDH) (unit/liter)	483.0 (341.0-700.0)	561.0 (426.0-800.0)	416.0 (297.0-598.0)	< 0.0001
C reactive protein (CRP) (milligram/liter)	122.2 (64.4-209.0)	160.0 (88.0-260)	97.0 (50.0-171.0)	< 0.0001
D-dimer (nanogram/milliliter)	504 (296.0-1010.0)	831.0 (408.0-2297.0)	394.0 (268.0-677)	< 0.0001
Ferritin (nanogram/milliliter)	820.0 (377.0-1511.0)	987.0 (490.0-1932.0)	717.0 (356.0-1379)	0.0026

HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome.

may reflect the first two weeks of the epidemic and the lack of data on final outcomes on currently hospitalized patients. Our patients had a higher burden of underlying medical conditions, in particular HTN,^{14,16} which is expected in urban populations.

Odds of death during hospitalization were higher with increased age, which is in accordance with findings in other recent studies.¹⁷ Additionally, we found three important admission laboratory markers – D-dimer, CRP levels, and lymphopenia – to be useful in predicting outcomes (Table 3). Elevated D-dimer may represent alteration of the coagulation cascade including development of severe microembolic disease. Microembolic disease appears to be a major contributor of

death in COVID-19 patients.

Triage models built on these risk factors would assist in allocation of resources and managing patients in appropriate critical care or modified units.

LIMITATIONS

Our study has certain limitations as the excluded patients were still in the hospital with continuing clinical care at the time of preparation of this manuscript. Therefore, impact of outcome of these individuals is not currently known. The majority of our patients were Hispanics and Blacks, constituting more than 90% of the total study population. Thus, we did not make any

Table 2. Multivariable analysis of baseline characteristics of hospitalized patients diagnosed with coronavirus disease 2019 (COVID-19).

	Univariable OR (95% CI)	P-value	Multivariable OR (95% CI)	P-value
Demographic and clinical characteristics				
Age, years	1.05 (1.03-1.73)	<0.0001	1.04 (1.01-1.06)	0.0003
Male gender (vs female)	1.71 (1.11-2.64)	0.0149	1.37 (0.79-2.37)	0.2520
Comorbidity present (vs not present)				
Hypertension	2.43 (1.57-3.77)	<0.0001	1.46 (0.82-2.62)	0.2046
Diabetes	1.96 (1.29-2.98)	0.0014	1.58 (0.94-2.65)	0.0841
Cardiovascular disease	2.48 (1.42-4.38)	0.0012	1.56 (0.78-3.11)	0.2025
Obstructive airway disease	1.22 (0.71-2.11)	0.47		
Chronic kidney disease	2.34 (1.28-4.29)	0.0058	1.33 (0.63-2.77)	0.3039
HIV/AIDS	2.48(1.02-6.07)	0.0464		
Chronic liver disease	2.19 (0.83-5.79)	0.1127		
Laboratory markers (at the time of admission)				
Absolute neutrophil count (ANC) (x10 ³ /microliter)				
<1.5 x10 ³ /microliter	1.23 (0.12-2.75)	0.4956	1.75 (0.31-9.95)	0.5273
1.5-8.0 x10 ³ /microliter	1 (ref)			
>8.0 x10 ³ /microliter	2.11 (1.32-3.38)	0.0019	1.57 (0.82-2.99)	0.1646
Absolute lymphocyte count (ALC) (x10 ³ /microliter)				
<1.0x10 ³ /microliter	3.17 (2.0-5.02)	<0.001	2.63 (1.47-4.69)	0.0010
1.0-4.8 x10 ³ /microliter	1 (ref)			
>4.8 x10 ³ /microliter	2.86 (0.39-21.06)	0.3021	5.69 (0.69-46.9)	0.1056
(ANC/ALC) ratio (>11.0)	1.58 (1.03-1.09)	<0.0001	0.75 (0.37-1.53)	0.4385
Lactate dehydrogenase (LDH) (> 700 unit/liter)	2.51 (1.55-4.07)	0.0002	1.43 (0.79-2.59)	0.2357
C reactive protein (CRP) (> 200 milligram/liter)	2.85 (1.78-4.57)	<0.0001	2.43 (1.36-4.34)	0.0028
D-dimer (> 1000 nanogram/milliliter)	4.62 (2.79-7.63)	<0.0001	3.16 (1.75-5.73)	<0.0001
Ferritin (nanogram/milliliter)	1.87 (1.16-3.00)	0.0092	1.58 (0.89-2.80)	0.1183

OR, odds ratio; CI, confidence interval; HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome.

conclusions regarding association between ethnicity and outcome due to very minimal representation from other ethnic groups.

CONCLUSION

Our findings suggest that older age, admission D-dimer (>1000 ng/mL), CRP (>200 mg/L), and lymphopenia (1.0 x10³/microliter) provide a reliable panel of tools to evaluate patients hospitalized with COVID-19 (Table 3). Our study is the

only one to report lymphopenia and its association to mortality, as prior studies in this regard were inconclusive.^{18,19} In a surge, EDs need tools to appropriately triage patients and maximize utilization of critical care beds. Although our study population mainly represents Hispanics and Blacks, we believe results could be applied to all ethnic groups.

Table 3. Key demographic and laboratory factors associated with mortality from COVID-19.

1. Elderly age (OR 1.04 for every one year increase; 95% CI, 1.001-1.06; p = 0.0003)
2. Admission D-dimer level >1000 nanograms/milliliter (OR 3.16; 95% 1.75-5.73; p<0.0001)
3. Admission CRP level >200milligrams/liter (OR 2.43; 95% CI, 1.36-4.34; p = 0.0028)
4. Admission lymphopenia (<1.0x10³/microliter, OR 2.63; 95% CI, 1.47-4.69; p = 0.0010)

OR, odds ratio; CRP, C Reactive Protein, CI, confidence interval.

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Identifying Patients at Greatest Risk of Mortality due to COVID-19: A New England Perspective

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Introduction: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread rapidly since December 2019, resulting in a pandemic that has, as of May 24, 2020, yielded over 5.3 million confirmed cases and over 340,000 deaths.¹ As businesses move to safely reopen and frontline healthcare workers (HCW) continue to face this crisis, it is essential that health officials know who in the population is at the greatest risk of mortality if hospitalized and, therefore, has the greatest need to protect themselves from being infected. We examined the factors that increase the risk of mortality among hospitalized COVID-19 patients.

Methods: This was a retrospective cohort study including confirmed COVID-19 patients admitted to the four Trinity Health of New England hospitals (THONE) in Connecticut and Massachusetts who either died or were discharged between March 1–April 22, 2020. Demographics, comorbidities, and outcomes of care were extracted from the electronic health record. A model of in-hospital mortality was made using a generalized linear model with binomial distribution and log link.

Results: The analysis included 346 patients: 229 discharged and 117 deceased. The likelihood of in-hospital mortality was increased for patients who were aged 60 or older (relative risk [RR] = 2.873; 95% confidence interval [CI], 1.733–4.764; $p = <0.001$), had diabetes (RR = 1.432; 95% CI, 1.068–1.921; $p = 0.016$), or had chronic obstructive pulmonary disease (COPD) (RR = 1.410; 95% CI, 1.058–1.878; $p = 0.019$). Hyperlipidemia had a protective effect, reducing the likelihood of mortality (RR = 0.745; 95% CI, 0.568–0.975; $p = 0.032$). Sensitivity and specificity of the model were 51.4% and 88.4%, respectively.

Conclusions: Being age 60 or older or having a history of diabetes or COPD are the most useful risk factors associated with mortality in hospitalized COVID-19 patients. As states ease stay-at-home orders, risk factors of severe disease can be used to identify those more likely to have worse outcomes if infected and hospitalized and, therefore, who in particular should continue to follow public health guidelines for avoiding infection: stay home if possible; practice physical distancing; and wear a facemask. [West J Emerg Med. 2020;21(4)785-789.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the causative agent of coronavirus disease 2019 (COVID-19), first described in Wuhan, China, in December 2019. The virus has spread rapidly, resulting in a pandemic that

has, as of May 24, 2020, yielded over 5.3 million confirmed cases and over 340,000 deaths.¹ Overall, the case fatality rate (CFR) is estimated to be around 3.6%.² In hospitals, risk of exposure is high; Saint Mary's Hospital in Waterbury, CT, saw confirmed SARS-CoV-2 positive cases peak at 68% of the hospital's census conducted on April 17, 2020, (Paul Porter, MD, phone communication, April 29, 2020). To decrease potential exposures between patients and healthcare workers (HCW), the US Centers for Disease Control and Prevention (CDC) and various specialty societies released guidelines recommending postponement of elective procedures, and many providers turned to telemedicine to conduct their scheduled visits.^{3,4,5}

The risk of death for COVID-19 patients who are hospitalized is significant. In Trinity Health of New England (THONE) hospitals, an internal report released on April 10, 2020, found that 33.2% of hospitalized COVID-19 patients had died since the beginning of the pandemic (Paul Porter, MD, phone communication, April 29, 2020). Emerging studies are aiming to describe characteristics of hospitalized patients and identify risk factors for mortality. Increased age, chronic obstructive pulmonary disease (COPD), cardiovascular disease, diabetes, hypertension, and smoking history are common characteristics that have been observed in hospitalized patients in New York and China.^{6,7,8} As hospitals respond to this crisis and businesses work to reopen safely, it is crucial to enhance this body of evidence and re-examine the risk factors that increase mortality risk among hospitalized COVID-19 patients. This way, public health officials can identify which individuals carry the greatest risk of death so that precautions may be taken as members of the public consider re-entering the workforce and returning to outpatient offices.

METHODS

This was a retrospective cohort study of confirmed COVID-19 patients admitted to four THONE hospitals: Saint Mary's Hospital in Waterbury, CT; Saint Francis Hospital in Hartford, CT; Johnson Memorial Hospital in Stafford, CT; and Mercy Medical Center in Springfield, MA. Expedited, non-exempt institutional review board approval was obtained. The study included patients admitted between March 1–April 22, 2020, who died or were discharged as of April 22, 2020, excluding patients who were still hospitalized. An initial data extraction from the electronic health record system, EPIC, was conducted to acquire demographic information and smoking history. For comorbidities, chart abstraction was conducted following standard abstraction protocol.⁹ Two medical students performed all abstraction using explicit inclusion and exclusion criteria in case selection. Both received the same EPIC training and abstraction guidance, and a sample of 10 patient charts were reviewed simultaneously before proceeding to independent abstraction.

Protocol included checking both the initial internal medicine note after hospital admission and the discharge note, and characterizing a patient as having a comorbidity only if it were either included in their problem list or explicitly stated by

Population Health Research Capsule

What do we already know about this issue?
Studies from New York and China have shown age, diabetes, chronic obstructive pulmonary disease (COPD), and cardiovascular disease to be associated with COVID-19 mortality.

What was the research question?
What risk factors are associated with in-hospital mortality among hospitalized COVID-19 patients?

What was the major finding of the study?
Age 60 or older, diabetes, and COPD increase risk of in-hospital mortality.

How does this improve population health?
Awareness of those most at risk of mortality if hospitalized for COVID-19 will focus attention on those who should exercise the greatest caution.

their provider in either note. It was at the reviewers' discretion to determine whether these notes were insufficient; if needed, all other notes post-admission were available for abstraction. Throughout the process, we conducted meetings to ensure abstractors had not encountered problems and were following proper protocol. Monitoring, blinding, and testing of inter-rater agreement were not done.

To test the bivariate relationship between risk factors and in-hospital mortality, we used Fisher's exact test to compare all categorical variables, while an independent samples T-test was used for the continuous variables. A model of in-hospital mortality was made using a generalized linear model with binomial distribution and log link. We initially included all variables in the model, and we then used a manual, stepwise backward elimination approach to remove non-significant variables.

RESULTS

The analysis included 346 patients hospitalized for COVID-19: 229 discharged (66.18%), and 117 deceased (33.82%). The study sample had a mean age of 66.86 years and had a high incidence of hypertension (69.7%), hyperlipidemia (48.3%), diabetes (47.1%), cardiovascular disease (46.8%), and neurological disease (27.5%), as seen in Table 1. The deceased population had a significantly higher incidence of hypertension, diabetes, cardiovascular disease, chronic kidney disease (CKD), COPD, and cancer compared to the discharged group. The

mean body mass index (BMI) of the study sample was 30.58 kilograms per meter squared, and 45.2% of patients were obese, compared with 39.8% of individuals over age 20 nationally.¹⁰ The groups also differed significantly with regard to age; the mean age of discharged patients was 63.56, and the mean age of deceased patients was 73.31 ($p < 0.001$). Applying a Bonferroni correction and using a new p-value cut-off for significance of 0.004, we found that age and COPD remained significant, with diabetes bordering on significance.

The results of the generalized linear model are shown in Table 2. The model showed that the likelihood of mortality was increased for patients who were aged 60 or older (relative risk [RR] = 2.873; 95% confidence interval [CI], 1.733-4.764; $p < 0.001$), had diabetes (RR = 1.432; 95% CI, 1.068-1.921; $p = 0.016$), or had COPD (RR = 1.410; 95% CI, 1.058-1.878; $p = 0.019$). Hyperlipidemia had a protective effect, reducing the likelihood of mortality (RR = 0.745; 95% CI, 0.568-0.975; $p = 0.032$). While hypertension, cardiovascular disease, and cancer were significant in the bivariate analysis, they were insignificant predictors in the model and were therefore removed per our manual, stepwise backward elimination approach. Sensitivity and specificity of the model were 51.4% and 88.4%, respectively.

DISCUSSION

Our model of COVID-19 hospitalized patients in Connecticut and Massachusetts identified that patients with

increased age, diabetes, or COPD were at significantly greater risk of death. An early cohort study of patients in Wuhan, China, also modeled in-hospital mortality, finding advanced age to be a significant predictor, while a meta-analysis of studies on patients across China reported diabetes and COPD as predictors of more severe outcomes.^{6,7} A large case series study conducted in the New York City area, while not a predictive model, also showed severe outcomes associated with both age and diabetes.⁸ Specifically, age greater than 65 years and diabetes were associated with a higher incidence of intensive care unit admission and invasive ventilation. While no other single study found age, diabetes, and COPD to be significant predictors of mortality, they all appeared in at least one of these studies. Additionally, similar to our study population, both the New York study and Chinese meta-analyses had high rates of hypertension and diabetes in their overall study populations.

The Chinese meta-analysis identified both hypertension and cardiovascular disease as significant risk factors for mortality. While our study did show both of these characteristics to be significantly more common in deceased patients compared to discharged patients, neither were found by our model to be significant predictors of mortality. The New York study, on the other hand, found no association between cardiovascular disease and severe outcomes. Cancer, while not a predictor of mortality, was also found to be significantly more common in deceased patients compared to discharged patients, which was not seen in other studies. These differences in findings could be due to

Table 1. Bivariate analysis; patient demographics and comorbidities on admission.

Characteristics	Total (n=346)	Discharged (n=229)	Deceased (n=117)	P-value
Mean Age (years)	66.86	63.56	73.31	<0.001*
Mean BMI (kg/m ²)	30.58	30.94	29.85	0.252
Sex	--	--	--	0.647
Male	194 (56.1%)	126 (55.0%)	68 (58.1%)	--
Female	152 (43.9%)	103 (45%)	49 (41.9%)	--
Ever smoker	140 (44%)	89 (40.3%)	51 (52.6%)	0.05*
Comorbidities	--	--	--	--
Hypertension	241 (69.7%)	151 (65.9%)	90 (76.9%)	0.037*
Hyperlipidemia	167 (48.3%)	107 (46.7)	60 (51.3%)	0.429
Diabetes	163 (47.1%)	95 (41.5%)	68 (58.1%)	0.004*
Cardiovascular disease	162 (46.8%)	96 (41.9%)	66 (56.4%)	0.012*
Neurological disease	95 (27.5%)	59 (25.8%)	36 (30.8%)	0.373
CKD	82 (23.7%)	45 (19.7%)	37 (31.6%)	0.016*
COPD	58 (16.8%)	27 (11.8%)	31 (26.5%)	0.001*
Cancer	51 (14.7%)	27 (11.8%)	24 (20.5%)	0.037*
Asthma	47 (13.6%)	35 (15.3%)	12 (10.3%)	0.246
Hypothyroid	45 (13.0%)	25 (10.9%)	20 (17.1%)	0.128

*meets 0.05 p-value level.

BMI, body mass index; CKD, chronic kidney disease; COPD, chronic obstructive lung disease.

Table 2. Generalized linear model; risk factors associated with in-hospital mortality.

Risk factors	RR (95% CI)	P-value
Age of 60 or older	4.70 (2.40-9.12)	<0.001*
COPD	1.41 (1.06-1.88)	0.019*
Diabetes	1.43 (1.07-1.92)	0.016*
Hyperlipidemia	0.75 (0.57-0.98)	0.032*

*meets 0.05 p-value level.

COPD, chronic obstructive pulmonary disease; RR, Relative Risk; CI, confidence interval.

insufficient sample sizes in this and other studies, variation between sample populations, or variability in the definition of cardiovascular disease. The New York study, for example, used cardiovascular disease as an umbrella term representing hypertension, coronary artery disease, and congestive heart failure and did not comment on the significance of coronary artery disease or congestive heart failure as risk factors. Our population, with a mean age of 66.86, was older than the populations of the studies in Wuhan (56.0) and New York (63), and, with an average BMI of 30.58, it had more obesity than the sample in New York, in which only 41.7% were obese (BMI \geq 30). Our population also had a higher incidence of hypertension (69.7%), diabetes (47.1%), and COPD (16.8%).

Notably, hyperlipidemia was found to be protective, which differed from the results of other studies.^{6,7,8} It is possible that this effect can be explained by the outpatient use of statins, as these medications are known to have anti-inflammatory properties; recent studies have even proposed that they could have a role in COVID-19 treatment regimens.^{11,12} Our study also differs from the others discussed here, in that it offers a regional perspective; New England is a different geographical and political environment than both New York City and China.

Some regions across the US have seen COVID-19 cases and deaths peak and decline, and many are now seeing a softening of social distancing restrictions. The risk factors that we have identified can be used to aid in the decision-making of HCWs as they guide patients' impending return to in-person healthcare. Professional society guidelines for physicians' return to practice are calling for the continued use of telemedicine, when possible, to minimize the exposure for vulnerable or at-risk patients.^{13,14} Based on our findings, in which patients with age \geq 60, diabetes, and COPD were at greater risk of death when infected, we suggest that these risk factors can be used to identify vulnerable patients. HCWs should continue to postpone in-person care for patients with these risk factors. If HCWs themselves have these risk factors, they should protect themselves by continuing to use proper personal protective equipment or postpone in-person care, if possible.

LIMITATIONS

Chart abstraction yielded several limitations. Some

documentation was incomplete or overly brief, likely exacerbated by the overburdened hospital system. This was especially true for those who arrived at the hospital unconscious, obtunded, or otherwise unable to give a complete history. Data gathering was also limited by incomplete adherence to the standards of chart abstraction.⁹ Performance of chart abstractors was not monitored by an external source, abstractors were not blinded to the hypothesis or patient's group assignment, inter-rater agreement was not tested, and abstraction training was not tested; all are potential sources of bias.

While the final model included only four variables, the modeling process began with 14 variables, yielding 8.36 outcomes per variable. This is less than the ideal number, which increases the likelihood of overfit and type I error. Additionally, we were limited by our small sample size. Low counts of individual comorbidities reduced the likelihood that they would be statistically significant factors in our model.

CONCLUSION

As governments push to re-open businesses and relax restrictions for those returning to work across all industries, including healthcare, we must apply the same precautions based on identification of risk factors for mortality, which our study identified as patients with age \geq 60, diabetes, and COPD. Members of the public should continue prevention measures including frequent handwashing, wearing masks, and avoiding close contact. However, individuals with one or more of the identified risk factors should adhere to CDC guidelines and take extra precautions, including maintaining extra distance, disinfecting common surfaces, or staying home if possible while their coworkers return to the office.^{15,16} Asymptomatic transmission continues to make the spread of COVID difficult to control; thus, the best way to protect the most vulnerable individuals is to reduce as many potential exposures as possible.^{17,18} If we are to reduce burden on the healthcare system and successfully fight this pandemic, we must protect those at greater risk of mortality if hospitalized.

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Novel Barrier Enclosure for Both Aerosol and Droplet Protection Model

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Emergency physicians are on the front lines of treating patients with highly infectious respiratory diseases. Personal protective equipment is one defense against contamination from droplet and aerosol secretions. Intubation is a procedure that greatly can increase provider's risk of exposure. Utilization of an intubation box has been discussed and recommended on social media platforms. There has been scant literature demonstrating the effectiveness of such devices. This study aimed to determine degree of droplet contamination to the intubator utilizing a novel barrier enclosure with a fluorescent simulated respiratory contagion. This model confirmed both added protection to the providers performing intubation, and reduction of spread of the droplets when such a device is applied to patient care. [West J Emerg Med. 2020;21(4)790-794.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

With the spread of severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) worldwide, hospitals must provide equipment and strategies to protect frontline healthcare workers especially during procedures likely to generate aerosols and droplets. Hospitals that have implemented effective strategies to protect healthcare staff have shown low infection rates for healthcare workers.¹ Studies of previous SARS viruses has shown that tracheal intubation is one of the highest risk procedures.² COVID-19 patients frequently present in respiratory distress and often require emergent airway interventions, leading to high risk for exposure to droplet and airborne secretions to healthcare personnel performing pre-oxygenation, induction, and intubation.

The use of an "intubation box" or barrier may protect staff

during intubation.³ A modified barrier was constructed from a 3D printed design and used by investigators. This intubation box was then modified by UNMC anesthesia staff. The design is easily manufactured from snowmobile windshield material at low a cost (\$65-\$100 US), allowing for easy assembly, and disinfection. Unique features include the compact size when folded, making it more portable and easier to store than other alternative boxes constructed from rigid materials. This intubation box is similar in function to the COVid aErosol pRotEction Dome ("COVERED") developed at the University Hospital - Frankfurt, Germany with differences in design.⁴

We performed a simulation exercise to characterize the difference in exposure to an individual using standard (PPE), both with and without the protection from the novel folding intubation box. In comparisons to the recent *New England Journal of Medicine* (NEJM) simulation study, our study aimed to compare both large droplets in a simulated cough set up and micro-droplets using an atomizer.

METHODS

The intubation box is a rigid enclosure with two arm holes on either side for easy access by the intubator, as well as a small semicircle at the base to allow access for oxygen,

suction and ventilator tubing. The box is clear, to allow easy visualization of the patient and equipment.

We conducted three simulations to assess the effectiveness of the device, noting the difference in droplet and aerosol spread for each simulation. The investigators performed a control intubation with standard PPE including: gown, gloves, N95 mask, and face shield, but without the use of the intubation box. Second and third trials with similar PPE were performed using the intubation box used as a barrier to protect the user (Figure 1) in both simulated cough and atomized trials. The mannequin and intubator were decontaminated between all of the simulated trials.

To simulate a cough, we instilled 5 mL of Glo Germ (Glo Germ Company, Moab UT), a fluorescent plastic particle, reconstituted in saline. The 5 mL filled syringe was attached to a bag valve mask (BVM) and a catheter was placed through the neck and into the oropharynx of the high-fidelity mannequin in a retrograde intubation fashion (Figure 2). Using a single hand, the BVM was used to simulate a forceful cough expelling a 5mL volume. Additionally, to generate aerosolization and micro- droplets, a second device was used by attaching the 10 mL filled syringe to an atomizer. To replicate micro droplet dispersal, another 5 mL of fluorescein dye was then atomized (Figure 3). Of note, plastic particle suspension was not used as it was too viscous to successfully atomize. The use of both devices provided replication of both fine and coarse droplets and aerosol spread. After each simulation, an LED black light was used to visualize the spread of the droplets by visualizing the fluorescent dye.

RESULTS

Comparing the area of simulated contamination between our control and experimental models demonstrated marked



Figure 1. Demonstrations of intubation in proper PPE using intubation box.
PPE, personal protective equipment.

Population Health Research Capsule

What do we already know about this issue?
Health care workers are put at risk when performing droplet and aerosol generating procedures. The amount of exposure can be reduced by donning proper personal protective equipment.

What was the research question?
Would a novel barrier device add additional protection to health care workers from droplets and micro-droplet contamination?

What was the major finding of the study?
The intubation box was effective in reducing the amount of direct exposure to simulated respiratory secretions.

How does this improve population health?
Not only would this protect the health care workforce individually, but could have the potential to reduce community spread of asymptomatic highly infectious respiratory diseases.



Figure 2. Large Droplet Cough Model using retrograde intubation technique allows for expelled secretions to come directly from mannequin's mouth. BVM used to forcefully expel 5 mL of fluorescent solution.
BVM, bag valve mask; mL, milliliter.

reduction in spread of fluorescein droplets when using the intubation box. With use of the intubation box, we effectively reduced the contamination of the proceduralist (Figure 4), with exposure limited to the proceduralist's hands and PPE exposed inside the intubation box only and no identified contamination of PPE outside of the enclosure. Spread of fluorescent dye inferiorly onto the patient's chest and lower extremities of greater than 4 feet did occur. In contrast, performing intubation without the intubation box resulted in significant contamination of both the intubator and the room. (Figure 5). The intubator had two areas of exposure that were not covered by PPE, one on the ear and one on the neck (Figure 6). The amount of droplet spread around the room was more than 6 feet without the box and with multidirectional distribution. The video laryngoscope and other equipment outside of the enclosure also showed contamination when the intubation box was not utilized (Figure 7A). Due to the small droplet size from the atomizer, we noticed less spread than the forceful large droplet cough.

DISCUSSION

This simulation demonstrated several important findings pertaining to the protection of healthcare staff during intubation. The intubation box was effective in reducing the amount of direct exposure to simulated respiratory secretions that reached the intubator during a simulation of droplet and aerosol generation during intubation. In addition, the increased exposure to secretions on the proceduralist's PPE without the intubation box leaves them more vulnerable to being exposed after the procedure by imperfect doffing. The box also decreased the amount of simulated secretions that was spread around the room. The majority of the spread of fluorescent droplets were caudal in location. The box is left open for the patient's torso, intravenous support and monitor lines. Our study also showed that proper PPE use is effective in helping to protect the proceduralist from direct exposure from a cough during intubation without a barrier. Overall, the intubation box provided additional protection for healthcare providers during procedures that are high risk to generate aerosols and potentially spread infectious particles, such as intubation.

LIMITATIONS

Some limitations to our simulation were effectively simulating the aerosolization of all secretions from a cough. It was difficult to model this accurately in the simulation lab, and therefore difficult to characterize the box's effect on the generation of the smallest microscopic particles. With the accuracy of the droplet and aerosol simulation difficult to achieve, we are unable to quantify the results. Computerized modeling could be used for quantification and confirmation.

In addition, the box does make the intubation procedure somewhat more technically difficult, as the hand holes restrict freedom of movement of the intubator's arms during the



Figure 3. Micro Droplet Model using atomized 5 mL aliquot of fluorescein to replicate fine particle secretions. Intubator's face shield post intubation without intubation box. mL, milliliter.



Figure 4. Despite heavy contamination of mannequin with large droplet cough using the intubation box; note only limited exposure to intubator's hand that was inside of intubation box. No contamination on intubator's face or torso.



Figure 5. Extensive contamination on intubator's head, and face shield when intubation box was not utilized during a simulated large droplet cough.

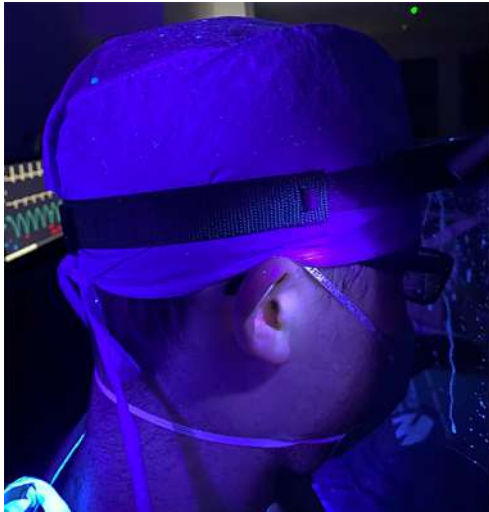


Figure 6. Note additional contamination on intubator's surgical cap ties, and exposed ear during cough simulation when intubation box was not used. Increasing risk of exposure during doffing procedures.

procedure. Current successful use in our hospital's operating rooms shows that the box allows for safe intubation, but considerations should be taken before use including proper training in the procedure and achieving familiarity with the box prior to implementation. The effect experience with the intubation box has on the spread of contaminating droplets is an opportunity for further assessment.

Our model effectively demonstrated the spread of particles with forcible turbulent airflow, as seen with a cough (see supporting slow motion video in the digital format). However, a productive cough was difficult to replicate accurately with attention to velocity, viscosity, and volume of fluid. The utility of this model is more in identifying protection from respiratory secretion exposure. Modifications of the box with a tapered end or even placing a surgical drape at the caudal end of the box may provide additional protection from droplet spread (Figure 7B).

CONCLUSION

One future application for this box could be as a tool to help protect providers who are administering nasopharyngeal swabs to test for SARS-COV-2. The hand ports provide easy access to the patient, while the barrier would help protect the healthcare provider from direct droplet exposure. This is especially important in swab collection procedure requires the patient to remove their mask, and the noxious stimulation of the swab makes the patient more prone to cough, sneeze or gag.

Overall, the use of the novel folding intubation box may prove useful in decreasing the spread of droplet contamination while performing intubation on patients with suspected highly infectious respiratory diseases. Further investigations



Figure 7. Panel A: Not just the laryngoscope blade, but the video laryngoscope screen and cart were also contaminated when intubation box was not employed. Panel B: Modifications to novel intubation were made to reduce the spread of droplets and contamination of room and equipment by adding clear surgical drape to the caudal end of the intubation box (arrow).

into the mitigation of airborne particles, as well as other improvements, should be considered by physicians around the world to create innovative solutions to the problem of protecting healthcare workers worldwide during the SARS-COV-2 pandemic.

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Copyright: © 2020 BranECKi et al. This is an open access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) License. See: <http://creativecommons.org/licenses/by/4.0/> potentially spread infectious particles, such as intubation.

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Management of Agitation During the COVID-19 Pandemic

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The coronavirus disease 2019 (COVID-19) pandemic caused by the coronavirus SARS-CoV-2 has radically altered delivery of care in emergency settings. Unprecedented hardship due to ongoing fears of exposure and threats to personal safety, along with societal measures enacted to curb disease transmission, have had broad psychosocial impact on patients and healthcare workers alike. These changes can significantly affect diagnosing and managing behavioral emergencies such as agitation in the emergency department. On behalf of the American Association for Emergency Psychiatry, we highlight unique considerations for patients with severe behavioral symptoms and staff members managing symptoms of agitation during COVID-19. Early detection and treatment of agitation, precautions to minimize staff hazards, coordination with security personnel and psychiatric services, and avoidance of coercive strategies that cause respiratory depression will help mitigate heightened risks to safety caused by this outbreak. [West J Emerg Med. 2020;21(4)795-800.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

The World Health Organization declared the novel coronavirus disease 2019 (COVID-19) as a pandemic in March 2020, with rising infection rates around the world and within the United States.¹ This outbreak has radically altered delivery of care in emergency departments (ED), as efforts continue to prevent transmission and combat the disease.² Although attention has appropriately been focused on clinical management and emergency preparedness during COVID-19, this historic event has also had significant consequences for mental health that may

be easily overlooked. Unprecedented hardship due to ongoing fears of exposure, threats to personal safety, and limited access to resources have broad psychosocial impact on patients and healthcare workers alike.³ These changes can significantly affect how individuals with behavioral symptoms may present and what management strategies are most appropriate during the care of behavioral emergencies.

Agitation is one of the most common behavioral emergencies in the ED, with 1.7 million episodes⁴ annually in emergency settings and a recent estimated overall ED prevalence of 2.6%.⁵ Agitated patients are among the most challenging to evaluate and manage by emergency physicians, as their excessive psychomotor activity can escalate quickly into violent acts and physically aggressive behavior.⁶ Nationwide, 78% of emergency physicians reported being targets of workplace violence in the previous 12 months.⁷ In 2012, the American Association for

Emergency Psychiatry (AAEP) published Project BETA (Best practices in Evaluation and Treatment of Agitation), consisting of a landmark series of consensus guidelines to provide effective and safety-minded strategies for agitation management with the best interests of the patient in mind while ensuring the safety of healthcare workers.⁴ The Project BETA guidelines focus on a noncoercive approach to manage these patients with an emphasis on de-escalation, safety and risk assessment, and addressing potentially life-threatening medical concerns.^{8,9} Forced medication and physical restraint are reserved as the last resort to control agitation symptoms, given that their use is associated with elevated risk for both patients and staff.¹⁰

The management principles encapsulated within Project BETA remain applicable in the COVID-19 era, but adaptations are needed in light of the unique circumstances and environmental conditions due to the pandemic. Given the possibility of a projected lengthy timeline before this outbreak abates,¹¹ awareness of its effects on the management of agitation is needed now to ensure safety of both patients with behavioral symptoms and frontline healthcare workers caring for them. On behalf of AAEP, we aim to highlight in this work some important unique considerations for the management of agitation in the ED during COVID-19 (Table 1).

COVID-19 EFFECTS ON PATIENT VISITS AND PRESENTATIONS

Psychosocial Factors

The COVID-19 pandemic is occurring during a time of unprecedented digital interconnectedness.¹² Advancements in digital platforms and intense media coverage have amplified the intensity of associated psychological fear, creating a novel “digital pandemic” that significantly exacerbates symptoms of anxiety and stress.¹³ The large-scale public lockdown efforts to implement social distancing has secondarily forced many individuals to stay indoors for prolonged periods of time, increasing the risk of social isolation, tensions within the home, and disruption of positive adaptive behaviors to relieve symptoms of mental illness.¹⁴ In addition, COVID-19 may directly affect workflow and slow down assessments in the ED, leading to escalation of agitation symptoms for those who require immediate attention.

Hospital visitor restrictions reduce risk of transmission¹⁵ but also remove vital links of social and family support for individuals during times of crisis. Since asymptomatic carriers can silently transmit the virus,¹⁶ some patients are fearful that they may unknowingly contract COVID-19 during their time in the ED. Others with symptoms concerning for COVID-19 may escalate their behavior if their expectations for testing or disposition are not met due to limited capacity for EDs to widely test or hospitalize members of the community they serve.¹⁷ These added pressures can increase the risk of agitation even for visits that may not be associated with a behavioral chief complaint. With reports of recent surges in firearm sales across the US,¹⁸ extra vigilance is needed regarding potential dangers due to

weapons both in the healthcare setting and at home, especially for patients with elevated risk of self-harm or violence.¹⁹

Access to Services

Patients presenting with agitation often represent socioeconomically disadvantaged populations with significant health disparities.²⁰ Unfortunately, individuals with homelessness, mental illness, and substance use disorders face additional potential problems with screening, quarantine, and symptom treatment during pandemics.²¹ Preliminary data demonstrating associations between mortality and challenges in accessing healthcare resources have already surfaced during COVID-19.²² Economic hardship and disruption of outpatient mental health services may limit the ability for these individuals to refill their maintenance medications for psychiatric and/or substance use conditions, causing exacerbation or decompensation of their illnesses. This is compounded by closure of shelters, detoxification units, and other high-density communal settings (eg, drop-in centers and soup kitchens) which may reduce their access to critical social services and increase their likelihood to present to the ED in need. As the support systems and outpatient services deteriorate for these patients, the likelihood that they develop decompensation of their underlying mental illness may increase, leading to ED visits and agitated behaviors during their stay.

Clinical Presentations

Although it may seem that increased stress and anxiety would inherently increase the volume of behavioral visits during natural disasters and pandemics, experiences from past events have demonstrated that the effects are quite complex and even counterintuitive.²³ Total mental health-related visits may actually initially decrease as individuals focus on immediate survival and self-protection,²⁴ but those who do seek care appear to have more severe symptoms.²⁵ For example, inpatient psychiatric admissions fell by 20% for the first 30 days following the devastating earthquake in Christchurch, New Zealand.²⁶ New psychiatric presentations following the 2011 Fukushima nuclear plant disaster also decreased, but those admitted had high rates of confusional, manic, and delirious states.²⁷ Given the public perceptions of fear and mistrust around the government’s response to the pandemic,²⁸ individuals with chronic psychotic disorders may incorporate those perceptions into their delusional content and manifest as themes of contamination, persecution, and conspiracy theories. Particular sensitivity and extra efforts to counteract and redirect these sentiments may be needed as part of the management of agitation.

In addition, there are increasing reports of neuropsychiatric symptoms due to COVID-19. Several case reports have documented encephalopathy and delirium as the presenting syndrome for the disease rather than the more common respiratory or gastrointestinal complaints.^{29,30} The Centers for Disease Control and Prevention also found that 6% of hospitalized patients with confirmed COVID-19 had associated

Table 1. Summary of COVID-19 effects.

Effects on visits and presentations	
Psychosocial factors	<ul style="list-style-type: none"> • Increase in stress/anxiety symptoms exacerbated by digital media • Public lockdown increases tensions between individuals in constant close proximity at home & disrupts healthy coping mechanisms • Stress/anxiety due to banning of visitors and fear of COVID-19 exposure when in the hospital • Extra vigilance regarding potential weapons on patients given increase in firearm purchases
Access to services	<ul style="list-style-type: none"> • Patients are likely socioeconomically disadvantaged and suffer more during COVID-19 • Limited access to their prescribed psychiatric/substance use disorder medications • Challenges accessing social services, detox centers, homeless shelters
Clinical presentations	<ul style="list-style-type: none"> • Individuals with milder symptoms may refrain from coming to ED • Patients may be in more severe forms of agitation and delirium • Possible COVID-19 encephalopathy and delirium syndromes • Fears regarding the pandemic may incorporate/feed into delusional content
Effects on care delivery	
Individual staff factors	<ul style="list-style-type: none"> • Staff stress/anxiety levels are high during COVID-19 • Risk to personal safety is elevated from viral transmission and may be compounded during episodes of physical violence • Maneuvering, spatial orientation, awareness of safety, establishing rapport, attempting de-escalation can be limited by being in PPE
Clinical resource limitations	<ul style="list-style-type: none"> • Ancillary services (chaplain, social work) and psychiatric consultation (deployed elsewhere) may be limited during COVID-19 • Medications may be on limited supply due to increased need in ICUs (eg, sedatives) • Lower staffing and slower responses from security personnel due to lower clinical volumes and need to conserve PPE
Evaluation and management recommendations to reduce/address agitation	
Evaluation	<ul style="list-style-type: none"> • Obtain collateral information early • Perform components of the physical exam from a distance if accurate and feasible • Don appropriate PPE and minimize number of staff in direct contact with patient • Consider judicious use of diagnostic studies • Lower threshold for COVID-19 testing before definitive psychiatric evaluation
Management	<ul style="list-style-type: none"> • Pre-emptive action and extra vigilance to detect and treat early signs of agitation and escalating behavior • Prompt and careful coordination with security personnel and psychiatric services • Budget extra time and effort for de-escalation and non-coercive strategies • Treat underlying cause or precipitants of delirium • Caution with sedatives (especially benzodiazepines) and physical restraints for COVID-19+ patients

ED, emergency department; PPE, personal protective equipment; ICU, intensive care unit.

symptoms of altered mental status and confusion.³¹ Elderly patients are at the highest risk for morbidity and mortality related to the disease.³² Acute agitation in patients with delirium caused by hypoxia, a prominent clinical feature of patients infected with COVID-19, complicates the presentation of dementia and psychiatric illness, particularly in the older population.³³ Given the elevated rates of clinical and adverse events associated with delirium and the various neuropsychiatric symptoms that may be associated with COVID-19,³⁴ emergency physicians need to be mindful of these potential complications when evaluating these patients. A thorough mental status exam³⁵ will also help clinicians evaluate the diverse etiologies of any acute behavioral presentation that may be present in this cohort of patients.

COVID-19 EFFECTS ON CARE DELIVERY

Individual Staff Factors

COVID-19 has taken its toll on healthcare workers amidst

multiple additional stressors imposed upon them.³⁶ These include rapid changes in clinical roles and responsibilities, extra workload, disrupted supplies in personal protective equipment (PPE), rationing of resources, and valid fears regarding potential exposure to the disease.³ In particular, those on the front lines in the ED may have increased feelings of anxiety, frustration, and resentment due to these added stressors in a dynamic and high-stress clinical environment.³⁷ Given that de-escalation requires clinicians to remain calm and compassionate despite displays of aggression or violence, these negative emotions due to COVID-19 can significantly undermine efforts to use patient-centered approaches during management of agitation.³⁸

As emergency healthcare workers care for rising volumes of infected patients presenting in extremis, they work at an elevated risk to personal safety from potential occupational exposure to COVID-19.^{39,40} This risk increases further during episodes of patient agitation. Clinicians may come into close physical

contact with COVID-19 positive patients to de-escalate, provide physical control of disruptive behavior, and perform diagnostic and therapeutic procedures. As a result, professional societies recommend that emergency clinicians continuously wear PPE during their entire shift in the ED. They also note that close contact during procedures or processes, including a physical examination, can generate potentially infectious aerosols and requires a higher level of PPE that includes an N95 respirator.⁴¹ However, use of PPE may compromise the emergency clinician's spatial orientation, maneuverability, and awareness of personal safety, which are all vital skills to safely evaluate and manage the agitated patient.^{42,43} PPE also adds physical limitations to recognizing facial features and body language, removing key aspects of nonverbal communication that support successful de-escalation and rapport with agitated patients.

Clinical Resource Limitations

In some geographic areas, EDs are overwhelmed by the volume of COVID-19 infected patients combined with critical shortages of supplies, staffing, and physical space.⁴⁴ Other EDs anecdotally report lower census levels, likely due to a combination of fewer accidental injuries during public lockdown efforts and ED avoidance behaviors by patients fearing exposure to the virus. As a result, staffing models have either decreased or adjusted to focus attention on the surges of COVID-19 cases⁴⁵ and there may be fewer staff available to handle agitated patients in many EDs. In addition, security personnel may have extra responsibilities related to COVID-19 (eg, visitor restrictions, minimizing traffic), impacting the ability for rapid and timely responses to episodes of agitation in the ED. Requirements to ration use of PPE⁴⁶ may further limit the time, attention, and resources normally needed to safely respond to agitation. The increased number of COVID-19 patients with critical care needs has disrupted and limited supplies of sedative medications in the ED.⁴⁷ Ancillary services and psychiatric consultation are also less readily available as they are either furloughed to minimize exposure or deployed to other clinical units with more urgent needs related to the pandemic.¹⁷ Clinicians need to pre-emptively consider these limitations when managing patients at risk for agitation before behavior escalates and resources are needed rapidly.

EVALUATION AND MANAGEMENT RECOMMENDATIONS

In a healthcare system that is already taxed with additional stressors on multiple levels, these factors unique to the COVID-19 era discussed above need to be taken into consideration to mitigate escalation to violent behavior and address potential threats to safety associated with agitation. In light of this elevated occupational hazard, extra measures are needed to continually protect the safety of ED personnel and effectively combat an anticipated lengthy battle with this pandemic, regardless of the clinical concerns or level of agitation.⁴⁸ We highlight specific recommendations on the

evaluation and management of the agitated patient in the setting of COVID-19.

The medical and psychiatric evaluation should proceed in a manner that minimizes COVID-19 exposure risk while effectively detecting dangerous and reversible causes of agitation. Collateral information should be obtained early to counteract limitations of history taking due to social distancing and PPE requirements. The Joint Statement for Care of Patients with Behavioral Health Emergencies and Suspected or Confirmed COVID-19 supports the use of telehealth for screening,⁴⁹ which may not be applicable in every situation but can significantly reduce exposure. If direct contact is required, donning of appropriate PPE, limiting the amount of time clinicians are less than six feet away from the patient, and minimizing the number of staff members at the bedside will reduce any exposure risk.³ The virus has been detected in the saliva of infected patients,^{50,51} and precautions must be taken to minimize aerosol and droplet exposure, which may be magnified in those agitated patients who present with pressured speech or spit at ED personnel.⁵² Judicious use and careful consideration of the utility in diagnostic studies are needed to safely evaluate for potentially life-threatening causes of the patient's agitation. Finally, given known asymptomatic transmission of COVID-19,⁵³ there should be a lower threshold to test these patients for the presence of the virus before admission for medical causes of their agitation or transferring them to definitive psychiatric care.

Project BETA strongly encourages early de-escalation, which combines targeted verbal and nonverbal strategies to assist the patient with calming down and reducing aggressive behavior.⁸ In light of COVID-19, extra vigilance and early pre-emptive action are needed to detect and treat any signs of agitation, including use of objective scales to assess the level of agitation and prompt de-escalation by qualified ED personnel. Extra investment in time and effort to develop a therapeutic relationship and establish trust may be needed to overcome additional patient stressors and physical barriers to create rapport. Clinical personnel should communicate early with hospital security if there is any concern about escalation or violent behaviors to allow for lengthier response times and higher potential for escalation, even in milder forms of agitation. Care coordination with psychiatric services is critical in light of limitations to outpatient mental health and social services.

Patients who are delirious and acutely agitated with concomitant COVID-19 infection deserve special attention given elevated patient risks associated with the viral illness. Unfortunately, the ability to implement non-coercive techniques¹⁰ and reorientation strategies⁵⁴ in treatment of agitation and delirium is compromised by social distancing and isolation measures to minimize COVID-19 spread. Patients who experience persistent and severe agitation or delirium despite de-escalation and attempts to treat underlying causes or precipitants may require physical restraint and use of sedative medication therapy. It is possible that the threshold to use pharmacotherapy may be lower during this pandemic given the

elevated risk to both patients and staff caring for them. Low doses of first-generation antipsychotics such as haloperidol or second-generation antipsychotics such as olanzapine and risperidone have been found to be equally effective in patients with delirium, but have differing onset and side-effect profiles.⁵⁵ Extrapyramidal symptoms are most common with haloperidol, and sedation occurs most frequently with olanzapine.⁵⁶ Adverse events associated with restraints and sedatives, including apnea and respiratory depression, will be significantly more dangerous in light of discordance between clinical and imaging evidence for degree of pulmonary involvement, rapid deterioration in the clinical course, and profound hypoxia associated with COVID-19.⁵⁷ If these pharmacologic measures are required, the patient should be closely monitored with frequent vital signs and continuous cardiac, pulse oximetry, and capnometry monitoring.

CONCLUSION

The COVID-19 pandemic has created unique stressors that may contribute to agitation symptoms. It has also increased personal risks for healthcare staff working in the ED, while adding new limitations to appropriately and effectively manage agitation due to measures needed to combat viral transmission. Extra measures for early detection, treatment of underlying causes for agitation, precautions to minimize staff hazards, coordination with security and psychiatric services, and avoidance of coercive strategies that cause respiratory depression will help mitigate heightened risks to safety caused by this outbreak.

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Telehealth Solutions for In-hospital Communication with Patients Under Isolation During COVID-19

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The coronavirus disease 2019 (COVID-19) pandemic is a public health crisis that has quickly overwhelmed our healthcare system. It has led to significant shortages in personal protective equipment (PPE), ventilators, and intensive care unit beds across the nation. As the initial entry point for patients with suspected COVID illness, emergency departments (ED) have had to adapt quickly to prioritize the safety of patients and providers while still delivering optimal, timely patient care. COVID-19 has presented many challenges for the ED that also extend to all inpatient services. Some of these key challenges are the fundamental tasks of communicating with patients in respiratory isolation while minimizing PPE usage and enabling all patients who have been affected by hospitals' visitor restrictions to connect with their families. We discuss the design principles behind implementing a robust in-hospital telehealth system for patient-provider and patient-family communication, provide a review of the strengths and weaknesses of potential videoconferencing options, and deliver concise, step-by-step guides for setting up a secure, low-cost, user-friendly solution that can be rapidly deployed. [West J Emerg Med. 2020;21(4)801-806.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

We have taken for granted the convenience of evaluating our patients directly by walking into rooms and having a conversation. The traditional workflow of taking a history, performing a physical exam and diagnostic tests, monitoring

treatments, and disposition planning necessitates multiple bedside interactions between patients and hospital staff. The coronavirus disease 2019 (COVID-19) pandemic has caused a national shortage of personal protective equipment (PPE).¹ With so many in respiratory isolation and a limited supply of PPE, how do we adapt patient-provider communication to minimize unnecessary entry-exit cycles?²⁻⁴ Additionally, hospitals' bans on visitors have impacted all patients, not only those with COVID-19.^{5,6} Hospitals worldwide are seeking methods to communicate with patients under isolation precautions while protecting their staff, efficiently using PPE, and enabling patients to virtually be with their families at a time when they

are ill and alone.^{7,8} Given the current crisis, rapid deployment of communication solutions is urgently needed.^{3,7,9} Some hospitals are already integrating telehealth into their workflows, but many are unsure how to do so appropriately.¹⁰⁻¹²

Prior to this pandemic, only Health Insurance Portability and Accountability Act (HIPAA)-compliant software offering business associate agreements (BAA) were allowed for medical use. Even if the same company offered a free version of the same software, it could not be used because no BAA agreement existed between the company and the hospital. However, with the sudden demand for accessible telehealth options, the Department of Health and Human Services (HHS) temporarily expanded allowable applications (apps) and “will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered healthcare providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency...us[ing] any non-public facing remote communication product that is available to communicate with patients.”¹³

Current telemedicine technologies leverage mobile devices and high-speed Internet access to connect patients with providers. Numerous established companies and startups offer telemedicine products. Typically, telemedicine platforms are used for consultations¹⁴⁻¹⁶ or remote treatment monitoring.¹⁷⁻²⁰ Few studies have focused on implementing real-time videoconferencing in the emergency department or inpatient settings,^{16,21} and none have described a specific implementation strategy for doing so within the unique constraints of the COVID-19 pandemic.

Our academic medical center is part of the second-largest public hospital system in the country, and, like many, we are challenged with limited PPE stock and readily accessible funding for telehealth equipment and software. To address this unmet need for in-hospital patient communication, we developed a cost-effective plan for rapid implementation with minimal equipment and setup. In this article, we discuss the design principles to effectively implement such a solution and compare common videoconferencing apps. Based on these factors, we produced a step-by-step guide to implement the protocol we deployed in our health system (see Supplements 2-3 for detailed guides). We hope that this work provides a blueprint for how resource-limited hospitals can rapidly implement an affordable, in-hospital telehealth communication solution during the COVID-19 pandemic.

GOALS

Staff Communication

With limited PPE supply and exposure risks associated with frequent PPE doffing, hospitals should minimize entry-exit cycles by necessary staff to isolated patients' rooms.^{10,22-24} Staff who only need to speak to the patient should not have to enter the room at all.⁹ Examples include registration clerks, case managers, and social workers. Room entry is not necessary for answering many patient questions, updating care plans, or recording during

a resuscitation. In the case of teaching hospitals, the entire team does not need to enter the room; attendings and other learners may stand outside to observe the patient encounter.

Family Communication

A vital part of humanistic care for all patients during this crisis is to provide a way for them to connect with their families. When patients are under isolation precautions, visitation is restricted.²⁵ During the current pandemic, some hospitals have instituted blanket “no visitors” policies⁵ for all patients, which can have significant detrimental impacts on patient mental health and recovery.²⁶⁻²⁸ Both COVID-19 and non-COVID-19 patients admitted to the hospital are often quite ill, feel isolated from their loved ones,²⁹ and may be faced with daunting goals of care conversations.³⁰ For patients who do not speak English, do not own a mobile phone, or are not used to navigating the healthcare system alone, isolation creates additional anxiety.³¹

DESIGN PRINCIPLES FOR COMMUNICATION SOLUTIONS

With the above goals in mind, we factored in cost of implementation, privacy concerns,³² administrative overhead, and ease of use in practice into the final design choices. In addition to hospital-provided videoconferencing solutions to the communication problem, multiple low-tech methods were considered (Supplement 1). We provide an analysis of the advantages and disadvantages of each method.

Major advantages of video communication are that it provides a more personal connection and participants can better assess non-verbal cues. Implementation is limited by high upfront costs of purchasing devices and HIPAA-compliant software for videoconferencing. Without hospital-backed funding, the recurring costs of these subscription services become prohibitive. However, during the COVID-19 crisis, the most recent HHS notice¹³ enables providers who are otherwise unable to afford HIPAA-compliant technologies to leverage free software that meets these requirements to provide urgent patient care.

Device Costs

The upfront cost of buying tablets may be restrictive for resource-limited hospitals. The most common tablets run one of three operating systems (Android, Windows, iOS), and cost approximately \$50-\$500. If the hospital cannot buy particular devices because of funding or contractual constraints, community donations of used tablets are another option.

Device Security

To restrict user access to other applications and device settings, tablets may be placed in “kiosk mode,” a feature commonly used in retail that is available on Android (screen pinning), Microsoft Surface (kiosk mode), and iOS devices (guided access). All three major platforms also offer enterprise management solutions to set up and electronically secure devices. The limitation of Microsoft Surfaces is that, other than

Skype, most conferencing services are not native apps available through the Microsoft Store and may have to be used in the web browser; thus, browser restrictions would also need to be set.

Patient Privacy

Although HHS will not penalize hospitals for using software that is not officially HIPAA compliant during the COVID-19 pandemic, hospitals must still ensure patient privacy when implementing telehealth solutions. Depending on the chosen app, the methods to maintain patient privacy are either to create unique accounts for each patient or to choose an app that only allows calls from an approved contact list. If calls cannot be restricted to a given list, there is a risk of strangers calling patients.

As the devices will be used with multiple patients, video capture and screenshots should be disabled so that recordings or photos of staff or patients are not stored on the device. With standard, off-the-shelf devices rather than enterprise devices, it is not possible to globally disable device screenshot settings, but individual apps may restrict screenshots. For apps that do allow recording or screen capture, hospital staff would need to verify that everything is deleted from the device after each use.

Staff Safety

By using commonly available free apps for patient communication, hospital staff may wish to use their own devices for expediency. However, this access should be prohibited for both patient privacy and staff safety. Staff members' personal accounts should not be able to call hospital devices, and patients should not have access to staff members' personal contact information. Instead, there should be additional hospital accounts or devices available for staff to call patients. The device and app settings must also be configured so that patient-facing devices are secure from settings changes and unapproved downloads.

Usability

User-friendly apps decrease the need for staff to repeatedly enter patient rooms to help patients use the devices, which would negate efforts to limit exposure and PPE usage. Apps should be easy to use and have limited menu options; multiple menus are confusing and make initiating calls difficult.³³ For programs that are only available via a web browser (rather than a native app), patients could accidentally close the tab and have difficulty returning to the app without staff assistance. All common operating systems also include accessibility settings, which enable larger font sizes for patients with decreased vision. When possible, these should be enabled by default.

Although staff can help a patient troubleshoot the app, if the family is not familiar with the corresponding app, hospital staff will have difficulty remotely helping the family troubleshoot. Apps that generate a website link, instead of requiring family to download an app or create an account, will be the most broadly accessible. Of the apps tested, only Zoom

provides this option.

Administrative Overhead

Unlike with HIPAA-compliant enterprise versions, free services have less granular control over app settings. For apps where settings are accessible by patients from within the app, these settings have to be re-verified between patients.

Videoconferencing apps enable patients to see and speak to family members who are not allowed to visit. Adding family members' contact information to an app creates minimal administrative burden while bringing great psychological and emotional benefit to patients. However, giving family members account information to reach their loved ones also means giving families future access to other patients if settings are not configured properly.

Apps must have settings that restrict contacts and maintain anonymity, or unique accounts must be created for each patient in order for shared devices to maintain patient privacy. For apps with settings that restrict calls to approved contacts only, new accounts do not need to be generated between each patient use; however, call and chat logs should be deleted so that the next patient cannot see prior conversations or non-hospital contacts. Enterprise management solutions offer remote device resets between patients, but may not be able to remotely clear the call and chat logs of individual apps. For apps that do not restrict callers, the administrative burden of generating unique accounts for each patient or even asking patients to create their own accounts is high.

Free Google accounts are limited to 10 lifetime accounts per person; thus, non-enterprise creation of free unique accounts for Google-based apps is not sustainable. Regardless of which devices or apps are used, at minimum, accounts will need to be created for the devices. For those who are unable to provision enterprise accounts, for non-Google products a domain name can be purchased for approximately \$10 per year and used to generate an unlimited number of usernames that route to a single email account for easy account and password management.

COMPARISON OF FREE APPLICATIONS

We compared the advantages and disadvantages of four well-known, commonly available free videoconferencing apps (Table). The app features described in the table address the principles of security (app settings hidden from patients, encryption); patient privacy (calls restricted to contacts only); usability (cross-platform, dials landlines); and administrative overhead (call logs). Another major usability factor is the user interface (UI). FaceTime and Google Duo have simple UIs where the focus of the app is to make a call. The other apps have multiple tabs for chats, calls, contacts, or settings.

DISCUSSION

Ultimately, based on ease of setup, patient privacy settings, UI simplicity, and ease of between-patient maintenance, we implemented our protocol using FaceTime.

Table. Videoconferencing applications and features.

Service	Cross-platform ^a	App settings hidden ^b	Restricted contacts ^c	Dials landlines ^d	E2EE ^e	Call logs only ^f	Additional factors
FaceTime	No	Yes	Yes	With cell provider	Yes	Yes	--
Google Duo	Yes	No	No	No	Yes	Yes	Free version limit of 10 lifetime accounts per person
Google Hangouts	Yes	No	Yes	Yes	No	No	Free version limit of 10 lifetime accounts per person
Skype	Yes	No	Yes	\$3/account/month for unlimited calls within United States	Option*	No	On iPhone only, unable to disable integrated calling, so both app and device call log need to be cleared
Zoom	Yes	No	Yes	Price varies based on usage	No	No	

E2EE, end-to-end encryption; *app*, application.

*Skype provides an E2EE option for chats and audio calls, but the option is difficult to find and must be reselected via multiple menus each time you initiate a call.

^aCross-Platform: Available on multiple different operating systems and devices.

^bApp Settings Hidden: If the app settings are visible and editable by patients, the settings would need to be manually checked and reset after each use.

^cRestricted Contacts: If an app is unable to restrict calls to contacts only, in order to maintain patient privacy a new account or password would need to be generated for each patient. Even if an app can restrict contacts, if the app settings aren't hidden, the patient may still be able to remove the restriction within the app. The only free service that we tested that provides full restriction is FaceTime.

^dDials Landlines: Services that do not offer free calls to landlines limit the ability to call a translator or loved ones without smartphones or computers. Services that require an associated cell phone number cost upwards of \$15 per month for unlimited calls.

^eE2EE: All of these services offer some degree of encryption. E2EE is the most secure form of encryption; only the people in the conversation can see or hear messages; no third parties can decrypt any transmitted data—even the company that makes the product.

^fCall Logs Only: Apps that enable typed chats generate chat logs, which, in addition to call logs and contact lists, need to be deleted after each patient's use.

Choosing FaceTime limited us to using iPads rather than Android devices, which can cost less. However, by repurposing existing devices and using donated devices that our health system received from a nonprofit organization, our total device and application cost was \$0.

Compared to other options, FaceTime was the easiest to set up. FaceTime comes preinstalled. Other than each device's login information, no additional downloads or accounts needed to be made. FaceTime is the only free app we tested that fully hides app and device settings from patients when both kiosk mode and parental controls are activated. These restrictions and the absence of chats allow for the greatest device security, patient privacy, and ease of between-patient maintenance. Unlike Zoom, Skype, or Google Hangouts, FaceTime has only one function: making calls. FaceTime does not have additional menus that patients, particularly non-English-speaking patients, could be confused by, thereby decreasing provider time required to teach patients how to use the app.

Although FaceTime has superior usability and security advantages, the major drawback is that FaceTime is only available on Apple products. This limitation does not affect in-hospital communication with staff, but patients can only call loved ones with Apple devices. To enable patients whose

families do not have Apple devices to make calls, we set up an on-site family call center. Regardless of the app chosen, using apps to call families will create barriers for those who do not have tablets or laptops, have difficulty downloading apps or setting up accounts, or have limited access to the Internet. Offering a call center where families can use hospital-provided tablets would address this limitation.

We worked with multiple stakeholders—including patients, staff, hospital administration, clinical informaticists, infection control, and facilities management—to implement the optimal solution for our health system. Engaging hospital and health system leadership early enabled us to seek approval from the various branches in parallel, expediting the process. Enterprise solutions are preferred for easy, standardized maintenance, but can be cost-prohibitive.

In recent weeks, hospitals have attempted to rapidly expand in-hospital telehealth, and preliminary experiences have been positive.^{34,35} Whereas most pre-pandemic telehealth tools targeted outpatient care, the increased demand for in-hospital usage creates opportunities for new solutions. Now that we have implemented a telehealth solution in our hospital to address this care gap, we plan to conduct a longitudinal study to quantify the value of these tools to patients and providers in facilitating communication and improving

quality of care. The success of programs like ours would provide justification for health systems to invest in HIPAA-compliant solutions post-pandemic or regulatory bodies to expand the definition of HIPAA-compliant software. Moving forward, in-hospital video telemedicine use can be expanded beyond communicating with isolated patients to enhance the following processes: increased ability of offsite consultants to perform limited evaluations; safer triage practices during future pandemics, and minimizing staff during resuscitations by enabling additional staff to safely observe from outside the room.

Our in-depth analysis presented here can guide readers seeking to expand in-hospital telehealth capabilities by adapting existing systems based on these design principles for their own hospitals. For readers in need of an immediate solution during this pandemic, we provide detailed, step-by-step setup and usage guides (Supplements 2-3) for the solution we implemented. We believe that our novel work will serve as a blueprint for how resource-limited hospital systems can quickly implement a secure, low-cost, user-friendly telehealth communication solution to safely care for a large number of isolated patients while conserving PPE usage during the ongoing COVID-19 pandemic.

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COVID-19 Pandemic and Care of Older Adults at Risk for Delirium and Cognitive Vulnerability

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BACKGROUND

We are facing a global coronavirus disease 2019 (COVID-19) pandemic since the virus emerged in Wuhan, China. Although this virus does not discriminate on the basis of race, ethnicity, gender, or socioeconomic status, it has the highest mortality rate in older adults. Mentation is an important part of the geriatric evaluation, as it is listed as part of the age-friendly healthcare framework that incorporates four key interventions – what matters; medication; mentation; and mobility (4Ms). Geriatric conditions such as delirium, dementia, and depression will confound an emergent evaluation because of an atypical manifestation of COVID-19 and non-COVID-19 related illness. Furthermore, these conditions are exacerbated by the effects of either social distancing or the financial crisis on vulnerable members of society.¹ There is a particular concern that delirium will increase amid the COVID-19 pandemic due to the use of infectious disease isolation, and also pose a unique challenge to the evaluation of mentation in older adults, due to both COVID-19 and the common central nervous system (CNS) pathology not related to the COVID-19 such as cerebrovascular accident (CVA).

COVID-19, Stroke, and Encephalopathy

A recent study showed that the rate of altered consciousness, a cardinal feature of encephalopathy with COVID-19, is about 15%.² As the prevalence of COVID-19 increases, one study found that 30-40% of the COVID-19 patients had non-specific neurological symptoms such as headaches, while more classic and typical symptoms of fever,

cough, and dyspnea developed later.² There is a risk of missing CVA if altered mental status is presumed due to COVID-19, since the rate of CVA is 5-6% among the COVID-19 patients.² This study included 214 patients with a mean age of 52.7 years, but there is a paucity of literature focused on older adults who may be at even higher risk due to underlying, more advanced, atherosclerosis.

The mechanism for encephalopathy may be due to an accelerated inflammatory response, the use of sedatives to facilitate mechanical ventilation, and multiple organ dysfunction. In addition, there are reports of meningitis and encephalitis from COVID-19.³ The CNS COVID-19 infection occurs through hematogenous spread and also directly via the olfactory nerve. One case report has identified the viral RNA in cerebrospinal fluid even when a nasopharyngeal swab did not detect SARS-CoV-2. A study focused on the geriatric patient population is urgently needed to understand the typical and atypical manifestations of the COVID-19 related CNS pathology.

The Effect of Social Distancing and Personal Protective Equipment on Cognitively Vulnerable Older Adults

Social distancing measures will likely isolate older adults who live in the community and skilled nursing facilities, which could increase their risk of delirium. As delirium is a response to changes in familiar stimuli in the elder brain, COVID social isolation is an extreme form of absence of stimuli that beget delirium. It is likely that social distancing is an extreme form of catalyst for delirium. The use of personal protective equipment (PPE) and social distancing will likely have a negative effect on patients with dementia and delirium.⁴ Hwang et al, with the Geriatric Emergency Department Collaborative, recently published a one-page handout on delirium in the emergency department that highlights a number of these issues.⁵

Reducing the workforce to minimize the spread of infection will negatively affect the hospital and skilled nursing facility programs that typically help those with or at

risk of cognitive impairment. Furthermore, communication, orientation, and early mobilization, which are key to preventing or treating delirium, will be more difficult when providers wear masks, distance themselves, and keep patients in their rooms without visitors. Masks may also introduce barriers for those with hearing impairments who may augment hearing with lip reading. The effects of these isolation precautions may have a negative impact that could trigger or exacerbate delirium or delirium with dementia.

Evaluation of Older Adults Using the Innovation

The use of telemedicine (tele-stroke) has been presented as an effective modality in the literature.⁶ Telemedicine has been used for diagnostic purposes for sore throat and appendicitis even before the COVID-19 pandemic, but this modality needs to be tested further for delirium evaluation and management. A delirium evaluation includes the confusion assessment method and other tools, and a concise review is available elsewhere.⁷ Delirium assessment over the telephone was conducted almost two decades ago, and study authors concluded that face-to-face assessment was preferred.⁸ Since then, newer tools that are more concise and adaptable with telemedicine have been developed and can be examined in future research.⁸ Hollander et al suggested the optimized use of telehealth visits; it is likely telemedicine will be an effective alternative to in-person visits, decreasing the risk of infection between patients and healthcare providers.⁹ Leveraging telemedicine to diagnose and management has been implemented in the psychiatry practice amid the COVID pandemic, and there is the potential to improve care for older adults.¹⁰

CONCLUSION

The unique aspect of neurological symptoms related to COVID-19 adds to the complexity of emergency preparedness and high-quality care for older adults while minimizing provider exposure. It is recommended that older adults with delirium be routinely evaluated for COVID-19; thus, PPE is necessary to avoid the risk of exposure when COVID-19 infection cannot be ruled out based on prehospital evaluation. The risk of stroke will increase with the COVID-19, and we will need to consider stroke mimics caused by the COVID-19. Telemedicine technology, although potentially disorienting itself, may provide an opportunity to engage, evaluate, and manage older adults more effectively while minimizing in-person exposure for COVID-19.

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Recommendations for Prehospital Airway Management in Patients with Suspected COVID-19 Infection

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In light of the rapid spread of coronavirus disease 2019 (COVID-19) across the United States, the Centers for Disease Control and Prevention (CDC) and hospitals nationwide have developed new protocols to address infection control as well as the care of critical patients. Airway management has been particularly difficult; the challenge of quickly establishing an airway in patients must be balanced by the risk of aerosolizing respiratory secretions and putting the provider at risk of infection. Significant attention has been given to developing protocols for the emergency department and critical care units, but little guidance regarding establishing airway and respiratory support for patients in the prehospital setting has been made available. While some of the recommendations can be extrapolated from hospital guidelines, other factors such as environment and available resources make these protocols unfeasible. Through review of current literature the authors established recommendations regarding airway management and the provision of respiratory support to patients developing respiratory failure related to COVID-19. [West J Emerg Med. 2020;21(4)809-812.]

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INTRODUCTION

Since the discovery of the novel human coronavirus (now SARS-CoV-2, commonly referred to as COVID-19) was reported to the World Health Organization on December 31, 2019, our understanding of the pathophysiology and treatment of the disease has rapidly evolved.¹ As of February 11, 14% of COVID-19 infections in China have been classified as severe and 5% as critical, with patients developing respiratory failure.² As early as March 4, Chinese health officials estimate the case fatality rate of COVID-19 at 3.7%.³ Current recommendations

for airway management in patients with respiratory failure have targeted in-hospital providers (emergency physicians, critical care physicians, and anesthesiologists) and have neglected to provide guidance for prehospital providers who may find themselves making these critical decisions without on-scene oversight.³⁻⁷ It is our goal to provide recommendations for emergency medical service (EMS) providers regarding establishing airway protection/respiratory support for patients with suspected COVID-19 infection.

PERSONS OF INTEREST AND INITIAL ASSESSMENT

As EMS is the likely first point of contact that many potential COVID-19 patients have with the healthcare system, it is important for EMS providers to be able to identify patients in whom COVID-19 infection should be suspected. Screening of patients for possible person under investigation (PUI) status should begin with 911 dispatch and other public

safety answering points. Screening for COVID-19 infection should include the following: history of foreign travel or travel to current hotspots identified by the Centers for Disease Control and Prevention; close contact (less than six feet for more than 10 minutes) of a known COVID-19 positive patient or PUI; or to a person with a flu-like illness with worsening dyspnea, body aches, sore throat, non-productive cough, and/or gastrointestinal symptoms.⁸ If no screening information has been provided, precautions should be taken when responding to any patient who reports dyspnea or flu-like illness. A surgical mask should be placed on the patient to minimize possible spread of infection as the first step in airway management to protect EMS providers. Suspicion of a possible PUI by dispatch, or after on-scene evaluation, should be communicated to the receiving hospital to allow for adequate preparations for the patient's arrival to the emergency department, especially if the need for a definitive airway appears imminent.

SUMMARY OF CURRENT IN-HOSPITAL RECOMMENDATIONS

Current recommendations for in-hospital providers regarding patients who develop respiratory failure involve endotracheal intubation using the rapid sequence intubation (RSI) technique and video laryngoscopy (VL) with minimal use of bag-valve mask (BVM) ventilation.³⁻⁵ BVM use should be limited to minimize aerosol generation as a potential source of viral exposure.^{4,5} For patients with normal airway, awake intubation should be avoided and modified RSI is strongly recommended. Sufficient paralysis should be assured before intubation to decrease the likelihood of aerosolizing infectious respiratory secretions as well as to prevent aspiration/vomiting.⁹ As previously shown, apneic oxygenation can prevent desaturation and should be implemented; however, it is important to take into consideration that the use of non-rebreather (NRB) or nasal cannula increases the risk of aerosolizing viral particles.^{4,10,11} A surgical mask should be placed over the NRB or nasal cannula to limit contamination of the environment. VL has also been shown in previous studies to be superior to direct laryngoscopy (DL) for first-pass success rate.¹² Therefore, to minimize exposure and maximize first-pass success, it is currently recommended to use VL for intubation. Following intubation, a HEPA filter is attached directly to the endotracheal tube and then attached to the ventilator.

The use of noninvasive positive pressure ventilation (NIV) in patients with suspected COVID-19 infections is controversial. While some observations have shown that high-flow nasal cannula has shown improvements in oxygenation and decreased rates of intubation, there have been no reported changes in mortality.⁴ NIV is associated with increased aerosolization of respiratory secretions and, if there is an improper seal, the risk of contaminating the work environment is significantly increased. Of the bedside therapies used to support oxygenation and ventilation, clinical experience taken from the 2012 SARS

coronavirus outbreak suggests that intubation, BVM manual ventilation, bedside suction, and non-invasive ventilation pose the highest airborne droplet exposure risks.¹³ It was also observed by Brewster et al that patients on NIV have a high rate of failure (76%), requiring intubation.⁴ This also mirrors findings from a multicenter cohort of 302 patients with Middle East respiratory syndrome coronavirus, in which 92% of patients treated with bilevel positive airway pressure failed this modality and required intubation.¹⁴ Therefore, consideration must be taken that most patients will fail NIV and if resources allow, patients should be considered for endotracheal intubation as the initial intervention, which will also provide source control as long as the ventilator circuit is intact.

Supraglottic airway (SGA) devices pose a unique challenge in dealing with the spread of COVID-19. While they are superior to NIV, they do not provide the same quality of seal compared to that of endotracheal intubation.^{4,5} Overinflation with bag ventilation could potentially aerosolize respiratory secretions, increasing the risk of spreading infection to healthcare providers as well as contaminating the workspace. However, second-generation SGAs (LMA ProSeal, intubating LMA Fastrach, laryngeal tube, laryngeal tube LTS II, Combitube, and Easytube) have been shown to have improved seal compared to their first-generation counterparts.^{4,15-17} In light of the current situation, EMS providers in Seattle, Washington, have already begun using I-gel SGAs with HEPA filters in the field for respiratory arrest or failure in the event of failed RSI.^{18,19}

PREHOSPITAL RECOMMENDATIONS

First and foremost, appropriate personal protective equipment (PPE) should be worn at all times while providing care for patients with a suspected COVID-19 infection. This should include a N95 mask or powered air purifying respirator (if not available, use a surgical mask), gloves, gown, and eye protection (minimum of glasses with temple shield). A surgical mask should be placed on the patient as soon as possible to prevent further contamination of the workspace with infectious respiratory droplets.^{8,20}

If first responders have access to VL and are able to perform RSI, then endotracheal intubation in the field should be attempted. Preoxygenation with nasal cannula and non-rebreather mask should be performed, making sure to cover with a surgical mask as well as leaving the nasal cannula in place while attempting intubation. Providers should only make a single attempt at endotracheal intubation, as multiple unsuccessful attempts will result in repeated, unnecessary exposure to potentially infectious respiratory droplets. Avoid DL in these cases for similar reasons. If a patient has impending respiratory failure and providers do not have access to VL or RSI, they should proceed immediately to SGA insertion with a second-generation device.

Following successful ET or SGA placement, a HEPA filter should be immediately attached *directly* to the ET tube or SGA (see Figure 1 for details). This will prevent contamination

of upstream equipment, such as capnography, tubing, and the bag-valve apparatus. Failure to do so could also result in contamination of the monitor, as capnography is not rated to filter out viral particles.²¹

Basic Life Support (BLS) crews may find themselves in a challenging predicament, as in some districts and states BLS crews are unable to use SGAs. The current American Heart Association guidelines allow for the use of BVM for BLS resuscitation with a tight seal and a HEPA filter while wearing appropriate PPE.²² BVM should only be used if unable to implement ET tube or SGA. In this scenario a two-person technique is recommended to provide the best seal as well as implementation of appropriate airway adjuncts (nasal pharyngeal airway, oral pharyngeal airway, etc). Caution should be taken to prevent over-inflation of the lungs. Plans to transfer care to an Advanced Life Support (ALS) crew or intercept should be implemented immediately.

CONCLUSION

The rapid spread of COVID-19 has posed unique challenges to prehospital providers with regard to airway management. Using appropriate PPE is essential in avoiding unnecessary exposure to prehospital providers. The placement of a surgical mask, as soon as logistically possible, on the patient and HEPA filter use with any airway adjuncts is crucial to prevent potential spread of infectious respiratory droplets. Important changes to the usual algorithm for intubating patients involves avoiding DL in favor of VL, the use of RSI if available, and progression to second-generation SGA if endotracheal intubation attempt fails or if RSI/VL is not available. By following these recommendations, prehospital providers will be able to minimize their risk of contracting COVID-19 infection while providing high-quality care for their critical patients.

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Home-based Testing for SARS-CoV-2: Leveraging Prehospital Resources for Vulnerable Populations

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Introduction: Expanded testing for SARS-CoV-2 is critical to characterizing the extent of community spread of COVID-19 and to identifying infectious cohorts. Unfortunately, current facility-based testing compounds shortcomings in testing availability, neglecting those who are frail or physically unable to travel to a testing facility.

Methods: We developed an emergency medical service (EMS)-based home testing and evaluation program, leveraging existing community EMS resources. This program has kept vulnerable populations out of the emergency department, reduced cost, and improved access to care.

Results: Our EMS-based testing program can test approximately 15 homebound patients per day. Through April 2020 our program had performed 477 home-based tests. Additionally, we have recently undertaken several mass testing operations, testing up to 900 patients per testing site.

Conclusion: Facility-based SARS-CoV-2 testing requires that a patient physically present to a facility for a nasopharyngeal swap to be collected. Unfortunately, access may be limited for patients that are homebound, chronically ill, or without a means of private transportation. By leveraging existing EMS infrastructure in new ways, our community has been able to keep almost 500 vulnerable patients in their home. Using EMS, we can strengthen the healthcare system's response to the evolving COVID-19 pandemic and support at-risk populations, including those that are underserved, homebound, and frail. [West J Emerg Med. 2020;21(4)813-816.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

COVID-19, the disease caused by the novel coronavirus

SARS-CoV-2, has rapidly developed into a global pandemic affecting millions of people across the world. As the pandemic spreads throughout the United States, healthcare systems simultaneously face increasing demand for services and constraints on resources available for laboratory testing, inpatient care, and infection control. Expanded access to testing in particular is critical to characterizing the extent of community spread and recognizing infectious cohorts.¹ Delays in testing can lead to devastating consequences, and

insufficient testing was identified as a critical shortcoming in the early response to SARS-CoV-2 in China and the US compared to countries with more aggressive testing programs.²⁻⁵ In February 2020 delayed recognition was at least partially responsible for the spread of the virus to 81 residents at a nursing facility in Washington State, resulting in 23 deaths.⁶

Current facility-based practices of testing for SARS-CoV-2 further compound present shortcomings in testing availability. In the US 9% of households do not have access to a private vehicle and more than 15% of older adults are characterized as frail and may be physically unable to travel to a facility for testing without assistance.⁷ Almost 6% of the Medicare population is mostly or completely homebound.⁸ These persons often rely on the assistance of others, who may either serve as a vector for COVID-19 or may inadvertently become infected by the homebound populations they serve. Inability to test homebound adults may not only have a role increasing spread to household members but also to personal care assistants taking care of other vulnerable populations at the same time. Furthermore, individuals facing related barriers to facility-based testing are often those most vulnerable to COVID-19 due to existing medical co-morbidities and socioeconomic risk. The evolving pandemic will likely further amplify existing barriers to healthcare, especially among people of advanced age and populations who are poor, homeless, or living with chronic illness, populations known to have a higher mortality rate from COVID-19.⁶ Further, these communities are more likely to be disconnected from medical care, lack safe places for shelter, and face financial strain if they become ill.

METHODS

Recognizing these inefficiencies and shortcomings, we designed an emergency medical services (EMS)-based SARS-CoV-2 home testing and evaluation program in partnership with local ambulance agencies. The goal of this program was to efficiently expand access to SARS-CoV-2 testing, leveraging a resource already available in most communities in the US. The use of EMS providers to respond to novel healthcare needs, termed mobile integrated healthcare (MIH), has been widely described in a variety of contexts. EMS providers have local ties and cultural competency similar to community health workers coupled with a high level of medical knowledge and procedural skills. Further, EMS providers are well versed in the evaluation and management of this complicated patient population, able to leverage their unique insights to identify subtle changes in patients' health status, making them well-suited and uniquely prepared to serve the communities that stand to be most dramatically impacted by the COVID-19 pandemic.

In the early days of the COVID-19 pandemic, our hospital system worked closely with a partner EMS agency to develop a mobile testing program. As part of emergency provisions pertaining to the COVID-19 response, the Massachusetts

Department of Public Health added the skill of nasopharyngeal swab collection to our 2020 Statewide Treatment Protocols as acceptable practice for providers at the emergency medical technician (EMT) or paramedic level. Initially, six paramedics were trained in the skill of nasopharyngeal swab collection for polymerase chain reaction analysis, specimen handling, and safe use of specialized personal protective equipment (PPE). We were able to quickly scale this workforce to 17 EMTs and paramedics over the first week of the program. Our standard training was of two hours duration, after which all providers were able to demonstrate proficiency not only in the skill of nasopharyngeal swab collection, but in the process of responding to a dispatch for SARS-CoV-2 testing as well.

RESULTS

In our program, after a physician or advanced practice provider deems that a patient requires testing based on symptoms and epidemiological or occupational risk factors, an EMS provider is deployed to the patient's home to collect a nasopharyngeal swab and then transports the specimen to the appropriate laboratory testing facility. EMS providers work in a team of no less than two, allowing for a monitor to carefully observe specimen collection for any PPE breeches, and to collect handoff of the specimen into a sterile receptacle after collection. The technician collecting the sample wears recommended PPE including an N95 mask, eye protection, an impermeable gown, and gloves. Gloves are changed after each patient encounter and gowns are changed any time the technician interacts with a new environment, in line with guidelines for facility-based testing. A mobile team of two providers can test approximately 15 homebound patients per day, depending on geographic distances. A larger team can test several hundred in highly orchestrated mass-testing operations. We currently operate up to two teams of two paramedics per day testing up to 20 patients, depending on the geographic distance covered. If the testing radius is small only two paramedics are needed.

Unfortunately, laboratory testing in the home introduces operational inefficiencies depending on patient geography. While the home visit to obtain the nasopharyngeal swab is quick, the team spends significant time traveling point to point. Most of our patients reside within a small geographic area, taking our paramedics an estimated 20 minutes to respond to an individual address. However, some patients reside up to an hour from our main hospital campus. These distances are mitigated by cohorting patients with similar geographic distributions, with one EMS testing unit responding to a geographic cluster of patients.

Like many healthcare systems with limited access to and supply of testing materials for COVID-19, our system's testing criteria are rapidly evolving. To date, the majority of patients tested through our program have been symptomatic. However in recent weeks, as access to testing capacity has increased, we have begun testing certain asymptomatic individuals as

well. One such example includes COVID-19 positive patients needing clearance to return to hemodialysis. As of April 30, our program has performed 477 home-based tests.

In addition to our home-based mobile testing operation, we have recently undertaken several mass-testing operations, using a larger team of six providers to test 900 patients at a single site over eight hours. These campaigns include sites such as senior living communities and skilled nursing facilities. Our Department of Public Health had leveraged our program to test over 11,667 patients as of April 30 at 941 facilities across the Commonwealth of Massachusetts.⁹

DISCUSSION

Facility-based SARS-CoV-2 testing, as employed within our system, requires a patient to physically present to a facility for a nasopharyngeal swab to be collected. Some of these facilities are traditional healthcare settings such as hospitals, while others such as “drive-through” testing sites may be more accessible. However, in almost all cases access is limited, particularly for patients who are homebound, chronically ill, or without a means of private transportation. Use of rideshare or public transportation is not possible due to the risk of spreading infection, and public transportation is similarly not an option. Lacking other viable options, these high-risk patients were transported to the facility by ambulance – a solution that was inefficient and costly, took ambulances offline and unable to respond to our community, and put additional healthcare workers at risk of exposure.

Leveraging community resources and employing an EMS provider model improves healthcare resource utilization by 1) ensuring that patients who do not need acute care are diverted away from crowded emergency departments and ambulatory clinics; 2) maximizing ambulance operational time; 3) reducing cost; and 4) accessing medically challenging and traditionally underserved patient populations. Future considerations for employing MIH programs for patients with COVID-19 include incorporating remote monitoring capabilities and outpatient home visits, as well as expanding operations of hospital-at-home programs offering inpatient level care at home. These efforts are designed to augment the health system’s capacity to deliver acute care services and meet the escalating demands of the COVID-19 pandemic. Furthermore, we believe these efforts will be sustained and extend any organization’s prior value-based care journey and which the COVID-19 pandemic has only accelerated.

LIMITATIONS

Our special pathogens home-testing program is subject to a few limitations. First, the program is currently limited to testing only, without incorporating home monitoring or treatment for COVID-19. Second, at-home testing introduces unavoidable inefficiencies. Mass testing is more efficient but can be challenging to coordinate, especially while complying with physical distancing restrictions. This service is also primarily hospital funded. While the Centers for Medicare and Medicaid

Services has suggested that there may be reimbursement for collection of SARS-CoV-2 tests for patients unable to travel, how or whether this will be implemented remains unclear. Finally, we do not yet have results to report for our patients and the prevalence of COVID-19 in our community may not be generalizable. As of April 30, our community had a positivity rate of 19% of patients who were tested.⁹

CONCLUSION

While this EMS-based home testing program created for COVID-19 is one of the first of its kind in the US, it will certainly not be the last. Healthcare organizations across the US can prepare for this rapidly expanding pandemic through the use of EMS and MIH to support diagnosis as well as evaluation, monitoring, and treatment of COVID-19. By leveraging the existing EMS infrastructure in new ways, our community has been able to keep almost 500 vulnerable patients in their homes. We have further been able to support our public health infrastructure by testing thousands of residents of vulnerable facilities including nursing homes, assisted living facilities, and other state-run facilities. Using EMS, we can strengthen the healthcare system’s response to the evolving COVID-19 pandemic and support at-risk populations, such as those that are underserved, homebound, or frail. These resources are already available in our communities and in the face of this pandemic, there is no time to wait.

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Low-cost Videolaryngoscope in Response to COVID-19 Pandemic

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To the Editor:

As the novel coronavirus 2019 (COVID-19) has rapidly become a global pandemic, emergency physicians worldwide play essential roles in the frontline management of critically ill patients with COVID-19. In emergency airway management, video laryngoscopes (VL) are recommended over direct laryngoscopy to minimize healthcare worker exposure to aerosolized particles.¹ However, the VL may be too expensive or unavailable in resource-limited settings, where it is needed to protect the limited number of healthcare providers. We, therefore, reintroduce the idea of creating a low-cost VL from the direct laryngoscope (DL) and a low-cost (approximately \$8) smartphone borescope, which is widely available to purchase online. The borescope camera should be secured at the same level as the light sources of the Macintosh blade for the optimal view (Figure, Video). Previous studies of such “Do-It-Yourself” (DIY) VL demonstrated an improved glottic view and increased ease of use in simulated settings for novices and may be comparable to the commercial VL for experienced intubators.^{2,3} Moreover, if the capability exists, the disposable blade could be produced from 3D printing.²

Emphasis should be on proper training with the DIY VL, as intubation with VL requires different skills when compared with DL and commercial VL.^{4,5} Our experience with the DIY VL has led to the following observations. First, we found the



Figure. A low-cost videolaryngoscope created from the direct laryngoscope and a low-cost smartphone borescope.

Video. The video shows a view from the low-cost videolaryngoscope during simulated intubation. Please see Supplementary File.

device was easy to use, even by novices. Importantly, instead of connecting to a smartphone, the device should be joined with a tablet to provide a larger screen to facilitate visualization. Second, since the borescope has a cylindrical shape, it easily rotates,

so the camera should be aligned correctly and tightly secured. If the camera is misaligned or rotated during intubation, the laryngoscopic view on the screen will be oblique or even turned upside down, which may lead to an unsuccessful intubation attempt. Lastly, we noted that the borescope functioned well after it was thoroughly cleaned with detergent and water and disinfected with ortho-phthalaldehyde, our general disinfection protocol. However, if there is a potential concern about contamination or provider safety, the borescope can be discarded as a single-use apparatus since the cost is affordable.

In conclusion, we believe DIY VL is an acceptable option in clinical settings with limited resources in response to emergency endotracheal intubation in the COVID-19 pandemic.

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Decrease in Trauma Admissions with COVID-19 Pandemic

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Introduction: The COVID-19 pandemic has led to social distancing and decreased travel in the United States. The impact of these interventions on trauma and emergency general surgery patient volume has not yet been described.

Methods: We compared trauma admissions and emergency general surgery (EGS) cases between February 1–April 14 from 2017–2020 in five two-week time periods. Data were compared across time periods with Poisson regression analysis.

Results: There were significant decreases in overall trauma admissions (57.4% decrease, $p < 0.001$); motor vehicle collisions (MVC) (80.5% decrease, $p < 0.001$); and non-MVCs (45.1% decrease, $p < 0.001$) from February–April 2020. We found no significant change in EGS cases ($p = 0.70$). Nor was there was a significant change in trauma cases in any other year 2017–2019.

Conclusion: The COVID-19 pandemic's burden of disease correlated with a significant decrease in trauma admissions, with MVCs experiencing a larger decrease than non-MVCs. [West J Emerg Med. 2020;21(4)819–822.]

Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

Trauma is a leading cause of death in the United States.¹ Trauma care has improved over the last decades, although mortality and morbidity remain high. Injury prevention efforts are the leading strategy to reduce trauma-related death.² Motor vehicle collisions (MVC) cause a large proportion of traumatic injuries in the US.³ Despite a focus on injury prevention, rates of traumatic injuries and deaths remain unchanged over the previous four decades.¹

Coronavirus disease COVID-19 has placed many constraints on Americans. Voluntary orders were imposed in New Hampshire, which our Level II trauma center serves, to close schools on March 16, 2020, and to stay at home on

March 27, 2020. These closures decreased the number of people interacting with others and out of the house in their communities.⁴ As MVCs are common mechanisms of traumatic injuries and are the most common cause of trauma at our Level II trauma center, we hypothesized that social distancing and isolation would be associated with significantly less trauma volume. Fewer people being out in their communities should result in fewer opportunities for injuries.

METHODS

This was a retrospective analysis of previously obtained quality improvement data; institutional review board approval was not required. We reviewed trauma admissions, divided into MVC and non-MVC-related, and emergency general surgery (EGS) cases per day from February 1–April 14 of 2017, 2018, 2019, and 2020. Data were divided into five approximately equal study periods: 1) February 1–14; 2) February 15–29; 3) March 1–15; 4) March 16–31; and 5) April 1–14. The second period ended with the first confirmed COVID-19 death in the US, and

the fourth period began with the closures of schools in New Hampshire. We compared trauma rates among years and time periods and years using log-linear Poisson regression models. The Poisson model was selected based on the distribution of trauma incident frequency, which is centered around low values and exhibits a right-skewed pattern with few days in which many trauma cases were recorded. These results were then followed up with pairwise Poisson rate ratio tests to further analyze the change in trauma, MVC, and non-MVC across these time periods. We used R software (R Foundation for Statistical Computing) for graphics and analysis.

RESULTS

Daily trauma volume from 2017 to 2020 is displayed in Figure 1. There is a qualitative drop off visible after February 29, 2020. The overall Poisson model demonstrates a significant overall increase in trauma volume each year from 2017 to 2020 (relative risk [RR] 1.09; 95% confidence interval [CI], 1.02-1.16; $p = 0.01$), as well as a significant decrease from one time period to another (RR 0.93; 95% CI, 0.88-0.98, $p < 0.001$). However, when broken down by year (Table 1), this difference between time periods is completely accounted for by the significant decreased in trauma volume in 2020 after February 29, 2020 ($p < 0.001$). There were no significant changes across the time periods in 2017-2019. There were no significant changes in EGS cases either from 2017-2020 (RR 1.05, 95% CI, 0.92-1.20, $p = 0.45$) or between the individual time periods (RR 1.04, 95% CI, 0.94-1.16, $p =$

Population Health Research Capsule

What do we already know about this issue?
This is the first study on the effect of COVID-19 and social distancing on trauma volume.

What was the research question?
How did COVID-19 and social distancing affect trauma volume and emergency general surgery (EGS) volume?

What was the major finding of the study?
There was a significant decrease in trauma volume but not EGS volume associated with the COVID-19 pandemic.

How does this improve population health?
Our study illustrates that population health measures enforcing social distancing also decreased trauma volume.

0.47). Similarly, when broken down by year (Table 1), there is no difference between EGS operations per day across the time periods in any individual year.

When trauma admissions were broken down into MVCs and

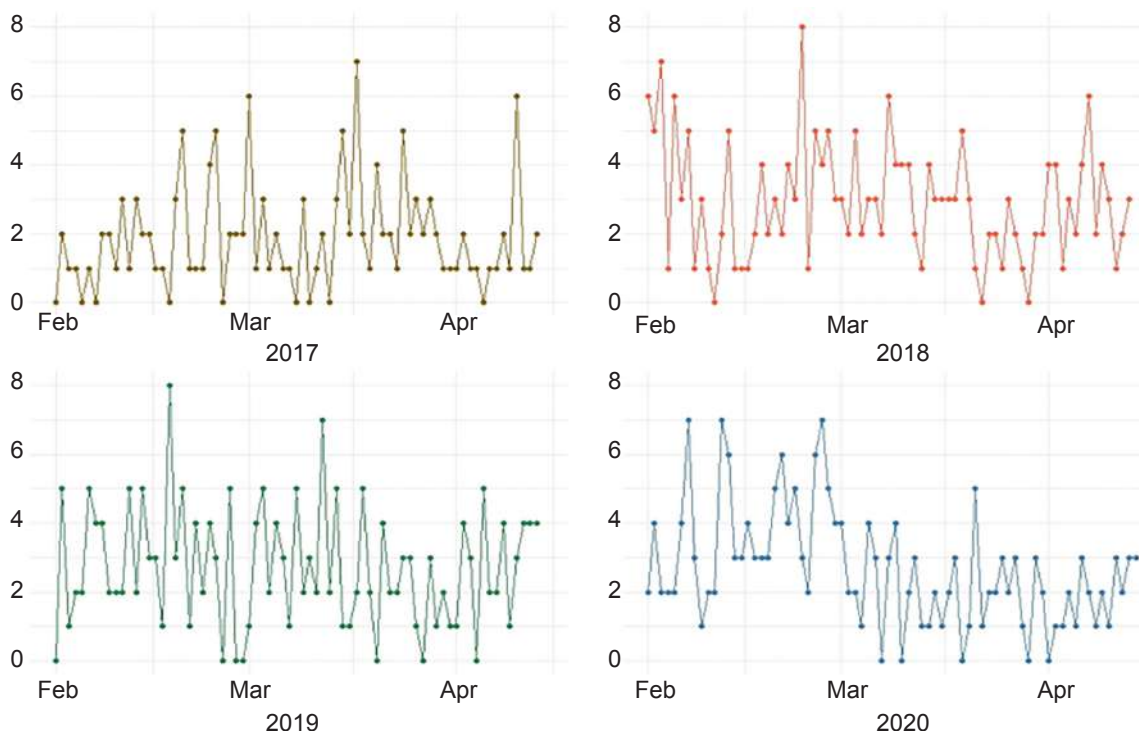


Figure 1. Daily trauma admissions at Portsmouth Regional Hospital from February 1-April 14, 2017-2020.

non-MVCs, there were significant decreases in both across the five time periods in 2020, with both p values <0.001 (Table 2). The percentage decrease in MVCs (80.5% decrease from peak in period 2 to trough in period 5) was larger than non-MVCs (45.1% decrease from peak in period 2 to trough in period 5).

DISCUSSION

The COVID-19 pandemic correlated with a significant decrease in trauma volume at our Level II trauma center. Although our model showed a steady increase in trauma volume at our center year over year from 2017 to 2020, trauma volume declined significantly across the five time periods in 2020. Both MVC and non-MVC trauma were affected. As might be expected given the effects of social distancing, the percentage decrease in MVC trauma admissions (80.5%) was greater than the decrease in non-MVC trauma admissions (45.1%) across the five time periods. It is surprising that the decrease in trauma volume at our Level I trauma center started in early March, as the community mobility report suggested that overall movement in New Hampshire did not decrease until after schools were closed on March 16.⁴ We postulate that although overall movement did not decrease until March 16, people were already modifying their behavior starting in early March. Similar data showing that consumer spending, time at work, and hours worked predated state-mandated closures in many states has recently been published in the *New York Times*.⁵ As opposed to trauma volume, EGS operative volume did not change significantly across the

four periods in 2020, or from year to year from 2017-2020. This is unsurprising because EGS pathologies, as opposed to trauma, are unrelated to physical distancing.

LIMITATIONS

Although this is a small study, it is the first report on the effect of social distancing on trauma morbidity. Trauma by its nature often has much variation from month to month, so it is possible that there were other factors involved in the decrease in trauma volume in March and April 2020 compared to February. However, since there was not a significant difference between these time periods in any other year from 2017-2020, and there was a significant overall increase in trauma volume year over year, this lends credence to the conclusion that COVID-19 and the public's fear of contracting it was responsible for the decrease. Further study is warranted as social distancing continues.

CONCLUSION

We report a significant decrease in trauma volume starting on March 1, 2020, possibly due to the COVID-19 pandemic, without effect on EGS operative volume. As the volume appeared to decrease prior to the state-mandated social distancing, we speculate that the general public was modifying its behavior independent of government orders. It is unclear whether trauma volume from domestic violence or self-injurious behavior will increase as social distancing continues. This may impact future injury prevention efforts.

Table 1. Total trauma admissions and emergency general surgery cases per day across five time periods from 2017 and 2020 with Poisson regression p-values.

	Year	2/1-2/14	2/15-2/29	3/1-3/15	3/16-3/31	4/1-4/14	P-value
Total trauma admissions per day	2017	1.36	2.00	1.73	2.75	1.50	0.32
	2018	3.20	3.21	3.20	2.13	2.93	0.19
	2019	2.93	3.00	3.07	2.00	2.71	0.28
	2020	3.33	4.20	2.13	1.94	1.79	<0.001
	Year	2/1-2/14	2/15-2/29	3/1-3/15	3/16-3/31	4/1-4/14	P-value
Emergency general surgery operations per day	2017	0.50	0.14	0.53	0.25	0.50	0.86
	2018	0.93	0.64	1.13	0.38	1.36	0.19
	2019	0.50	0.64	0.47	0.19	1.00	0.43
	2020	0.53	0.67	0.87	0.31	0.64	0.70

Table 2. Breakdown of 2020 trauma admissions per day into motor vehicle collisions (MVC) and non-MVCs across five time periods with Poisson regression p values.

	2/1-2/14	2/15-2/29	3/1-3/15	3/16-3/31	4/1-4/14	P-value
MVCs	0.93	1.47	0.47	0.56	0.29	<0.001
Non-MVCs	2.40	2.73	1.67	1.38	1.50	<0.001

MVC, motor vehicle collision.

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Mobilization of a Simulation Platform to Facilitate a System-wide Response to the COVID-19 Pandemic

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Disclaimer: Due to the rapidly evolving nature of this outbreak, and in the interests of rapid dissemination of reliable, actionable information, this paper went through expedited peer review. Additionally, information should be considered current only at the time of publication and may evolve as the science develops.

INTRODUCTION

While simulation plays a prominent role in healthcare education at every level,¹ the ability to perform traditional, in-person simulation has been practically eliminated by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV), or COVID-19, pandemic. Simultaneously, COVID-19-related education has become vital, as providers work to expand their knowledge base and learn new skills. Were it not for social distancing, simulation would play a major role in addressing the pandemic's challenges. Simulation-based education could help providers optimize patient care while minimizing viral aerosolization. Simulation could even teach strategies for coping with the emotional consequences of working during a pandemic.

Despite limitations on traditional operations, simulation platforms should explore opportunities to support the COVID-19 pandemic response. On a basic level, active engagement in the response helps keep simulation programs relevant. On a more idealistic level, simulation can play an important role in combating one of the greatest human challenges in recent memory. With modifications, versions of traditional simulation education can continue: some activities can move to videoconference, and mannequins can be distributed to clinical areas for in situ education. The pandemic also provides opportunities for simulation services to move beyond classic roles: simulation labs have medical supplies that can be repurposed clinically, and simulation specialists have unique skill

sets that can be applied outside the simulation lab.

In many ways, the simulation community has already shown its utility during the pandemic response, highlighting the utility of simulation for optimizing personal protective equipment (PPE) utilization and evaluating the readiness of a COVID-19 inpatient unit.^{2,3,4} We discuss strategies our simulation platform used to work synergistically with our emergency departments (ED) and our health system to address the COVID-19 pandemic. (Table 1) We hope this discussion stimulates ideas for unique and unexpected ways resources can be leveraged as part of the pandemic response.

STRATEGIES

Development of COVID-19-specific Simulation Modules for Emergency Medicine Residents

The value of simulation to emergency medicine (EM) residents during the pandemic is multifold: it allows them to develop and hone new skills for managing COVID-19 patients without risking viral exposure and compromising personal safety. We developed a simulation scenario featuring a COVID-19 patient with progressive respiratory distress. This low-fidelity simulation required only a videoconferencing platform, a rudimentary monitor, and the simulation moderator.

Residents were divided into groups of ~5 learners, and each group worked through the case, explaining COVID-19-specific interventions step-by-step. They had to identify the patient's high risk for decompensation, escalate oxygen therapy, highlight opportunities for reducing virus aerosolization, employ methods for awake proning, effectively preoxygenate, intubate, and subsequently manage the ventilator. Initial management was primarily performed by first-year residents; the peri-intubation phase was managed primarily by second-year residents; and

Table 1. Simulation strategies to combat the COVID-19 pandemic.

Videoconference-based simulation for emergency medicine residents
Self-directed <i>in situ</i> simulation augmented by video for training on new equipment
Repurposing simulation equipment for clinical use
Development of training videos for a rapidly-expanding telemedicine platform
Exploring personal protective equipment donations from partner companies
Redeploying simulation specialists to support telemedicine endeavors

the post-intubation phase was managed primarily by third-year residents. A debrief followed.

While EM resident simulations often push learners outside their comfort zones and force them to make important medical decisions in critically ill patients with limited information, this simulation was designed to provide learners with the confidence to manage the intricacies of respiratory failure due to COVID-19. The remote-learning format worked well because the simulation avoided a procedural focus and instead focused on differentiating COVID-19 management from classic acute respiratory distress syndrome management. The low-fidelity, distance-learning simulation was well received by residents and faculty moderators.

Facilitating Self-Directed *In Situ* Simulation

Frequently, simulation training on new equipment happens in groups, either in the simulation lab or *in situ*. It is usually moderated by an instructor who has a deep-rooted understanding of best practices and who can provide real-time, constructive feedback to learners. Because of the pandemic, training on new equipment has required modification of this approach.

Our health system provided each ED with a plexiglass box designed to reduce droplet spread of the COVID-19 virus by encapsulating a patient's head during intubation.^{5,6,7} With the controversy surrounding the utility of such barrier enclosure devices^{8,9,10,11} and with the changes in intubation mechanics required for their use, our providers could choose whether or not to incorporate the box into their clinical practice. To help providers assess the practicality of these devices and to allow providers the opportunity to practice with them, we deployed intubating heads, laryngoscopes, and endotracheal tubes to our departments for EM faculty and residents to practice with individually.

We also demonstrated a simulated intubation via videoconference, discussing changes in practice required by the box and highlighting potential challenges with its use. The session was recorded and subsequently distributed to our group via YouTube. By combining *in situ*, self-directed simulation with a recorded videoconference, we re-imagined how to train providers on newly introduced clinical equipment.

Repurposing Simulation Equipment for Clinical Use

Simulation labs frequently obtain durable medical equipment in two ways: 1) They purchase state-of-the-art equipment from vendors; or 2) they receive equipment donated from the clinical arena when it has been replaced or become outdated. Either way, this equipment has little or no difference from equipment used clinically. As such, in a crisis it can be repurposed for clinical use.

Because of the importance of video laryngoscope (VL)-based airway management during the pandemic,^{12,13} obtaining additional VL devices became a top priority for our EDs. Pre-COVID-19, most of our EDs had one or two VLs, and many of the VL blades undergo sterile processing before re-use. The prospect of multiple simultaneous COVID-19-related VL intubations led us to strategically distribute our simulation lab's four VLs among our EDs. Each laryngoscope was evaluated by the destination hospital's biomedical engineering department, and each received certification for clinical use. Some required minor maintenance, such as battery replacement. Other simulation materials that could be deployed clinically include anesthesia machines, which can be used as ventilators, and personal protective equipment (PPE).

Instructional Video Development for Telemedicine Provider Training

Because of the pandemic, use of telehealth in our EDs has expanded greatly: the number of EDs using a telehealth triage provider has increased, and EM telehealth providers may now discharge well-appearing, low-risk ED patients suspected to have COVID-19. These telehealth encounters vary significantly from in-person encounters: establishing rapport is different, and the evaluation relies heavily on the patient's history, vital signs, and overall appearance. On a technological level, providers need to navigate new electronic interfaces as they progress through the patient encounter.

Our simulation-focused emergency physicians addressed these challenges by creating video-recorded simulated patient encounters via screen-capture software. The videos showed telehealth providers the steps required to start and stop the visits, as well as the key components for each type of visit. The video of a simulated ED triage encounter highlighted the brevity of these visits, as patients are seen in-person later in their ED stay. The videos simulating candidates for ED discharge highlighted the depth required by these visits, as well as reasons patients should be sent into the main ED for further evaluation. A separate training video was created showing the steps required on the triage nurse's side of the telehealth interface. These videos were incorporated into telehealth training on the same day they were created.

Exploring Donation Possibilities from Partner Companies

Simulation labs often work with private companies to design and purchase materials that improve the fidelity of simulation. Some of these relationships, especially with design and three-

dimensional (3D) printing companies, can be longstanding and mutually beneficial. One of our partner 3D printing companies offered to donate thousands of face masks for clinicians. Exploring these partnerships for potential donations could be highly beneficial to health systems.

Simulation Staff Redeployment to Support a Telemedicine Platform

In mid-March, our health system's Simulation Training and Education Lab (SiTEL) canceled all classic simulation training. This was done, in part, for social distancing. Simultaneously, there was a greater need to support the system's rapidly growing telemedicine platform. As EM-based telehealth expanded, outpatient clinics added virtual appointments, and urgent care telemedicine visits increased nearly 50-fold.

In response, SiTEL redeployed 23 full-time simulation, training, and education staff, along with 65 other full-time associates, into telehealth support roles. Despite a lack of significant prior telehealth experience, the staff refocused their training and education expertise over the course of six days. They developed a telehealth support center that has since trained over 12,000 healthcare providers on the equipment necessary to participate in telemedicine. Support center staff conduct test calls, ensuring providers can navigate telemedicine interfaces, have quality audiovisual connections, and have professional-appearing workspaces.

CONCLUSION

During normal operations, simulation serves as a vital tool that allows learners to translate textbook concepts into safe,

exceptional bedside care. Both social distancing and preparations for a pandemic caused a near-complete shutdown of classic simulation operations. Using our robust simulation platform, we supported our health network's preparation for and management of the current pandemic. We used virtual and in situ simulation to prepare for critically ill COVID-19 patients; we repurposed simulation supplies for clinical use; we prepared healthcare providers to perform virtual evaluation and management of patients; we engaged vendors to obtain PPE; and we shifted our simulation staff's focus to telemedicine. We hope that many of these strategies can be adopted in other EDs, hospitals, and health systems. Additionally, we hope this discussion stimulates ideas for how existing resources can be re-imagined and leveraged in response to the COVID-19 pandemic.

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Fall Prevention Knowledge, Attitudes, and Behaviors: A Survey of Emergency Providers

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Introduction: Falls are a frequent reason geriatric patients visit the emergency department (ED). To help providers, the Geriatric Emergency Department Guidelines were created to establish a standard of care for geriatric patients in the ED. We conducted a survey of emergency providers to assess 1) their knowledge of fall epidemiology and the geriatric ED guidelines; 2) their current ED practice for geriatric fall patients; and 3) their willingness to conduct fall-prevention interventions.

Methods: We conducted an anonymous survey of emergency providers including attending physicians, residents, and physician assistants at a single, urban, Level 1 trauma, tertiary referral hospital in the northeast United States.

Results: We had a response rate of 75% (102/136). The majority of providers felt that all geriatric patients should undergo screening for fall risk factors (84%, 86/102), and most (76%, 77/102) answered that all geriatric patients screened and at risk for falls should have an intervention performed. While most (80%, 82/102) answered that geriatric falls prevention was very important, providers were not willing to spend much time on screening or interventions. Less than half (44%, 45/102) were willing to spend 2-5 minutes on a fall risk assessment and prevention, while 46% (47/102) were willing to spend less than 2 minutes.

Conclusion: Emergency providers understand the importance of geriatric fall prevention but lack knowledge of which patients to screen and are not willing to spend more than a few minutes on screening for fall interventions. Future studies must take into account provider knowledge and willingness to intervene. [West J Emerg Med. 2020;21(4)826-829.]

INTRODUCTION

Falls are common among the geriatric population. Annually, one in every three adults over the age of 65 living in the community falls.¹ These older adult fallers make up three million visits to the emergency department (ED) each year and represent 10% of the ED visits among that cohort.^{2,3} Direct medical care costs due to falls have been estimated to be \$200 million for fatal and \$19 billion for non-fatal, fall-related injuries.⁴ ED fall patients experience high rates of adverse events.⁵ This places a significant burden on emergency clinicians given the frequency with which

the ED cares for such patients.

In an attempt to standardize geriatric ED care, the Geriatric Emergency Department Guidelines were created.⁶ One of the areas of focus was care for geriatric patients following a fall. The guidelines recommend implementing a fall risk assessment tool, using a multidisciplinary team that includes physical therapy, occupational therapy, social work, nursing, and physicians to arrange expedited outpatient follow-up.⁶ However, current ED practice is not concordant with the ED fall guidelines.⁷ It is not clear whether providers do not know about the guidelines or

they do know but feel the guidelines are too cumbersome in their already time-constrained practice.⁷

To design a successful ED fall intervention, it is important to determine emergency providers' level of knowledge and practices and what they are willing to do for fall patients while they are in the ED. We conducted a survey of emergency providers including staff, residents, and physician assistants (PA) to assess their knowledge of fall epidemiology and the geriatric ED guidelines as well as to gather information on current ED practice for geriatric fall patients. Additionally, we asked providers which patients they thought should be evaluated for fall risk and how much time they were willing to dedicate to fall-prevention interventions.

METHODS

We conducted an anonymous survey in June–August 2017 of emergency providers including attending physicians, residents and PAs at a single, tertiary, Level 1 trauma center located in the northeast United States that sees approximately 100,000 adult patients per year, 25% of whom are over the age of 65. The survey was designed and administered using Redcap (Research Electronic Data Capture) a secure, web-based, electronic data capture tool. Fall experts and qualitative survey experts reviewed and provided feedback on the survey instrument. It was edited accordingly and subsequently piloted among attendings and PAs and ultimately approved by our institutional review board.

We obtained the names of all attendings, residents, and PAs who worked in the ED, using departmental and hospital e-mail listservs. We excluded PAs and attendings who worked per diem or did not see patients clinically. We then emailed each provider with information about the survey and sent two follow-up participation reminders on June 30, 2017, and July 19, 2017. The survey design and sampling methods were conducted in accordance with the guidelines described by Mello et al in a commentary on surveying in emergency medicine (EM).⁸ We compared the difference in proportions of the responses stratified by type of ED providers using chi-square or Fisher's exact analysis.

RESULTS

As displayed in Table 1, we had a response rate of 75% (102/136). Of the 102 respondents, 33 (32%) were attending physicians, 38 (37%) were resident physicians, and 31 (30%) were PAs. Non-responders were primarily residents (33%, 20/60) followed by attending physicians (23%, 10/43) and PAs (1%, 3/33). When stratified by type of provider there were no significant differences in responses except for vision (p-value 0.012), orthostatic blood pressure measurement (p-value 0.030), strength/absence or presence of peripheral neuropathy (p-value 0.010), and ensuring a home safety assessment (p-value 0.036).

In terms of knowledge about falls, most respondents overestimated the frequency with which older adults fall (which is approximately a third of the time).¹ When answering the question "On average, what percentage of community dwelling

patients >65 years of age fall annually?" 44% (45/102) answered 34–50%, while 13% (13/102) answered more than 50%. Our survey also showed that the vast majority of respondents were not familiar with the Geriatric ED Guidelines with 66% (67/102) and 32% (33/102) reporting being not at all familiar or only somewhat familiar with them.

Regarding fall screening, interestingly, the overwhelming majority of respondents, 84% (86/102), answered that all patients should undergo screening for fall risk factors, while 15% (15/102) felt only people who come to the ED with a recent fall (two weeks or less) should be screened. Only 1% (1/102) answered that only patients with extremely high risk for future falls should undergo screening. Furthermore, in response to the question "On which geriatric patients should emergency clinicians intervene?" most survey participants (76%, 77/102) answered that all geriatric patients screened and at risk for falls should have an intervention, while 23% (23/102) answered all geriatric patients who present after a fall should have an intervention.

While respondents felt it was important to prevent falls, most were not willing to spend more than five minutes to do so. When asked "How important is it to you to prevent recurrent falls among elderly ED patients?" 80% (82/102) answered very important and 3% (3/102) answered slightly important, indicating that participants at least think that fall prevention is important. Unfortunately, when asked "How much time would you be willing to spend on a fall risk assessment and prevention tool?" only 1% (1/102) reported being willing to spend > 10 minutes, 6% (6/102) were willing to spend 6–10 minutes, and 44% (45/102) were willing to spend 2–5 minutes with the rest reporting only being willing to spend < 2 minutes (46%, 47/102) or no time 3% (3/102).

Our respondents then reported the three major barriers to implementing geriatric falls prevention. The overwhelming response was "Not enough time" (87%, 89/102), followed by "Do not know how to intervene" (51%, 52/102), "No ED resources to intervene" (47%, 48/102), and "Inadequate training on fall evaluation/prevention" (45%, 46/102).

DISCUSSION

This survey demonstrates that ED providers understand the importance of fall prevention in the older population but lack knowledge of specific screening tools or interventions to prevent future falls in their patients. Our results also demonstrate a lack of knowledge about fall epidemiology and the existence of the Geriatric ED Guidelines, likely explaining why compliance with the guidelines is poor.⁷ While providers occasionally ask some fall-specific questions or conduct some type of intervention, fall interventions are not done on the majority of patients. This likely is due to a lack of consistency in the amount of EM geriatric training in residency and a lack of knowledge of fall guidelines.⁹

While our statistical analysis could only detect an overall difference in frequency of responses across providers on whether they tested vision, orthostatic blood pressure, strength/absence or presence of peripheral neuropathy and performed a home

Table 1. Emergency Department Provider Survey Responses to how frequently they ask about fall risk factors (N=102).

Question/measurement	Never, N(%)						Sometimes, N(%)						All the time, N (%)						
	Total N=102	Attending	Resident	PA	Total N=102	PA	Total N=102	Attending	Resident	PA	Total N=102	Attending	Resident	PA	Total N=102	Attending	Resident	PA	P-value
When obtaining a history from an older ED fall patients, how often do you do the following?																			
Ask about previous falls?	2(2)	0	1(50)	1(50)	72(71)	1(50)	24(33)	27(38)	21(39)	28(27)	9(32)	10(35)	9(32)	9(32)	28(27)	9(32)	10(35)	9(32)	0.964
Ask about difficulty with gait and/or balance?	5(5)	2(40)	3(60)	0	59(58)	0	20(34)	25(42)	14(24)	38(37)	11(29)	10(26)	11(29)	38(37)	11(29)	10(26)	17(44)	0.094	
Ask about syncope symptoms?	0	n/a	n/a	n/a	46(45)	n/a	14(30)	19(41)	13(28)	56(55)	19(34)	19(34)	19(34)	56(55)	19(34)	19(34)	18(32)	0.745	
Ask about specific comorbidities such as dementia, Parkinson's stroke, diabetes, hip fracture or dementia?	8(8)	2(25)	4(50)	2(25)	70(69)	2(25)	20(29)	28(40)	22(31)	24(24)	11(46)	6(25)	11(46)	24(24)	11(46)	6(25)	7(29)	0.505	
Ask about patient's vision?	27(27)	10(37)	12(44)	5(19)	60(59)	10(37)	23(38)	19(32)	18(30)	15(15)	0	7(47)	0	15(15)	0	7(47)	8(53)	0.012	
Ask about difficulties with activities of daily living?	14(14)	6(43)	6(43)	2(14)	70(69)	6(43)	21(30)	27(39)	22(31)	18(18)	6(33)	5(28)	6(33)	18(18)	6(33)	5(28)	7(39)	0.584	
Ask about type of footwear used?	70(69)	21(30)	27(39)	22(31)	30(30)	27(39)	12(40)	9(30)	9(30)	2(2)	0	2(100)	0	2(2)	0	2(100)	0	0.469	
Review patient medications specifically for fall risk?	26(26)	9(35)	11(42)	6(23)	68(67)	9(35)	22(32)	25(37)	21(31)	8(8)	2(25)	2(25)	2(25)	8(8)	2(25)	2(25)	4(50)	0.751	
When doing a physical exam on an older ED patient, how often do you do the following?																			
Measure orthostatic blood pressure on fall patients	36(35)	16(44)	15(42)	5(14)	64(63)	16(44)	17(27)	22(34)	25(39)	2(2)	0	1(50)	0	2(2)	0	1(50)	1(50)	0.030	
Assess strength and presence/absence of peripheral neuropathy	16(16)	8(50)	5(31)	3(19)	64(63)	8(50)	24(38)	23(36)	17(27)	22(22)	1(5)	10(45)	1(5)	22(22)	1(5)	10(45)	11(50)	0.010	
Evaluate patient gait	0	n/a	n/a	n/a	72(71)	n/a	24(33)	31(43)	17(24)	30(29)	9(30)	7(23)	9(30)	30(29)	9(30)	7(23)	14(47)	0.050	
Conduct functional testing (e.g. Get-up-and-go test)	55(54)	18(33)	22(40)	15(27)	43(42)	18(33)	14(33)	16(37)	13(30)	4(4)	1(25)	0	1(25)	4(4)	1(25)	0	3(75)	0.424	
Consult or refer to Physical Therapy/ Occupational therapy for fall patients	0	n/a	n/a	n/a	64(63)	n/a	19(30)	29(45)	16(25)	38(37)	14(37)	9(24)	14(37)	38(37)	14(37)	9(24)	15(39)	0.081	
Ensure patients have home safety assessments done	21(21)	3(14)	13(62)	5(24)	67(66)	3(14)	25(37)	23(34)	19(29)	14(14)	5(36)	2(14)	5(36)	14(14)	5(36)	2(14)	7(50)	0.036	
Recommend exercise	30(30)	12(40)	8(27)	10(33)	64(63)	12(40)	19(30)	26(40)	19(30)	8(8)	2(25)	4(50)	2(25)	8(8)	2(25)	4(50)	2(25)	0.666	

ED, emergency department; PA, physician assistant.

safety evaluation, it appears that when providers respond “all the time” this was largely due to PAs’ responses. This could be due to falls training that PAs may have received in PA school or other geriatric-focused conferences or training. However, McEwan et al concluded that improving education on falls, creating easy access to protocols and guidelines, and having the senior staff mentor junior staff on the screening and interventions led to greatest compliance.¹⁰ Hence, improving fall training for providers should improve ED fall intervention.

More research into which patient population would most benefit from screening and interventions is needed. Interestingly, most emergency providers in our study thought all patients should be screened and intervened upon but then admitted not knowing whom to screen or how to intervene. While clearly certain patients should be excluded from screening because they are too sick, the question remains which patients must be screened and who would benefit the most from an ED intervention. Another challenge is determining which screening tool to use. A recent meta-analysis of ED-based, fall risk stratification instruments was unable to provide a single best fall screening strategy.¹¹ It did find that the ideal fall risk screening instrument would be brief, easy to use by all clinical staff, and would not require additional space or equipment for screening.¹¹

A few screening tools have been validated for ED use, but currently there is no agreed-upon tool. One screening tool that can be used is the Centers for Disease Control and Prevention Stopping Elderly Accidents Deaths and Injuries (CDC STEADI), which recommends using three brief screening questions routinely for patients over the age of 65.¹² The questions are: 1) Have you fallen in the past year? 2) Do you feel unsteady when standing or walking? and 3) Do you worry about falling? If a patient answers “yes” to any of the three questions they are at increased risk of falling and further assessment is recommended.¹² Follow-up information regarding exercise classes to improve balance and ways to enhance home safety should also be given to the patient. One small, ED-based study by Greenberg et al provided patients in the intervention arm with a CDC STEADI brochure with standardized information about controlling risk factors for falls and found that 12% of patients in the intervention arm started an exercise class and had their medications checked by their primary care provider compared to none in the control arm.¹³ Among intervention patients, 85% (22/26) chose a fall prevention strategy compared to 25% (6/24) in the control group ($p < .001$). The study did not examine outcome such as repeat falls or ED return visits.

Multifactorial fall-intervention programs have also had mixed outcomes. The landmark PROFET study found that an intensive fall-intervention program significantly reduced fall risk and led to the implementation of many multifactorial fall-prevention programs.¹⁴ However, follow-up studies results have been mixed. Morello et al did a systematic review and meta-analysis that included 12 randomized control trials of patients aged 60 and older who presented to the ED after a fall.¹⁵ Included studies had to have a multifactorial falls-prevention intervention

and examine at least one falls-related outcome such as recurrent fall, repeat ED visit, or subsequent hospitalization.¹⁵ Their analysis concluded that there is little evidence that multifactorial falls-prevention interventions reduce falls in older ED patients.¹⁵

In a different systematic review and meta-analysis by Hopewell et al, 41 randomized control trials of patients 65 and older who lived in the community and presented to the ED after a fall were examined. They concluded that multifactorial fall interventions did reduce falls in the intervention groups, but given the considerable heterogeneity their confidence in the results was low.¹⁶ These mixed results of fall intervention programs are likely due to the complex physiology of falls, limitations in resources, and difficulty standardizing a process when every healthcare system functions differently. A root cause analysis of why certain programs do not succeed or what factors contributed to another program’s success is needed to provide more guidelines for implementing fall prevention programs in EDs.

While most respondents thought that all geriatric patients should be screened and intervened upon in the ED, this was not how most providers practice. This finding shows a disconnect between what providers think is important and what they are able to accomplish in practice and creates a major challenge in implementing screening and fall interventions. Perhaps most revealing is that most providers are only willing to spend less than five minutes on an intervention. Any successful ED-based intervention needs to be concise or not dependent on the main ED provider. It remains to be seen whether it is practical or efficient to intervene on all geriatric patients, only those who had a fall, or those at highest risk of falling.

LIMITATIONS

This study was done at one academic ED in an urban setting; therefore, the survey results may not be generalizable. We had a response rate of 75% and therefore may have missed the opinions and input of other providers who did not respond to the survey. The lowest response rates were from resident physicians likely due to their schedule being the most demanding. The fact that most providers felt that all patients should be screened may be due to the social desirability bias. However, this seems less likely as the respondents were frank about the small amount of time they were willing to dedicate to a falls intervention.

CONCLUSION

Geriatric fall patients are a growing population that will continue to present to the ED. Results of this survey indicate that emergency providers understand the importance of fall prevention in older adults but lack knowledge of which patients to screen and how to prevent future falls. This is likely due to both lack of education and no standard ED fall screening/intervention program. Successful interventions will need to be short, supported by the staff, and not dependent solely on the emergency provider. Research into ED-based fall-prevention screening tools and interventions are needed to help create and implement future guidelines.

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Prevalence and Predictors of Driving after Prescription Opioid Use in an Adult ED Sample

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Introduction: Prescription opioid use and driving is a public health concern given the risks associated with drugged driving, but the issue remains under-studied. We examined the prevalence and correlates of driving after taking prescription opioids (DAPO) among adults seeking emergency department (ED) treatment.

Methods: Participants (aged 25-60) seeking ED care at a Level I trauma center completed a computerized survey. Validated instruments measured prescription opioid use, driving behaviors, and risky driving. Patients who reported past three-month prescription opioid use and drove at least twice weekly were administered an extended study survey measuring DAPO, depression, pain, and substance use.

Results: Among participants completing the screening survey (n = 756; mean age = 42.8 [standard deviation {SD} = 10.4]), 37.8% reported past three-month prescription opioid use (30.8% of whom used daily), and 14.7% reported past three-month DAPO. Of screened participants, 22.5% (n = 170) were eligible for the extended study survey. Unadjusted analyses demonstrated that participants reporting DAPO were more likely to use opioids daily (51.1% vs 15.9%) and had higher rates of opioid misuse (mean Current Opioid Misuse Measure score 3.4 [SD = 3.8] vs 1.1 [SD = 2.1]) chronic pain (80.7% vs 42.7%), and driving after marijuana or alcohol use (mean intoxicated driving score 2.1 [SD = 1.3] vs 0.3 [SD = 0.8]) compared to patients not reporting DAPO (all p<0.001). Adjusting for age, gender, employment, and insurance in a logistic regression model, participants reporting DAPO were more likely to report a chronic pain diagnosis (odds ratio [OR] = 3.77, 95% confidence interval [CI], 1.55-9.17), daily opioid use (OR = 3.81, 95% CI, 1.64-8.85), and higher levels of intoxicated driving (OR = 1.62, 95% CI, 1.07-2.45). Alcohol and marijuana use, depression, and opioid misuse were not associated with DAPO in adjusted analyses.

Conclusion: Nearly one in six adult patients seeking ED care reported DAPO. The ED may be an important site for interventions addressing opioid-related drugged driving. [West J Emerg Med. 2020;21(4)830-839.]

INTRODUCTION

Motor vehicle collisions (MVC) are a leading cause of death in the United States (US) (37,133 roadway fatalities in 2017),¹ and are estimated to cost more than \$41 billion annually.² Since the increases in opioid pain reliever prescribing throughout the 1990s,³ the proportion of fatally injured drivers testing positive for prescription opioids has increased sevenfold.⁴ Despite improved prescribing practices in response to the ongoing opioid overdose crisis, US opioid prescribing rates remain threefold higher than they were in 1999.⁵ This highlights the need for more research into driving under the influence of opioids, including determining the rates and correlates of contemporaneous driving and opioid use. Such data would better inform road safety efforts in this area, which lag behind those addressing alcohol-impaired driving (e.g., developing roadside screening assays).⁶

Opioids are associated with a dose-dependent diminution in motor and sensory function in human studies,⁷ where experiments in healthy volunteers have demonstrated deleterious effects of opioids on the neurocognitive and psychomotor functions requisite for safe motor vehicle operation (e.g., logical reasoning, reaction time, eye-hand coordination).⁸ While older studies of driving behavior among patients on chronic, stable, opioid regimens largely affirmed the notion that opioid medications did not dynamically impair driving ability,⁹⁻¹² few of these studies measured real-world driving, and may not have accounted for the entire breadth of cognitive and motor skills necessary to drive safely.¹³ Further, the relevance of prior research supporting the safety of driving after taking prescription opioids (DAPO) has been limited by a focus on patients being treated for cancer or opioid use disorders,^{14,15} reliance on historical controls, small samples of opioid users,¹⁶⁻¹⁸ and methodological concerns (e.g., lack of blinding, or using purely psychological tests to estimate driving aptitude).^{14,19} Indeed, as noted in a review by Gjerde et al,²⁰ unlike prior epidemiological studies, those performed after 1998 in most cases (17 of 25 identified) *did* identify a significant association between opioid use and MVC risk.

Given the dramatic increase in the rates of opioid prescribing to treat chronic non-cancer pain²¹ and the prevalence of opioid use disorders,²² there is a need to revisit the risks associated with DAPO. More recent epidemiological studies have cast doubt on the safety of driving after taking prescription opioids, linking both MVC risk to the initiation of prescription opioids,^{23,24} and higher prescribed opioid dosages to road traffic injuries.²⁵ Further, while co-occurring use with alcohol and other drugs (e.g., cannabis) is common among fatally injured drivers testing positive for opioid analgesics,⁴ there are few published data on the relationships between DAPO, other drugged driving, and driving under the influence of alcohol (DUI) in ambulatory samples.

Emergency providers must be equipped to provide informed advice to patients using opioids about the safety

Population Health Research Capsule

What do we already know about this issue?
Drugged driving crashes are a serious public health concern, but the relationship between driving and prescription opioid use is poorly understood.

What was the research question?
What is the prevalence of adult ED patients driving after prescription opioid use?

What was the major finding of the study?
Nearly 1 in 6 adult ED patients reported driving after taking prescription opioids in the past 3 months.

How does this improve population health?
Understanding the prevalence and risks of prescription opioid drugged driving could help emergency physicians better identify high-risk patients for interventions.

of such tasks as motor vehicle operation, and are frequently charged with assessing patients for the presence of risky opioid use. While emergency physicians (EP) are responsible for only 4% of all opioid prescriptions written annually in the US, approximately 20% of all emergency department (ED) prescriptions are for opioid analgesics.²⁶ Because persons with chronic non-cancer pain and other painful conditions often require urgent or unscheduled care,²⁷⁻²⁹ the ED may be an opportune site for studying rates and correlates of DAPO. Understanding the risks of DAPO may better allow ED care providers to present informed advice to patients about the safety of prescribed opioid analgesics, and better equip them to screen patients for risky opioid use and driving behaviors. However, few studies on driving behaviors among patients taking prescription opioids have been conducted in this setting. Greater understanding regarding the prevalence of DAPO among ED populations—and its associated predictors—could advance the ability of emergency care providers to screen for dangerous opioid use, provide counseling and/or interventions to reduce DAPO, and assess the need for treatment referral in patients with suspected opioid use disorders.

In this study, we determined the prevalence of prescription opioid use and driving after prescription opioid behavior (and their demographic correlates) in a screening sample of adults ages 25-60 seeking ED care, then examined the predictors of

DAPO in the subset of patients who both reported prescription opioid use and drove regularly (at least twice per week). We hypothesized that adult ED patients who reported DAPO would be more likely to misuse these prescription opioids, have associated mental health and substance use problems, and engage in other risky driving (including driving after alcohol or marijuana use).

METHODS

Study Design

We conducted a cross-sectional analysis of prescription opioid use and driving behaviors among adult patients seeking emergency department care as part of the Health Behaviors and Prescription Opioids Study (HBPOS). The University of Michigan Institutional Review Board approved the study protocol, and a Certificate of Confidentiality was obtained from the National Institutes of Health.

Study Setting and Population

Patients were recruited from the University of Michigan Health System ED, a Level I trauma center located in Washtenaw County (median household income \$62,484, 74.4% white), with an annual ED patient census of ~85,000 adult patients.³⁰

Study Protocol

Study participants were recruited seven days a week (excluding holidays) between September 22, 2016–February 1, 2017, by trained research assistants (RA), between the hours of 9 AM and 10 PM. Potentially eligible participants were identified using electronic patient tracking logs, and approached for screening in private treatment rooms. Because both adolescents/young adults and elderly patients may differ in their risky driving behaviors, the sample was limited to adults aged 25-60.

We excluded patients from screening if they were cognitively impaired by intoxication, illness, or injury; lacked adequate command of English; were in police or corrections custody; were presenting for evaluation and treatment of sexual assault or suicidal ideation; were classified by ED staff as a Level I trauma; or required special precautions due to the risk of infectious disease exposure. Patients reporting a history of schizophrenia were excluded from the survey due to both a concern about their ability to provide adequate informed consent and the degree of psychosocial needs that such patients often require during their ED visit, which precludes adequate time for completion of all study procedures. When there was concern with the capacity of patients with other psychiatric diagnoses (e.g., depression or bipolar disorder) or cognitive impairment to provide informed consent, the RA administered a Mini-Mental Status Exam.

RAs obtained verbal informed consent for the screening survey, which was completed by the participant on a

computerized tablet. Participants were remunerated with a gift worth ~\$1.00 (e.g., Sudoku booklets). Patients completing the screening survey were eligible for the extended survey if they reported any past three-month prescription opioid use, and drove at least twice per week in the prior three months. Survey participants completing the extended survey provided written consent. All surveys were administered privately (i.e., family/friends were not allowed to see questions) using tablet computers, and paused as required for medical care. Participants were remunerated \$20 cash for completing the extended survey. All patients were given a community resource brochure with local mental health and substance use resources.

Measurements

Driving After Prescription Opioids (DAPO)

The main outcome variable, driving after prescription opioids (DAPO), was determined by any affirmative response to the question, “In the past three months, how many times did you drive after taking opioid pain medications?”

Demographics

We obtained sociodemographics (eg, age, gender, race, employment/school status, disability, and insurance coverage) using self-report measures. Race was dichotomized as White vs non-White for analysis. Employed/school was coded as positive for participants reporting full-time or part-time employment or being a student when queried about current employment status; disability was determined by the selection of the response “Unemployed, disabled” within the same measure. Private insurance included positive responses to either having private insurance (yes/no) or group insurance (yes/no).

Opioid Use

We defined daily opioid use as a response of “Daily or almost daily” to the question, “In the past three months, how often have you used opioid pain medications (For example: Vicodin, Codeine, OxyContin, morphine, oxycodone, hydrocodone, methadone, hydromorphone, meperidine, fentanyl, or Norco)?” Opioid misuse behaviors were measured by the sum of eight items from the Current Opioid Misuse Measure (COMM), a validated scale.³¹

Risky Driving Behaviors and Consequences

For the purposes of this study, we constructed composite risky driving (eg, speeding, tailgating) and intoxicated driving (alcohol and marijuana) scores by summing the responses of 16- and 7-question subsets, respectively, of the Risky Driving Survey.³² Responses were on a five-point Likert scale (1-Never, 2-Rarely, 3-Sometimes, 4-Often, 5-Always). Driving under the influence of opioids was determined by an affirmative answer to the question, “In the past 30 days, how often have you driven while you were feeling the effects of

opioid pain medications, either alone or with alcohol, other drugs, and/or medications?" Patients' plans to drive after prescription opioids in the next three months were measured on a 10-point Likert scale (from "Not very likely" to "Very likely"), and were dichotomized as either "Less likely" (≤ 5) or "More likely" (≥ 6).

Depression and Chronic Pain

We determined depression severity using the Patient Health Questionnaire-9 (PHQ-9),³³ a 27-point scale where higher scores indicate greater frequency of depressive symptoms. Chronic pain was assessed with the question, "Have you been told by a doctor that you have chronic pain (Yes/No)?"

Alcohol and Marijuana Use

We measured alcohol and marijuana use by summing numerically coded responses to the National Institute on Drug Abuse and the Alcohol, Smoking and Substance Use Involvement Screening Tests (NIDA-ASSIST).^{34,35}

Data Analysis

We performed statistical analyses using SAS 9.4 (SAS Institute, Cary, NC). First, we examined data from the screening survey to determine the prevalence of DAPO among the general adult ED population, and calculated descriptive statistics for this sample. Second, we examined DAPO among the subset of screening participants who received the extended study survey (ie, those who reported past three-month opioid use and twice-weekly driving). We limited the analysis of factors associated with DAPO to those taking the extended study survey because many of the measures of interest (e.g., high-risk driving behavior, substance use) were only measured in that subsample. We conducted bivariate comparisons between those who did and did not endorse DAPO among respondents to the extended study survey using *t*-tests for continuous variables and χ^2 tests for categorical data. Third, adjusted comparisons between participants with and without DAPO were modeled using logistic regression. We added variables to the logistic regression model sequentially, beginning first with demographics, and then substance use, depression, and chronic pain; and, finally, driving behaviors. The determination of predictor variables in the adjusted analysis was based on both theoretical considerations and parsimony (given the relatively small study sample).

RESULTS

Rate of Driving After Prescription Opioids Among the Screening Sample of Adult Patients Seeking Emergency Treatment

The recruitment flowchart is shown in Figure. A total of 1111 ED patients ages 25-60 were approached; 756 (68.0%) of these patients completed the screening survey, of whom 170

(22.5%) were eligible and agreed to be enrolled in the extended study survey, providing complete data on key variables.

Overall, the screening sample ($n = 756$) had a mean age of 42.8 (standard deviation [SD] = 10.4), was 61.4% female, 74.5% White, and 25.1% low income ($< \$20,000/\text{year}$). Among screened participants, 37.8% reported past three-month prescription opioid use (30.8% of whom reported daily use) and 14.7% reported past three-month DAPO. Among those reporting driving after taking opioids, 53.2% reported that they had also been driving under the influence of opioids, and 35.1% reported that they planned to continue driving after taking prescription opioids in the subsequent six months.

Extended Study Survey Analysis

Among screened participants, 22.5% ($n = 170$) met the study criteria of past three-month prescription opioid use and regular driving (i.e., at least twice weekly) and completed the extended study survey. The remainder of reported analyses are on this subsample of participants.

Unadjusted Analysis

The bivariate analysis of DAPO and its predictors is shown in Table 1. Participants reporting DAPO were more likely than those not reporting DAPO to use opioids daily (51.1% vs 15.9%), have higher levels of opioid misuse (mean COMM score 3.4 [SD = 3.8] vs 1.1 [SD = 2.1]), and have higher rates of chronic pain (80.7% vs 42.7%; all $p < 0.001$). Further, participants endorsing DAPO demonstrated higher rates of other impaired driving behaviors (e.g., driving after marijuana or alcohol use): the mean intoxicated driving score for those reporting DAPO was 2.1 [SD = 1.3], compared with 0.3 [SD = 0.8]) among those not reporting DAPO.

Logistic Regression Model

Logistic regression results are shown in Table 2. Addition of the substance use, depression, and chronic pain variables substantially improved model fit (Model 2; $p < 0.001$) relative to the demographics-only model, and addition of the driving and opioid use characteristics substantially improved fit (Model 3; $p < 0.001$) relative to the second model. The final model (Model 3) had an area under the receiver operator characteristic curve of 0.82, indicating good model discrimination. Adjusting for age, gender, employment, and insurance, patients reporting DAPO were more likely to disclose a prior diagnosis of chronic pain (odds ratio [OR] = 3.77, [95% confidence interval {CI}], 1.55-9.17), daily opioid use (OR = 3.81, 95% CI, 1.64-8.85), and greater frequency of intoxicated driving (OR = 1.62, 95% CI, 1.07-2.45) compared to the non-DAPO group. Depression, alcohol use, marijuana use, and prescription opioid misuse were not associated with DAPO in the adjusted model, nor were there any significant associations with sociodemographic covariates.

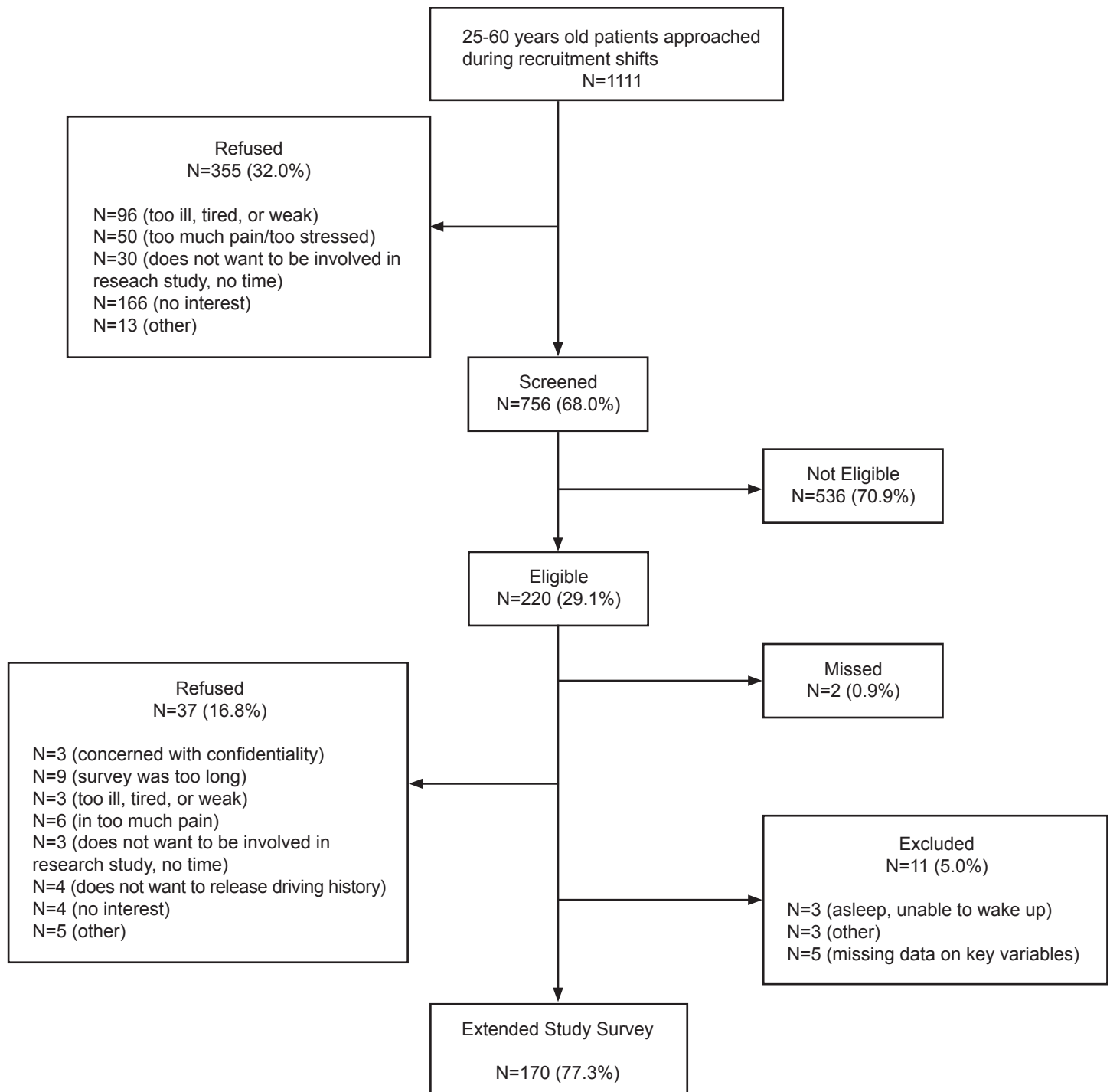


Figure. Health behaviors and prescription opioids study (HBPOS) recruitment flowchart (September 22, 2016-February 1, 2017).

DISCUSSION

To our knowledge, this is the first study of DAPO prevalence and its relationship to other substance use and risky driving behaviors in an ED sample. Nearly one in six adults surveyed during the enrollment period reported

DAPO during the prior three months. Among regular drivers, those who reported DAPO were more likely to also report driving after marijuana and alcohol use, highlighting this as a particularly high-risk sample of drivers. Over a third of those reporting DAPO reported future plans to drive after taking

Table 1. Bivariate analysis examining participants engaged in driving after taking prescription opioids (DAPO) compared with those not engaged in DAPO among the extended study sample (n = 170).

	DAPO (n = 88)	No DAPO (n = 82)	All (n = 170)
Sociodemographics			
Age [†]	43.1 (10.2)	42.6 (9.0)	42.8 (9.6)
Female gender [‡]	50 (56.8)	58 (70.7)	108 (63.5)
White race	71 (80.7)	17 (78.1)	135 (79.4)
Employed/in school*	42 (47.7)	55 (67.1)	97 (57.1)
Disabled	27 (30.7)	22 (26.8)	49 (28.8)
Private insurance*	41 (46.6)	52 (63.4)	93 (54.7)
Prescription opioid use			
Daily opioid use***	45 (51.1)	13 (15.9)	58 (34.1)
Total COMM score***	3.4 (3.8)	1.1 (2.1)	2.3 (3.3)
Risky driving/consequences			
[‡] Intoxicated driving score***	2.1 (4.0)	0.3 (0.8)	1.25 (3.0)
[†] Risky driving score	6.7 (6.9)	5.1 (6.0)	5.9 (6.5)
Depression and chronic pain			
Total PHQ-9 score**	9.7 (5.9)	7.0 (5.3)	8.4 (5.8)
Chronic pain (n, %)**	72 (80.7)	35 (42.7)	106 (62.4)
Substance use			
Total ASSIST alcohol	5.4 (8.6)	4.4 (6.7)	4.9 (7.7)
Total ASSIST marijuana**	4.4 (1.7)	1.7 (3.9)	3.1 (5.9)

[†]n_{missing} = 1; [‡]n_{missing} = 3.

[†]Continuous variables listed as mean, standard deviation.

[‡]Categorical variables listed as n, %.

*p<0.05; **p<0.01; ***p<0.001.

COMM, Current Opioid Misuse Measure; PHQ-9, Patient Health Questionnaire-9; ASSIST, National Institute on Drug Abuse and the Alcohol, Smoking and Substance Use Involvement Screening Tests.

opioids, suggesting a substantial need for prevention efforts among this group.

Among our screening cohort of adults ages 25-60 seeking ED care, 37.8% of participants reported past three-month prescription opioid use (medical use or misuse). While direct comparisons between our study sample and other ED populations are difficult given the dearth of published data, this is in contrast to the 37.8% (note: coincidentally identical value) past 12-month prevalence of prescription opioids among respondents to the 2015 National Survey on Drug Use and Health; the latter includes only non-institutionalized, civilian adults, and may reflect a lower risk population than do ED samples.³⁶ In light of the persistently elevated rates of both US opioid prescribing and opioid-related deaths³⁷ – and considering prescription opioids' abuse potential and associated overdose risk – the prevalence in this study illustrates the ongoing significance of prescription opioid use for emergency care providers. Further, because patients with complications from opioid use disorders

frequently access EDs for care, the ED may be an ideal venue in which to provide interventions aimed at reducing opioid-related harms (e.g., overdose).³⁸

Our findings suggest that DAPO is prevalent among adult ED patients, with 14.7% of study participants reporting driving after prescription opioids. Further, a majority of those in the DAPO group also reported driving while under the effects of these drugs, and more than a third of these individuals planned on driving after taking opioids in the future. While we are not aware of any analogous published data on the prevalence of DAPO among adult ED patients in the same age range, a study of 586 emerging adults (ages 18-25) seeking ED care demonstrated that 24% of surveyed participants reported past 12-month drugged driving, 19% of whom reported DAPO.³⁹ In the 2013-2014 National Roadside Survey, 7.5% of drivers (ages 16 years and older) reported past two-day use of prescription opioids.⁴⁰ Our study was not sufficiently powered to reveal more definitive relationships between DAPO and MVC outcomes (only two crashes were

Table 2. Logistic regression models predicting driving after taking prescription opioids in the study population (n = 167*).

	Model 1 (OR, 95% CI)	Model 2 (OR, 95% CI)	Model 3 (OR, 95% CI)
AUC	0.65	0.77	0.82
-2 Log L	218.2	193.7	168.5
Chi-square (p < 0.05)		2 vs 1: p=0.00006 (DF=4)	3 vs. 2: p=0.00001 (DF=3)
Demographics			
Age	1.00 (0.96, 1.03)	1.01 (0.97, 1.06)	1.02 (0.97, 1.06)
Female gender	0.52 (0.26, 1.04)	0.54 (0.25, 1.18)	0.60 (0.25, 1.45)
Employed (full/part) or student	0.49 (0.25, 0.95)	0.89 (0.40, 1.94)	0.89 (0.38, 2.10)
Private insurance	0.60 (0.30, 1.17)	0.86 (0.41, 1.80)	1.10 (0.48, 2.53)
Depression, chronic pain, substance use			
PHQ-9 (total score)		1.07 (1.01, 1.15)	1.02 (0.95, 1.10)
Chronic pain		3.76 (1.70, 8.30)	3.77 (1.55, 9.17)
ASSIST alcohol (total score)		1.01 (0.95, 1.06)	0.98 (0.92, 1.05)
ASSIST marijuana (total score)		1.06 (0.99, 1.14)	0.99 (0.90, 1.08)
Opioid use and driving behaviors			
COMM score (total score)			1.09 (0.91, 1.31)
Daily opioid use			3.81 (1.64, 8.85)
Intoxicated driving (total score)			1.62 (1.07, 2.45)

*Three participants did not answer the intoxicated driving questions.

OR, odds ratio; CI, confidence interval; AUC, area under the curve; PHQ-9, Patient Health Questionnaire-9; ASSIST, National Institute on Drug Abuse and the Alcohol, Smoking and Substance Use Involvement Screening Tests; COMM, Current Opioid Misuse Measure.

reported in the extended study sample [data not shown]). However, considering epidemiological studies linking prescription opioid use and MVCs,^{13,41} and the prevalence of both past three-month prescription opioid use and future plans to drive after prescription opioid use in our study population, ED screening and interventions for risky opioid use and driving behaviors may have the potential to reduce opioid-related consequences such as MVCs.

We found that DAPO was more likely among participants who reported a prior diagnosis of chronic pain. This finding is consistent with prior studies examining the impact of opioid therapy in chronic pain patients, which have been associated with an increased risk of opioid use disorders,⁴² ED visits,⁴³ overdose,⁴⁴ and death.⁴⁵ However, there are only sparse data on MVC risk among patients on prescribed chronic opioids. While several older studies of patients on opioid therapy for non-malignant pain (e.g., Galski et al, 2000)¹⁷ purported that stable doses of these drugs did not impair motor vehicle operation, such studies had key methodological limitations (discussed above). Chronic pain syndromes are prevalent in the US broadly,⁴⁶ and among ED populations specifically,²⁸ and are frequently treated with opioid pain relievers.⁴⁵ Considering research linking prescription opioid use with cognitive impairments⁹ and impaired driving performance,¹³ our study highlights the importance of further research

investigating chronic pain as a risk factor for opioid drugged driving and related morbidity.

The need for risk reduction around driving and opioids is underscored by our finding that drivers reporting DAPO were also more likely to drive under the influence of marijuana and/or alcohol. Emerging research is illuminating the relationships of marijuana and alcohol use and drugged driving behavior.⁴⁷ In a study of younger adults, higher rates of opioid use correlated with higher frequencies of drugged driving; drugged driving, in turn, was associated with increased rates of hazardous drinking.³⁹ Polysubstance use among drivers is an important public health problem. In a recently published study of 118 rural DUI offenders, 60% reported past-year drugged driving, and nearly half of those ever reporting drugged driving reported DAPO.⁴⁸ In a 10-year analysis of Fatality Analysis Reporting System data published in 2017, 30% of fatally injured, opioid-positive drivers had blood alcohol levels ≥ 0.01 milligrams per deciliter.⁴ Our study findings, especially in the context of these data, suggest that DAPO may be a risk factor for other impaired driving behaviors, and further supports the importance of developing predictive tools for better identifying ED patients at risk for impaired driving.

This study suggests roles for primary and secondary prevention efforts in the ED aimed at reducing harms from

prescription opioids.⁴⁹ Considering the prevalence of DAPO in our sample, and epidemiologic data linking prescription opioids to increased MVC risk,⁵⁰ ED prescribers may reasonably include these disclaimers when discussing the safety of DAPO, and consider such risks when deciding whether to initially prescribe an opioid analgesic. Studies have shown that opioid-alternative analgesics are as efficacious as opioids in treating acute extremity pain,⁵¹ and result in comparable pain control scores on post-discharge patient satisfaction surveys.⁵² ED prescribing guidelines may be effective at reducing the proportion of patients prescribed opioids on discharge,⁵³ while electronic health record (EHR) default options for prescription opioids may affect emergency clinician quantity choice.⁵⁴ Enhancing current EHRs with automatic reminders of the risks of DAPO may aid clinicians in providing this critical information to patients at the time they prescribe opioid medications.

EHR-integrated prescription drug monitoring program (PDMP) data may facilitate screening for potentially risky, prescription-opioid behaviors during the ED visit, and may be useful in assessing patients with daily use and/or chronic pain for potential interventions to reduce overdose risk.⁵⁵ While recent ED-based research suggests that PDMP data may lack the predictive power to identify patients with opioid use disorders per se,⁵⁶ previous studies have demonstrated that the availability of PDMP data may alter EP opioid prescribing.^{57,58} Further, states with more robust PDMPs have lower rates of opioid dispensing overall (including lower rates of dispensing high dosages) to patients on long-term, chronic opioid therapy, as well as lower rates of death from prescription opioid analgesics.^{59,60} Additional study is needed to better inform ED practitioners and patients alike about the risks of DAPO among patients with daily opioid use and/or chronic pain, and to develop optimal screening instruments and public health interventions to identify and address those who are at the greatest risk for DAPO-related harm.

LIMITATIONS

Because our sample was recruited from a single, academic ED embedded in a city with high levels of education and income, results may not be generalizable to ED samples in dissimilar communities. Data were self-reported; however, previous research has supported the validity of these types of survey results.⁶² The exclusion of intoxicated patients, those in police custody, and the lack of RA coverage at night may have resulted in the underestimation of DAPO. Last, causal inferences are precluded by the cross-sectional nature of this study.

CONCLUSION

Our results demonstrate that DAPO is prevalent among adult ED patients, is associated with other impaired driving behaviors, and that patients reporting DAPO are more likely to engage in risky driving behaviors in the future. These

findings highlight the need to better understand other risks associated with DAPO, and to develop screening tools to better allow healthcare providers to identify at-risk individuals for potential interventions. Identifying predictive factors among routinely collected clinical data (e.g., past medical history and medications) may also help ED providers identify patients at risk for morbidity and mortality from drugged driving, especially when combined with data from PDMPs. Future research into the effects of prescription opioids on driving abilities and behaviors, including the role of dosing, frequency, and formulation, will be required to better understand the dynamic effects of these drugs on safe motor vehicle operation, and may better allow ED care providers to present informed advice to patients about the safety of prescribed opioid analgesics.

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Current Understanding of the Neurobiology of Agitation

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Introduction: Managing agitation in the clinical setting is a challenge that many practitioners face regularly. Our evolving understanding of the etiological factors involved in aggressive acts has better informed our interventions through pharmacologic and behavioral strategies. This paper reviews the literature on the neurobiological underpinnings of aggressive behaviors, linking psychopathology with proposed mechanisms of action of psychiatric medications shown to be effective in mitigating agitation.

Methods: We performed a review of the extant literature using PubMed as a primary database. Investigation focused on neurobiology of agitation and its relation to the current evidence base for particular interventions.

Results: There are well-established pathways that can lead to increased autonomic response and the potential for violence. Psychopathology and substance-induced perceptual distortions may lead to magnification and overestimation of environmental threat, heightening the potential for aggression. Additional challenges have arisen with the advent of several novel drugs of abuse, many of which lead to atypical clinical presentations and which can elude standard drug screens. Our interventions still lean on the evidence base found in Project BETA (Best Practices in Evaluation and Treatment of Agitation). Although not a new drug and not included in the Project BETA guidelines, ketamine and its use are also discussed, given its unique pharmacology and potential benefits when other protocolized interventions have failed.

Conclusion: Aggression can occur due to manifold reasons in the clinical setting. Having an informed understanding of the possible determinants of agitation can help with more tailored responses to individual patients, limiting the unnecessary use of medications or of interventions that could be deemed forceful. [West J Emerg Med. 2020;21(4)840-847.]

INTRODUCTION

Managing agitation in acute clinical settings is a challenge for many practitioners. There have been exciting advances in the neurosciences over the past few decades, allowing for some correlation between what is observed clinically and underlying neuroendocrine alterations leading to aggressive behaviors. While our pharmacologic tools have not necessarily progressed at the same pace, there is a greater appreciation of how particular interventions work on a neurobiological level. Importantly, there is also an awareness of the limitations to some of our forms of treating aggression. One emerging challenge is the use of novel substances of abuse, many of which elude traditional drug

screening (e.g., synthetic cannabinoids).^{1,2} Thus, practitioners may see how patients are presenting, yet do not have the tools at their disposal to make a more precise diagnosis. We review the extant literature on the neurobiological underpinnings of aggressive behaviors, linking psychopathology with proposed mechanisms of action of psychiatric medications shown to be effective in mitigating agitation.

METHODS

We performed a literature search using the PubMed electronic database looking for English-language research articles addressing the neurobiology of agitation and its management.

No start date limitations regarding the date of publication were employed. The search was limited to articles published by October 29, 2019, the last date the search was conducted. In order to discuss the neurobiological underpinnings of agitation and how this correlates with current, evidence-based, treatment options, we selected the following search terms as title/abstract words, independent terms, text words, or medical subject headings (MeSH) terms and subsequently combined them with the Boolean term “and” 1) *neuroscience* or *neurobiology*; 2) *medications* or *psychiatric medications* or *psychopharmacology*; 3) *emergency medicine* or *emergency psychiatry*; and 4) *agitation* or *aggression* or *violence*. Additionally, we conducted hand searches of reference lists of selected articles for this review to identify other relevant articles. The search strategy was performed by one of the authors (CM).

Out of 5,641 articles yielded by the search, further review of titles and abstracts for relevance to the topic of this paper reduced the number to 480. To maintain focus on the neurobiology of agitation and the psychopharmacologic interventions currently in clinical use, we excluded studies evaluating non-pharmacologic interventions – other than to recognize their importance and evidence base. Following the exclusion of such articles and further review of the studies assessing key results and limitations, 55 articles were selected for final inclusion.

RESULTS AND DISCUSSION

Neuroscientific Underpinnings of Agitation

There are well-established pathways that can lead to increased threat perception, autonomic response, and aggression. The amygdala, a component of the limbic system, is sensitive to signs of threat and reciprocally innervates areas involved in salience-driven responses (e.g., locus coeruleus [LC], bed nucleus of the stria terminalis [BNST], anterior insula, periaqueductal gray [PAG], and hypothalamus).^{3,4} These connections regulate stress hormone release. Efficient coupling of higher cortical areas (e.g., medial prefrontal cortex [mPFC], orbitofrontal cortex [OFC] and anterior cingulate cortex [ACC]) with limbic regions modulates top-down inhibitory control.⁵ This allows for risk-reward considerations and calibration of behaviors to social cues prior to engaging in action. This permits responses that are not excessively driven by immediate salience and affective tone.

However, psychopathology and substance-induced perceptual distortions may lead to erroneous interpretation of environmental stimuli and overestimation of threat, heightening the potential for aggression. In such instances there is an excessive bottom-up activation, with insufficient behavioral control from higher cortical regions. Some psychiatric disorders (e.g., borderline and antisocial personality disorders) are notable for hypoactivity in cortical areas, leading to a default of affectively-driven behavioral reactions, with little recourse for deploying more adaptive strategies.^{6,7}

Overestimation of environmental threat, through

activation of the hypothalamic-pituitary-adrenal axis, causes excessive release of catecholamines (e.g., norepinephrine and dopamine), glutamate, and acetylcholine. Aggressive states are also marked by diminished levels of serotonin and gamma-aminobutyric acid (GABA), both of which are involved in the top-down control of limbic activation; indeed, these latter two neurotransmitter systems develop in tandem early in life, informing one’s ability to modulate dysphoric reactions. This is conceptually important, as fear activation pathways and the circuitry involved with aggressive responses demonstrate considerable overlap.⁸ An individual experiencing a behavioral emergency may experience the environment as unsafe and deploy strategies deemed necessary to ensure survival. The amygdala expresses adrenoceptors and dopamine D2 receptors, and there are direct projections onto amygdalae nuclei from both the ventral tegmental area and LC, brainstem areas responsible for synthesis and release of dopamine and norepinephrine, respectively. Increase in these catecholamines (as seen, for instance, in acute psychosis, mania, and stimulant intoxication) can increase amygdala excitation, exacerbating conditioned fear responses and paranoia, which may reach delusional proportions.^{9,10}

In addition to these subcortical effects, excess in norepinephrine release may bias cortical activation toward more posterior and inferior areas. The PFC has reciprocal connections with the LC, modulating tonic activity in the latter and thus regulating norepinephrine release.¹¹ Optimal levels of norepinephrine are important for appropriate PFC activity, including working memory and executive functioning. Of the three families of noradrenergic receptors ($\alpha 1$, $\alpha 2$, and β), norepinephrine has the highest affinity for $\alpha 2$,¹² with $\alpha 2A$ being the most abundant subtype located in the PFC.^{13,14} Thus, in low-stress situations $\alpha 2$ receptors are engaged preferentially, allowing for access to PFC functioning, including control of limbic activity. As stress levels rise and more norepinephrine is released, $\alpha 1$ and β receptors are engaged, and an individual’s ability to think and consider different behavioral options may be diminished. Interventions aimed at decreasing autonomic arousal and the consequent behavioral overtones that might ensue can include anti-adrenergic drugs such as propranolol (a non-receptor-specific beta-blocker); the latter has been shown to be effective in conditions such as intermittent explosive disorder and aggressive behaviors associated with traumatic brain injuries, in which agitation may be out of proportion to the inciting stimulus.¹⁵⁻¹⁷

Produced in the dorsal and median raphe nuclei, serotonin is a predominantly inhibitory neurotransmitter, shown to be involved with controlling aggressive behaviors directed at self and others. Low levels of the serotonin metabolite 5-hydroxyindoleacetic acid have been demonstrated in the cerebrospinal fluid of individuals with aggressive personality traits and in those who have attempted suicide by violent means.^{18,19}

While it is beyond the scope of this review to cover all substances of abuse in detail, it should be noted that many

recreationally used drugs have complex mechanisms of action that accentuate autonomic drive, threat perception, and limbic-based behavioral responses. Stimulants such as cocaine and amphetamines work predominantly as norepinephrine-dopamine reuptake inhibitors. Some of the phenylethylamines, such as methylenedioxymethamphetamine and methamphetamine, also have serotonergic properties, with the potential for long-term neurotoxic effects on the serotonin pathway, resulting in impulsive and aggressive behaviors, due to insufficient top-down modulation. For instance, methamphetamine use has been associated with decreased serotonin transporter density in the OFC and ACC, a finding correlated with increased levels of aggression.²⁰ Some ergoline (e.g., lysergic acid diethylamide [LSD]) and tryptamine (e.g., dimethyltryptamine) hallucinogens may act as mixed 5-HT_{1A}/5-HT_{2A} agonists, leading to imbalance in excitatory/inhibitory glutamatergic transmission, with potential for sensory distortions and threat magnification. Also, LSD has been shown to possess intrinsic activity at striatal D₂ receptors, which may contribute to euphoria, depersonalization, and psychotomimetic effects.²¹

A growing concern is with synthetic blends of cannabinoids, many of which possess stronger activity at cannabinoid receptor 1 (CB₁) compared to tetrahydrocannabinol. CB₁ is G-protein linked and primarily pre-synaptic; it is involved with regulating neuronal release of neurotransmitters such as glutamate and catecholamines; this helps control neuronal excitability. The use of exogenous cannabinoids may disrupt this process, resulting in excessive glutamatergic and dopaminergic tone, leading to anxiety, paranoia, and psychotic symptoms in susceptible individuals.²² The potential for adverse effects is furthered with the synthetic blends, which in many instances *lack cannabidiol*, a component with antipsychotic and antiepileptic properties.²³

Management of Agitation – Pharmacological Options

In 2012 the American Association of Emergency Psychiatry put forth evidence-based guidelines for treatment of agitation, termed Project BETA (Best Practices in the Evaluation and Treatment of Agitation).²⁴ While an extensive review of these guidelines is beyond the scope of this paper, we have attempted to discuss the utility of particular interventions in light of the neurobiological considerations mentioned previously. Importantly, agitation may be multifactorial. Medical causes (e.g., hypoglycemia, hypoxia, ictal phenomena) should always be considered, as treating the underlying etiology is the intervention of choice in such situations.²⁵

When treating agitation of unclear etiology, the first-line treatment is benzodiazepines,²⁴ many of which have considerable advantages in terms of route of administration and predictability of onset. Lorazepam has the additional benefit of not undergoing stage I hepatic oxidation, making it an attractive option when liver function may be relevant but cannot be gauged. Acting as GABA-A receptor agonists, benzodiazepines can aid with

top-down cortical-limbic inhibitory control. GABA is the main inhibitory neurotransmitter in the central nervous system (CNS), influencing 60-70% of all synapses.²⁶ Inhibitory coupling of areas of the PFC with the amygdala is mediated by GABAergic interneurons,²⁷ which may be compromised in agitated states. In states of dysphoria, this inhibitory circuitry may be entirely bypassed in favor of a more direct activation of the central amygdala, leading to less flexible behavioral and affective responses.²⁸ Benzodiazepines are also the treatment of choice in clinical scenarios in which there is a relative deficiency of GABAergic tone, leading to autonomic and behavioral symptoms (e.g., withdrawal from alcohol or from chronic benzodiazepine use). In cases where known GABA-A agonists (e.g., alcohol) may be *causing* behavioral activation, providers should *refrain* from using benzodiazepines, as exposure to additional GABA-A agonism may promote further disinhibition.²⁹ In line with this, the treatment of choice for agitation due to alcohol intoxication is haloperidol, per Project BETA.²⁴

Acute management of aggression in the context of psychosis aims to decrease stimulation that could be perceived as menacing, as well as to provide medications that are sedating and anxiolytic. Antipsychotic drugs, with few exceptions, display D₂-blocking properties and have variable adrenoceptor binding properties, modulating CNS adrenergic neurotransmission. As antipsychotics have been shown to bind to the amygdala,³⁰ these mechanisms of action may help mitigate catecholaminergic drive and threat perception. Project BETA recommends atypical antipsychotics (e.g., risperidone or olanzapine) as first line for psychosis-driven agitation, with or without addition of a benzodiazepine. Second-line treatment would consist of a typical agent (e.g., haloperidol) in combination with a benzodiazepine.²⁴ The preference for atypical antipsychotics may derive from their receptor-binding profile, providing clinical benefit with less propensity for extrapyramidal symptoms (EPS). Indeed, using high-potency, typical antipsychotics usually warrants concomitant use of an anticholinergic agent to prevent EPS,³¹ although this has been debated in the literature.³²

In addition to generally showing higher antagonistic affinity for histamine-1 receptors as compared to typical agents,³³ thus providing more sedative effects, atypical antipsychotics antagonize 5-HT_{2A}. This mechanism can decrease excitatory glutamatergic tone as well as increase local release of dopamine in the nigrostriatal pathway, thus providing some protection against EPS. These ancillary mechanisms are important, as they may factor more into immediate behavioral control than D₂-blocking properties, which require longer-term use to achieve appropriate receptor occupancy and full clinical effect. It should be noted that this wider receptor profile is also shared to some extent by lower-potency typical antipsychotics (e.g., chlorpromazine), which have clinical use in management of agitation. However, their side-effect profiles can limit more regular use; for instance, chlorpromazine has been associated with significant

orthostatic hypotension, particularly with parenteral formulations. Figure 1 schematically depicts the neural pathways and relevant medication effects discussed thus far.

Of note, Project BETA guidelines for agitation in psychosis also apply for individuals who have a diagnosis of bipolar disorder and are presenting with acute mania. As drugs such as lithium and antiepileptics may take up to two weeks to achieve a steady state, more immediate behavioral control with antipsychotics (with or without benzodiazepines) may be necessary. One important caveat applies with regard to mania. Despite being approved by the US Food and Drug Administration (FDA) for control of mania, as well as being listed in Project BETA guidelines as a third-line agent for agitation in such scenarios, ziprasidone (an atypical antipsychotic) may lead to enhanced adrenergic output and serotonergic neurotransmission, working in effect as a serotonin-norepinephrine reuptake inhibitor, which could ostensibly worsen a patient's symptoms if such activation is not offset by the sedative properties of the drug.³⁴

With regard to delirium, a wide differential diagnosis of possible medical conditions should be kept in mind. While environmental interventions are imperative to mitigate agitation and worsening of confusion in the patient (e.g., controlling sensory stimuli, early mobility, nutrition, and providing frequent reorientation), certain pharmacologic principles should be heeded. Delirium is, in effect, a hyperdopaminergic and anticholinergic state. Despite this neurobiological substrate, there is *not* compelling evidence for use of antipsychotics for prophylactic prevention of delirium,³⁵ and recent evidence has questioned whether use of antipsychotics actually leads to improved outcomes in patients with *established* delirium.³⁶ As such, if antipsychotics are necessary, their use should be short-term and limited to situations in which delirium is accompanied by behavioral dyscontrol.³⁷ When selecting an antipsychotic, the suggested approach is the use of typical antipsychotics, ideally those with high D2-blocking potency and low intrinsic anticholinergic properties (e.g., haloperidol).²⁴ Given the pathology-driven anticholinergic tone in this condition, there is relative protection against EPS, allowing for high doses of antipsychotics to be given.³⁸ At such doses, it has been suggested that haloperidol, in addition to its D2-blocking properties, may also have antioxidant properties due to interaction with opioid receptors. Benzodiazepines should also be avoided (except for management of substance withdrawal),^{35,37} given the potential for worsening of the clinical picture.

Managing agitation in patients with dementia should be largely non-pharmacological, when possible, as there is an evidence base supporting a number of such interventions.^{39,40} In Alzheimer dementia, in addition to the decline noted in cholinergic neurotransmission, the accumulation of amyloid plaques and neurofibrillary tangles may result in glutamatergic release, with potential for excitotoxicity. Available

pharmacologic options include atypical antipsychotics (e.g., risperidone and olanzapine), antiepileptics (e.g., carbamazepine, gabapentin), serotonergic agents, and even less conventional options such as dextromethorphan/quinidine combination, the latter possessing antiglutamatergic properties.⁴¹⁻⁴⁴ However, there is limited efficacy in use of pharmacologic agents, and the side-effect profile needs to be carefully weighed against potential benefits.⁴⁰ For instance, atypical antipsychotics can lead to excess sedation, metabolic side effects, and EPS. In addition, a boxed warning from the FDA alerts prescribers to the increased risk of death associated with use of atypical antipsychotics in elderly patients with dementia-related psychotic symptoms.

Finally, we briefly discuss treatments with unique routes of administration or mechanisms of action. Alternative forms of administering medications may prove necessary when patient compliance or tolerance for oral medications is limited. An inhaled formulation of loxapine, a mid-potency typical antipsychotic, was approved in 2012 by the FDA for control of agitation associated with schizophrenia and bipolar disorder. While showing effectiveness in management of agitation,⁴⁵ providing this medication effectively requires a considerable degree of patient cooperation, which may not always be feasible. In addition, the recommended dosing is limited to a one-time 10-milligram (mg) administration per 24-hour period, with patients requiring monitoring for bronchospasm for one hour after use.

The use of ketamine, a non-competitive antagonist at glutamatergic N-methyl-D-aspartate (NMDA) receptors, has gained considerable interest in psychiatric practice. Ketamine has a complex mechanism of action, showing different pharmacodynamic receptor profiles and clinical effects according to the dose administered.⁴⁶ While trials assessing antisuicidal and antidepressant properties typically employed doses of 0.5 mg per kilogram (kg),⁴⁷ ketamine can be used in either intramuscular or intravenous formulations at doses of 2-4 mg/kg to control agitation. Pre-clinical and human studies have suggested that ketamine pharmacology follows an inverted "U-shaped" curve (Figure 2); in effect, at lower doses (used in depressive disorders), it can lead to a "glutamatergic burst," given augmentation of α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) receptor transmission.⁴⁸ At progressively higher doses, there is a decrease in glutamatergic tone, as well as binding to mu and sigma-opioid receptors.⁴⁶ This accounts for the higher dosage requirement in agitation as compared to those used in depression and suicidality. It has the important advantages of *not* a) increasing intracranial pressure (ICP) (indeed, it may actually *decrease* ICP in some cases),^{49,50} b) causing respiratory depression;⁵¹ or c) leading to clinically significant hemodynamic changes.⁵² However, its use can be limited by its dissociative effects, which become more pronounced at the higher doses that may be required depending on the degree of agitation. It has a rapid onset of action, and may be an attractive option for cases of severe agitation,

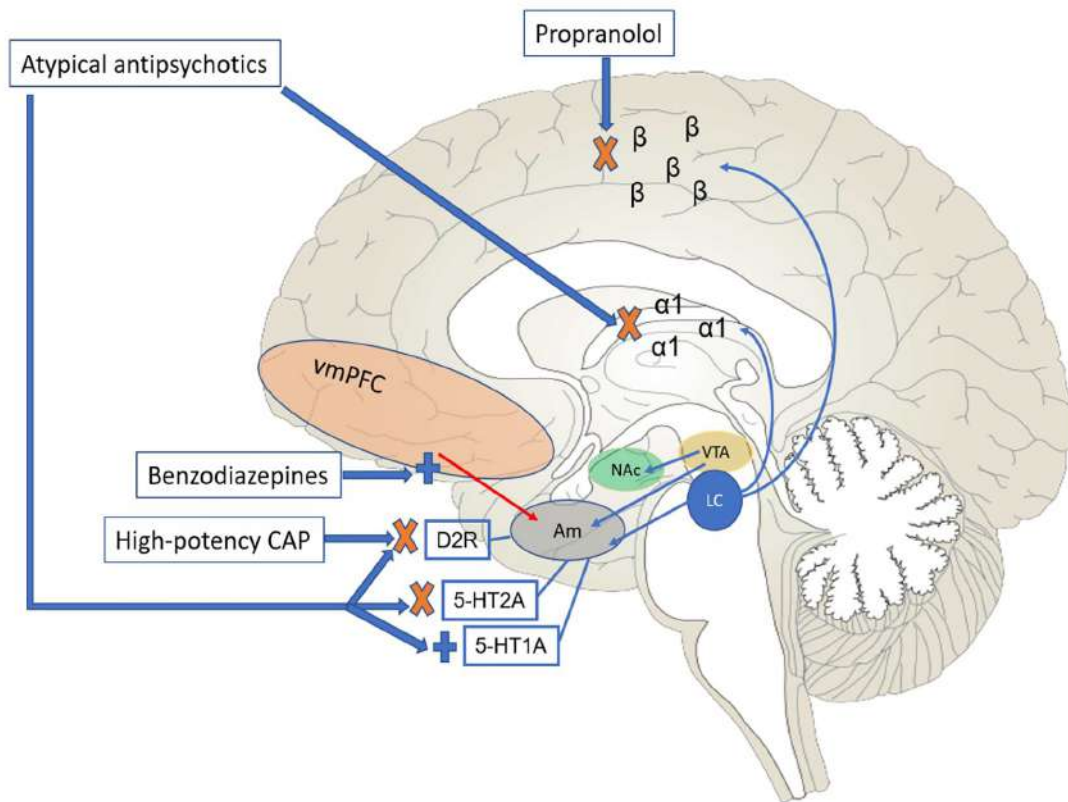


Figure 1. Schematic depiction of medial surface of cortex, subcortical areas, and brainstem, demonstrating key neural circuitry linked with the mechanisms of action of drugs used for the treatment of acute agitation. In states of heightened catecholaminergic tone, such as stimulant intoxication, acute psychosis, or mania, there may be excessive dopamine availability, binding amygdala D2 receptors and increasing conditioned fear responses. In addition, noradrenergic input from the locus coeruleus may also be elevated, contributing to autonomic arousal and feelings of paranoia. As levels increase, binding of norepinephrine will be shifted from the prefrontal cortex (PFC) to posterior cortical and subcortical regions (indicated by β and α_1 receptors – schematically depicted for didactic simplicity), decreasing the individual's ability to cognitively negotiate the situation at hand, particularly as PFC-amygdala coupling is diminished. Medications used for agitation can mitigate the effects of this neurotransmitter and circuitry make-up through the following mechanisms: 1) benzodiazepines, through GABA-A agonism, increase the PFC inhibitory control over the amygdala; 2) beta-blockers (e.g., propranolol, an agent with considerable lipophilicity), in addition to their peripheral effect on autonomic arousal, can decrease norepinephrine binding to posterior adrenoreceptors, thus allowing for greater PFC binding; (3) conventional, or typical antipsychotics, particularly the high-potency agents (e.g., haloperidol), work primarily through D2 receptor blockade – this occurs within the striatum, but also in the amygdala, decreasing threat perception; 4) atypical antipsychotics have a complex mechanism of action – a) D2 blockade occurs, though therapeutic occupancy is less than required with typical agents, b) several act as α_1 receptor antagonists, decreasing subcortical adrenoreceptor binding, c) through subcortical serotonergic modulation, anxiolysis is promoted – several atypicals (e.g., clozapine, ziprasidone, lurasidone, quetiapine, and aripiprazole) agonize the Gi-linked (inhibitory) 5-HT_{1A} receptor and all atypicals antagonize the Gq-linked (excitatory) 5-HT_{2A} receptor, thus diminishing amygdala activation. Am, amygdala; CAP, conventional (first-generation) antipsychotic; D2R, dopamine 2 receptor; LC, locus coeruleus, NAc, nucleus accumbens; vmPFC, ventromedial prefrontal cortex; VTA, ventral tegmental area.

especially when the etiology is unknown.

One study assessed the need for re-dosing of medications for agitation across a spectrum of diagnostic categories.⁵³ Control of agitation was not always optimal when ketamine was the first drug used (although dosage varied considerably, from 40 mg - 400 mg); however, when used in refractory cases – poorly responsive to benzodiazepines and/or antipsychotics – ketamine had remarkable efficacy, with no cases requiring additional drug administration in the following three hours. Of note, the efficacy and safety of ketamine in geriatric patients

and in individuals with neuropsychiatric disorders are still being investigated and need further study, although some small studies suggest lack of significant adverse effects in these populations.^{54,55} Finally, because doses of ketamine used to control behavior are more likely to lead to considerable sedation, with arguably less leeway to titrate to a minimal effective dose to reach a more measured state of calmness, it could be posited that this drug should not be considered as a first-line strategy, but rather reserved for refractory cases in which a rescue or second-line medication is needed.

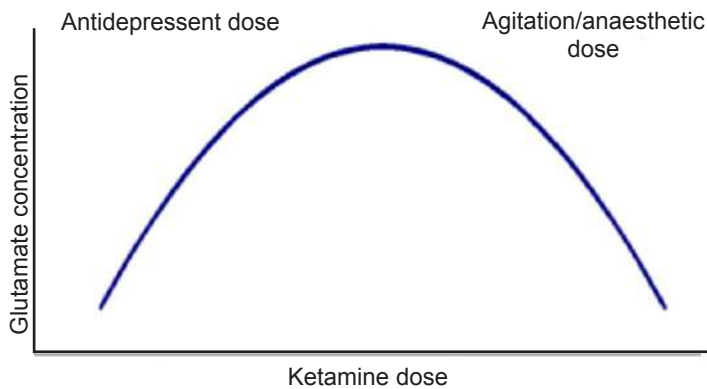


Figure 2. Depiction of dose-dependent inverted “U-shaped” curve associated with ketamine. Doses of ketamine used in antidepressant trials (0.5mg/kg) are associated with heightened down-stream glutamatergic neurotransmission, enhancing AMPA receptor activity. As doses increase toward those used in anesthesia and agitation (2-4mg/kg), there is a depression of glutamatergic tone, as well as an accretion of additional pharmacodynamic effects, including binding of opioid receptors. Thus, higher doses are typically required for behavioral control.

LIMITATIONS

While this paper provides an overview of the main neuroscientific aspects underlying agitation in clinical settings, it is difficult to account for atypical presentations, and there are instances informed by medical co-morbidity and pharmacologic side effects that were not covered in this paper. Also, despite the exciting developments in the neurosciences, they are still somewhat in their nascency, and any attempt to draw neurobiological parallels with clinical presentations will necessarily be limited by gaps and contradictions in the extant literature. While there is an evidence base that many of our interventions for agitation are effective, hopefully future research will allow for more tailored management, optimizing behavioral control while minimizing side effects.

CONCLUSION

Aggression can present for manifold reasons in the clinical setting. Having a more informed understanding of the possible determinants of agitation can help with targeted treatment strategies, limiting the unnecessary use of medications or of interventions that could be deemed forceful. Decreasing catecholaminergic drive and/or augmenting GABAergic tone are particularly relevant considerations in management of agitation and are mechanistically germane to the treatment options posited by Project BETA. Although not discussed in this paper, it should be reiterated that non-pharmacological interventions are still essential considerations, in particular as the recovery model has been increasingly promoted to assist patients to feel a greater sense of control and partnership in the management of their care, even when they engage in violent acts in clinical settings.

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Adult Patients with Respiratory Distress: Current Evidence-based Recommendations for Prehospital Care

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Introduction: We developed evidence-based recommendations for prehospital evaluation and treatment of adult patients with respiratory distress. These recommendations are compared with current protocols used by the 33 local emergency medical services agencies (LEMSA) in California.

Methods: We performed a review of the evidence in the prehospital treatment of adult patients with respiratory distress. The quality of evidence was rated and used to form guidelines. We then compared the respiratory distress protocols of each of the 33 LEMSAs for consistency with these recommendations.

Results: PICO (population/problem, intervention, control group, outcome) questions investigated were treatment with oxygen, albuterol, ipratropium, steroids, nitroglycerin, furosemide, and non-invasive ventilation. Literature review revealed that oxygen titration to no more than 94-96% for most acutely ill medical patients and to 88-92% in patients with acute chronic obstructive pulmonary disease (COPD) exacerbation is associated with decreased mortality. In patients with bronchospastic disease, the data shows improved symptoms and peak flow rates after the administration of albuterol. There is limited data regarding prehospital use of ipratropium, and the benefit is less clear. The literature supports the use of systemic steroids in those with asthma and COPD to improve symptoms and decrease hospital admissions. There is weak evidence to support the use of nitrates in critically ill, hypertensive patients with acute pulmonary edema (APE) and moderate evidence that furosemide may be harmful if administered prehospital to patients with suspected APE. Non-invasive positive pressure ventilation (NIPPV) is shown in the literature to be safe and effective in the treatment of respiratory distress due to acute pulmonary edema, bronchospasm, and other conditions. It decreases both mortality and the need for intubation. Albuterol, nitroglycerin, and NIPPV were found in the protocols of every LEMSA. Ipratropium, furosemide, and oxygen titration were found in a proportion of the protocols, and steroids were not prescribed in any LEMSA protocol.

Conclusion: Prehospital treatment of adult patients with respiratory distress varies widely across California. We present evidence-based recommendations for the prehospital treatment of undifferentiated adult patients with respiratory distress that will assist with standardizing management and may be useful for EMS medical directors when creating and revising protocols. [West J Emerg Med. 2020;21(4)848-856.]

INTRODUCTION

Adults with respiratory distress make up 6-12% of all patients transported by emergency medical services (EMS).¹⁻³ This subgroup of EMS patients is older and sicker than other transported patients and patients who arrive to the ED by other transport methods. A study of adults with dyspnea in Australia and New Zealand showed the average age is 74 years, 76% are admitted, 6% are intubated, and 6% of admitted patients do not survive to hospital discharge.⁴⁻⁶ Three diagnoses (pneumonia, heart failure, and chronic obstructive pulmonary disease [COPD] exacerbation) account for 60% of cases.⁴

EMS personnel play a prominent role in triage, transport, and initial management of adult patients with respiratory distress. For these patients, Stiell et al demonstrated that, compared with Basic Life Support, Advanced Life Support-level prehospital care results in a decrease of mortality to 12.4% from 14.3% and a substantial improvement in symptom relief due to early therapeutic interventions.⁶ The delivery of early, targeted therapy by paramedics is often hindered by the diagnostic challenge of respiratory distress. Diagnostic accuracy of paramedics in patients with acute dyspnea has been shown to vary between 53% and 77%.^{4,5,7-9} They perform better in patients with asthma or COPD and worse in patients with acute pulmonary edema (APE).^{4,5,7,10}

Without widely accepted guidelines, EMS care continues to vary greatly across the United States. In 2007 the Institute of Medicine report, "Emergency Medical Services at the Crossroads," advocated for the development of evidence-based model prehospital protocols so that all patients would receive the current standard of care. Therefore, we aim to provide a summary of the evidence for prehospital treatment of adult patients with respiratory distress, and to assess the consistency of California protocols with respect to our recommendations.

METHODS

The state of California divides EMS care into 33 local EMS agencies (LEMSA). Each of these geographically divided governmental regulatory bodies has a set of medical control protocols in accordance with California EMS Authority scope of practice. Medical directors of those agencies, along with other EMS medical directors, make up the EMS Medical Directors Association of California (EMDAC). EMDAC supports the various agencies and makes recommendations to the California EMS Authority about policy, legislation, and scope of practice issues. In an effort to improve quality and decrease variability in EMS practice in California, EMDAC has endeavored to create evidence-based recommendations for EMS protocols.¹¹⁻¹⁴

A subcommittee of EMDAC, the Medical Advisory Committee, chose the elements that should be included in any protocol for an adult patient with respiratory distress. Searches of MEDLINE, MEDLINE Scopus, Web of Science, and the Cochrane Database were performed. All searches were limited to English-language sources, adults, and human studies. In addition, relevant articles from the bibliographies of included studies and more recent emergency department (ED) and

Population Health Research Capsule

What do we already know about this issue?
Adults with respiratory distress make up 6-12% of EMS transports and are older, sicker, and have a high mortality. Prehospital care has demonstrated a decrease in mortality.

What was the research question?
An evidence-based review will highlight treatments that benefit these patients and demonstrate areas that need more research.

What was the major finding of the study?
Reducing the variability and optimizing the prehospital care of the adult respiratory patient will decrease medical costs and improve survival.

How does this improve population health?
Nitrates in patients with acute pulmonary edema are likely helpful but have poor quality research to support them.

prehospital articles identified by committee members and reviewers were included. When there was minimal prehospital research, the most pertinent ED data was reviewed.

Additionally, the references of included papers were examined for additional studies. The interventions that were found in published prehospital and ED studies were then used to create clinical questions using the population, intervention, control group and outcome (PICO) format. Recommendations, based on the studies found, were created for each PICO question.

The Medical Advisory Committee assigned levels of evidence (LOE) and graded their recommendations based on a tailored modification of the American College of Emergency Physicians clinical policymaking process.¹⁵ LOE (Table 1) were assigned based on the study design, including features such as data collection methods, randomization, blinding, outcome

Table 1. Level of evidence definitions.

LOE Level	Definition
I	Randomized, controlled trials, prospective cohort studies, meta-analysis of randomized trials or prospective studies, or clinical guidelines/comprehensive review.
II	Nonrandomized trials and retrospective studies.
III	Case series, case reports, and expert consensus.

LOE, levels of evidence.

measures and generalizability. (A brief summary of the reviewed studies is available in an electronic appendix.) After assigning LOE to the studies, these were translated to clinical grades of our recommendations using the standards described in Table 2.

In January 2019, we reviewed the protocols of all 33 LEMSAs for comparison with our recommendations. We deemed institutional review board approval not necessary for this review of publicly available research and clinical protocols.

RESULTS

PICO Question: Does the titration of oxygen in patients with respiratory distress improve outcomes?

Summary of Current Evidence

In both hospital and prehospital care, oxygen is among the most common therapies administered to patients. Excess oxygen, however, has been linked to central nervous system toxicity, coronary vasoconstriction, and acute lung injury.¹⁶ A number of publications and recommendations have addressed oxygen use and titration in medically and surgically ill adults.¹⁶⁻¹⁹

Chu et al published one of the largest systematic reviews in *Lancet* using 25 randomized control trials that enrolled 16,037 patients with sepsis, critical illness, stroke, trauma, myocardial infarction, cardiac arrest, and patients who required emergency surgery.¹⁶ They compared patients receiving a liberal oxygen strategy (median fraction of inspired oxygen [FiO_2] of 0.52) with a conservative oxygen strategy (median FiO_2 of 0.21). The study showed that patients treated with a liberal oxygen strategy had increased in-hospital mortality (relative risk [RR] 1.21; confidence interval [CI] 1.03-1.43) and 30-day mortality (RR 1.14; CI 1.01-1.29) but showed similar morbidity. The authors concluded that supplemental oxygen may be harmful above peripheral capillary oxygen saturation (SpO_2) 94-96%.¹⁶

Following the results published by Chu et al, the *BMJ* published clinical practice guidelines on oxygen management.¹⁷ For patients receiving supplemental oxygen, it was recommended to aim for SpO_2 no more than 96%. For patients with acute myocardial infarction and stroke, it was recommended to not start supplemental oxygen for SpO_2 greater than or equal to 93% (strong recommendation, or greater than or equal to 90-92%, weak recommendation). The authors also recommend that a target SpO_2 range of 90-94% seems reasonable for most patients and 88-92% for patients at risk of hypercapnic respiratory failure. Excluded are patients who require a higher oxygen target closer to 100% to treat an underlying medical condition such as pneumothorax, carbon monoxide poisoning, cluster headache, and sickle cell crisis.

Recommendation

Level B Recommendation

For patients who are receiving oxygen for respiratory distress, oxygen should be titrated to target SpO_2 no more than 94-96%. This does not apply to those patients for whom 100% oxygen is the treatment of the underlying disorder or

Table 2. Recommendation definitions.

Level Recommendation	Definition
A	Prehospital recommendations with a strong degree of certainty based on one or more LOE I studies or multiple LOE II studies.
B	Prehospital recommendations with a moderate degree of certainty based on one or more LOE II studies or multiple LOE III studies.
C	Prehospital recommendations based on only poor quality or minimal LOE III studies or based on consensus.

LOE, levels of evidence.

for those who are being preoxygenated prior to advanced airway placement.

PICO Question: Does the prehospital titration of oxygen to patients with suspected COPD improve outcomes?

Summary of Current Evidence

A number of retrospective studies have demonstrated worse outcomes in patients with acute exacerbations of COPD treated with excessive oxygen such as higher rates of death, respiratory failure,²⁰ or increased rates of respiratory acidosis.²¹ A prehospital, cluster-randomized, controlled, parallel group trial of oxygen therapy in patients aged 35 years or older with suspected bronchospasm was performed.²² It compared titrated oxygen (SpO_2 of 88-92%) to high flow oxygen regardless of SpO_2 . Titrated oxygen treatment significantly reduced mortality, hypercapnia, and respiratory acidosis compared with high flow oxygen in acute exacerbations of COPD.

Recommendation

Level A Recommendation

In prehospital patients with COPD exacerbations, oxygen should be titrated to a target of 88-92%.

PICO Question: In patients with suspected bronchospasm (asthma or COPD) in the prehospital environment, does prehospital administration of steroids have a benefit?

Summary of Current Evidence

Characterized by respiratory distress and wheezing, asthma and COPD are both diseases of pulmonary obstruction. They often are both treated in EMS using protocols for bronchospasm. In examining the literature supporting steroid use, however, the disease entities are usually studied separately.

Asthma

A meta-analysis by Rowe et al examined studies on the administration of steroids during an asthma exacerbation and

its effect on pulmonary function, admission rates, and relapse rates.²³ While having an equivalent effect on pulmonary function, steroids were effective at preventing relapse (odds ratio [OR] 0.15; CI 0.05-0.44) and admissions in adults (OR 0.47; 95% CI 0.27-0.79) and children. The authors concluded that steroids were an important part in the emergency treatment of asthma exacerbations.

In 1999, Lin et al published a randomized, double blind, controlled trial exploring the effect of 125 milligrams (mg) of intravenous (IV) methylprednisolone vs placebo in 60 patients who failed to completely respond after one nebulized albuterol treatment.²⁴ They found that patients who received methylprednisolone showed statically greater improvement in pulmonary function, and an improvement that occurred faster than the control group. They concluded that steroids should be given early in the course of treatment of patients with asthma exacerbations.

A subsequent Cochrane review by Rowe et al in 2001 examined studies looking at steroids in asthma treatment on the primary outcome of admission rates.²⁵ They included 12 studies in their analysis and found that when steroids were received within one hour of arrival to the ED, there was decrease in admission rates. This effect was first present two hours after steroid administration and most pronounced between 4-6 hours after administration.

In an attempt to explore whether the effect of systemic steroids extended to the prehospital arena, Knapp et al published a retrospective case review comparing admission rates in patients with moderate to severe asthma exacerbations who received 125 mg IV methylprednisolone via EMS compared to in the ED.²⁶ They found that patients who received steroids via EMS had a lower admission rate (13% compared to 33%) and had a quicker resolution of symptoms (15 +/- 7 minutes compared to 40 +/- 22 minutes).

Chronic Obstructive Pulmonary Disease

In 2014, a Cochrane review by Walters et al examined the effect of systemic steroids on acute exacerbations of COPD.²⁷ They identified 16 studies comparing orally or parenterally administered steroids with placebo in COPD treatment. While there was no mortality difference, they found high quality evidence that systemic steroids reduced the likelihood of treatment failure by over half (OR 0.48; CI 0.35-0.67). There was also moderate quality data that systemic steroids reduced the rate of relapse by one month and reduced total hospital length of stay in admitted patients. It also found that route of administration (parenteral vs oral) did not lead to any difference in primary outcomes of treatment failure, relapse, mortality, or any secondary outcome.²⁷ This has been demonstrated by other studies as well. Lindenauer et al demonstrated oral low-dose steroids did not result in worse outcomes compared to high-dose IV steroids among hospitalized patients with COPD exacerbations.²⁸

We identified no prehospital studies that explored the use of steroids in patients with COPD exacerbations. The Cochrane review noted that about 1 in 6 patients experience an adverse effect from corticosteroid administration: the most common of these was hyperglycemia. This was higher in those doses given parenterally. There was a non-significant increase in psychiatric disturbance. Intensive care unit studies did not show significant increase in gastrointestinal bleeding, or hypertension.²⁸

Recommendation

Level B Recommendation

In patients with suspected bronchospasm (asthma or COPD), systemic steroids (by mouth or IV) should be administered in the prehospital environment.

PICO Question: Does the prehospital administration of albuterol to patients with suspected bronchospasm improve outcomes?

Summary of Current Evidence

The studies looking at the use of albuterol in patients with respiratory distress and suspected bronchospasm are limited.²⁹⁻³⁴ Many prehospital observational studies demonstrate the safety of prehospital use of nebulized albuterol and improvements in subjective symptoms and peak expiratory flow rates. The available literature becomes slightly more expansive when including other beta-2 agonists such as levalbuterol,^{31,35} salbutamol,³⁰ and terbutaline.^{30,36}

In one large observational cohort study of 3351 prehospital patients, patients demonstrated significant improvement in reported dyspnea and peak flow rates.³⁷ In a different retrospective study, prehospital administration of nebulized albuterol did not affect travel interval, length of stay in the ED, or medication use after ED presentation.³³

One prehospital randomized double-blind trial studied asthma patients receiving either subcutaneous terbutaline or nebulized albuterol.³⁶ This small study of 83 patients demonstrated a greater improvement in respiratory distress visual analog scale scores than did the terbutaline group. Hospital admission rates, vital signs, and peak expiratory flow rates were not significantly different.

Recommendation

Level B Recommendation

In patients with suspected bronchospasm (asthma or COPD), albuterol should be administered in the prehospital environment.

PICO Question: Does the prehospital administration of ipratropium to patients with suspected bronchospasm improve outcomes?

Summary of Current Evidence

There is weak evidence from the ED management of acute asthma that ipratropium improves airflow obstruction and possibly reduces hospital admissions when used as an adjunct

to beta 2 agonists.³⁸⁻⁴⁰ A single before-and-after analysis of the addition of ipratropium to albuterol was the only identified prehospital study.⁴¹ It found no differences in outcomes as compared to albuterol alone.

Recommendation

Level C Recommendation

In patients with suspected bronchospasm, ipratropium can be administered; however, there is limited data from the prehospital setting. The benefits are greatest in confirmed asthmatics and in those having a severe exacerbation.

PICO Question: In patients with suspected acute pulmonary edema, does prehospital use of nitroglycerin have a benefit?

Summary of Current Evidence

A number of case series and retrospective studies have demonstrated the clinical effects of nitroglycerin in patients with suspected APE. Nitroglycerin is a potent vasodilator that improves hemodynamics by decreasing pulmonary arterial pressure and reducing left ventricular preload and afterload.^{42,43}

A randomized trial by Cotter et al examined patients with severe pulmonary edema who received either a high dose of isosorbide dinitrate and a low dose of furosemide vs a low dose of isosorbide dinitrate and a high dose of furosemide. With 52 patients in each arm they found that patients who were randomized to receive a higher dose of nitrates had a lower rate of mechanical ventilation (13% vs 40%), myocardial infarction (17% vs 37%) and death (1.9% vs 5.8%).⁴⁴

In a secondary analysis of a multicenter randomized controlled trial (RCT) of ED non-invasive ventilation vs oxygen, Gray et al aimed to examine the effect of diuretics, nitrates, and opiates on patients with severe pulmonary edema.⁴⁵ The study concluded that there was no evidence that nitrates were associated with any difference in mortality, improvement in acidosis or respiratory distress. The authors suggest these findings may reflect that nitrates are most effective when given to patients with pulmonary edema and hypertension.⁴⁵

There are several thoughtful reviews regarding prehospital care nitrates. In a 2003 review, the authors conclude by consensus that high-dose nitrates represent the out-of-hospital treatment of choice for APE.⁴² They outline prehospital treatment that uses parameters such as systolic blood pressure and severity of symptoms to guide nitrate treatment.

Overall the evidence on prehospital use of nitrates is limited and at times conflicting. An important theme in the literature is the high rate of misdiagnosis of APE and the implications of incorrect administration of nitrates. If nitrates are to be used prehospital, there should be clearly defined parameters, for example systolic blood pressure minimums (90 millimeters of mercury), that might help target APE patients who would benefit most from the effects of nitrates.¹¹

Recommendation

Level C Recommendation

In patients with APE in the prehospital environment, administration of nitrates may be beneficial in critical, hypertensive patients. The ability to correctly diagnose prehospital APE may limit potential benefits of nitrates.

PICO Question: In patients with suspected APE, does prehospital use of furosemide have a benefit?

Summary of Current Evidence

Furosemide is frequently used in the treatment of congestive heart failure. The diuretic effect helps decrease total body fluid volume, which can decreasing left ventricular filling pressure.⁴⁶ A 1987 prospective study examined medication treatment of 57 prehospital patients with presumed APE.⁴⁷ Outcomes included subjective patient responses, vital sign improvement, scaled respiratory distress evaluation, and adverse effects. Investigators concluded that furosemide does not add to the efficacy of treatment for presumed prehospital APE and may be in fact deleterious; cases of hypotension and hypokalemia were noted, and 25% of patients later required fluid resuscitation. Despite its small sample size this is the only prospective study identified in the review of current literature.

A retrospective chart review in 2006 identified 144 patients who received prehospital furosemide for presumed APE.⁴⁸ Investigators found the rate of misdiagnosis high at 41%. Furosemide was administered when it was not indicated in 42% of patients and potentially harmful in 17% of patients, such as those with sepsis due to pneumonia. Given the high prevalence of inappropriate and harmful administration of furosemide, the investigators advised against prehospital diuretic use.

Overall the evidence on prehospital furosemide for APE is limited. An important finding in the literature is the rate of misdiagnosis of APE and the implications that can have for incorrect administration of furosemide.

Recommendation

Level C Recommendation

In patients with APE in the prehospital environment, there is insufficient evidence to demonstrate that furosemide may be beneficial.

Level B Recommendation

There is moderate evidence to support that prehospital furosemide administration may be harmful, particularly when patients are incorrectly diagnosed with APE.

PICO Question: In patients with respiratory failure, does prehospital use of non-invasive positive pressure ventilation (NPPV) have a benefit? Is there benefit in those with APE? Is there benefit in those with bronchospasm?

Summary of Current Evidence

NPPV provides ventilatory assistance to those in respiratory distress by supporting both oxygenation and ventilation.^{49,50} Use of NPPV has steadily increased in the ED, and a number of randomized trials and meta-analyses have evaluated its safety and effectiveness to assist those patients with severe respiratory distress and hypoxia from an acute asthma exacerbation,^{50,51} APE,^{49,52-54} or undifferentiated respiratory distress.⁵⁵ These studies have generally found earlier improvement of respiratory distress, vital signs, and metabolic abnormalities.⁵⁵ There is moderate evidence that NPPV lowers the rate of intubation. A number of these studies have also demonstrated a mortality benefit.

NPPV, primarily continuous positive airway pressure (CPAP) due to equipment limitations, gained traction in EMS in the late 1990s. Current models create pressure from a positive end-expiratory pressure valve or adjusting the amount of oxygen going to the device. Early prehospital retrospective studies demonstrated safety and likely clinical improvements.⁵⁶⁻⁵⁹ Studies have also examined the effectiveness of NPPV on the treatment of an acute COPD exacerbation,⁵⁷ APE,^{56,58,60,61} and undifferentiated significant respiratory distress.^{59,62-66}

A prospective, non-blinded RCT looking at the use of prehospital CPAP for patients with acute respiratory failure compared with standard care found that intubations decreased by 30% and mortality decreased by 21%.⁶² Although the study included a relatively small number of patients, the clinical outcome was significant.

A subsequent systematic review and meta-analysis focused on studies examining prehospital CPAP and its effect on intubations and mortality in patients with acute respiratory failure.⁶⁴ Three RCTs, one non-randomized comparative study, and one retrospective chart review included 1002 patients and found significantly fewer intubations (OR 0.31; 95% CI 0.19–0.51) and lower mortality (OR 0.41; 95% CI 0.19–0.87) with CPAP use.⁶⁰⁻⁶⁶

Recommendation

Level A Recommendation

There is sufficient evidence that demonstrates the safety and benefit of non-invasive ventilation (primarily CPAP) in those patients with undifferentiated respiratory distress.

Level A Recommendation

There is sufficient evidence that demonstrates the safety and benefit of non-invasive ventilation (primarily CPAP) in those patients with suspected APE.

Level A Recommendation

There is sufficient evidence that demonstrates the safety and benefit of non-invasive ventilation (primarily CPAP) in those patients with suspected respiratory distress due to bronchospasm.

Comparison with 33 Local EMS Agency Protocols

All 33 LEMSAs had at least one protocol for the prehospital management of respiratory distress as shown in Table 3.

Table 3. The protocols of the 33 Local EMS Agencies (LEMSAs) in California were examined regarding specific treatments in the care of patients with respiratory distress. There is variability among the different agency protocols. This is most pronounced in the titration of oxygen for patients with and without COPD.

Titration of oxygen in patients with respiratory distress (to no more than 96%) varied significantly among protocols: 21 LEMSAs included either oxygen titration or an acceptable lower limit of normal prior to oxygen administration, most commonly 94%.

Titration of SpO₂ in COPD was recommended in three LEMSAs ranging from 88-92% to 92-94%. One LEMSA recommended reduced oxygen but did not provide a goal SpO₂.

Administration of albuterol in suspected bronchospasm was included in all LEMSAs.

Administration of ipratropium in suspected bronchospasm was included in 15 LEMSAs.

Administration of nitroglycerin in suspected APE was included in all LEMSAs but varied in the dosing, titration parameters, and contraindications. A single 0.4 mg sublingual tablet was the most common initial dose and form of the medication. Eight protocols included instructions for nitroglycerin paste and one included nitroglycerin spray in addition to the tablets. The minimum systolic blood pressure varied between 90 and 100 mmHg. Eleven protocols noted that nitroglycerin administration is contraindicated if a patient is taking phosphodiesterase inhibitors.

Administration of furosemide in suspected APE was only included in one protocol.

The use of NPPV for acute pulmonary edema was included in all LEMSAs.

The use of NPPV for bronchospasm was included in all LEMSAs.

The use of NPPV for undifferentiated respiratory distress was included in 26 LEMSAs.

COPD, chronic obstructive pulmonary disease; *APA*, acute pulmonary edema; *NPPV*, non-invasive positive pressure ventilation.

DISCUSSION

There is a paucity of research on specific prehospital practices used in managing respiratory distress. Hospital-based studies can inform the development of EMS protocols, but limitations such as provider skills, diagnostic ability, time, and scene dynamics make direct correlation impractical. Whenever possible, prehospital studies are preferred. A major theme of the prehospital literature is the diagnostic challenge undifferentiated respiratory distress presents. Inappropriate use of nitroglycerin or furosemide has the potential to be harmful. However, the benefit of NPPV for several etiologies of respiratory distress is well supported.

The respiratory distress protocols reviewed varied greatly in content and structure between LEMSAs in California, reflecting the variation between states.¹¹⁻¹⁴ Goal SpO₂ and O₂ titration varied widely. Seventeen agency protocols include a lower limit of acceptable SpO₂ before oxygen is to be administered, and three protocols recommended further titration after oxygen is applied. This is reasonable given that supplemental oxygen is intended to treat hypoxemia and has not been shown to consistently relieve breathlessness in the absence of hypoxemia.¹⁸ For those patients with COPD, only four protocols called for lower SpO₂ goals. Current literature and guidelines reinforce that liberal oxygen administration is not benign and should be dosed appropriately. Adjusting current SpO₂ targets for patients in respiratory distress should be relatively easy to implement. While this adjustment would likely increase the attention needed to avoid over- and under-oxygenation, titration would need no new equipment, use less overall oxygen, and likely be more comfortable for the patient. As stated above, this recommendation for titration does not apply to those patients for whom oxygen is the treatment for the underlying condition such as pneumothorax and carbon monoxide poisoning.

Albuterol is recommended by all LEMSAs while ipratropium is only prescribed by 15. The evidence supporting prehospital ipratropium is weaker than for albuterol in patients with exacerbations of COPD and asthma. These conditions are relatively easier to diagnose in the prehospital environment since both chronic conditions are prevalent and patients tend to be familiar with their own symptoms.

Currently, steroids are not administered by EMS in California for bronchospasm. The literature reviewed supports its introduction for the treatment of asthma and COPD as it helps in symptom resolution and reducing both relapse and hospital admissions. The most common side effect described was hyperglycemia in those patients with COPD, which is reduced by using oral steroids. Oral administration (most commonly 60 mg prednisone) was found to be as effective as parenteral steroid administration (most commonly 135 mg IV methylprednisolone).

Nitroglycerin is prescribed by every LEMSA but there are significant variations in dosages, treatment intervals, and blood pressure parameters. The variation in dosing mimics the variation often found in EDs, with recent data demonstrating the use and safety of higher loading doses of nitroglycerin.⁶⁷

Only one LEMSA included furosemide in the treatment of APE. The research found did not support widespread use of furosemide outside of the hospital. The protocol appears to have been written for a rural environment and requires base hospital contact prior to medication administration as well as a transport time exceeding 45 minutes.

Non-invasive ventilation, CPAP, is present in the protocols of every LEMSA for the treatment of APE and bronchospasm. CPAP is also indicated for undifferentiated respiratory distress in most protocols.

LIMITATIONS

We analyzed the protocols of only one state; therefore, the protocol conclusions cannot be generalizable to other states. We did not contact the individual LEMSAs to learn about motivation for differences between protocols. There are always inherent biases when synthesizing available data into recommendations. Finally, many recommendations are at least partly derived from hospital-based studies because of a lack of adequate prehospital studies.

CONCLUSION

Protocols for respiratory distress vary widely across the state of California. The evidence-based recommendations created via GRADE methodology (Grading of Recommendations Assessment, Development and Evaluation) for the prehospital management of this condition may be useful for EMS medical directors tasked with creating and revising these protocols.

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Rural Interfacility Emergency Department Transfers: Framework and Qualitative Analysis

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Introduction: Interfacility transfers from rural emergency departments (EDs) are an important means of access to timely and specialized care.

Methods: Our goal was to identify and explore facilitators and barriers in transfer processes and their implications for emergency rural care and access. Semi-structured interviews with ED staff at five rural and two urban Veterans Health Administration (VHA) hospitals were recorded, transcribed, coded, and analyzed using an iterative inductive-deductive approach to identify themes and construct a conceptual framework.

Results: From 81 interviews with clinical and administrative staff between March–June 2018, four themes in the interfacility transfer process emerged: 1) patient factors; 2) system resources; and 3) processes and communication for transfers, which culminate in 4) the location decision. Current and anticipated resource limitations were highly influential in transfer processes, which were described as burdensome and diverting resources from clinical care for emergency patients. Location decision was highly influenced by complexity of the transfer process, while perceived quality at the receiving location or patient preferences were not reported in interviews as being primary drivers of location decision. Transfers were described as burdensome for patients and their families. Finally, patients with mental health conditions epitomized challenges of emergency transfers.

Conclusion: Interfacility transfers from rural EDs are multifaceted, resource-driven processes that require complex coordination. Anticipated resource needs and the transfer process itself are important determinants in the location decision, while quality of care or patient preferences were not reported as key determinants by interviewees. These findings identify potential benefits from tracking transfer boarding as an operational measure, directed feedback regarding outcomes of transferred patients, and simplified transfer processes. [West J Emerg Med. 2020;21(4)857-864.]

INTRODUCTION

The emergency department (ED) is a central access point for healthcare in the United States. More than 60% of hospitalizations originate in the ED, which has become a default location for specialty consultations and diagnostic evaluations. This is particularly the case in rural areas, where hospitals have disproportionately closed in the past decade.^{1,2} As a result, interfacility transfers, in which a patient is transferred from an ED to another ED or hospital, are becoming a more common pathway to access care, even for time-sensitive emergencies.³⁻⁶

Rural ED visits to non-Veterans Health Administration (VHA) hospitals rose by more than 50% from 2006 to 2015, and a quarter of the ~4.2% patients who were transferred traveled more than 50 miles, most commonly for cardiovascular conditions.^{7,8} Rural patients at VHA EDs and urgent care clinics (UCC) are three times more likely to undergo interfacility transfers than their non-rural counterparts, and the most common reasons are for mental health conditions (34%), followed by cardiovascular conditions (12%; internal VHA data). Prolonged transfer times are common, and patients and their families often bear significant travel and economic burdens.^{9,10} This is particularly relevant in the VHA, where some rural healthcare facilities have limited clinic or specialty resources but maintain an ED or UCC. The 2018 VA MISSION Act included a new requirement to cover non-VHA urgent care access to care, further adding urgency to the need to better understand interfacility transfers.¹¹ Therefore, to inform the design and implementation of a planned intervention to address interfacility transfers, we sought to understand the interfacility transfer process and identify and explore facilitators, barriers, and their implications for acute care access for rural veterans.

METHODS

We conducted qualitative analysis of semi-structured interviews at multiple VHA facilities. We interviewed staff, clinicians, and administrators at seven VHA hospitals that accept and transfer patients from their EDs from March–June 2018 in accordance with CONSolidated criteria for REporting Qualitative (COREQ) research guidelines.^{12,13}

Recruitment and Data Collection

After piloting within the research team, semi-structured interviews (Supplement) were conducted by CDM and MJW, who are both emergency physicians and researchers with experience conducting interviews and qualitative analysis. Sites were chosen from 140 VHA ED/UCCs based on the proportion and number of ED/UCC visits that involved an interfacility transfer, as well as support from local leadership for conducting interviews, and geographic distribution. Staff were notified of the project by a local leader. We used purposeful and snowball sampling strategies to identify experienced stakeholders on both day and night shifts,

Population Health Research Capsule

What do we already know about this issue?
Interfacility transfers from rural emergency departments are an important means of access to timely and specialized care.

What was the research question?
Identify and explore facilitators and barriers in transfer processes and their implications for emergency rural care and access.

What was the major finding of the study?
Patient factors, system resources, processes and communication all determine where patients are transferred.

How does this improve population health?
Interfacility transfers from rural EDs are complex, resource-driven processes. Transfer boarding should be tracked, and simplified transfer processes are needed.

including physicians, advanced practice providers, nurses, technicians, clerks, hospitalists, transfer coordinators, and clinical leadership.¹⁴ Interviews conducted at facilities were audiorecorded and transcribed, all identifiable information was removed, and field notes were reviewed for context and themes after each interview day. Recruitment ended when both agreed no additional information was being obtained. No repeat interviews were conducted. The Tennessee Valley Healthcare System internal review board determined these activities were quality improvement, and accordingly informed consent was obtained from each participant but not documented.

Qualitative Analysis

We used an iterative, inductive-deductive approach to develop a conceptual framework for interfacility transfers at VHA facilities of different sizes in urban and rural locations.¹⁵ Deductively, we started with a framework developed in previous qualitative transfer work,¹⁶ combined with historical knowledge of ED processes. Inductively, we reviewed 10 interviews to refine categories and subcategories, and to develop higher order themes and relationships among themes. Four members of the team (CDM, MJW, KB, and DS) refined the coding framework until consensus was achieved. After a 10% random sample of transcribed interviews revealed no revisions to the coding framework, KB and SC recoded the preliminary set and remaining interviews.

RESULTS

We conducted 81 interviews at two urban and five rural VHA hospitals, with 5-15 ED beds each (Table 1).

Interviews were conducted among ED clinicians (N = 26), nurses (N = 24), and other staff such as clerks and respiratory therapists (N = 5); non-ED staff included administrators (N = 13), hospitalists (N = 11), and others (N = 4). No participants declined or dropped out; interviews were 10-45 minutes long. Interviews revealed core components of the interfacility ED transfer process, which are illustrated in Figure 1 and followed by a brief description. This process is made more complex by four themes that emerged from the interviews, which make up the conceptual framework (Figure 2) and have implications for access to care: 1) patient factors; 2) system resources; and 3) processes and communication for transfers, which culminate in 4) location decisions (ie, where, how, and when an ED patient is transferred).

The interfacility transfer process (Figure 1) includes history, physical exam, and potentially diagnostic testing. Once the need for transfer is identified (Figure 2), administrative steps are performed by multiple team members, including obtaining administrative approval (in some cases) and patient consent to transfer, finding an appropriate accepting facility, completing necessary forms and orders, arranging transportation, and conducting handoffs. The patient receives treatment until leaving the ED (ie, during transfer boarding). For each central theme in the conceptual framework, components and barriers are highlighted with representative quotes.

Patient Factors

Patient *need for specialty care, illness severity,* and *patient/family preferences* were important considerations in the interfacility ED transfer process and location decision (top, Figure 2). This decision sometimes involved clinicians outside the ED, including hospitalist(s), mental health, surgery, and/or intensivist providers, as also described under the section

System Resources. Diagnosis and comorbid conditions that required specialty care contributed to transfer and location decisions. When this assessment involved multiple clinicians, the process became complex.

“If I have a straightforward patient, like a neurosurgical patient, that’s relatively easy [because we automatically transfer them]....They get more complicated as the hospitalists get involved...[and w]hen a patient might go to surgery here...we need to make sure that they will allow them to go under anesthesia here, and anesthesia has their own criteria.” [Emergency physician 1, Facility A]

Yet, even in the setting of available specialty care, multiple clinicians and staff participated in the determination of whether a patient’s illness severity merited transfer.

“[Our hospital] tends to err on the side of sending the patient out if there is any indication that this patient might anything of a severe nature, or if they feel the patient *will develop* [emphasis added] any complications during their stay.” [Emergency physician 1, Facility A]

Where possible, patient and family preferences were considered in the transfer decision and location, particularly for long distances or if the patient had received prior care at another facility.

“By and large, none of [the ED patients] want that [to be transferred]. Because it’s a long trip, they won’t really be able to have any family visit them while they’re down there; it’s four hours down there. ... [Transferring] would definitely not be the veteran’s choice.” [Emergency physician 1, Facility D]

System Resources

Each region included urban and rural, VHA and non-VHA hospitals of varying sizes and distances from each other, and with different of *hospital bed capacity, specialty services, diagnostics, staff, and transportation* (bottom, Figure 2), which might be partially or completely unavailable depending on the hour, shift, or day of week or fluctuating staffing, ED patient arrivals, and other resource demands.

Table 1. Description of facilities and interviewees regarding the emergency department interfacility transfer process.

Facility	ED/UCC beds	URH classification	Accepts EMS	ED clinician*	ED nurse	ED staff	Administrative staff	Hospitalist	Other	Total
A	8	Rural	Yes	7	4	1	1	3	0	16
B	15	Urban	Yes	3	3	0	1	2	2	9
C	5	Rural	Yes	3	6	1	4	2	1	17
D	14	Rural	No	3	3	0	3	2	0	11
E	13	Urban	Yes	3	5	1	2	0	0	11
F**	5	Rural	No	3	2	1	2	0	1	9
G	6	Rural	No	2	3	1	0	2	0	8

*Clinicians included board-certified and non-board-certified physicians; nurse practitioners; and physician assistants.

**An urgent care clinic.

ED, emergency department; UCC, urgent care clinic; URH, urban/rural/highly rural classification; EMS, emergency medical services.

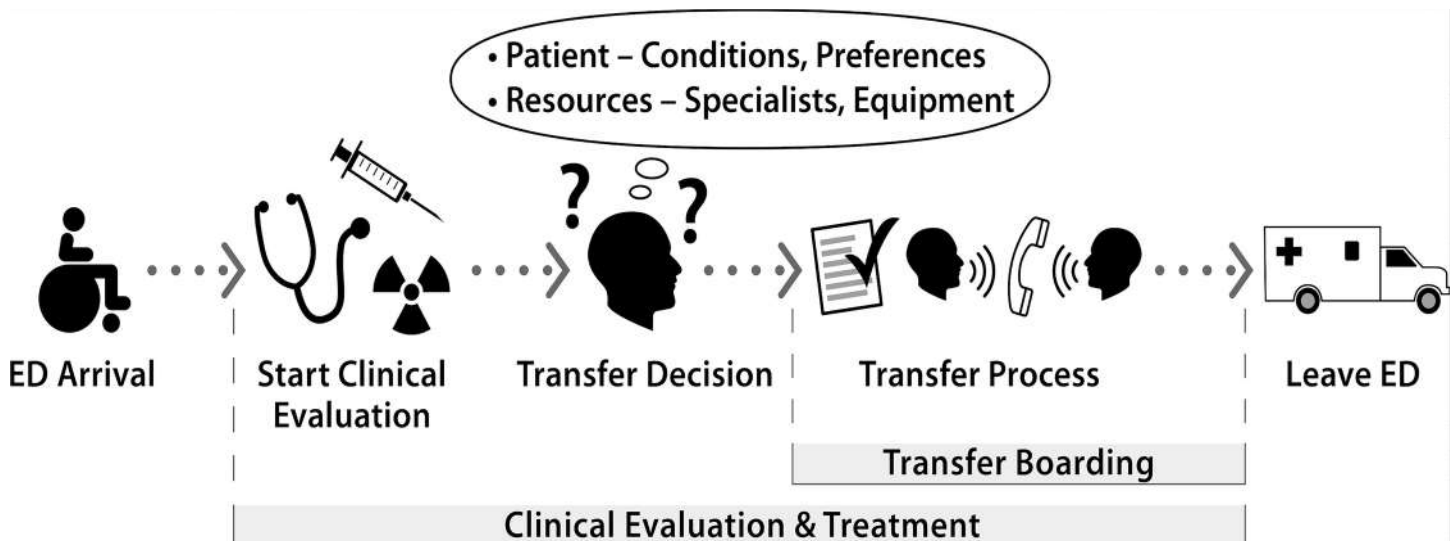


Figure 1. Core components of the interfacility emergency department transfer process.

Fluctuating hospital bed capacity due to bed, bed type, or nursing availability was reported as one of the most important drivers of transfers. Access to specialty and diagnostic services varied by time of day and day of week; determination of need or anticipated need for specialty care could involve non-ED clinicians and staff (see also, Patient Factors above, and Clinical Processes, below).

“[ED transfer frequency] depends on our bed availability in the ICU and on the floors. Last week we did a lot of transferring because we had no ICU beds...and the floor wasn’t taking any patients last week due to staffing issues.” [ED Nurse 1, Facility A]

“We only have one person each of every specialty. So for example, let’s say the [gastroenterology] GI doctor is out this week. ... My hands are tied at that point. I can’t hang on to a patient with a hemoglobin of 6 [milligrams per deciliter] without the GI doctor here, whether it’s Monday morning or Friday evening.” [Hospitalist 1, Facility G]

“We have [CT] available 24/7, and basic imaging. But as far as MRI, we only have that on Monday, Tuesday, and Wednesdays. A lot of times on Thursday and Fridays we would send them to [the next closest VHA facility].” [Hospitalist 1, Facility G]

Patients were evaluated and treated by a complex team that could include ED and non-ED physicians, nurse practitioners or physician assistants, nurses, respiratory therapists, clerks, administrators, and others; they shared responsibilities when necessary to meet clinical demands, although this diverted resources from other ED patients.

“If it’s a Saturday, it’s you [the emergency physician alone]. [I]t’s literally like I’m going down and I’m banging a door to Radiology and saying, ‘I need you to burn these images onto a disk. I need them in 10 minutes.’” [Emergency physician 2, Facility D]

“We’ll have the one-to-one sitter tied up [with a mental health patient while we wait up to six hours for transportation to arrive]. ... When [there are only two nurses on shift overnight] the nursing supervisor will come and help us and sit there and do one-to-one for us.” [ED Nurse 1, Facility G]

Type and timing of transportation was arranged by the transferring facility and determined by the patient’s clinical severity, local requirements (eg, secure transportation for mental health patients), and availability of local resources such as ambulance services and staff. At facilities with a contract with a single ambulance service, staff reported that transfer boarding was longer when they used the contract service compared to when they received approval to use local emergency medical service (EMS) transportation. For time-sensitive transfers, the ability to use ground or aeromedical EMS varied.

“[T]he only thing we’re approved to call 911 [for EMS transportation] for is STEMI.” [Emergency physician 2, Facility A]

Additional requirements for mental health transfers (eg, special transportation such as secure transportation or police vehicle) and concerns for staff safety were described as contributing to prolonged transfer boarding times and as diverting already limited resources from other ED patients.

“The biggest part with mental health [transfers] is our transportation. It takes hours and hours and hours to usually get them out of here.” [ED nurse 2, Facility G]

“If they [a mental health patient] are agitated...they get more agitated [while waiting to transfer.]” [Hospitalist 1, Facility G]

Processes, Communication and Coordination

Multifaceted interactions between system resources and patient factors occurred through *clinical and administrative processes* that occurred via complex *communication and coordination* within and across facilities (center, Figure

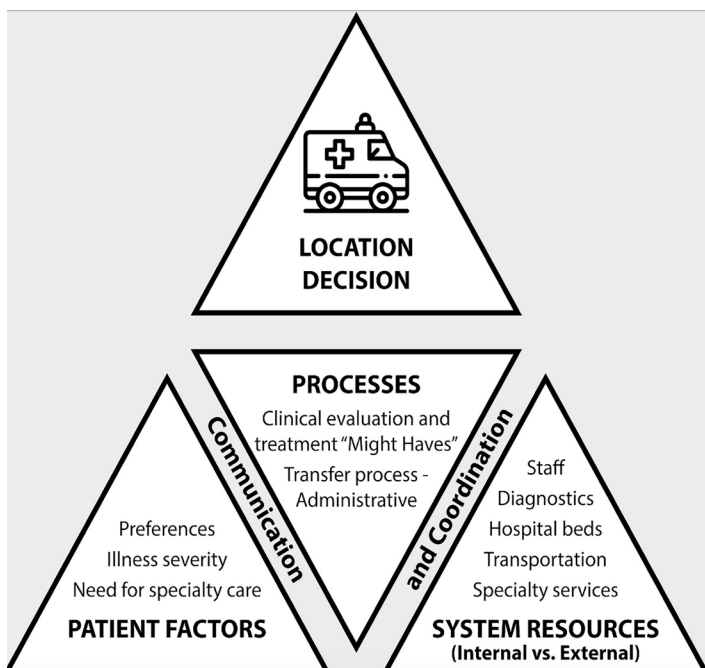


Figure 2. Interfacility emergency department (ED) transfer conceptual framework, with complex interplay among the central themes of 1) patient factors; 2) system resources; and 3) processes and communication among ED and non-ED clinicians, nurses, staff, which together culminate in 4) location decision, i.e., where, how, and when an ED patient is transferred.

2). Clinical evaluation was an ongoing process and could prompt transfer, but *anticipated* resource need and clinical course were also described as important drivers in the transfer decision. Several interviewees described these as “might have” situations, in which a patient *might have* a condition requiring specialist consultation or *might have* clinical deterioration in the next 48 hours. Flexibility on the part of the ED team was required for clinical management and decisions about when, where, and how to transfer a patient.

“I’ve had a couple of occasions where [the admitting hospitalist has] come down and said, ‘I’m not as comfortable with [admitting the patient here] as I thought.’” [Emergency physician, Facility G]

Institutional steps for coordinating resources and making transfer arrangements varied by facility but were described as burdensome, complex, and primarily the responsibility of the treating ED clinician because other team members varied by facility, day of week, and time of day. A minimum of four forms and multiple phone conversations, typically by the ED clinician, were required prior to transfer. Interviewees reported that considerable clinician time was diverted from clinical duties to these administrative tasks. If a potential accepting facility declined the transfer, the process started over.

“After I notify the administrative officer, then I notify the patient and collect their informed consent, and get a signature.

And then [I complete 4 forms:] an...interfacility transfer note and a non-VA medical or surgical consult...and [the transportation form] and my [ED clinical] note.” [Emergency physician 1, Facility A]

“We do a paper consent. ... Like 50% of my job is transfer[ring ED patients].” [ED nurse practitioner, Facility C]

“A significant portion of our clinical day is actually spent transferring patients out [including] obtaining the consent, which on the computer sometime can be laborious and time consuming, but in addition to that having to speak to multiple facilities and multiple providers to see if they will accept our patients.” [Emergency physician 1, Facility A]

“I’m frustrated filling out redundant forms, forms that I know if it wasn’t some antiquated computer system, everything could populate over.” [Emergency physician, G]

Clear communication and coordination within and across facilities were vital for timely identification of patients who needed transfer and completion of the complex administrative transfer step. Staff reported that handoffs and multiple communication methods (phone, in-person, texts, etc.) were common, as were barriers and pitfalls. While transfer coordinators simplified and streamlined the process, most transfers occurred after daytime shifts; at multiple facilities, communication and coordination therefore defaulted back to the ED clinician at the same time of day that ED demand peaked and its role expanded to include communication and coordination of patient flow throughout hospital.

“[W]e [in the ED] serve as a buffer...for the system.” [Emergency physician, Facility E]

“[D]epending on the part of the day, it’s different people who facilitate the transfer. After [4 PM], it’s the [administrator on duty], that’s just one person. During daytime hours, it can include social work assisting with the transfer, and it can include the transfer coordinators assisting with the transfer. The transfer coordinator can say, “This guy’s been accepted. We need X amount of paperwork and then they can travel” ... Then when that’s cleared and we have an accepting physician, provider handoff has to happen and nurse handoff has to happen. We also have to communicate with EMS... It can be a lot of red tape.” [ED nurse, Facility B]

Location Decision

The final transfer location decision depended upon a complex interplay among patient factors, resources, and the clinical and administrative processes. Historical experiences (eg, whether a transfer was likely to be requested by local hospitalists and which facilities were likely to accept transfers) were described as playing an important role in how individual team members approached their tasks and therefore contributed to the final transfer location decision. Clinicians and administrative staff involved in the transfer process said they had to maintain a sense of what services were available and where to go to get access to needed resources. Community-wide lack of capacity, particularly for

mental health facilities, was described as a barrier to finding an accepting facility.

“You have to know the capacities of [the other hospitals] and what they can safely accept and not accept.” [Emergency physician 3, Facility A]

“One time all the psych hospitals were full, including ours, and I had to sit on [a mental health patient who needed to be transferred] down here [in the ED].” [Emergency physician 1, Facility A]

Staff reported that facilities with transfer centers were preferred because the transfer request process was faster and the results more predictable.

“Each of the major tertiary facilities has a transfer center, which greatly aids us. . . . Sometimes people call. . . . the smaller local hospital here, which has fairly good specialty coverage. I don’t tend to call there. . . . because it is an onerous process.” [Emergency physician 3, Facility D]

Interviewees reported that it was often easier to transfer to non-VHA facilities regardless of facility resources or distance, because non-VHA facilities were more likely to have transfer centers and beds available.

“It’s easier to get [transfers] accepted at those [non-VHA] hospitals now that most of them have transfer centers.” [Emergency physician 4, Facility A]

In light of prolonged time between the decision to transfer and leaving the ED delayed treatment, staff said they workarounds to find accepting facilities based on their prior experiences.

“[A recent] patient was here [in the ED] for. . . almost two days [while we tried to find an accepting facility] . . . In the meantime he wasn’t receiving any care that he needs, while we were just holding him and giving him his maintenance routine meds. Our [emergency] physician. . . had spent most of his shift. . . on the phone back and forth with [multiple hospitals to find an accepting facility].” [Emergency physician 5, Facility A]

“[While transferring a patient] I just try to go with the flow. And if we hit a roadblock, I just sort of float around it and go to the next option. Very rarely do I get stiffed completely.” [Emergency physician 1, Facility A]

DISCUSSION

This qualitative study examined drivers of and processes for transferring rural emergency patients to other facilities. We conducted 81 interviews at seven geographically distinct VHA facilities and identified four key components of interfacility ED transfers: 1) patient factors; 2) system resources; and 3) processes and communication for transfers, which culminate in 4) location decisions. According to information from interviews, transfer decisions were based on actual and anticipated resource needs and were strongly influenced by the transfer process itself, with the goal of timely transfer via the least complex process. Perceived quality or outcomes at the receiving location or patient preferences were not reported by

interviewees as primary drivers of location decisions, perhaps in part because outcomes and quality of care for transferred patients were rarely, if ever, known.

Several staff reported that they kept manual track of outcomes for transferred patients by calling accepting facilities days or weeks later, but they would prefer a systematic method for post-transfer feedback as a means of continuing to improve patient care. Transfer process details varied but were frequently described as overly burdensome and diverting resources away from clinical care, including care for other ED patients. Transfers were also recognized as a burden for patients and their families. Finally, mental health transfers were perceived as having particularly prolonged transfer-boarding times.

Although interfacility ED transfers make up a minority of overall ED patient volume, they were perceived as using a disproportionate amount of clinical time and resources because of burdensome administrative processes and complex communications. Although anticipated need for resources (eg, potential need for specialized care in the next several days) was a common reason for transfer, there was no formal process for learning whether such transfers improve patient outcomes.

Transferring location was heavily influenced by process complexity; simpler processes were highly favored. Notably absent was a discussion of perceived quality or outcomes at receiving hospitals. Although not the focus of these interviews, prior work has found that transfer practices are based on relationships¹⁷ rather than patient outcomes and quality.¹⁸ Simplified transfer processes that address patient and family preferences while also providing objective feedback on patient outcomes¹⁶ are needed to create a transfer environment that minimizes disruption caused by transfers while maximizing patient outcomes.

Mental health transfers were described as particularly challenging. This is highly relevant for the VHA, where suicide prevention is among the top priorities¹⁹ and a common reason for seeking emergency care. Between 2012–2014, mental health conditions were the sixth most common reason for VHA ED visits (~2 million ED visits/year) and the most common reason for ED transfer, comprising 40.9% of all VHA ED transfers (internal VHA data). Interfacility ED transfers appeared to be an important strategy to access urgent and emergent mental health resources; therefore, simplified transfer processes and alternative means to access emergent mental health care (eg, telehealth²⁰) should be carefully considered as alternatives to ED transfers.

Systematic assessment of transfer boarding may provide an opportunity to measure facility performance and assess strategies to mitigate these waits. Rural veterans and rural VHA healthcare sites are particularly reliant upon interfacility transfers to access emergency care because rurality contributes to disparities in quality, appropriateness, and efficiency of unscheduled mental health care.²¹ Our interviews highlight the tradeoff between use of interfacility ED transfers to obtain

access to emergency care at the cost of transfer boarding, which was perceived as compromising quality patient care and staffing. This was particularly noted for patients with mental health conditions because they occupied more clinical and physical resources for longer periods and experienced greater delays starting definitive treatment, and it is borne out in research examining the impact of rising emergency care demands for mental health.²² Admission boarding is a well-known marker of ED and hospital performance²³; although several interviewees at different facilities described mental health transfer boarding lasting hours and even days, transfer boarding is not to our knowledge a common operational metric.

LIMITATIONS

While the ED-to-ED interfacility transfer process was broadly similar across facilities, and interviews were conducted until saturation was achieved based on review by multiple research team members, it is possible that transfer processes and their associated facilitators and barriers may differ at other VHA facilities. While we strove for diversity in geography and demographics, our findings may not be generalizable to all VHA facilities. Local context, including other non-VHA facilities, and local policies play an important role in the transfer process and its barriers and facilitators. Reasons for transfer may also differ for VHA compared to non-VHA ED facilities; thus, further work is needed to understand the degree to which these results apply to non-VHA settings. Finally, despite use of standardized qualitative methods, interviews may be influenced by social desirability bias, friendliness bias, acquiescence bias, or recall bias. Future work using quantitative methods, eg, tracking ED boarding time, should be compared to these findings.

CONCLUSION

Interfacility transfers are multifaceted, time-consuming processes that require complex coordination of patient factors and system resources. The transfer process itself and anticipated needs play important roles, rather than quality of care or patient preferences. Mental health transfers epitomize these challenges. Future steps to improve emergency care for rural patients should consider reporting transfer boarding as an operational measure, providing transfer outcome feedback, simplifying transfer processes, and developing alternative strategies to obtain access to specialty care.

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Emergency Department-based Intensive Care Unit Use Peaks Near Emergency Department Shift Turnover

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Introduction: The Emergency Critical Care Center (EC3) is an emergency department-based intensive care unit (ED-ICU) designed to improve timely access to critical care for ED patients. ED patients requiring intensive care are initially evaluated and managed in the main ED prior to transfer to a separate group of ED-ICU clinicians. The timing of patient transfers to the ED-ICU may decrease the number of handoffs between main ED teams and have an impact on both patient outcomes and optimal provider staffing models, but has not previously been studied. We aimed to analyze patterns of transfer to the ED-ICU and the relationship with shift turnover times in the main ED. We hypothesized that the number of transfers to the ED-ICU increases near main ED shift turnover times.

Methods: An electronic health record search identified all patients managed in the ED and ED-ICU in 2016 and 2017. We analyzed the number of ED arrivals per hour, the number of ED-ICU consults per hour, the time interval from ED arrival to ED-ICU consult, the distribution throughout the day, and the relationship with shift turnover times in the main ED.

Results: A total of 160,198 ED visits were queried, of which 5308 (3.3%) were managed in the ED-ICU. ED shift turnover times were 7 AM, 3 PM, and 11 PM. The mean number of ED-ICU consults placed per hour was 221 (85 standard deviation), with relative maximums occurring near ED turnover times: 10:31 PM - 11:30 PM (372) and 2:31 PM - 3:30 PM (365). The minimum was placed between 7:31 AM - 8:30 AM (88), shortly after the morning ED turnover time. The median interval from ED arrival time to ED-ICU consult order was 161 minutes (range 6-1,434; interquartile range 144-174). Relative minimums were observed for patients arriving shortly prior to ED turnover times: 4:31 AM - 5:30 AM (120 minutes [min]), 12:31 PM - 1:30 PM (145 min), and 9:31 PM - 10:30 PM (135 min). Relative maximums were observed for patients arriving shortly after ED turnover times: 7:31 AM - 8:30 AM (177 min), 4:31 PM - 5:30 PM (218 min), and 11:31 PM - 12:30 AM (179 min).

Conclusion: ED-ICU utilization was highest near ED shift turnover times, and utilization was dissimilar to overall ED arrival patterns. Patients arriving immediately prior to ED shift turnover received earlier consults to the ED-ICU, suggesting these patients may have been preferentially transferred to the ED-ICU rather than signed out to the next team of emergency clinicians. These findings may guide operational planning, staffing models, and timing of shift turnover for other institutions implementing ED-ICUs. Future studies could investigate whether an ED-ICU model improves critically ill patients' outcomes by minimizing ED provider handoffs. [West J Emerg Med. 2020;21(4)865-869.]

INTRODUCTION

From 2001–2009, the annual hours of critical care delivered in United States (US) emergency departments (ED) increased substantially, driven by an increasing proportion of ED visits requiring critical care and an increasing ED length of stay (LOS) for these patients.¹ Concurrently, 33% of US intensive care unit (ICU) admissions from the ED have an ED LOS longer than six hours.¹ This amount of ED boarding time of critically ill patients has been associated with increased hospital LOS, ICU LOS, morbidity, and mortality.^{2–8} Novel strategies are being investigated and implemented to combat this issue, including ED-based ICUs.^{9–11}

In 2015 Michigan Medicine opened an ED-ICU, the Joyce and Don Massey Family Foundation Emergency Critical Care Center (EC3), with the objective of improving timely access to critical care for patients in the ED.¹¹ It contains five resuscitation bays and nine patient rooms immediately adjacent to the main ED. All ED patients are initially evaluated and treated by the main ED team in resuscitation bays or ED treatment rooms, and are subsequently transitioned to the EC3 team for ongoing critical care delivery.

Transitions of care in the ED occur at the end of every shift. They are used to hand off important information from clinician to clinician and are crucial for the continuity of patient care. However, breakdown in communication during transitions of care is a leading root cause of sentinel events,¹² and is associated with delays of care, near misses, and ICU transfers.^{13,14} With the increase in hours of critical care delivery in US EDs,¹ transitioning care of critically ill ED patients can prove a complex task susceptible to high error rates with serious consequences.¹⁵ One factor to consider when implementing an ED-ICU is its impact on transitions of care within the ED.

The timing of patient transfers to the ED-ICU may decrease the number of transitions of care between ED teams and have an impact on both patient outcomes and optimal provider staffing models, but has not been previously studied. Investigating methods to smooth and load level transitions of care from the ED to an ED-ICU may provide insight into more effective resource utilization, staffing models, and patient throughput. The objective of this study was to examine patterns of consultation to the ED-ICU and their relationship with shift turnover times in the main ED. We hypothesized that the number of transfers to the ED-ICU increases near ED shift turnover times.

METHODS

This was a retrospective review of data from all ED visits from January 1, 2016–December 31, 2017. This study was conducted at a single, large, academic medical center with approximately 75,000 adult ED visits per year. Data collection and analysis were performed in 2018, and manuscript preparation was conducted in 2019. The institutional review board (IRB) at the University of Michigan reviewed and

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What do we already know about this issue?
The timing of consultations to an ED-ICU may decrease handoffs between main ED teams and have an impact on outcomes and optimal staffing models.

What was the research question?
Do patterns of consultation to an ED-ICU correspond to ED shift turnover times?

What was the major finding of the study?
ED-ICU utilization was highest near ED shift turnover times and dissimilar to overall ED arrival patterns.

How does this improve population health?
These findings may guide operational planning, staffing models, and timing of shift turnover for other institutions implementing ED-ICUs.

approved this study (HUM00171720) and granted exemption from continuing IRB review. We treated all data in a manner compliant with the Security Rule and the Privacy Rule of the Health Insurance Portability and Accountability Act. This study is reported in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.¹⁶

We identified all adult (>18 years) patients presenting to the adult ED in 2016 or 2017 via a search of electronic health records (EHR), and all patients managed in the ED-ICU were identified and included for analysis. De-identified patient data, including ED arrival time, ED-ICU consult order time, time changed to ED-ICU status, and reason for ED-ICU consult were queried and analyzed. We divided patients into 24 cohorts based on the hour of day of ED arrival time.

The methods used in this study minimized several types of bias associated with retrospective studies. We obtained data from all patients presenting to the ED with a consult to the ED-ICU, thus minimizing selection bias. The operational data used for the analyses performed was for all patients included and are a result of regular workflows in the ED, therefore unlikely to be subject to inaccuracies and minimizing both information bias and measurement errors. The study size was arrived at by defining the time interval of patient presentations to include the following: the ED-ICU opened in 2015, and we allowed for a “wash-out period” prior to collecting and analyzing all patient encounters in 2016 and 2017.

RESULTS

We identified and analyzed a total of 160,198 ED patient encounters, of which 5308 (3.3%) had ED-ICU consults placed. ED-ICU consult reasons included severe sepsis/septic shock (15%); altered mental status/overdose (10%); metabolic, including diabetic ketoacidosis/electrolytes (9%); gastrointestinal bleed (7%); respiratory distress/respiratory failure (5%); and other (41%). ED shift turnover times were 7 AM, 3 PM, and 11 PM, whereas ED-ICU shift turnover times were 8 AM and 8 PM. The main results of the study are summarized in Figure 1.

The overall rate of ED arrivals per hour for the study period was 9.13. The number of ED arrivals per hour was maximum at 11:31 AM - 12:30 PM (10,353 total ED arrivals), remained relatively stable until 4:31 PM - 5:30 PM, and steadily decreased until a minimum at 4:31 AM - 5:30 AM (2234 total ED arrivals). The overall rate of ED-ICU consults placed per hour for the study period was 0.30. We identified two relative maximums in the number of ED-ICU consults per hour, both occurring at ED shift turnover times: 10:31 PM - 11:30 PM (372) and 2:31 PM - 3:30 PM (365). The minimum number of ED-ICU consults per hour occurred between 7:31 AM - 8:30 AM (88), shortly after the 7 AM shift turnover time. Two additional relative minimums in ED-ICU consults per hour were observed shortly after the 3 PM and 11 PM sign-out times.

During day hours (8:31 AM - 8:30 PM), there were 111,640 ED arrivals and 2826 ED-ICU consults (2.5%), while during night hours (8:31 PM - 08:30 AM) there were 48,558 ED arrivals and 2482 ED-ICU consults (5.1%). The median interval from ED arrival time to ED-ICU consult order was 161 minutes (range 6-1434; interquartile range 144-174).

Relative minimums were observed for patients arriving shortly prior to ED shift turnover times: 4:31 AM - 5:30 AM (120 minutes), 12:31 PM - 1:30 PM (145 minutes), and 9:31 PM - 10:30 PM (135 minutes). Relative maximums were observed for patients arriving shortly after ED shift turnover times: 7:31 AM - 8:30 AM (177 minutes), 4:31 PM - 5:30 PM (218 minutes), and 11:31 PM - 12:30 AM (179 minutes).

DISCUSSION

Results of this study indicate that ED-ICU utilization was highest near ED shift turnover times, and ED-ICU utilization was dissimilar to overall ED arrival patterns. Patients arriving immediately prior to ED shift turnover received earlier consults to the ED-ICU, suggesting these patients may have been preferentially transferred to the ED-ICU rather than handed off to the next team of ED providers. These findings may guide operational planning, staffing models, and timing of shift turnover for other institutions implementing ED-ICUs.

As shift end approaches, off-going emergency clinicians must determine disposition or transition the care of each patient being managed to the next emergency clinician. Breakdown in communication during transitions of care is a leading root cause of sentinel events,¹² and is associated with delays of care, near misses, and ICU transfers.^{13,14} We hypothesized that emergency clinicians would opt to consult an ED-ICU for critically ill ED patients near the end of their shifts rather than transition care to the oncoming emergency clinician team to potentially mitigate these breakdowns in communication. We hypothesized maximum numbers of ED-ICU consults near shift turnover times (7 AM, 3 PM, 11 PM) and quicker ED-ICU consults for patients arriving shortly

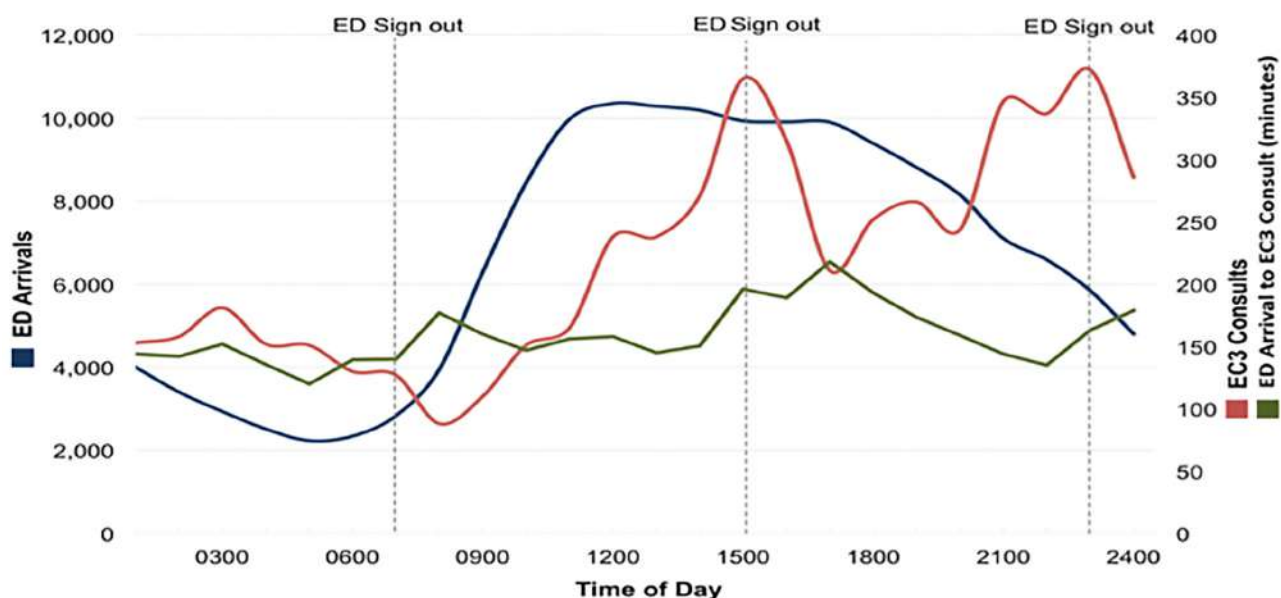


Figure 1. Comparison between ED arrivals (blue), ED-ICU (EC3) consults (red), and time from ED arrival to ED-ICU consult (green). ED, emergency department; ED-ICU, emergency department-based intensive care unit; EC3, emergency critical care center.

prior to (compared to shortly after) ED shift turnover times would be observed. The results of this study support both hypotheses. We observed relative maximums in consults to an ED-ICU near ED shift turnover times, occurring independently of ED volume, as evidenced by the relative maximum number of ED-ICU consults near the 11 PM ED shift turnover despite declining total ED volume (Figure 1).

The retrospective nature of the data gives strength to our findings because the clinician decisions were not influenced by the fact their behavior was being observed. It is feasible that when faced with the option of transferring a critically ill patient to an ED-ICU or transitioning care to an oncoming ED team, emergency physicians opt for a shorter ED LOS and more rapid transfer to an ED-ICU near the end of their shifts.

A relative minimum time to ED-ICU consult was observed for patients arriving shortly before shift turnover, suggesting clinicians opt to offload critically ill patients rather than transition care to an oncoming physician. Simultaneously, emergency physicians appear to preferentially manage critically ill patients for longer durations when more time is available during their shifts. A relative maximum time to ED-ICU consult was observed for patients arriving just after shift turnover, suggesting clinicians were more likely to perform further resuscitative actions early in their shifts.

Future studies could investigate whether an ED-ICU model improves critically ill patients' outcomes by minimizing ED clinician handoffs and could also assess the external validity of these findings in other institutions.

LIMITATIONS

A limitation of this study is the lack of patient-oriented outcomes, and we cannot imply better or worse outcomes related to the time of transfer to ED-ICU based on data collected for this study. We were unable to assess for confounding and recognize that additional factors could influence how quickly an emergency clinician decides to transfer a patient to the ED-ICU. These could include factors such as patient volume, acuity of additional patients being managed, availability of beds in the ED-ICU or inpatient ICUs, and whether the managing physician was an emergency medicine-intensivist. It is unknown whether the observed temporal trends of ED-ICU utilization are similar to other forms of ED disposition. The focus of this study was to evaluate patterns of consultations to the ED-ICU to better inform operational and staffing planning for institutions with or considering an ED-ICU. Therefore, we did not perform an analysis of consultation or disposition data to other units and did not explore whether they follow similar temporal characteristics. Our data generates the question of whether these temporal trends would also be observed with consultation and disposition to other services or units. This could be further explored in future research. This study was conducted at a single center in the United States, and external validity / generalizability of results is unknown.

CONCLUSION

Utilization of an ED-ICU was highest near ED shift turnover times, and utilization was dissimilar to overall ED arrival patterns. Patients arriving immediately prior to ED shift turnover received earlier consults to the ED-ICU. A possible explanation for this observation is preferential transfer to the ED-ICU over transitioning care to the oncoming emergency clinician team. These findings may aid other institutions implementing ED-ICUs for operational planning, staffing models, and timing of shift turnovers. Future studies could investigate whether an ED-ICU model improves critically ill patients' outcomes by minimizing ED provider handoffs.

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The Utility of Color Doppler to Confirm Endotracheal Tube Placement: A Pilot Study

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Introduction: Grayscale ultrasound (US) imaging has been used as an adjunct for confirming endotracheal tube (ETT) placement in recent years. The addition of color Doppler imaging (CDI) has been proposed to improve identification but has not been well studied. The aim of this study was to assess whether CDI improves correct localization of ETT placement.

Methods: A convenience sample of emergency and critical care physicians at various levels of training and experience participated in an online assessment. Participants viewed US video clips of patients, which included either tracheal or esophageal intubations captured in grayscale or with CDI; there were five videos of each for a total of 20 videos. Participants were asked to watch each clip and then assess the location of the ETT.

Results: Thirty-eight subjects participated in the online assessment. Levels of training included medical students (13%), emergency medicine (EM) residents (50%), EM attendings (32%), and critical care attendings (5%). The odds ratio of properly assessing tracheal placement using color relative to a grayscale imaging technique was 1.5 ($p = 0.21$). Regarding the correct assessment of esophageal placement, CDI had 1.4 times the odds of being correctly assessed relative to grayscale ($p = 0.26$). The relationship between training level and correct assessments was not significant for either tracheal or esophageal placements.

Conclusion: In this pilot study we found no significant improvement in correct identification of ETT placement using color Doppler compared to grayscale ultrasound; however, there was a trend toward improvement that might be better elucidated in a larger study. [West J Emerg Med. 2020;21(4)870-875.]

INTRODUCTION

Determination of correct endotracheal tube (ETT) placement is an essential part of airway management. Unrecognized esophageal intubation can lead to morbidity and mortality due to hypoxia and iatrogenic aspiration

due to stomach insufflation. There are multiple methods to confirm correct ETT tube placement that include direct visualization, capnography, visualization of chest rise, and direct auscultation; however, each of these methods has its limitations.^{1,2} Quantitative waveform capnography combined

with clinical assessment comprises the most reliable method to confirm ETT placement. However, the utility of capnography can be limited in cases of poor cardiac output, low pulmonary blood flow, airway obstruction, or after the administration of epinephrine.²⁻⁴

Grayscale ultrasound (US) has become an increasingly popular adjunct for confirming ETT placement in recent years. US is widely available in emergency department settings, and there is a growing base of evidence supporting its use to confirm ETT placement⁵⁻⁹; however, even this technique can be limited by patient anatomy or user experience. The addition of color Doppler imaging (CDI) has been proposed to improve ETT localization by highlighting ETT movement, but this technique has not been well studied.^{10,11} Only one prior investigation has compared the use of CDI with grayscale US for confirming ETT placement, and that study did not find a difference between the techniques in a cadaver model.¹¹ However, cadaver tissue often appears different from and lacks the respiratory variations of live human tissue with ultrasound imaging; thus, a cadaver model may not accurately reflect the performance of CDI in confirming ETT placement in live humans.^{12,13}

In this pilot study, we used video captured from live humans, with either tracheal or esophageal intubations, to evaluate whether CDI can improve correct ETT localization compared to grayscale US using an online assessment of medical professionals. We also investigated whether there is a relationship between the accuracy of US interpretation for this indication and the training level of participants.

METHODS

Experimental Design and Participants

This was a convenience sample of emergency and critical care attending physicians, resident physicians, and medical students from a single academic hospital who participated in an online assessment. Subjects were recruited via email with a link to the online assessment. This study was approved by the institutional review board (IRB); subjects provided informed consent.

Video Clips

The online assessment used looped, six-second, trans-tracheal ultrasound video clips from a de-identified archive of patients who were intubated in the operating room prior to elective surgery. The archive was collected over a two-year period as part of a separate IRB-approved research study, and the video clips were maintained for educational and research purposes. Anesthesiologists performed all the intubations, and emergency ultrasound fellowship-trained physicians performed all the ultrasound examinations. The video clips were obtained using Sonosite Edge I ultrasound machines (Sonosite, Bothell, WA) equipped with a high-frequency linear transducer (L25x) that was applied at the level of the cricothyroid membrane. The video archive included

Population Health Research Capsule

What do we already know about this issue?
Grayscale ultrasound is an adjunct for confirming endotracheal tube placement. The addition of color Doppler imaging (CDI) has been proposed to improve localization.

What was the research question?
Does CDI improve correct endotracheal tube localization compared to grayscale ultrasound?

What was the major finding of the study?
In this pilot study, there was no significant improvement in localization using CDI.

How does this improve population health?
This pilot study suggests that CDI may not provide much clinical value compared to grayscale imaging alone.

video images of both tracheal and esophageal intubations. Intentional esophageal intubation was briefly performed on a subset of patients prior to endotracheal intubation; the location of each intubation was verified by direct visualization, auscultation of the stomach and lungs, and quantitative capnography. The location (esophageal vs tracheal) of each intubation was noted and kept in the archive, but no labels were present on the clips used in the online quiz. All clips were recorded post-intubation, using grayscale and/or CDI. CDI clips were captured while longitudinally oscillating the ETT manually.

The entire video archive contained a total of 964 clips from 142 patients (Figure 1). Each patient in the archive had a range of 3-14 clips of either a tracheal or an esophageal intubation; 82 of the subjects had clips captured in either grayscale or CDI, and 60 of the patients had pairings acquired in both grayscale and CDI. For this study, video clips were selected from 10 of the 60 patients, which had pairings of the same ETT placement (tracheal or esophageal) acquired in both grayscale and CDI. A total of 44 patients with tracheal intubations and 16 patients with esophageal intubations met this criterion. Five patients from each of these two groups were selected using a random number generator. One grayscale and one CDI video were used from each of these 10 patients to yield a total of 20 video clips that were included in the online assessment (Figure 1). If patients had more than the two required video clips in the archive, the video with the earliest time stamp was used unless the color Doppler box had been placed incorrectly. To reduce bias we excluded videos

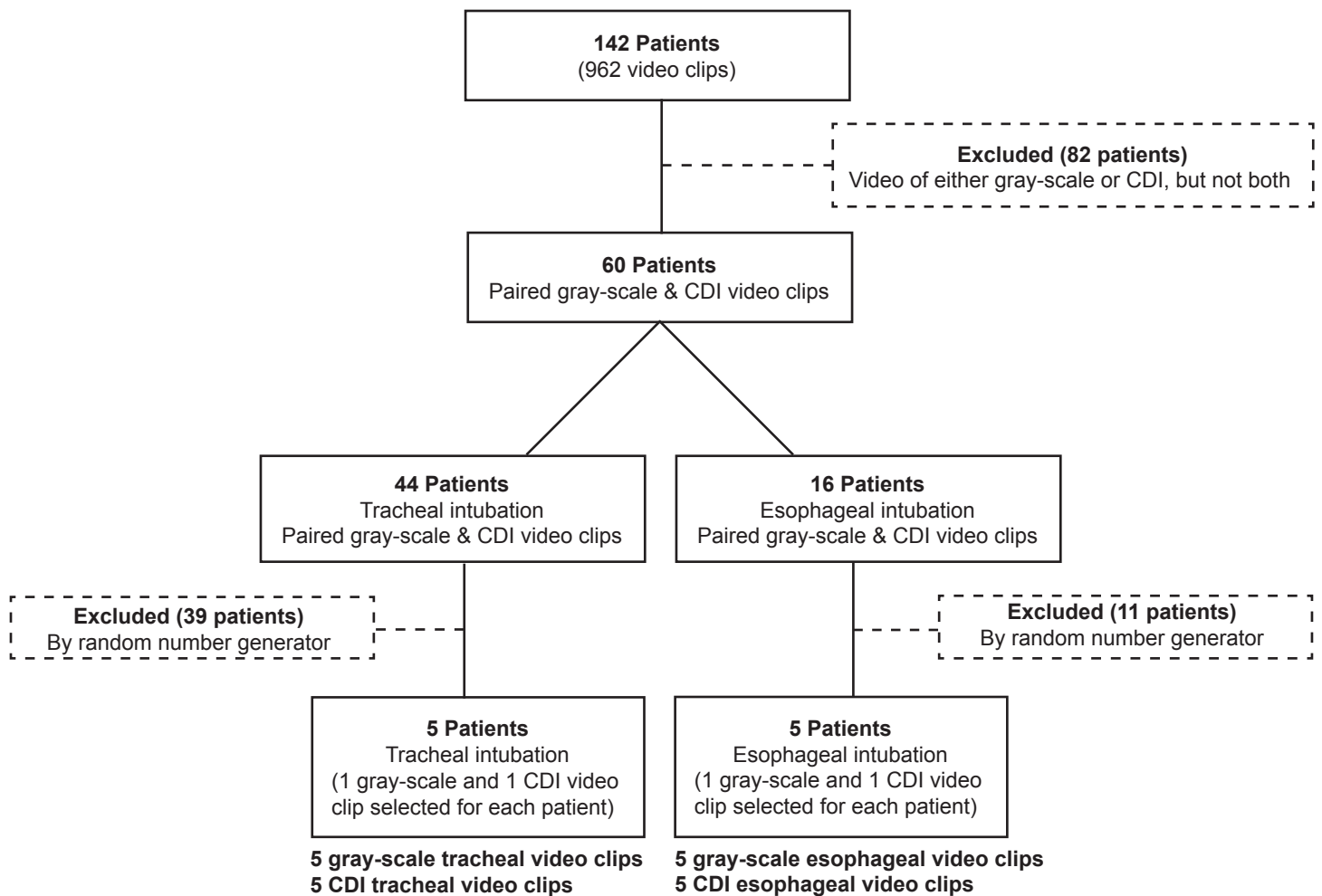


Figure 1. Selection of video clips used in an online assessment of clinician accuracy in determining tracheal versus esophageal endotracheal tube placement using color Doppler imaging (CDI) relative to grayscale imaging technique.

that were located to one side or the other of the screen rather than centered over both the trachea and esophagus.

Online Assessment

The online assessment included a seven-minute instructional video (Supplement 1), a background survey, and an ETT placement quiz. The instructional video demonstrated the proper interpretation of grayscale and CDI transtracheal images (Figure 2). The clips in the instructional video were not used in the online quiz. The background survey queried participants about their medical specialty, level of training, and whether they had any specialized training in ultrasound (“fellowship trained or ultrasound faculty”). The assessment consisted of 20 questions; each question was comprised of a single video clip that participants were asked to identify as either an esophageal or tracheal intubation. The assessment included an equal number of esophageal and tracheal intubations, and it included both the grayscale and CDI clips from the pairs described above. The assessment was administered

using Qualtrics (Qualtrics, Provo, UT). To establish face validity of the online assessment and to ensure the quality of the content, four independent emergency ultrasound fellowship-trained physicians were included in a trial run of the assessment prior to enrollment of study participants.

Statistical Analysis

Continuous data are presented as means with standard deviations (SD). Odds ratios (OR) are reported for categorical frequency data. We used a mixed-effects logistic regression model to adjust for clustering when determining the effects of properly assessing grayscale vs color and to observe the relationship between correct assessments and training level.

RESULTS

A total of 38 subjects participated in the online assessment. The training level for participants and corresponding mean quiz scores are shown in Table 1. Three of the EM attending physicians (8% of the total subjects, 25% of the EM attendings) had specialized training in ultrasound; no other participant had

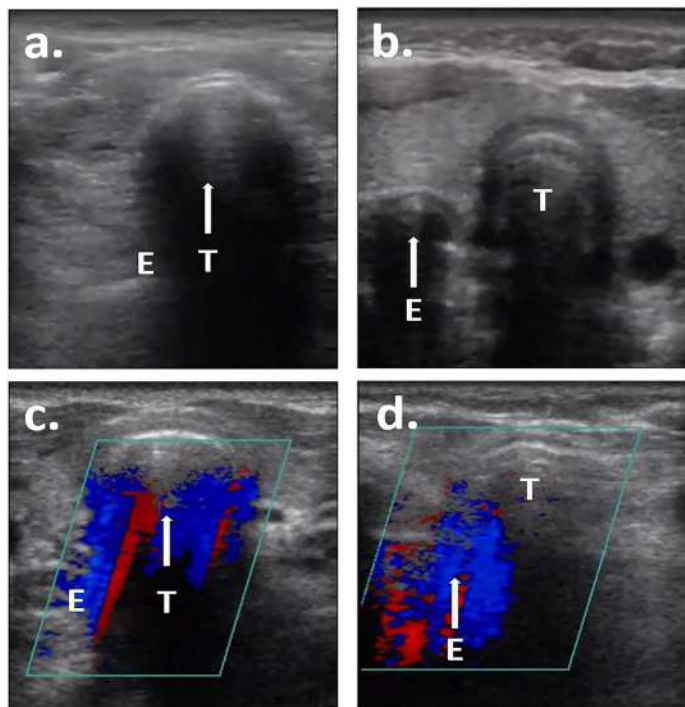


Figure 2. Representative screenshots from online assessment videos: a) tracheal intubation in grayscale (single air-mucosal interface with reverberation artifact within the trachea); b) esophageal intubation in grayscale (double air-mucosal interface); c) tracheal intubation in color Doppler imaging (CDI) (color signal deep to the trachea); and d) esophageal intubation in CDI (color signal deep to the esophagus). Arrow indicates location of intubation. T, trachea; E, esophagus.

specialized ultrasound training. The mean quiz score for the three attendings with specialized ultrasound training was 19 (SD 1.0; 95% confidence interval).¹⁴⁻²⁰ The OR of properly assessing tracheal or esophageal placement with CDI relative to a grayscale imaging technique is shown in Table 2. The relationship between training level and correct assessments was not statistically significant in either the tracheal or esophageal placements.

DISCUSSION

This is the first study describing the potential utility of CDI to confirm ETT placement via transtracheal ultrasound in live human subjects. In this pilot study we found no significant improvement in correctly identifying tracheal or esophageal placement with CDI relative to grayscale imaging. However, there was a trend toward improved correct identification with CDI, which merits further study. Further prospective work should be performed to determine whether CDI adds a benefit when used in real time.

In our study, participants generally identified the correct ETT placement location approximately 85% of the time with both grayscale imaging and CDI. These results are lower than the findings of three recent systematic review and meta-analyses that described sensitivities and specificities of >93%

Table 1. Participant specialty and training levels.

Training level	N (%)	Mean Quiz Score [SD]	95% CI
Medical student	5 (13)	17 [1.9]	14-19
Emergency medicine resident	19 (50)	17 [1.6]	17-18
Emergency medicine attending	12 (32)	17 [1.7]	16-19
Critical care attending	2 (5)	14 [0.71]	7.1-20

SD, standard deviation; CI, confidence interval.

and >97%, respectively.¹⁴⁻¹⁶ There are several factors that might contribute to this difference. First, most of the studies included in the meta-analyses had operators interpreting images in real time; this real-time control over the imaging and the tactile input could help participants correctly interpret images. Second, in the archive from which our videos for this study were drawn, not all images were of equal quality, and videos were selected randomly to decrease bias. It is possible that some lower quality videos could have negatively impacted our results, although all the videos were reviewed by point-of-care ultrasound experts prior to enrollment, and none were deemed to be technically limited. When images are being interpreted in real time, at the point of care, if the operator is dissatisfied with a view, he or she can adjust until a satisfactory image is acquired. Additionally, most of the participants in this study had no prior experience with transtracheal ultrasonography and relied on a seven-minute video for training. In contrast, most of the studies included in the meta-analysis put their participants through hours of training, which may be another explanation for the difference in results. Lower accuracy has been described in other recent studies in which participants had less training time. For example, Gottlieb et al trained residents on transtracheal ultrasound in 10 minutes and reported a sensitivity and specificity of 95.5% and 71.7%, respectively.¹⁷ Additionally, Stuntz et al trained participants by distributing a paper handout to participants a week before and again on the day of the study; this investigation reported a sensitivity and specificity of 62.0% and 37.9%, respectively.¹⁸ In our group, the physicians with specialized ultrasound training had quiz scores that trended higher than the other groups, which also suggests that additional ultrasound training may improve accuracy; however, due to the variance attributable to small sample size, a larger study would be required to verify this supposition.

Although we were unable to demonstrate a significant difference between assessing tracheal or esophageal placement with CDI relative to a grayscale imaging technique, we did see a trend toward improvement with CDI in correctly identifying both. This was especially interesting given the fact that this trend was seen over a wide range of interpreter experience levels. A larger study may verify this implication, yet the question of clinical significance remains. A post-hoc sample-

Table 2. Results of online quiz testing how accurately clinicians confirm ETT* placement when using grayscale vs color Doppler imaging techniques (CDI).

ETT Location	Grayscale Questions Correct Total (%)	CDI Questions Correct Total (%)	Odds Ratio (95% CI)	p-value
Trachea	162 (85%)	170 (89%)	1.5 (0.8-2.7)	0.21
Esophagus	155 (82%)	163 (86%)	1.4 (0.8-2.4)	0.26

ETT, endotracheal tube; CI, confidence interval.

size calculation revealed that a comparison of more than 50 subjects would be necessary to detect a difference between CDI and grayscale performance, which raises the question about the circumstances under which CDI might be clinically useful. The need for a larger sample size suggests that CDI may be useful occasionally, but perhaps not very frequently. Nonetheless, the addition of CDI only takes a few extra seconds to perform and may have some benefit in certain cases.

Another unanswered question is whether power Doppler may improve assessment compared to either CDI or grayscale imaging. Power Doppler is a newer ultrasound technique that has a greater sensitivity to detect movement compared to conventional CDI; thus, it may be able to provide more information about the subtle movements of an ETT.

LIMITATIONS

Participants in this study represent a convenience sample that was recruited via email; this is a potential source of selection bias. Participants who were more confident in their ultrasound abilities may have enrolled at a higher rate, which would blunt the difference between the physicians with specialized training and those without. Additionally, we did not assess retention of knowledge in this study. More work on the retention of point-of-care ultrasound skills and knowledge is needed in general; this is not limited to the use of CDI for airway management. Finally, although airway ultrasound may be useful in a variety of settings there was not an equal number of critical care and emergency physicians included in this study. Nonetheless, this pilot study provides a quantitative reference for the difference between grayscale and CDI among physicians with varied ultrasound experience that can be used to conduct larger prospective investigation on the topic.

CONCLUSION

In this pilot study we found no significant improvement in correct identification of ETT placement using color Doppler imaging compared to grayscale imaging; however, there was a trend toward improvement, over a wide range of interpreter experience levels, that might be better elucidated in a larger study.

Video. Excerpt from the instructional video demonstrating how to recognize an esophageal intubation with Color Doppler Imaging.

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A Review of Journal Impact Metrics and Characteristics to Assist Emergency Medicine Investigators with Manuscript Submission Decisions

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Introduction: A crucial, yet subjective and non-evidence-based, decision for researchers is where to submit their original research manuscripts. The approach of submitting to journals in descending order of impact factor (IF) is a common but imperfect strategy. The validity of the IF as a measure of journal quality and significance is suspect, and a number of other journal impact scores have emerged, such that no one scale is universally accepted. Furthermore, practical considerations, such as likelihood of manuscript acceptance rates and times for decisions, may influence how authors prioritize journals. In this report, we sought to 1) review emergency medicine (EM) journal impact metrics, and 2) provide a comprehensive list of pertinent journal characteristics that may influence researchers' choice of submission.

Methods: We systematically reviewed five impact metrics (IF, H Index, CiteScore, Source-Normalized Impact per Paper, and SCImago Journal Rank) and other relevant characteristics of 20 EM journals.

Results: We found good to excellent agreement in ordinal rankings of four of the journal impact metrics, as measured by the Spearman rank correlation coefficient. The median acceptance rate for original research manuscripts in the EM category was 25% (interquartile range [IQR] 18, 31%), and the median initial decision time was 33 days (IQR 18, 56 days). Fourteen EM journals (70%) accepted brief reports, and 15 (75%) accepted case reports/images.

Conclusion: We recommend replication, expansion, and formalization of this repository of information for EM investigators in a continuously updated, open-access forum sponsored by an independent organization. [West J Emerg Med. 2020;21(4)876-881.]

INTRODUCTION

With over 5200 journals currently indexed in Medline,¹ investigators often face a daunting task when choosing where to submit their original research manuscripts. The simple *start with the highest impact factor (IF) and work your way down* approach has considerable limitations. Many experts have questioned the validity of the IF as a measure of journal quality and influence.^{2,3} Furthermore, a number of other journal impact scores have emerged, such that no one scale is universally accepted as the gold

standard impact metric.^{4,5}

Beyond the limitations of relying on one or more impact metrics, researchers must consider the likelihood of acceptance, time until decision, reach of audience, and expected number of citations. Although the comments to authors after rejections may help improve subsequent submissions, reflexively submitting to high-prestige journals with low likelihood of acceptance can nevertheless waste inordinate amounts of time for decisions and effort toward serial reformatting for particular journal requirements.⁶⁻⁸ This futile effort can delay investigators

from otherwise publishing in less prestigious journals that may be more likely to accept the manuscript, potentially rendering what may have been a timely, novel publication into a stale or redundant article and interrupting the natural evolution of using their published research as a launch point for other projects and grant proposals.

With minimal published guidelines, a common approach for junior (and other) investigators seeking assistance in manuscript submission decisions is to turn to senior academicians for advice – ironically rendering this critical step in their otherwise objective scientific work into a subjective, non-evidence based process. The single, objectively derived decision model for manuscript submissions is one proposed by Wong et al, which requires multiple inputs including journals' manuscript acceptance rates, times for first decision, and open access fees that may not be readily available.⁷ With the concept of a lack of objective data to assist emergency medicine (EM) investigators with their manuscript submission decisions in mind, we sought to 1) review EM journal impact metrics, and 2) provide a comprehensive list of pertinent journal characteristics that may influence their choice of submission.

METHODS

Analysis of Journal Impact Metrics

After review of the most commonly used journal impact metrics,^{3-5,7-12} we analyzed the following journal impact metrics: IF, H index, CiteScore, Source-Normalized Impact per Paper (SNIP), and SCImago Journal Rank (SJR). See Figure 1 for descriptions of these metrics.⁸⁻¹⁵ We abstracted values for H index, SNIP, CiteScore, and SJR from websites detailing these factors^{11,12} and IF from the Clarivate Analytics 2018 report.¹⁶ To generate a summary ranking of EM journal impact metrics, we summed each journal's ordinal rankings according to each of the five impact scores. In this model, the highest impact journal would have the lowest sum of ordinal ranks or the lowest mean ordinal rank.

As a secondary analysis, we sought to compare the agreement of the ordinal rankings of the five IF metrics, ie, the correlation between how the individual metrics ranked journals. For this analysis, we calculated the Spearman rank correlation coefficient, rho, for each pairwise combination of metrics. We conducted these analyses using Stata v13 (StataCorp, College Station, TX) and Excel X for Mac (Microsoft Corporation, Redmond, WA).

Submission Decision Journal Characteristics

With an explicit goal to provide practical, readily available information to inform submission decisions, we reviewed literature (including the decision model proposed by Wong et al) about pertinent journal characteristics,⁷ and sought to obtain the following features: manuscript acceptance rates; median times for manuscript decision; open access fees/options; and whether journals accept submissions of brief research reports/letters, and case reports/case images. For

these characteristics, we first reviewed all of the individual journal official websites. Given that very few published this information, we then sent emails to the contact person(s) listed on these journal websites asking them to provide this data:

- 1) *What is your acceptance rate for original research manuscripts (# accepted for publication/# submitted)?*
- 2) *What is your median or mean time for decisions on submitted manuscripts (how many days/weeks/months from submission to time that a decision is rendered and sent to the authors)?*

We sent four follow-up emails to non-responders at 10-day intervals and a final inquiry a month after the fourth request. When journals provided vague or incomplete information, the lead investigator asked for further clarification from their editorial staff. As a review of published materials without any patient considerations, this project was categorized as exempt from institutional review board review.

Journals Reviewed

To generate the journal list, we reviewed the list of top 30 journals in the EM category on the Scimago Journal & Country Rank website (sorted by SJR rank as of May 14, 2019).¹¹ We excluded journals with a narrow, non-EM focus, e.g., *Current Heart Failure Reports*, *MicroRNA*, and journals that did not typically publish original research manuscripts (*Emergency Medicine Clinics of North America*). We also excluded journals that did not have a 2017 IF on the 2018 Journal Citation Reports 2018 Clarivate Analytics report of IFs¹⁶ (the latest version available to us at the time of our analysis) and that did not respond to our queries for their 2017 IF.

RESULTS

Of the 30 journals listed in the EM category, we excluded eight for irrelevant or narrow focus, one for not publishing original research, and one because of no IF in 2017. We present impact factor metrics and other characteristics of the remaining 20 EM journals in Table 1. Of these 20 journals, 13 (65%) were published out of Europe and seven (35%) were published in the United States. All were English-language journals. Nearly all journals had an open access option with a median charge of \$2845. Fourteen journals (70%) accepted brief reports/research letters, and 14 journals (70%) accepted case reports/case images. The median acceptance rate for original research manuscripts was 25% (interquartile range [IQR] 18, 31%) and the median initial decision time was 33 days (IQR 18, 56 days).

We present the ranking of EM journals by summation of impact factor metrics in Table 2. We calculated the Spearman rank correlation coefficient for each pair of impact metrics; these metrics ranged from 0.13 to 0.82 as

Impact Factor (IF) The Web of Science calculates a journal's impact factor by dividing the total number of times its articles were cited by the total number of citable articles over a two-year period. For 2017, this would be the total # of citations of Journal X 2015 and 2016 citable articles by indexed journals in the year 2017/total # of Journal X citable articles in 2015 and 2016.

CiteScore (CS) is very similar to IF with three differences: 1) It is calculated from the SCOPUS database of approximately 22,000 journals; 2) Instead of two years, it uses the totals over three years (2017 would reflect articles from 2014-2016); and 3) It includes all publications (editorials, etc.) – not just “citable” articles. For this last reason, CiteScores are typically lower than IFs.

H Index While more commonly used as a gauge of individual authors' publications, a journal's H Index is based on the set of a journal's most cited papers and the number of citations that they have received in other publications. It is intended to measure both quantity and quality of publications.

SCImago Journal Rank (SJR) considers both the number of citations received by a journal and the prestige of the journals that the citations come from. The prestige criterion in SJR is determined using an iterative algorithm that weighs a number of factors. Like CiteScore, SJR is calculated from citations over the preceding three years.

Source Normalized Impact per Paper (SNIP) provides additional context beyond impact factors by weighting citations according to the total number of citations in a subject field. Assigning higher values to citations in subject areas where citations are less common, it theoretically corrects for differences in citation practice between different scientific fields. Producing a narrower range than IF, SNIP is calculated using the formula $SNIP = RIP / (R/M)$, in which RIP = raw impact per paper, R = citation potential and M = median database citation potential.

Figure 1. Descriptions of impact metrics.

presented graphically in Figure 2. The H index showed the lowest agreement with other metrics, and the CiteScore index showed the highest agreement.

DISCUSSION

Original research investigations are generally laborious and lengthy, often consuming years from start to finish. When considering where to submit the final product of their research for publication, investigators should be afforded as much objective, easily accessible information as possible. Toward this end, we sought to provide a comprehensive review of EM journal impact metrics and other characteristics for investigators.

We found that all but one of the impact metrics showed good to excellent agreement in their ordinal rankings, suggesting that these metrics and their formulas capture only slight nuances in impact. The poor correlation of the H index may be due to the fact that it is generally intended as a metric for authors – not journals. Although several websites provide general descriptions of these and other impact metrics, we were unable to find a similar specific analysis of journal impact metric correlation in any subspecialty field of medicine.

We are not advocating that our summary impact ranking is a general proxy of journal quality, and it should not become a de facto “one-two-three...” template for sequential targeted submission. Detailing all the factors that influence journal choices is beyond the scope of this work. The journal characteristics and the criteria for journal inclusion on these lists were chosen by a single investigator after review of the literature and consideration of the submission decision model proposed by Wong et al. EM investigators and their research are eclectic, and their publication priorities reflect this breadth of experience.¹⁷ Overall, we recommend that authors use this

work to help in their high impact vs likelihood of acceptance computations for submissions. Additionally, although this review is not intended to replace careful inspection of journal websites and instructions for authors, investigators may use our tables as a shortcut to avoid having to slog through numerous websites for other basic journal characteristic information.

Although the information presented in this study is purported to be readily available, we were surprised by the difficult and time-consuming nature of the data collection process. We anticipated that we would only need to conduct simple searches over a month (or less) to gather our desired data – it took nearly five months. Although three websites provided much of the standardized journal impact metric data,^{11,12,16} they did not offer any of the other journal characteristics we sought to provide. We found information regarding open access options/fees and whether journals accept case reports and brief reports on most journal websites, but it was often buried and sometimes unclear.

Very few journals published information regarding acceptance rates and decision times, and only 28% of our first email inquiries to journal staff were answered. Given these difficulties, we recommend the development of an independently maintained, expanded repository that gathers this information on an ongoing basis – with our work and tables providing a template or roadmap toward this goal. Considerations of conflict of interest or bias toward their affiliated journals notwithstanding, the most logical sponsors of such an endeavor are EM professional organizations such as the Society for Academic Emergency Medicine or the American College of Emergency Physicians. Regardless of who performs this service, the most appropriate home for its output is a freely available, open access website. From a sustainability standpoint, we expect that journals

Table 1. Emergency medicine journals' impact factor metrics and journal characteristics (presented alphabetically; N = 20).

Journal*	Country*	IF	H index	CS	SNIP	SJR	Open access fee	Acceptance rate (%)	Decision time** (days)	Brief reports?	Case reports?
Acad Emerg Med	US	2.612	110	2.38	1.352	1.436	\$3,000	18	10	Yes	No
Am J Emerg Med	US	1.29	73	1.21	0.746	0.67	\$2,550	27	18	Yes	Yes
Ann Emerg Med	US	4.68	137	1.6	1.951	1.439	\$3,000	8.3	12	Yes	Yes
CJEM	CA	1.481	39	0.99	0.763	0.456	\$3,010	32.4	60	Yes	Yes
Crit Care Resusc	AU	2.014	27	1.52	0.794	1.133	NR	NR	NR	No	Yes
Emerg Med Australas	AU/NZ	1.353	45	0.97	0.725	0.664	\$3,300	NR	NR	Yes	Yes
Emerg Med J	UK	2.046	67	1.43	1.216	0.841	£1,950	11	35	Yes	Yes
Euro J Emerg Med	EU	1.729	39	1.11	0.685	0.514	\$2,800	12	23	Yes	No
Euro J Trauma Emerg Surg	DE	1.704	18	1.44	0.905	0.45	\$3,140	30	44	No	No
Injury	NL	2.199	102	1.99	0.634	0.249	\$2,500	NR	56	No	Yes
Intern Emerg Med	IT	2.453	36	1.49	0.709	0.713	\$3,760	30	20	Yes	No
J Emerg Med	US	1.207	66	1.04	0.707	0.576	\$2,500	23	50	Yes	Yes
Prehosp Disaster Med	UK	0.971	43	0.97	0.671	0.511	\$1,760	23.2	55	No	Yes
Prehosp Emerg Care	UK	2.269	53	2.45	1.361	1.349	\$2,950	21.5	17	Yes	Yes
Resuscitation	NL	5.863	117	3.86	1.944	3.183	\$3,000	NR	NR	Yes	No
Scand J Trauma Resusc Emerg Med	NO	2.312	35	2.05	1.251	0.742	\$2,325	NR	41	No	Yes
Shock	US	3.005	92	2.6	1.031	1.354	\$2,800	25	14	Yes	No
West J Emerg Med	US	1.68 [#]	46	1.65	1.091	0.823	\$500	31.3	75	Yes	Yes
Wilderness Environ Med	US	1.161	35	0.87	0.776	0.47	\$3,000	38	32	Yes	Yes
World J Emerg Surg	UK	3.198	1.098	3.3	2.137	0.992	\$2,890	40	30	No	Yes

*National Library of Medicine Title Abbreviation

*Country of publication abbreviated according to the United Nations Code List

**Median

[#]Retrieved from Scimago Journal & Country Rank, not Clarivate (Web of Science, Science Citation Index Expanded).

IF, impact factor; CS, CiteScore; SNIP, Source Normalized Impact per Paper; SJR, Scimago Journal & Country Rank; NR, no response to queries; \$, United States dollars; OA, open access.

would, over time, recognize the benefits of collaboration and transparency of this repository and provide the input data more freely.

LIMITATIONS

While journal impact metrics are calculated by third parties in an objective, standardized fashion, the primary limitation of this report is the reliance on journal self-reports for acceptance rates and times for decisions. A few journals either did not respond to our inquiries or stated that they do not provide this information, and so this data remains incomplete. Furthermore, even though we specifically requested data regarding original research, some journals may have provided acceptance rates

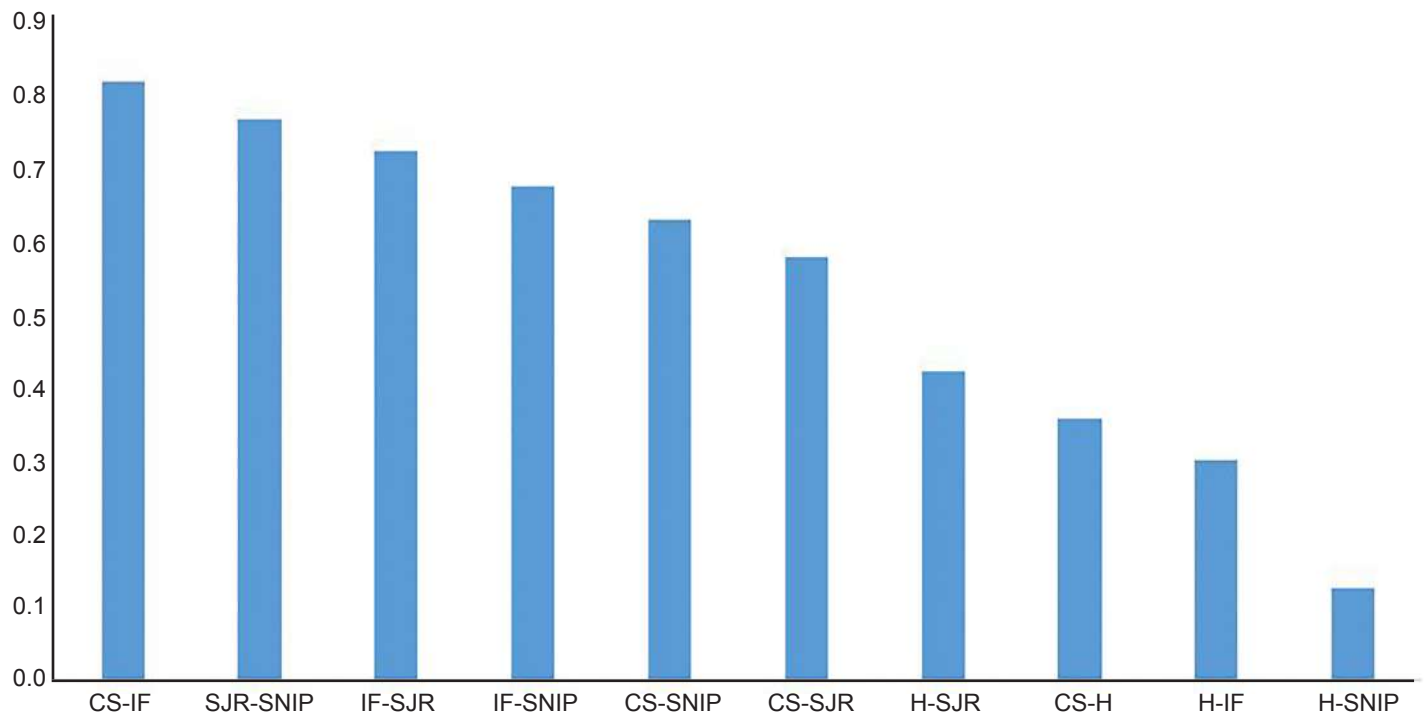
for *all* types of manuscripts. Similarly, in terms of median/mean times for decisions, their data may have been skewed if they referred to all submissions, including those that were immediately rejected and not sent out for review. Furthermore, use of the median and mean decision times without standard deviations or IQRs of the individual journals may obscure another important factor – the variation in time to decisions within a journal.⁶ Finally, these impact metrics and other journal characteristics are a snapshot of what was available from May–August 2019. Several journals sent us updated IFs and one EM journal that did not have a 2017 IF sent us their newly acquired 2018 IF. To maintain methodologic consistency, we chose not to include updated scores in this report.

Table 2. Summary ranking (highest to lowest) of top 20 emergency medicine journals by summation of ordinal rankings.

Journal*	IF	H	CS	SNIP	SJR	Average rank	Median rank	Range
Resuscitation	1	2	1	3	1	1.6	1	1 - 3
Ann Emerg Med	2	1	9	2	2	3.2	2	1 - 9
Acad Emerg Med	5	3	5	5	3	4.2	5	3 - 5
Shock	4	5	3	9	4	5	4	3 - 9
Prehosp Emerg Care	8	9	4	4	5	6	5	4 - 9
World J Emerg Surg	3	20	2	1	7	6.6	3	1 - 20
Emerg Med J	10	7	12	7	8	8.8	8	7 - 12
Scand J Trauma Resusc Emerg Med	7	16	6	6	10	9	7	6 - 16
West J Emerg Med	14	10	8	8	9	9.8	9	8 - 14
Intern Emerg Med	6	15	10	16	11	11.6	11	6 - 16
Injury	9	4	7	20	20	12	9	4 - 20
Am J Emerg Med	17	6	13	14	12	12.4	13	6 - 17
Crit Care Med	11	18	19	11	6	13	11	6 - 19
Eur J Emerg Med	13	19	11	10	19	14.4	13	10 - 19
Emerg Med Australas	12	13	14	18	15	14.4	14	12 - 18
Eur J Trauma Emerg S	16	11	17	15	13	14.4	15	11 - 17
J Emerg Med	18	8	15	17	14	14.4	15	8 - 18
CJEM	15	13	16	13	18	15	15	13 - 18
Prehosp Disaster Med	20	12	17	19	16	16.8	17	12 - 20
Wilderness Environ Med	19	16	20	12	17	16.8	17	12 - 20

*National Library of Medicine Title

IF, Impact Factor; CS, CiteScore; SNIP, Source Normalized Impact per Paper; SJR, SCImago Journal Rank.

**Figure 2.** Spearman rank-order correlation.

IF, Impact factor; CS, CiteScore; SNIP, Source Normalized Impact per Paper; SJR, SCImago Journal Rank; H, H Index.

CONCLUSION

We present summary tables of EM journal impact metrics and characteristics to inform original research manuscript submission choices for EM investigators. Considering the effort to acquire this data and annual changes in journal impact metrics, we recommend development of a centralized, open access website repository that can be updated from year to year.

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Consensus Guidelines for Digital Scholarship in Academic Promotion

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Introduction: As scholarship moves into the digital sphere, applicant and promotion and tenure (P&T) committee members lack formal guidance on evaluating the impact of digital scholarly work. The P&T process requires the appraisal of individual scholarly impact in comparison to scholars across institutions and disciplines. As dissemination methods evolve in the digital era, we must adapt traditional P&T processes to include emerging forms of digital scholarship.

Methods: We conducted a blended, expert consensus procedure using a nominal group process to create a consensus document at the Council of Emergency Medicine Residency Directors Academic Assembly on April 1, 2019.

Results: We discussed consensus guidelines for evaluation and promotion of digital scholarship with the intent to develop specific, evidence-supported recommendations to P&T committees and applicants. These recommendations included the following: demonstrate scholarship criteria; provide external evidence of impact; and include digital peer-review roles. As traditional scholarship continues to evolve within the digital realm, academic medicine should adapt how that scholarship is evaluated. P&T committees in academic medicine are at the epicenter for supporting this changing paradigm in scholarship.

Conclusion: P&T committees can critically appraise the quality and impact of digital scholarship using specific, validated tools. Applicants for appointment and promotion should highlight and prepare their digital scholarship to specifically address quality, impact, breadth, and relevance. It is our goal to provide specific, timely guidance for both stakeholders to recognize the value of digital scholarship in advancing our field. [West J Emerg Med. 2020;21(4)882-890.]

INTRODUCTION

The promotion and tenure (P&T) process requires the appraisal of individual scholarly impact in comparison to scholars across institutions and disciplines. Comparative metrics such as the journal impact factor and the h-index are used to quantify and compare the quality of an individual’s scholarship and, therefore, his or her academic merit.¹ As knowledge dissemination methods evolve in the digital era, we must adapt traditional P&T processes to include emerging forms of digital scholarship.² In this paper, we aim to first situate our readers within the literature on the topic of academic scholarship, after which we will describe the process by which we derived and refined our consensus guideline. Finally, we will outline the recommendations for the use of digital scholarship for academic promotion made by this particular guideline group.

The Evolution of Scholarship

Scholarship is persistently dynamic. Analog technologies progressed from tablet and stone to pen and paper; modern digital scholarship is evolving with blogs, podcasts, and digital journals. Still, the standards for evaluation are consistent and focus predominantly on impact and quality of the scholarship.³ In 1990, Ernest Boyer of the Carnegie Foundation originally redefined scholarship for the professoriate as belonging to one of four types.⁴ A decade later, Charles Glassick followed up this work by describing criteria for evaluating scholarship.^{5,6} To further develop nuances around the scholarship of teaching and learning, Lee Shulman and Patricia Hutchings further clarified specific criteria for this subtype of scholarship (to differentiate it from high-quality, scholarly, and evidence-based teaching).⁷ These foundational concepts are summarized in Table 1 below.

Traditionally, peer-review processes of academic journals served as a safeguard to ensure overall quality, with evaluators deferring to experts and peers within a scholar’s domain to provide an appraisal for quality and an estimate of impact. Similarly, bibliometrics of journals (eg, journal impact factor)⁸ and number of citations are surrogates for scholarly reach and proof of impact.³ Despite well-described limitations, these metrics are quantifiable and defined processes that are easily compared. Thus, they are highly relied upon by P&T

committees to compare scholars from disparate disciplines. When scholarship using new media is produced, it is reasonable to scrutinize the methodology, content, impact, and quality of these new forms of scholarship, such as digital scholarship. Our use of the term “digital scholarship” in this paper reflects original content that is disseminated digitally, whether that content is research, teaching materials, enduring resources, commentaries, or other scholarly work.

It is unsurprising that as the world becomes more digital, so do scholarly contributions.⁹ Online-only journals, pre-print archives,¹⁰ and post-production, peer-review journals (eg, *Cureus*) are rapidly changing the landscape of peer-reviewed publication.^{11,12} Similarly, with the advent of peer-reviewed blogs,¹³ self-published peer-reviewed books,¹⁴ and educational resource repositories, we see an increased breadth of expression from those engaging in the scholarship of teaching. These varied forms increasingly mirror the rigor required by Glassick’s criteria and Shulman’s paradigms.^{15,16}

Quantity vs Quality

Judging these new forms of scholarship is different. In many ways, with advanced web analytics, it is easier to quantify the reach and attention (eg, pageviews, podcast downloads, IP addresses that have accessed the content, and time on page) of these digital assets. (See Table 2 for common analytics available for new digital scholarship.) For example, the PubMed-indexed repository MedEdPortal provides download analytics of the published resources that aid in describing entries as fitting within the scholarship of teaching.

However, since many disciplines both within and outside of medicine have not yet fully embraced digital scholarship as enthusiastically as emergency medicine (EM) and critical care,¹⁷ it is no surprise that P&T committees do not yet have specific or universal standards for presentation or evaluation of digital scholarship.¹⁸ Those without digital scholarship experience may grapple with understanding the nuances of determining impact and quality in this new era, and their lack of understanding may even result in general skepticism of novel products. Thus, fields that have already established robust methods for determining the quality of digital scholarship can lead the way. Since digital scholarship has matured in EM,^{19,20} it is appropriate for our field to call

Table 1. Foundations of education and teaching scholarship.

Boyer’s Scholarly Domains 1990	Hutchings and Shulman Criteria for Scholarship of Teaching 1999	Glassick’s Criteria for Evaluating Scholarship 2000
1) Scholarship of discovery	1) Public	1) Clear goals
2) Scholarship of integration	2) Available for peer review & critique according to the standards of a field	2) Adequate preparation
3) Scholarship of application	3) Able to be reproduced and extended by other scholars	3) Appropriate methods
4) Scholarship of teaching		4) Significant results
		5) Effective presentation
		6) Reflective critique

for the identification of best practices for evaluating digital scholarship and for consensus in the inclusion of such items in promotions decisions.

Specific guidelines for P&T are lacking despite robust digital contributions proliferating among academicians. In this work, we provide a guiding framework for the presentation and evaluation of digital scholarship for the applicant for promotion, referees for the candidate, and members of P&T committees.

METHODS

We conducted a blended, expert consensus procedure using a nominal group process to create a consensus document.²¹ Invited participants met at the Council of Emergency Medicine Residency Directors (CORD) Academic Assembly on April 1, 2019 (Seattle, WA), to discuss recommendations for evaluation and promotion of digital scholarship with the intent to develop specific, evidence-supported recommendations to P&T committees and applicants. We began with a live, brainstorming event. The meeting notes were compiled by a leadership team and formatted into a collaborative working document. All authors continued formulating this document via a collaborative

online authorship using Google Docs (Google LLC, Mountain View, CA).²²

Participants

The participants were selected by the leadership of the CORD Social Media and Digital Scholarship Committee (EB, ZR, AH). Participants were selected based on criteria of known interest or scholarship in the area, national and international level contributions to EM digital scholarship, and availability to attend the conference in person or by phone. Supplemental Digital Appendix A lists original invitation list and individual selection rationale. The complete list of attendees of the in-conference proceedings is listed in the acknowledgments.

Procedures

As a large group, the consensus conference participants democratically developed the discussion and brainstorming procedures. Based on suggestions from the floor about previous consensus procedures at other similar conferences,^{23,24} our group decided to engage in small- group brainstorming discussions aligned with the expertise and interests of the participants, which was then discussed as a large group and vetted by the

Table 2. Summary of metrics used to demonstrate digital scholarship impact, role and quality, with a sample scholarly work.

Promotion metric	Supporting data	Example with metrics
Impact <i>Demonstration of impact shows your work reaches your intended audience</i>	Pageviews Time Spent on Page Likes Impressions Dissemination (Shares) Unique Users Geographic Reach Followers on Professional Social Media Accounts Social Media Index Digital Object Identifier (DOI) Alexa Ranking Altmetrics	Thoma B, Chan T, Benitez J, Lin M. Educational Scholarship in the Digital Age: A Scoping Review and Analysis of Scholarly Products. <i>The Winnower</i> . 2014. doi:10.15200/winn.141827.77297 Pageviews 4137 Altmetric Score 61 202 tweets from 86 users, with an upper bound of 263,362 followers
Role <i>Demonstration of your "brand" or role within digital scholarship helps establish your area of expertise</i>	Editor Author Curator Reviewer Invited Commentaries Podcast Guest or Editor	[Invited Commentary] Berg A, Weston V, Gisondi MA. Journal Club: Coronary CT Angiography Versus Traditional Care. NUEM Blog. http://www.nuemblog.com/blog/cta-for-chest-pain/ Published online 4/12/16.
Quality <i>While also demonstrating commitment to scientific rigor in your work, you may also highlight novel quality assurance methods unique to digital scholarship.</i>	METRIQ-5 and -8, rMETRIQ ALiEM AIR Score SAEM Online Academic Resources (SOAR) Social Media Index (SMi) The Quality Checklists for Health Professions Blogs and Podcasts	[Peer-reviewed blog] Long, B. "Myths in Heart Failure: Part I - ED Evaluation" emDOCs.net http://www.emdocs.net/myths-in-heart-failure-part-i-ed-evaluation/ published online 7/23/2018. Selected as ALiEM AIR Cardiovascular, Non-ACS module 2019. ³⁹ This post was deemed to be of an acceptable score within the ALiEM AIR Scoring tool, and was granted the designation "AIR Approved" by the adjudicating group of educators. There is a second tier below, known as "honorable mention" for posts of moderate quality that did not meet the threshold for inclusion.

ALiEM, Academic Life in Emergency Medicine; AIR, approved instructional resources; SAEM, Society for Academic Emergency Medicine

rest of the participants. Consensus was defined as universal agreement of the participants.

Ideation and refinement

The participants self-identified their areas of expertise or interest, and then separated into three groups based on these content areas using an iterative process to formulate specific recommendations. The three discussion groups were tasked with formulating recommendations for the following:

1. The P&T applicant for promotion of one's digital scholarship;
2. P&T committee members for evaluation of quality of digital scholarship;
3. P&T committee members for evaluation of the impact of digital scholarship.

Small groups presented preliminary recommendations to the entire group and made further revisions via iterative discussion. Participants transcribed an outline of the discussion and final recommendations and agreed upon them in a democratic fashion. Participants self-selected areas of the manuscript to prepare based on expertise, interest and group approval. All members developed the manuscript from the outline via collaborative authorship. All participants contributed to the manuscript, and CORD Social Media and Digital Scholarship committee members (AH, MS, ZR, EB) served as final editors of the manuscript.

RESULTS

Recommendations for Presenting Digital Scholarship for Promotion and Tenure

Demonstrate Scholarship Criteria

When presenting digital scholarship to a P&T committee, begin by ensuring and demonstrating that it meets the criteria of scholarship as defined by Glassick and expanded upon by Sherbino and colleagues with regard to social media.^{25,26} The adapted criteria are as follows: 1) create original content; 2) advance the field of health professions education by building on theory, research or best practice; 3) be archived and disseminated, and 4) provide the health professions education community with the ability to comment on and provide feedback in a transparent fashion that informs wider discussion. In addition, consider providing evidence of archival and dissemination, such as Google Scholar indexing or inclusion of a digital object identifier (DOI).

Provide External Evidence of Impact

Ensure that your digital scholarship is reflected consistently throughout your promotions dossier. Dissemination metrics are important to include as measures of impact. For example, some blog editors will provide information about how many times a post has been accessed and the locations of its readers, if requested for P&T purposes.

Such metrics of dissemination and impact should be presented in the dossier as evidence of your professional reputation as a scholar in your field.

Additional metrics include pageviews, downloads, and geographic reach. Other programs assessing the reach of scholarship, such as altmetrics, may also be valuable.²⁷ The Social Media Index is a relatively newer technique to assess the impact of websites and could be used as a surrogate for impact, much the same as a journal's impact factor.²⁸ See Table 2.

Other measures of impact could include letters of support and awards. If permitted by your institution, consider obtaining letters of support with regard to your digital scholarship. You may also consider inviting both peer letters and letters from non-collaborators discussing the dissemination metrics and impact of specific pieces of scholarship, or simply your overall impact. There are also a number of digital scholarship-based awards, which may be of value for demonstrating scholarly impact.²⁹

Include Digital Peer-review Roles

Include editor or peer-reviewer roles for digital scholarly content in your curriculum vitae (CV) in a similar manner as you would for traditional print literature. It is important to highlight these supporting components of digital scholarship and they should be factored into the P&T decisions.²⁵

Citing Digital Scholarship

Cite scholarly work on your CV using a consistent format, whether that work was published in a hard-copy journal or as digital content. Reorganize the categories of scholarly publications on your CV to include a section for "Digital Scholarship," which is the appropriate subheading for items such as blog posts, podcasts, and videos. See Table 3 below for example subheadings for the scholarly bibliography of your CV. Include only those items that reflect true scholarship and relate to the health professions or sciences. Do not list citations for personal website posts or other digital content that is unrelated to your academic position.

Table 3. Subheadings for "Scholarly Bibliography" section of curriculum vitae.

1	Original Research Articles - Peer Reviewed
2	Editorials, Reviews, Case Reports, Letters, Commentaries - Peer Reviewed
3	Textbooks, Textbook Chapters
4	Proceedings and Non-Refereed Papers
5	Digital Scholarship
6	Abstracts
7	Exhibits, Audiovisuals, Teaching Materials
8	Media Appearances and Quotes - Print, Television, Online

Consistently format your scholarship across all subheadings on your CV following the *American Medical Association (AMA) Manual of Style, 10th Ed.*³⁰ The *AMA Manual* describes the methods for citing scholarship in most of the categories listed. Examples of each citation type are provided above, and selected citations are adapted in Table 4. Digital scholarship is best formatted using the *AMA Manual* instructions for “Internet Documents.”³³ *Academic Life in Emergency Medicine (ALiEM)* also offers guidelines for citing digital scholarship, with examples.³¹

Digital scholarship is often criticized for lack of peer review, which leads to confusion about the quality and integrity of articles published in exclusively online journals. Peer review is a requirement for all journals to be indexed and available on PubMed, including online journals. Research articles published in online-only journals that have a PubMed unique identifier (PMID)³² should *not* be listed under “Digital Scholarship,” but rather alongside similar scholarly work published in peer-reviewed print journals. Regardless of the mode of publication, all peer-reviewed research should be listed under the same CV subheading in the “highest” possible category.

Blog posts that are cited under a “Digital Scholarship” CV subheading can be peer reviewed as well. For example, some blogs offer a peer-review process for authors and identify which posts have undergone peer review.³³ Therefore, use qualifiers to identify any digital scholarship citation on your

CV that was peer-reviewed or invited. These qualifiers may add additional credibility to your scholarship when a P&T committee reviews your CV.

DISCUSSION

Crafting a Digital Scholarship Mission Statement

A digital scholarship mission statement can provide a framework for your P&T committee to understand and interpret your digital scholarship.³⁴ Akin to the educational philosophy statement of a teaching portfolio, the digital scholarship mission statement provides a lens through which the committee can interpret the congruence and value of your scholarship.^{35,36} This narrative should articulate the beliefs that drive your digital work in ways that give perspective to your activities and provide consistency with the academic and social media strategies of each institution. Table 5 below lists specific considerations to include. Please see Supplemental Digital Appendix B for a sample narrative.

Use Traditional Frameworks: Harnessing the Teaching Portfolio

We recommend using traditional frameworks to describe digital scholarly activity and support for academic promotion. One such example of this is the teaching portfolio. As not all institutions require a separate educational portfolio, we recommend that you present your digital scholarship

Table 4. Suggested examples of digital scholarship citations and qualifier use.

Format:

Last Name, First Initial. “Title of Submission.” Name of Publisher. URL as hyperlink. Published online XX/XX/XX.

Example:

Gisondi MA, Stefanac L. “The Feedback Formula: Part 1, Giving Feedback.” International Clinician Educators Blog. <https://icenetblog.royalcollege.ca/2018/10/02/the-feedback-formula-part-1-giving-feedback/>. Published online 10/02/18.

Example Qualifiers for Curriculum Vita:

[Blog Post] Gisondi MA. “Leadership in Medical Education: Addressing Sexual Harassment in Science and Medicine.” International Clinician Educators Blog. <https://icenetblog.royalcollege.ca/2019/01/15/leadership-in-medical-education-addressing-sexual-harassment-in-science-and-medicine/> Published online 1/15/19.

[Podcast Guest] Kellogg A, Gisondi MA. “Sex and Why Episode 10: How to Give Better Feedback.” In: seX & whY Podcast (Wolfe J, Editor-in-Chief.) <https://www.sexandwhy.com/sex-why-episode-10-how-to-give-better-feedback/> Published online 1/29/19.

[Peer-Reviewed] Schnapp B, Fant A, Powell E, Richards C, Gisondi M. “8 Tips for How-to-Run an Awesome Works-in-Progress Meeting.” *Academic Life in Emergency Medicine*. <http://www.aliem.com/8-tips-works-progress-meeting/> Published online 11/1/15.

[Commentary, Invited] Berg A, Weston V, Gisondi MA. Journal Club: Coronary CT Angiography Versus Traditional Care. NUEM Blog. <http://www.nuemblog.com/blog/cta-for-chest-pain/> Published online 4/12/16.

[Video] Mason J. Placing a Transvenous Pacemaker. *Emergency Medicine: Reviews and Perspectives*. October 1, 2018. <https://www.emrap.org/episode/transvenous/transvenous>. Accessed November 21, 2018.

[Traditional Paper with Altmetrics] Chan TM, Gottlieb M, Sherbino J, Cooney R, Boysen-Osborn M, Swaminathan A, Ankel F, Yarris LM. The ALiEM faculty incubator: a novel online approach to faculty development in education scholarship. *Academic Medicine*. 2018 Oct 1;93(10):1497-502. Altmetrics data: <https://wolterskluwer.altmetric.com/details/43542602>

Table 5. Specific elements to consider within a mission statement.

1	Reinforce why your digital scholarship exists and is important to the field.
2	Explain your digital scholarship's broad goals and objectives.
3	Explain your perception of needs in the modern learning environment, and how that affects your methods.
4	Explain how your approach to digital scholarship/teaching has changed over time.
5	Explain the niche that you are filling, specifically highlighting how your role/expertise at your institution gives you a reputable voice.
6	Describe how your digital scholarship complements your other, more traditional forms of scholarship.
7	Explain how digital scholarship aligns with your overall career objectives.
8	Name your intended target audience and describe other collateral audience groups that may benefit from your public academic work.
9	Describe best practices for ensuring quality during the content creation process: <ol style="list-style-type: none"> Highlight team-based and interdisciplinary scholarship as markers of quality Preview external validation processes of your digital scholarship (below).
10	Highlight the ancillary benefits that have arisen because of your digital scholarship presence, such as invited lectures or collaborations on additional scholarship.

alongside traditional scholarship according to your institutional requirements. Refer to your respective institutional guidelines for requirements and formatting of teaching portfolios. Regardless, to facilitate appraisal by P&T committees you should create a dossier that includes a digital mission statement, demonstrates alignment with overall career development goals, and describes the scholarly significance of your digital work.²⁵

Digital scholarship should not replace materials that are typically included in a teaching portfolio, such as course evaluations or other traditional measures of teaching effectiveness. Teaching portfolios should summarize teaching *effort* and *quality* that meet the criteria of Boyer's scholarship of teaching.^{4,37} Within the teaching portfolio, you may reflect and provide exemplars of digital works and curricula that you have created or curated for learners, but you will not actually list item-by-item the digital scholarship you produce; this should take place in the CV. An entry in a portfolio would holistically describe the pedagogical principles behind a digital educational program or innovation (eg, if you are the creator of a popular podcast, you would explain how you developed the podcast, how you engaged stakeholders to develop the podcast, and, if possible, share data to convey its impact at large through analytics). In contrast, entries of digital scholarship on a CV would be entered individually. Table 6 provides some common examples of

digital scholarship, and how they might align best with previous descriptions of traditional academic scholarship (as per Boyer, Glassick, Hutchings and Shulman).

Appraising Impact

There are no hard and fast rules for determining impact. Cabrera and his colleagues have previously suggested scale-based assessments of social media-based impact in their 2017 paper.³⁴ They provide ample guidance to promotions committees for comparing size and scale of various media within a specific subtype (eg, international blog vs a local blog). We highly recommend that readers review this article for further guidance.

Another tool is the Social Media Index, which seeks to create an "impact factor"-like metric based on social media followership. This tool would be best used to judge the impact of an entire digital media collection, such as an entire website or podcast. This tool is available online (<https://www.aliem.com/social-media-index/>) and has been revised and validated against quality metrics within emergency medicine Free Open Access Medicine resources.³⁸

Appraising Quality

Due to lower barriers of entry allowing digital scholarship to be more easily produced, general skepticism due to less serious, nonmedical online content, as well as pseudoscientific and/or predatory online content, groups have sought to scaffold and support end-users and educators in seeking high-quality online resources.^{39,40} The online medical education community has worked to quell skepticism by establishing methods to appraise the quality of digital scholarship.³ See below for a list of critical appraisal tools for rating online secondary resources. For those who have been asked to review files as external referees, these tools may be very useful in guiding us toward high-quality educational content from an educator's CV or portfolio.

Some scholars in this space have proposed that we move beyond bibliometrics and surrogates for quality (eg, impact factor, citations, altmetrics), and that P&T committees consider applying direct quality assessments to items of interest (eg, applying the revised METRIQ⁴¹ or ALiEM Approved Instructional Resources (AIR series) scores³⁹ to a few choice works of digital scholarship from a faculty member's CV, or applying the PRISMA⁴² reporting guidelines to a few systematic reviews). Equitably applying both descriptive bibliometrics (eg, citation rate, h-index, etc.) and quality audits to all works of scholarship (digital or otherwise) would go a long way to augment P&T processes. Table 2 contains suggested critical appraisal tools to facilitate secondary resource evaluation.

LIMITATIONS

The live conference was limited to invited participants who could join in person or by phone. Those with scheduling conflicts were therefore excluded from the live session, perhaps limiting valuable insights and contributions. However, those that could not attend the live conference were still heavily involved

Table 6. How types of digital scholarship might be described using traditional descriptions of academic scholarship.

	Blogging	Podcasting	Tweeting
Example of digital scholarship	Blog post providing a new insight into a novel teaching technique, with a recipe for helping students learn about social justice by meeting patient partners.	Podcast synthesizing the role of human factor engineering in the emergency department.	Tweetorial reviewing and appraising the latest evidence on a topic
Does this meet the criteria for scholarship per Hutchings and Shulman?	1) Is it public? Yes 2) Is it available for peer review? Yes, some blogs have pre-publication peer review, others have comments enabled to allow for post-publication peer review)	1) Is it public? Yes 2) Is it available for peer review? Yes, listeners can leave comments on most podcast hosting sites. 3) Able to be reproduced and extended by other scholars? Yes, since it is available for review and extendibility since it is openly published on the internet.	1) Is it public? Yes 2) Is it available for peer review? Yes, tweetorials can be found by searching Twitter. 3) Able to be reproduced and extended by other scholars? Yes, since it is available for review and extendibility since it is openly published on the internet.
1) Public			
2) Available for peer review and critique according to the standards of a field			
3) Able to be reproduced and extended by other scholars	3) Able to be reproduced and extended by other scholars? Yes, since it is available for review and extendibility since it is openly published on the internet.		
What type of Boyer's scholarship is this?	Scholarship of teaching	Scholarship of integration (merging of engineering and medicine)	Scholarship of application (helping others to determine if evidence might be applied in their context)

in the organization and creation of the recommendations post-conference via a collaborative writing process. Additionally, all authors participated robustly in the asynchronous editing of this manuscript, reducing the potential that important viewpoints were excluded. Conference participants were selected by the committee members, and important contributors may have been overlooked. To reduce this possibility, invited members were requested to suggest additional invitees. Finally, as digital scholarship participants and creators, there may be bias toward legitimizing our own work over less-familiar scholarship.

We attempted to ground our recommendations using best available evidence in order to reduce this bias. However, there is certainly a paucity of literature on how social media is viewed upon (or accepted) as a form of scholarship by the academy. Thus, further explorations of the acceptability or evaluation of digital by P&T committees may be a useful program of research going forward. A paper has recently been published about perceptions in the librarian sciences world that is quite interesting, and worthy of replication within academic medicine.⁴³

CONCLUSION

As traditional scholarship continues to evolve within the digital realm, academic medicine must also adapt how that scholarship is evaluated. P&T committees in academia are at the epicenter for supporting the changing paradigm in scholarship. Unlike traditional academic products, where reach and impact were difficult to quantify, web-based metrics allow us to track unique users and their locations. The authors suggest that committees critically appraise digital scholarship using the methods outlined in this paper. Applicants for appointment and promotion should highlight and prepare their digital scholarship in a way that specifically addresses quality, impact, breadth, and relevance. It is our goal to provide specific, timely guidance for both stakeholders to recognize the value of digital scholarship in advancing our field.

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Impact of Emergency Department Crowding on Delays in Acute Stroke Care

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Introduction: Delays in identification and treatment of acute stroke contribute to significant morbidity and mortality. Multiple clinical factors have been associated with delays in acute stroke care. We aimed to determine the relationship between emergency department (ED) crowding and the delivery of timely emergency stroke care.

Methods: We used prospectively collected data from our institutional Get with the Guidelines-Stroke registry to identify consecutive acute ischemic stroke patients presenting to our urban academic ED from July 2016–August 2018. We used capacity logs to determine the degree of ED crowding at the time of patients' presentation and classified them as ordinal variables (normal, high, and severe capacity constraints). Outcomes of interest were door-to-imaging time (DIT) among patients potentially eligible for alteplase or endovascular therapy on presentation, door-to-needle time (DTN) for alteplase delivery, and door-to-groin puncture (DTP) times for endovascular therapy. Bivariate comparisons were made using t-tests, chi-square, and Wilcoxon rank-sum tests as appropriate. We used regression models to examine the relationship after accounting for patient demographics, transfer status, arrival mode, and initial stroke severity by the National Institutes of Health Stroke Scale.

Results: Of the 1379 patients with ischemic stroke presenting during the study period, 1081 (78%) presented at times of normal capacity, 203 (15%) during high ED crowding, and 94 (7%) during severe crowding. Median DIT was 26 minutes (interquartile range [IQR] 17-52); DTN time was 43 minutes (IQR 31-59); and median DTP was 58.5 minutes (IQR 56.5-100). Treatment times were not significantly different during periods of higher ED utilization in bivariate or in multivariable testing.

Conclusion: In our single institution analysis, we found no significant delays in stroke care delivery associated with increased ED crowding. This finding suggests that robust processes of care may enable continued high-quality acute care delivery, even during times with an increased capacity burden. [West J Emerg Med. 2020;21(4):891-898.]

INTRODUCTION

Delays in timely identification, imaging, and treatment of acute stroke are associated with significant morbidity and mortality.^{1,2} To ensure timely delivery of care, hospitals

develop robust processes to promptly identify and treat patients presenting with concern for acute stroke.³⁻⁷ National guidelines recommend administration of alteplase within 60 minutes of patient presentation, and achieving this target

is dependent on timely imaging and appropriate utilization of scarce emergency department (ED) resources.^{8,9} The availability of many critical resources may be further threatened with the increasing prevalence of ED crowding.¹⁰⁻¹² Previous studies have demonstrated the association of ED crowding with patient safety concerns, delays in care, and even patient mortality.¹³⁻¹⁵

Data regarding the relationship between ED crowding and acute stroke care in particular are limited. One study found that among patients presenting with acute symptoms (within three hours), imaging and thrombolysis times were not affected by ED crowding,¹⁶ whereas another reported that increased crowding was associated with poorer performance on door-to-imaging times (DIT).¹⁷

Given conflicting findings, we sought to investigate the relationship between ED crowding and timely imaging and treatment of acute stroke in our high-volume, urban, academic ED. We hypothesized that increased crowding would be associated with delays in imaging, alteplase delivery, and time-to-groin puncture for patients undergoing endovascular therapy. We further hypothesized that other factors associated with stroke care, such as higher stroke severity, may mitigate these delays during times of increased crowding.

METHODS

Data Source, Study Setting, and Population

This was a retrospective analysis of prospectively collected data on consecutive ischemic stroke patients presenting to a single, urban, academic comprehensive stroke center hospital with over 108,714 ED visits in 2017. The ED resources for acute stroke care include two dedicated ED computed tomography (CT) scanners as well as an in-person neurology team (24/7 availability). The CT scanners are located adjacent to the ED with a <2-minute stretcher transport from high acuity rooms. Code stroke is activated by ED care team members when a patient presents with signs or symptoms concerning for acute stroke. Code stroke activation results in a group page sent immediately to the ED neurology team, ED pharmacist, ED radiology team, and CT technologist. The CT scanner is then cleared and held for evaluation of the patient.

We used data from the institutional Get with the Guidelines-Stroke dataset, which includes patient demographics, and detailed clinical data including time of presentation, time of imaging, stroke severity (measured by National Institutes of Health Stroke Scale [NIHSS] score), time of alteplase administration, and time of puncture for endovascular therapy.^{18,19} We included all patients over 18 years of age with a final diagnosis of ischemic stroke, who presented through the ED between July 2016–August 2018.

We matched patients' time of presentation in the stroke registry data with data from our ED capacity logs. The log documents the state of ED utilization at all times on a three-point ordinal scale of normal capacity, high capacity, or

Population Health Research Capsule

What do we already know about this issue?
Delays in care of acute stroke lead to morbidity and mortality. ED crowding has also been associated with delays for other disease processes.

What was the research question?
For patients presenting with acute stroke, is ED crowding associated with delays in care?

What was the major finding of the study?
ED crowding was not associated in delays in care for patients presenting with acute stroke.

How does this improve population health?
Our findings suggest that robust systems may be protective in times of increased capacity burden. Further study may help identify other disease processes to target.

severe capacity constraints. High capacity-constraint status is automatically triggered when all monitored bays and half of the monitored hallway stretchers are occupied. A severe capacity-constraint status is triggered when all monitored beds, including bays and stretchers, are occupied. Patients in our registry were cross-referenced against ED capacity logs to determine the capacity state at time of arrival for each patient.

Because our objective was to determine whether time-dependent metrics were influenced by ED capacity constraints, we focused this analysis on patients with acute stroke who were potentially eligible for intervention on presentation (Figure 1). This included patients potentially eligible for alteplase (presenting within 4.5 hours of last known well [LKW] for all patients regardless of illness severity), and those potentially eligible for endovascular therapy (presenting within eight hours of LKW with moderate or severe disability, defined as NIHSS \geq 6).

Outcomes of Interest

Outcomes of interest were DIT, door-to-needle (DTN) time for alteplase delivery, and door-to-groin puncture time (DTP) for endovascular therapy. For the DIT analysis, we excluded transferred patients to focus on patients in whom previous imaging had not yet been completed. We secondarily examined DIT among all alteplase-treated patients. The DTN analysis included all patient arriving within 4.5 hours of LKW time and treated with alteplase. The DTP analysis included all patients arriving within eight hours of LKW time with NIHSS \geq 6 who

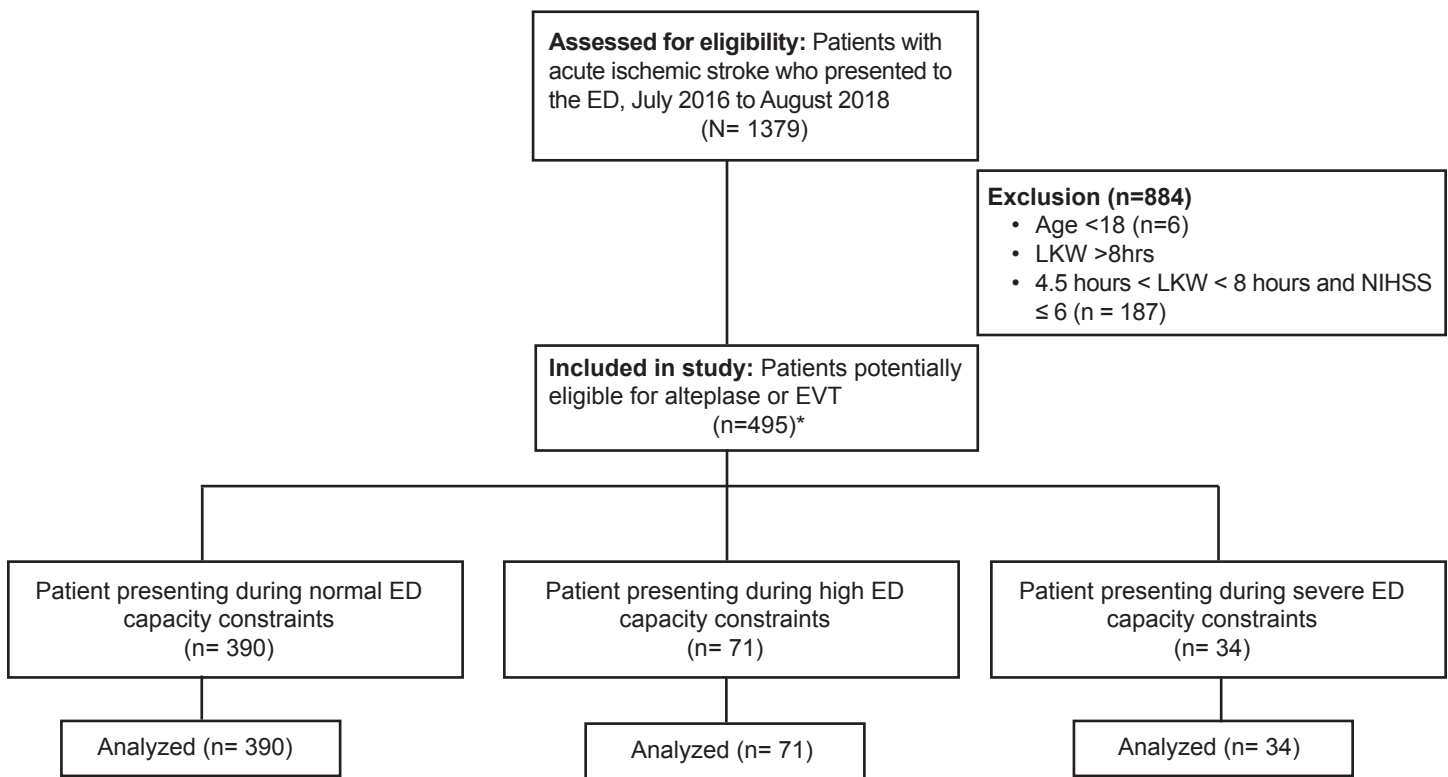


Figure 1. CONSORT diagram for patient inclusion criteria by study outcome.

*DIT analysis includes 298/495 patients who were non-transfers.

ED, emergency department; LKW, last known well; NIHSS, National Institutes of Health Stroke Scale; EVT, endovascular therapy; DIT, door-to-imaging time.

received endovascular therapy. In addition to our primary outcomes of interest (DIT, DTN, and DTP) we also examined compliance with guideline-recommended dysphagia screening and 25- and 60-minute windows for DIT and DTN, respectively.

Statistical Analysis

Our independent variable of interest was ED crowding at the time of patient presentation, as defined above. We used t-tests, chi-square, and Wilcoxon rank-sum tests as appropriate for bivariate comparisons. We used regression models to examine the relationship between ED crowding and outcomes of interest after accounting for patient age, gender, transfer status, arrival mode, and stroke severity (based on NIHSS). The covariates listed above included in the model were determined a priori based on clinical experience and prior literature.^{1-5,20-23} We conducted analyses using Stata 14.2 (StataCorp, College Station, Texas). The Massachusetts General Hospital Institutional Review Board approved the study and did not require informed consent for this retrospective data analysis.

RESULTS

We identified 1379 ED patients with ischemic stroke during the study period. Of this population, 495 were potentially eligible for alteplase or endovascular therapy

on presentation. Patient characteristics for this cohort are included in Table 1. Seventy-nine percent of patients with acute ischemic stroke presented in times of normal utilization, while 14% presented during high crowding and 7% presented during times of severe crowding. Patients were more likely to present as a transfer to our ED during times of normal capacity, and patients presenting during severe crowding had lower stroke severity than patients presenting during normal and high-capacity constraints; there were otherwise no other patient-level differences associated with differences in ED capacity status (Table 1).

We further assessed how the distribution of increased crowding for stroke patients compared with the general population. During the study period, our ED had normal capacity constraints 78% of the time, with increased and severe crowding 12% and 10% of the time, respectively. Eighty-one percent of increased crowding activations occurred Monday-Thursday, with the median time of activation 1:35 PM.

Door-to-Imaging Times

Of the 1379 patients in our sample, 298 patients presented directly (non-transfers) and were potentially eligible for alteplase or endovascular therapy (presented within 4.5 hours of LKW with any stroke severity or within eight hours of

Table 1. Patient and clinical characteristics.

Patient and clinical characteristics	All patients n=495	Normal capacity constraints n=390 (78.8%)	High capacity constraints n=71 (14.3%)	Severe capacity constraints n=34 (6.9%)
Gender				
Female	248 (50%)	201 (51.5%)	33 (46.5%)	14 (41.2%)
Age, median (IQR)	73 (62-83)	73 (61-84)	76 (66-84)	66.5 (58-81)
Race/ethnicity				
White	358 (72.3%)	286 (73.3%)	48 (67.6%)	24 (70.6%)
Black	39 (7.9%)	26 (6.7%)	8 (11.3%)	5 (14.7%)
Asian	22 (4.4%)	17 (4.4%)	2 (2.8%)	3 (8.8%)
American Indian/Alaska Native	1 (0.2%)	0 (0%)	1 (1.4%)	0 (0%)
Hispanic	29 (5.9%)	23 (5.9%)	6 (8.5%)	0 (0%)
Unavailable	75 (15.1%)	61 (15.6%)	12 (16.9%)	2 (5.9%)
Mode of ED arrival				
Private Transport	59 (11.9%)	41 (10.5%)	10 (14.1%)	8 (23.5%)
EMS	243 (49.1%)	184 (47.2%)	39 (54.9%)	20 (58.8%)
Interfacility Transfer	193 (39.0)	165 (42.3%)	22 (40.0%)	6 (17.7%)
NIHSS on Admission#, median (IQR)	7 (2-16)	8 (3-16)	6.5 (2-12)	2.5 (1-8.5)
NIHSS > 6 on admission	304 (61.4%)	250 (64.1%)	42 (59.2%)	12 (35.3%)

IQR, interquartile range; ED, emergency department; EMS, emergency medical services; NIHSS, National Institutes of Health Stroke Scale.

LKW with NIHSS score of 6 or greater). Median DIT among this cohort was 26 minutes (interquartile range [IQR] 17-52) and did not significantly differ by ED capacity constraints at time of presentation in bivariate testing (Table 2 and Figure 2), or in multivariable regression after accounting for patient characteristics, EMS arrival, and stroke severity (Supplementary Table). EMS arrival was independently associated with faster DIT. Median DIT among the 82 alteplase-treated patients was 18 minutes (IQR 14-26) and did not significantly differ by ED crowding at time of presentation in bivariate testing (Table 2).

Door-to-Needle Time for Alteplase Receipt

Among the 82 alteplase-treated patients in our sample, median DTN was 43 minutes (IQR 31-59) and did not significantly vary by ED capacity status at time of presentation in bivariate testing (Table 2, Figure 2) or after accounting for patient characteristics, stroke severity, and EMS arrival (Supplementary Table). Of these patients, 78% had DTN within 60 minutes of arrival.

Door-to-Groin Puncture for Endovascular Therapy

Among the 52 patients who received endovascular therapy, median DTP was 68.5 minutes (IQR 56.5-100 minutes), and DTP times did not vary by ED capacity status at time of presentation in bivariate testing (Table 2, Figure 2), or after accounting for patient characteristics, stroke severity, and EMS arrival (Supplementary Table).

DISCUSSION

This study investigated the relationship between ED crowding and prompt recognition and management of patients with acute ischemic stroke. We found no significant difference in time to imaging, administration of alteplase, or to endovascular therapy when the ED was experiencing high or severe capacity constraints. This suggests that robust, protocolized systems in place to address the time-sensitive requirements of stroke treatment may be protective against increasing ED capacity constraints.

Previous data regarding the impact of ED crowding on stroke evaluation and treatment is limited and mixed. Chatterjee et al found that ED crowding was not associated with delays in imaging for patients presenting less than three hours from symptoms onset. However, the study did demonstrate delays if symptoms had been present for longer, suggesting that less emergent care may be delayed in times of worsening ED crowding.¹⁶ Recently, a study by Reznek et al found an association between ED crowding and failure to comply with DIT goals under 25 minutes.¹⁷ This is in contrast to our results, in which crowding was not associated with delays in DIT.

There are multiple potential explanations for this difference. First, our institution has multiple CT scanners available to the ED, which may be protective in times of increased volume. Additionally, differences in the populations included in the studies may have contributed to the difference in results. The population included in the Reznek et al study

Table 2. Study outcomes by capacity.

	All Patients n=495	Normal capacity constraints n=390 (78.8%)	High capacity constraints n=71 (14.3%)	Severe capacity constraints n=34 (6.9%)	P-value
Median DIT in minutes (IQR)	26 (17-52)	26.5 (17-54)	23 (17-37.5)	26 (17-76)	0.50
n (%)	716	222 (75%)	48 (16%)	28 (9.4%)	
Median DIT among patients receiving alteplase in minutes (IQR)	1 (14-26)	18.5 (14-26)	21.5 (12.5-32)	17 (15-20)	0.74
n (%)	82	62 (76%)	12 (15%)	8 (10%)	
Median DTN in minutes (IQR)	43 (31-59)	43 (32-60)	35 (29-47)	45 (36.5-54)	0.41
n (%)	82	62 (76%)	12 (15%)	8 (10%)	
Median DTP in minutes (IQR)	68.5 (56.5-100)	68.5 (56-100)	72 (58-95)	54	0.54
n (%)	52	46	5	1	
DIT < 25 mins among all non-transferred patients treated with alteplase					
Yes	59 (72%)	45 (73%)	7 (58%)	7 (88%)	0.45
No	23 (28%)	17 (27%)	5 (42%)	1 (13%)	
DTN < 60 mins among all patients treated with alteplase					
Yes	64 (78%)	47 (76%)	10 (83%)	7 (88%)	0.39
No	18 (22%)	15 (24%)	2 (17%)	1 (12%)	
Dysphagia Screen performed in the ED among all acute stroke patients					
Yes	864 (63%)	675 (62%)	129 (64%)	60 (64%)	0.35
No	514 (37%)	406 (38%)	74 (36%)	34 (36%)	

DIT, door-to-imaging time; IQR, interquartile range; DTN, door-to-needle time; DTP, door-to-groin puncture time; mins, minutes; ED, emergency department.

included all patients in whom a “code stroke” was activated, with symptom onset within 12 hours. This may have led to the inclusion of patients who were not candidates for acute treatment, and as such the time-dependency of their imaging may have been considered less critical. The patients included in our study were those with a retrospective diagnosis of acute stroke and who were also potentially eligible for treatment on presentation. Given that the patients included in our sample had potential for intervention on arrival to the ED, expediting their evaluation may have been even further prioritized. Thus, these patients experienced no delays in care in times of increased crowding.

Other studies have also examined other patient or clinical factors in addition to ED crowding that are associated with prompt imaging and management of acute stroke. These factors have included gender, symptom severity, and mode of ED arrival.²¹⁻²³ We did not find any disparities by gender or race/ethnicity; however, consistent with previous reports, we did find an association between EMS arrival and faster DIT.

Our study expands on previous work by assessing the relationship between timely stroke care and capacity

constraints, and adds a novel analysis of DTP for endovascular therapy. Our findings underscore the value of dedicated ED protocols and processes to ensure high-quality delivery of time-critical care irrespective of ED volume. Having a dedicated ED stroke team, ED pharmacist, and neuroradiology support in the ED may reduce any variation in imaging times that capacity constraints would otherwise impose. However, the availability of these resources may be both institution- and disease-specific. Some institutions with resource constraints may be more likely to experience delays in acute care with only marginal increases in ED crowding. Further study may identify what level of crowding may lead to delays for stroke care as well as the resources needed to protect against capacity constraints.

Our results have potential implications for the organization of stroke systems of care. In the prehospital triage of patients with suspected stroke due to large vessel occlusion (LVO), it is hypothesized that transport directly to thrombectomy-capable centers could introduce harm due to possible over-triage. There is concern that this action may lead to increased crowding and worse outcomes for patients at these hospitals. However, our results suggest that for patients presenting within the treatment

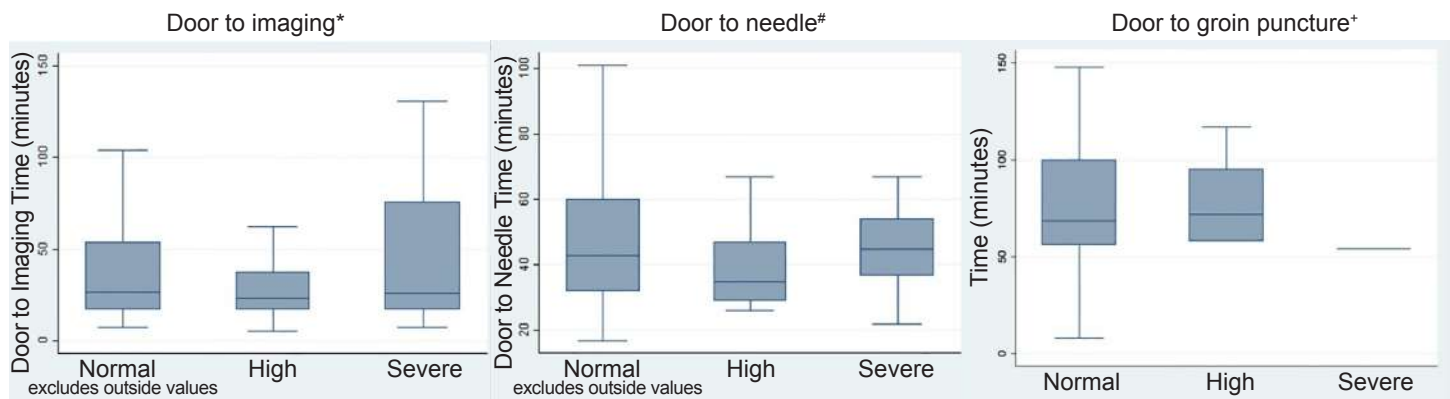


Figure 2. Study outcomes by capacity constraints on the effect of timely treatment of stroke patients.

*Includes 286 patients with complete data who were non-transfers, and potentially eligible for alteplase or endovascular therapy.

#Includes 82 patients who were not transferred and were treated with alteplase within 4.5 hours of presentation.

+Includes all 52 patients who were eligible and received endovascular therapy.

windows for alteplase or thrombectomy, crowding does not contribute to slower treatment times. Thus, protocolized care may enable treatment without delays, regardless of crowding conditions, in scenarios of transport directly to a thrombectomy-capable hospital.

As crowding and capacity challenges continue to be a pervasive issue for many EDs, developing and maintaining efficient processes to ensure high-quality care for high acuity, time-critical patients is paramount. Studies have highlighted how defined systems of care for critical disease processes can protect against delays in care, yet even these results have been mixed. For example, there are conflicting results regarding the impact of ED crowding on delays in percutaneous coronary intervention for acute myocardial infarction.²⁴⁻²⁶ For sepsis care, studies have demonstrated significant delays in core treatments including time to intravenous fluids and antibiotic administration.^{27,28} ED crowding continues to have large implications for delays in less emergent care as well. For example, studies have found delays in community-acquired pneumonia treatment as well as increased mortality associated with increased ED crowding for these patients.^{14,29-31} Multiple studies have also demonstrated an association between increased ED volume and delays in analgesia administration; this notably includes patients with sickle cell crises.³²⁻³⁴ As capacity constraints continue to grow, understanding and creating better processes of care for defined patient populations may become even more essential in the ED.

One potential explanation for our findings could be that times of peak crowding occurred concurrently with times of increased resource availability. Given that most patients presenting during times of crowding arrived during the day and on a weekday, it is likely that increased hospital staffing and resource availability could contribute to expedited care during peak hours. In fact, recent studies have shown that a reduction in available physicians and nurses has been associated with increased DIT and DTN times, respectively.³⁵

Reassuringly, we found that the distribution of capacity constraints for stroke patients presenting to the ED was similar to that for the general population. Further study may be warranted to better characterize how ED staffing models and time of presentation may affect delays in stroke care during times of increased ED crowding.

LIMITATIONS

Our retrospective analysis is not without limitations. We assessed the impact of capacity constraints in a large, urban, academic center with a robust system in place for acute stroke care. This may limit generalizability, as the relationship between crowding and care delivery may vary based on practice type and resource availability. However, we believe that our findings are valuable in highlighting the potential to maintain high-quality, time-critical care delivery even in the face of major capacity challenges.

Another limitation is that our retrospective analysis may not have been powered to detect a difference in our study outcomes, despite the fact that our comprehensive stroke center sees the largest number of patients with acute stroke in our state, and we were able to capture clinical data on all acute stroke patients during the study period, we did have a relatively smaller proportion of patients presenting during times of the highest crowding. One explanation for this is that our institution is closed to outside hospital transfers during times of severe crowding, which may limit the number of patients with ischemic stroke at this time. In our large cohort, we found no trend towards significance for the study outcomes, yet it remains plausible that with larger samples, specifically for high and severe capacity constraints, there may exist a significant effect.

Additionally, with the exception of patients with LVO, our institution did not accept interfacility transfers during times of severe crowding, which narrows our study population. We also used an eight-hour window for thrombectomy consideration

based on institutional protocols, although in the latter six months of the study period this expanded to 24 hours. We chose not to include the expansion because the expanded protocol was in variable implementation during that time. Our population also includes a relatively greater proportion of patients arriving via EMS as well as a relatively racially homogenous population. Findings may differ in settings with different demographics or different patterns of prehospital care.

Another limitation of our analysis is that we were unable to directly evaluate for delays to recognition of or diagnosis of stroke due to the nature of our data. However, given that our registry includes all patients with a final diagnosis of stroke, and imaging times were not different between patients presenting during times of crowding, this suggests that it is unlikely that there were substantial delays to diagnosis in these patients. Last, we could not measure the effect of prioritizing stroke care over other diseases also relying on advanced imaging to make a diagnosis. It is plausible that care for other disease states may be delayed while resources are being used for acute stroke patients.

CONCLUSION

In our single-institution, observational study, we found that ED capacity constraints were not significantly associated with delays in acute stroke care, suggesting that robust processes of care for critically ill patients may be protective from the growing burden of ED crowding.

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Patient Safety Event Reporting and Opportunities for Emergency Medicine Resident Education

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Introduction: Healthcare systems often expose patients to significant, preventable harm causing an estimated 44,000 to 98,000 deaths or more annually. This has propelled patient safety to the forefront, with reporting systems allowing for the review of local events to determine their root causes. As residents engage in a substantial amount of patient care in academic emergency departments, it is critical to use these safety event reports for resident-focused interventions and educational initiatives. This study analyzes reports from the Virginia Commonwealth University Health System to understand how the reports are categorized and how it relates to opportunities for resident education.

Methods: Identifying categories from the literature, three subject matter experts (attending physician, nursing director, registered nurse) categorized an initial 20 reports to resolve category gaps and then 100 reports to determine inter-rater reliability. Given sufficient agreement, the remaining 400 reports were coded individually for type of event and education among other categories.

Results: After reviewing 513 events, we found that the most common event types were issues related to staff and resident training (25%) and communication (18%), with 31% requiring no education, 46% requiring directed educational feedback to an individual or group, 20% requiring education through monthly safety updates or meetings, 3% requiring urgent communication by email or in-person, and <1% requiring simulation.

Conclusion: Twenty years after the publication of *To Err is Human*, gains have been made integrating quality assurance and patient safety within medical education and hospital systems, but there remains extensive work to be done. Through a review and analysis of our patient safety event reporting system, we were able to gain a better understanding of the events that are submitted, including the types of events and their severity, and how these relate to the types of educational interventions provided (eg, feedback, simulation). We also determined that these events can help inform resident education and learning using various types of education. Additionally, incorporating residents in the review process, such as through root cause analyses, can provide residents with high-quality, engaging learning opportunities and useful, lifelong skills, which is invaluable to our learners and future physicians. [West J Emerg Med. 2020;21(4)899-904.]

INTRODUCTION

Healthcare systems often expose patients to significant, preventable harm on par with other chronic medical conditions at rates estimated between 44,000 and 98,000 deaths annually,¹ although some suggest it may be even higher.² These reports have highlighted the importance of patient safety and safety event reporting. These reporting systems allow for local review of events and identification of whether they are local issues or a system-level vulnerability.^{3,4} Aligned with efforts to identify such errors, research is beginning to focus on how we learn from the reported events. One benefit of reporting is the potential to reprioritize, learn, and fix system processes by identifying contributing factors and helping providers address these issues.⁵⁻⁹ However, research has been limited. Improvements have been made in incident reporting, but this alone does not lead to systems changes or enhanced patient care. Pronovost et al concluded that reporting systems alone were “insufficient to gain the knowledge needed to learn how [patient safety report systems] can improve patient safety.”^{10,11} It must also include the establishment of organizational leadership and safety champions to spearhead learning from events.¹²

While health systems have reporting structures and processes to address patient safety, residents are not always purposefully engaged in reporting problems and vulnerabilities. The Accreditation Council for Graduate Medical Education (ACGME) through the Clinical Learning Environment Review and milestone competencies has increasingly stressed resident education about safety events, along with other important educational domains. However, it is unclear how safety event reporting has been used to educate residents. Within patient safety reporting systems, residents have the opportunity to be actively engaged in the identification of adverse events, near misses, unsafe conditions, and potential systems issues. However, to successfully instill lifelong, improvement-based practices within our physician learners, we must close the loop by providing feedback, education, and enhanced training opportunities based on submitted safety reports, including those by residents and others.

As a high percentage of care in an academic emergency department (ED) is provided by residents, it is critical to include them in interventions and educational initiatives to address patient safety in the ED. From our own institutional resident learning environment survey, ED residents indicated that they received adequate feedback on safety event reports submitted through the formal submission system only 50% of the time. This finding suggested that resident input into safety may not be well considered, encouraging a deeper look into the use of our safety event reporting system. This low rate of feedback is concerning because residents appear to be trying to engage in the safety reporting system, but the lack of feedback may discourage their engagement in safety event reporting. Therefore, the objectives of this study were first to

Population Health Research Capsule

What do we already know about this issue?
Academic EDs are tasked with educating residents while still providing high quality care. When errors occur, residents often do not receive adequate feedback.

What was the research question?
How can patient safety event reports identify opportunities for EM resident education and interventions?

What was the major finding of the study?
69% of event reports required educational intervention with 46% needing individual/group directed feedback.

How does this improve population health?
By using safety event reports to inform and educate, residents can know how to help correct identified system errors to prevent further unsafe events.

analyze patient safety reporting and, second, determine the urgency and opportunity for resident learning and education from the event report.

METHODS

Setting

The included patient safety event reports for this study are from an inner city ED from the Virginia Commonwealth University Health System with approximately 100,000 visits annually. All providers and staff are encouraged to enter patient safety net reports (PSN) into an online system. Residents are encouraged to submit one to two PSNs a year. The standard process is that PSNs are reviewed and addressed by the ED quality and safety leadership team, which includes an attending physician, the nursing director, and a registered nurse.

Coding

To meet the first objective of understanding and categorizing the types of PSNs, the team determined categories for the PSNs based on the literature and the expertise of the research group (Table 1). Then three team members, subject matter experts who routinely review and address PSNs (i.e., attending physician, nursing director, and registered nurse), categorized 20 PSNs together and resolved any issues or gaps identified in the coding schemas. They then coded 100 safety reports individually to determine the level of

Table 1. Categorizing patient safety notes as part of process to determine how best to address concerns.

Category	Labels	Frequency (%)
Harm score	Unsafe condition	65 (13%)
	Near miss	97 (19%)
	No harm evident, physical or otherwise	126 (25%)
	Emotional distress or inconvenience	110 (21%)
	Additional treatment	92 (18%)
	Temporary harm	17 (3%)
	Permanent harm	4 (1%)
	Severe permanent harm	0 (0%)
	Death	2 (<1%)
Actionable	Critical action	10 (2%)
	Actionable	400 (78%)
	Not actionable	103 (20%)
Addressed in the moment	Yes	405 (79%)
	No	91 (18%)
	Unknown	17 (3%)
Target of safety report	Communication	62 (14%)
	Employee behavior	21 (5%)
	Environment	28 (6%)
	Equipment	65 (15%)
	Issue related to patient assessment	19 (4%)
	Issues related to resident and staff training	114 (26%)
	Lack or misinterpretation of info	32 (7%)
	Nursing documentation	8 (2%)
	Patient or family behavior	24 (5%)
	Policies and procedures	49 (11%)
	Safety and security	11 (2%)
	Supplies	8 (2%)
	Type of education	No education required
Directed feedback		235 (46%)
Quarterly/monthly update		100 (20%)
Urgent communication		15 (3%)
Provider simulation		2 (<1%)

inter-rater reliability using kappa, which indicated high levels of agreement (0.92). The high inter-rater reliability indicated that they could reliably code the remaining 400 safety reports with a single coder.

The PSNs were coded in multiple categories (Table 1). We looked specifically at the types of events and how they

should be addressed through resident and staff education. The types of education were coded to identify how best to respond to safety event reports such that the residents would benefit from their submission and resolution. The events that could result from safety event reporting were categorized into the following five levels: 0 – no education; 1 – directed feedback

to individual/group; 2 – quarterly/monthly educational update; 3 – urgent communication (e.g., email within one week; discussion at resident conference, daily huddles, or morbidity and mortality presentation [M&M]); and 4 – provider simulation.

The criticality of the event was determined by the ED quality and safety leadership team. If the event was immediately life threatening, it was deemed of critical importance. If the report focused on something that needed to be addressed but was not of immediate importance, it was categorized as an actionable event that allowed time to research the most effective way to address the event. To code whether the events in the PSNs were addressed in the moment, the coders reviewed the event description provided in the submission. If the event description included details of the event having been addressed at the time of the occurrence, then it was coded as having been addressed, whereas if the description was clearly indicating the event was not addressed, it was coded as such. Those PSNs that did not provide sufficient detail were coded as being unknown whether it was addressed at the time of the event.

RESULTS

From January 1, 2019, to May 31, 2019, 513 PSNs were submitted for the ED. Of these, 4.5% (23) caused harm including two deaths. (It was not clear whether the patients died directly from the event.) An additional 18% (92) of patients required additional treatment related to the event, 21% (108) reached the patient in some way (e.g., inconvenience, inefficiency, redundant tests), and the remaining 56% (288 patients) were near misses – unsafe events that resulted in no harm to patients.

All PSNs were also categorized by the type of action that should be taken in response to the reported safety event. Of the 513 PSNs, 2% (10) required a critical review or action, which includes the ED quality committee (i.e., an attending physician, the nursing director, and a registered nurse) reviewing the event, conducting a root cause analysis, and addressing the systems issues (e.g., communication and team breakdown; failure to rescue or escalate; vulnerabilities within the informatics system; etc); 78% (400) were actionable but did not require critical action (e.g., direct communication to residents or group communication about systems or equipment); and 20% (103) were not actionable (i.e., based on the PSN, no further action was required). The majority of the PSNs (79%, 405 events) were addressed in the moment when the event happened compared to 3% (17) in which the reporter or team did not address the issue at the time. However, 19% (17) of PSNs contained insufficient information as to whether the event was addressed in the moment and were coded as “unknown.”

There were many different foci for the PSNs (Table 2), including some submissions that had multiple foci (e.g., employee behaviors, patient assessment issue, a policy/

procedure issue, and nursing documentation issue). However, the most common events were issues related to staff and resident training (25%, 129); communication (18%, 93); and equipment (14%, 71). The PSNs were then categorized to what type of action should be taken based on the event.

Approach to Safety Event Education

The type of educational intervention that should have been used was determined within the department based upon the type and severity of event. These interventions could be provided through the traditional venues for communication built into residency programs, such as M&Ms, conferences, and mentoring relationships for one-on-one developmental feedback. The relevance of the safety events to residents was determined by whether a resident was directly engaged in the event if known and the potential value to residents' long-term capabilities if education related to the event were provided. This value was determined by the ED quality and safety leadership team review in collaboration with the ED residency leadership team to determine what appropriate educational opportunities related to the safety event reports would be.

About one third (31%) of PSNs required no educational intervention. Nearly half of the PSNs (46%, 235) were educational level 1 that would require directed educational feedback to an individual or group. Examples include a need to escalate to the attending for consult or admissions with a dialysis patient requiring bilevel positive airway pressure; delayed acceptance to the intensive care unit (ICU); and a delayed ultrasound to rule out deep vein thrombosis to be performed before transfer to an inpatient bed but there was no technician to perform inpatient studies overnight. As a result, educational feedback could be given to ED residents for alternative methods of dealing with similar situations, including escalation procedures when dealing with an interprofessional care team.

Twenty percent (100) of the PSNs were classified as level 2, indicating that education should be carried out through monthly safety updates or at faculty/resident meeting. Examples included the following: a long length of stay in the ED with patient decompensation that required escalation of care; a patient with a dangerous level of hyperkalemia and severe hyperglycemia who received calcium, bicarbonate, and albuterol but did not have an insulin drip started before transferring to the ICU; and a pediatric emergency physician-ordered medication based on the body mass index instead of the patient's weight, resulting in improper dosage. Level 2 PSNs should result in a review of the incidents and the situational factors contributing to the events during monthly faculty and resident meeting and inclusion in safety updates.

Three percent (15) of PSNs were classified as a level 3, requiring urgent communication by email or in person at a meeting such as at a weekly resident conference. Examples of level 3 education included incorrectly discharging a cancer patient with hypercalcemia who required admission;

Table 2. Patient safety note (PSN) issues.

PSN Issue	% (N)	Example
Issues related to resident and staff training	25% (129)	Sharps left at bedside after a procedure
Communication	18% (93)	Consultant recommendation delay
Equipment	14% (71)	Limited accessibility to end tidal CO ₂ in all rooms of ED
Policies and procedures	13% (69)	Provider questioning the process that led to a patient with a positive pregnancy test having imaging done
Lack or misinterpretation of info	9% (44)	Patient arrived after treatment from an outside area on antibiotics that were not effective for the infection he had
Employee behavior	9% (47)	Provider noted to enter a droplet isolation room without proper PPE
Issue related to patient assessment	7% (34)	Patient treated for gout and was later found to have osteomyelitis
Environment	6% (43)	Bedbug found in a patient care location
Patient or family behavior	5% (27)	Patient elopement
Safety and security	4% (21)	Assault by patient with security and police response
Documentation	3% (15)	Assessment found in wrong patient's chart
Supplies	2% (9)	Myelogram kit was supplied in place of standard lumbar puncture kit and this had three specimen vials instead of the expected four

66 PSNs noted multiple issues: 2 with four issues, 11 with three issues, and 55 with two issues.

ED, emergency department, CO₂, carbon dioxide; PPE, personal protective equipment.

inadequate antibiotic administration for aspiration pneumonia; and a misdiagnosis of gout, requiring subsequent admission for foot cellulitis that required surgical debridement. These events should result in immediate communication with the involved parties as well as an in-person debriefing to go over the specifics of the event.

Only three (<1%) reports (two of these reported the same event) were classified at the highest level 4 requiring simulation for providers. One was a pediatric death after ED discharge with a missed diagnosis, and the other was a retained guidewire during femoral central line placement. These could result in simulations related to the missed diagnosis or multiple practices placing central lines to ensure guidewires are removed. The remaining 30% of PSNs were determined to require no educational action.

DISCUSSION

Twenty years have passed since the publication of *To Err is Human: Building a Safer Health System*, and while gains have been made, extensive work remains to be done. For instance, the ACGME has begun to require that programs include quality and safety training as part of resident education, stating: "Residents must demonstrate the ability to analyze the care they provide, understand their roles within health care teams, and play an active role in system improvement processes... to critique their future unsupervised practice and effect quality improvement measures."¹³ To effectively provide feedback for PSNs, a method or algorithm must be developed so that every PSN submitted receives a meaningful response. Based upon our data and analyses, one

method may be analyzing and categorizing the event type in the report and distinguishing the level of education required. Afterward, to ensure closed-loop communication regarding the submitted report, emails would be sent to the submitter (if identified) and those involved in the event (if any indicated) to inform them of the action plan and resolution of the report.

Our study identified categories that allow for key personnel and departments to easily track events, including the degree of harm and their frequency. This allows the quality team to more efficiently target those events that result in the most harm and for consideration of events that have lower level of harm potential but still occur more frequently. For instance, these may be events that are waiting for the right time to trigger a more significant event or they may be simple irritants that create sustained frustration. Identification of these types of events can be intriguing points of discussion for residents and provides them the opportunities to practice functional problem-solving skills with these smaller but frequent events prior to involvement in other more systemic and severe issues. Although it was not possible to determine which reports involved or were submitted by residents specifically, each provides an opportunity to impact resident education and the quality of care they provide.

Once safety events have been categorized and prioritized, it is much more feasible to consider the event's specifics to determine the next steps to educate, improve, and prevent reoccurrence. However, depending on the event, it may only require direct communication and feedback to the individuals involved. Alternatively, review of the events in resident didactics, monthly safety newsletters, or simulations would

be the preferred educational modality for more generalizable events and to provide education related to the event to all residents. Furthermore, incorporating feedback at an individual and resident level reinforces to the residents and other members of the department that submitted reports are taken seriously and are valued by the department. This may also encourage further participation in event reporting and, potentially, in quality improvement efforts (e.g., developing action plans or simulations around existing concerns). The inclusion of residents in department quality and safety committees provides residents with useful, lifelong skills, making such an experience invaluable.

LIMITATIONS

There are several limitations to the results of this study. First, this was a single-institution, retrospective study, and the categories of safety events may need to be broadened or altered for other organizations and for prospective research efforts. Further, the safety event reporting system is for all members of the health system and does not require the submitters to include their role in order to encourage reporting and ensure confidentiality should there be any concerns of potential repercussions. Additionally, this reporting system does not allow an automatic pull of the role of the person that submitted the report, and this would have required each report to be opened manually to get this information. Thus, the events placed into this system include events beyond those submitted only by residents. This may have resulted in some events that had less specific relevance to resident concerns; however, those reports more focused on systems-issues still benefit residents as they should have the opportunity to learn how best to deal with those situations while still in an educational setting.

CONCLUSION

Through systematic analysis and categorization of safety event reports, this study showed that these events can be used to develop specific learning tools. However, naturally, there are barriers to this process. Providing education and feedback to residents and other providers requires a great deal of time and manpower. Additionally, flaws within reporting systems themselves will continue to be discovered and require potential redesigns of the system overall or smaller changes intermittently. This necessitates supportive communication and a good working relationship between the department and health system. Regardless, the end result is worth the effort to implement this resident education-based system, given that “feedback and experiential learning are essential to developing true competence in the ability to identify causes and institute sustainable systems-based changes to ameliorate patient safety vulnerabilities.”¹³

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Emergency Department-based Hepatitis A Vaccination Program in Response to an Outbreak

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Introduction: The Philadelphia Department of Public Health (PDPH) declared a public health emergency due to hepatitis A in August 2019.¹ Our emergency department (ED) serves a population with many of the identified risk factors for hepatitis A transmission. This study examines the impact of an ED-based hepatitis A vaccination program, developed in partnership with the PDPH, on incidence of hepatitis A infection and hospital admission.

Methods: We conducted a retrospective review of all ED visits in the 12-week period centered around the implementation of the ED-based hepatitis A vaccination program. All adult patients presenting to the ED were offered vaccination, with vaccines supplied free of charge by the PDPH. We compared the incidence of diagnosis and of hospital admission for treatment of hepatitis A before and after implementation of the program.

Results: There were 10,033 total ED visits during the study period, with 5009 of them prior to the implementation of the vaccination program and 5024 after implementation. During the study period, 669 vaccines were administered. Before the vaccination program began, 73 patients were diagnosed with hepatitis A, of whom 67 were admitted. After implementation of the program, 38 patients were diagnosed with hepatitis A, of whom 31 were admitted.

Conclusion: A partnership between an ED and the local public health department resulted in the vaccination of 669 patients in six weeks in the midst of an outbreak of a vaccine-preventable illness, with a corresponding drop in ED visits and hospital admission for acute hepatitis A. [West J Emerg Med. 2020;21(4):905-907.]

INTRODUCTION

In August 2019, the Philadelphia Department of Public Health (PDPH) declared hepatitis A a public health emergency. At that time, 154 cases had been identified, compared to fewer than 10 cases reported annually in prior years.¹

Populations at risk of acquiring hepatitis A include people experiencing homelessness, people who use drugs, men who have sex with men, and individuals recently incarcerated.¹ The homelessness crisis in many major United States cities has previously been identified as a contributing factor in the

increasing numbers of outbreaks of infectious diseases such as hepatitis A.² Prior data from a similar outbreak in San Diego in 2018 demonstrated that 64.7% of patients infected with hepatitis A were homeless and 39.8% reported drug use.³

The emergency department (ED) where the intervention took place is located within the section of Philadelphia where many hepatitis A cases were being reported, and also serves the identified high-risk populations. The population includes a high volume of patients with substance use disorder, with the highest frequency of naloxone administration compared to other larger EDs in the city.⁴

Coordination between the PDPH, ED leadership, physicians and nursing, and pharmacists was required to develop the program. It took approximately one month from initial contact between the ED and PDPH until program go-live. Vaccines were supplied by the health department and stored in refrigeration units in both the hospital pharmacy and ED. All adult patients were asked by nursing during triage if they would like to be vaccinated for hepatitis A during their visit, given the local outbreak. Risks and benefits of the vaccine were reviewed at that time.

If patients consented to the vaccination, a best practice advisory (BPA) that contained the order for the health department-supplied vaccine was created in the patient's chart and would automatically fire once the chart was accessed by a provider. The provider then ordered the vaccine to be administered free of charge. A recent study from the 2018 San Diego outbreak showed that utilization of a BPA within the electronic health record (EHR) helped identify high-risk patients and remind providers of vaccine availability, leading to an overall 77% vaccination rate of their target population.⁵

The Centers for Disease Control and Prevention recommends administering two doses of the vaccine, six months apart. However, a single dosage is up to 98% effective at preventing transmission, which is optimal for patients without primary care physician follow-up who present to the ED.⁶ The emergency physicians and public health department decided together that due to the urgency of the outbreak, the vaccination program would focus solely on getting the first of the series to as many patients as possible. To avoid the administration of repeated doses to a single patient, the BPA would not fire for patients who had already received the vaccine within the health system. We sought to evaluate the ED-based vaccination program and its impact on public health. Specifically, we tracked vaccine offered and administered, as well as suspected cases of hepatitis A presenting to the ED and patients admitted to the hospital for hepatitis A both before and after the intervention.

METHODS

The vaccination program was implemented on August 27, 2019. A retrospective review of all visits to the ED spanning the vaccination program, from July 16–October 8, 2019, was conducted. ED visits were evaluated for ultimate diagnosis of hepatitis A and were compared before and after implementation of the vaccination program. The EHR was queried for the number of BPAs that fired once the vaccination program was implemented, as well as the number of vaccines administered.

RESULTS

There were 10,033 total visits to the ED during the study period. Of these, 5009 visits preceded the vaccination program, while 5024 followed. The BPA fired on a total of

1164 ED patients. A total of 669 hepatitis A vaccines were administered between August 27, 2019–October 8, 2019. Before the vaccination program began, 73 patients were diagnosed with hepatitis A in the ED, 67 of whom were admitted. After the vaccination program was initiated, 38 patients were found to have a diagnosis of hepatitis A, of whom 31 were admitted. Results are summarized in Table 1.

DISCUSSION

A recent hepatitis A outbreak in Philadelphia prompted a collaboration between the PDPH and our ED. The ED-based vaccination program was successful in vaccinating a large number of individuals in a short period of time. We observed a corresponding drop in both identified cases of hepatitis A and admissions for hepatitis A in the post-intervention period. The intervention demonstrated the importance of this collaboration in using the ED to improve population health.

We were fortunate to be able to partner with the PDPH, which supplied vaccines at no cost. The usual cost to our pharmacy of a hepatitis A vaccine is \$58.40 per dose. While we did not collect data on costs associated with ED visits or admissions for treatment of hepatitis A either before or after our intervention, we believe that the savings associated with a reduction in incidence of hepatitis A far outweighs the total cost of vaccine administration.

It is likely that some of the drop in hepatitis A cases was the result of outside efforts from PDPH and other local organizations to get patients vaccinated, education of the public, and sanitation efforts. Several stand-alone vaccination events were held at nearby locations such as a busy needle exchange program. We were, however, able to vaccinate a large number of patients over a short period in an underserved area. Previous ED-based, hepatitis A vaccination programs have been reported, but have vaccinated smaller numbers of patients. For instance, a 2007 program in Boston vaccinated 122 patients. They targeted their intervention on a narrower group of patients experiencing homelessness, using drugs, or recently incarcerated.⁷

The ED will continue to provide vaccine beyond the reported time frame, until the outbreak is sufficiently addressed or vaccine is no longer available. The model has been adapted and scaled up to provide vaccination at a second, larger site within the same health system that serves a similar vulnerable population. The model has also been shared with other local EDs that are interested in developing ED-based, hepatitis A vaccination programs. To date, three other urban EDs are using this model to create their own programs.

A relevant question with this type of public health initiative is when and how vaccination programs should be used in an emergency setting. In our case, the PDHD identified hepatitis A as a sufficient threat to declare a state of emergency in the city. Many of the populations at risk

Table 1. Analysis of emergency department (ED) visits, hepatitis A vaccines administered, diagnoses of, and admissions for, hepatitis A during the study period.

	Total ED Visits	Hepatitis A Vaccines Administered	Cases of Hepatitis A	Admissions for Hepatitis A n (% of cases)
Pre	5009	0	73	67 (91.8%)
Post	5024	669	38	31 (81.6%)

"Pre" includes data collected from July 16–August 26, 2019. "Post" includes data collected from the go-live date of August 27–October 8, 2019.

have limited access to primary care. It has been previously reported that up to 73% of people experiencing homelessness identify at least one unmet health need.⁸ To reach these vulnerable groups, an innovative approach is required. When a local public health crisis is identified that affects populations with poor access to care, the ED may be considered as a potential setting for intervention.

LIMITATIONS

Limitations of the study include the relatively small sample size as a result of intervention at a smaller site. While we saw a promising correlation between our intervention and a reduction in incidence of hepatitis A, we did not examine other parameters, such as effect on hospital admissions, changes in length of stay, or cost-effectiveness of a vaccination program. Our ED serves a large number of at-risk populations, including people experiencing homelessness and people with substance use disorder; the intervention may be less effective at sites with smaller proportions of these populations. We did not examine whether patients diagnosed with hepatitis A had previously received the hepatitis A vaccine, which may have confounded the effect of the intervention. We also were not able to estimate how much of the effect that we saw was secondary to outside public health efforts aimed at our patient population.

CONCLUSION

A collaboration between a local ED and the public health department resulted in the vaccination of 669 patients in six weeks, in the midst of the outbreak of a vaccine-preventable illness. Stakeholders in the project included the ED leadership, physicians, nurses, pharmacists, and public health officials. The ability of the health department to furnish the vaccine free of charge and the support of the various stakeholders allowed a large number of patients in a high-risk area to be vaccinated quickly. We observed a corresponding drop in ED visits and inpatient hospitalizations for hepatitis. This model of collaboration between the ED and public health officials can be adopted by other departments experiencing outbreaks of vaccine-preventable illnesses, particularly those that affect high-risk populations that frequently use EDs for their care.

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Fever Incidence Is Much Lower in the Morning than the Evening: Boston and US National Triage Data

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Introduction: In this observational study, we evaluated time-of-day variation in the incidence of fever that is seen at triage. The observed incidence of fever could change greatly over the day because body temperatures generally rise and fall in a daily cycle, yet fever is identified using a temperature threshold that is unchanging, such as $\geq 38.0^\circ$ Celsius (C) ($\geq 100.4^\circ$ Fahrenheit [F]).

Methods: We analyzed 93,225 triage temperature measurements from a Boston emergency department (ED) (2009-2012) and 264,617 triage temperature measurements from the National Hospital Ambulatory Medical Care Survey (NHAMCS, 2002-2010), making this the largest study of body temperature since the mid-1800s. Boston data were investigated exploratorily, while NHAMCS was used to corroborate Boston findings and check whether they generalized. NHAMCS results are nationally representative of United States EDs. Analyses focused on adults.

Results: In the Boston ED, the proportion of patients with triage temperatures in the fever range ($\geq 38.0^\circ$ C, $\geq 100.4^\circ$ F) increased 2.5-fold from morning to evening (7:00-8:59 PM vs 7:00-8:59 AM: risk ratio [RR] 2.5, 95% confidence interval [CI], 2.0-3.3). Similar time-of-day changes were observed when investigating alternative definitions of fever: temperatures $\geq 39.0^\circ$ C ($\geq 102.2^\circ$ F) and $\geq 40.0^\circ$ C ($\geq 104.0^\circ$ F) increased 2.4- and 3.6-fold from morning to evening (7:00-8:59 PM vs 7:00-8:59 AM: RRs [95% CIs] 2.4 [1.5-4.3] and 3.6 [1.5-17.7], respectively). Analyses of adult NHAMCS patients provided confirmation, showing mostly similar increases for the same fever definitions and times of day (RRs [95% CIs] 1.8 [1.6-2.1], 1.9 [1.4-2.5], and 2.8 [0.8-9.3], respectively), including after adjusting for 12 potential confounders using multivariable regression (adjusted RRs [95% CIs] 1.8 [1.5-2.1], 1.8 [1.3-2.4], and 2.7 [0.8-9.2], respectively), in age-group analyses (18-64 vs 65+ years), and in several sensitivity analyses. The patterns observed for fever mirror the circadian rhythm of body temperature, which reaches its highest and lowest points at similar times.

Conclusion: Fever incidence is lower at morning triages than at evening triages. High fevers are especially rare at morning triage and may warrant special consideration for this reason. Studies should examine whether fever-causing diseases are missed or underappreciated during mornings, especially for sepsis cases and during screenings for infectious disease outbreaks. The daily cycling of fever incidence may result from the circadian rhythm. [West J Emerg Med. 2020;21(4)908-916.]

INTRODUCTION

As part of the circadian rhythm, body temperature generally rises and falls in a daily cycle, reaching its lowest values in the morning and its highest values in the afternoon and evening. The daily cycle of body temperature is a well-established aspect of human physiology that has links to the body's clock, sleep patterns, metabolism, and other bodily functions.¹ It is observed in both health and disease, although its form is modified by some diseases.^{2,3} For example, febrile diseases often produce exaggerated versions of the daily cycle of body temperature, in which normal or somewhat elevated temperatures occur in the morning and especially heightened temperatures occur in the afternoon and evening. Although other patterns of body temperature are also observed in febrile disease, this is the most common pattern.^{2,4}

Despite the daily cycle of body temperature, fever is identified using a constant temperature threshold, such as $\geq 38.0^{\circ}$ Celsius (C) ($\geq 100.4^{\circ}$ Fahrenheit [F]). It has been suggested that using a constant threshold to identify fever could lead to misdiagnosis because of the daily cycling of body temperature.⁵⁻⁸ In particular, fever-causing illnesses might be missed or underestimated in patients who present during the morning, since body temperature is usually lowest at that time.⁵⁻⁹ Additionally, fever false-positives could occur during the late afternoon and evening, when nonfebrile individuals generally have their highest body temperatures.^{1,5,6}

The idea that common definitions of fever are inconsistent with the cycle of body temperature was discussed almost 150 years ago by one of the founders of medical thermometry, Carl Wunderlich.⁶ Since then, studies have found that in-patients at high risk of fever are least likely to reach the fever range in the morning,^{7,8,10} that healthy temperature percentiles are lowest in the morning,⁵ and that use of endotoxin to induce fever in healthy men produces lower temperature rises during mornings than evenings.¹¹ Although these studies contribute useful evidence, they were limited to select patient groups¹⁰ and unusual experimental settings,¹¹ or simply included too few febrile patients ($n < 40$)^{7,8} to determine whether the time-of-day changes in fever incidence were small or large. Consequently, it is still unclear whether the daily cycles of fever incidence are common and large enough to be clinically relevant—or whether they are specific to nongeneralizable settings, or are simply too small to be of any practical relevance at all.

Here, our primary aim was to estimate the time-of-day variations in the incidence of fever that is observed at emergency department (ED) triage, including nationally generalizable results. Additionally, we performed several secondary analyses to examine the relationship between fever incidence and the circadian rhythm, including multivariable regression analyses that were used to adjust for potential confounders, evaluations of diurnal changes in temperature means and standard deviations that were used to relate the incidence of fever to more typical body temperatures, comparisons of younger and older adults that were used to examine age-associated body temperature changes

Population Health Research Capsule

What do we already know about this issue?

Fever is identified with a fixed cutoff, such as $\geq 38.0^{\circ}$ Celsius ($\geq 100.4^{\circ}$ Fahrenheit), yet body temperature usually changes from a morning low to an evening high.

What was the research question?

How does the observed incidence of fever change over the day? Could morning cases be missed by the cutoff?

What was the major finding of the study?

Fever-range temperatures were observed about half as often during mornings as during evenings at adult triages.

How does this improve population health?

Fever cutoffs may often miss fever-causing diseases in the morning. This should be considered in morning case management and during infectious disease screens.

(such as the “older is colder” phenomenon),^{12,13} and comparisons of weekdays and weekends that were used to check for the effects of weekly schedules.

METHODS

Study Planning

This observational study used data from two sources: a Boston ED and a nationally representative survey of United States (US) EDs.^{14,15} The Boston data were initially collected to assess fever incidence as a means of tracking disease outbreaks (syndromic surveillance).¹⁶ We also observed that mean body temperature followed a consistent diurnal cycle across days of the week and seasons of the year in the Boston ED.¹⁷ These results suggested that it would be useful to study how body temperature cycles relate to fever presentation. However, except for Wunderlich's research from the 1800s,⁶ little evidence was available to prepare specific research hypotheses. Therefore, we analyzed the Boston data exploratorily. Having done so, we used the national data to determine whether Boston results could be corroborated in an independent dataset, and to examine whether they generalized.

Settings and Participants

The Boston study was conducted at the ED of Beth Israel Deaconess Medical Center (Boston, MA) from September 2009–March 2012. During this period, 115,149 temperatures were

collected with data-logging thermometer systems during initial triage vital signs assessments. The national data were collected as part of the National Hospital Ambulatory Medical Care Surveys (NHAMCS) of the US Centers for Disease Control and Prevention. NHAMCS includes a nationally representative, multi-stage probability sample survey of ED visits. Each institution participating in NHAMCS was required to supply case records (including temperature) for every n -th ED visit after a random start. We analyzed ED visits from the 2003–2010 NHAMCS surveys, which included visits from December 2002–December 2010.^{14,15} During this period, 285,798 ED visits were reported to NHAMCS by participating institutions.

Although the Boston dataset mainly includes adults, the national dataset includes many children and infants (demographics: Appendix 1). For better comparability between the datasets, we only included adults (age ≥ 18 , $n = 218,574$) when analyzing national data in the main paper and most appendices (Appendices 2–5). However, results for younger ages are given in Appendices 6–7.

Measurements

In the Boston ED, temperatures and measurement times were collected with temporal artery thermometers attached to automatic data-loggers (TAT-5000 model thermometers; Exergen Corporation, Watertown, MA). During the study, 1–4 such thermometers were generally in use. Temperatures were not recorded for all patients, for example, because some simply did not have their temperatures taken. For the national data, the thermometry method was left to the discretion of clinicians and EDs, and is nationally representative of the thermometry methods used at US triages. Temperature measurements were recorded manually on NHAMCS forms.

Common thermometer modalities in EDs include temporal artery, tympanic membrane, oral, rectal, and axillary. There are no strict rules to compare the temperatures taken at these different sites, since each is affected by its own individual benefits and weaknesses of physiology and measurement ease.¹⁸ Loosely speaking, however, temporal, tympanic, and oral temperatures are often similar, while rectal temperatures are often higher and closer to core temperatures, and axillary temperatures are often the lowest and least similar to core temperatures.^{18,19}

Variables

In the Boston study, body temperature was not linked to other hospital records. This was required to preserve patient anonymity, and prevented analysis of potential confounders and age-specific analyses for the Boston data. In the national study, NHAMCS forms included many variables, allowing us to apply multivariable regression to control for 12 potential confounders: gender; age; immediacy to be seen after triage; pain level at triage presentation; race; Hispanic or Latino ancestry; hospital admission; diagnostic or screening services ordered or provided during visit; procedures provided during

visit; medications ordered or provided during visit; arrival by ambulance; and expected source of payment (Appendix 2). The purpose of the multivariable regression was to control (account) for changes in the composition of patients who showed up to the ED across the day.

Definitions

Body temperatures were classified as fever-range vs non-fever range. Various definitions of fever-range temperature are used in practice. To address this, we analyzed several definitions: $\geq 37.5^{\circ}\text{C}$ ($\geq 99.5^{\circ}\text{F}$), $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$), $\geq 39.0^{\circ}\text{C}$ ($\geq 102.2^{\circ}\text{F}$), and $\geq 40.0^{\circ}\text{C}$ ($\geq 104.0^{\circ}\text{F}$). For the purposes of our study, these categories were termed sub-fever, fever, high fever, and very high fever, respectively. The values were selected from fever thresholds and upper limits of normal appearing in *Rosen's Emergency Medicine*,²⁰ *Tintinalli's Emergency Medicine*,²¹ and *Harrison's Principles of Internal Medicine*.²²

Data Quality

As a byproduct of automatic data recording, Boston data included accidental measurements taken when thermometers were pointed at floors, walls, and elsewhere, as well as repeated measurements of the same patients. To filter these out we excluded (a) temperatures $< 35.0^{\circ}\text{C}$ ($< 95.0^{\circ}\text{F}$) ($n = 13,137$; 11.4%) because human temperatures are rarely $< 35.0^{\circ}\text{C}$ ($< 95.0^{\circ}\text{F}$), and (b) all but the last of any string of temperatures logged by a single thermometer less than 15 seconds apart ($n = 15,983$; 13.9%). The distribution of intermeasurement times suggested these strings of rapid measurements were likely repeated measurements of the same patient. Further, we excluded records affected by file corruption and other digital collection errors ($n = 1166$; 1.0%). The remaining 93,225 (81.0%) were analyzed.

The national data have the advantage of not including accidental or repeated measurements, since one temperature was recorded per patient manually. However, manual recording led to several disadvantages: First, values clustered at round numbers (e.g., 98.0°F and 102.0°F), suggesting errors in recall and record abstraction (a recognized limitation to NHAMCS^{14,23,24}). Second, measurement times were not recorded. We used patient arrival times as a substitute for our analyses. Third, some visit records lacked temperatures ($n = 19,057$; 6.7%) or arrival times ($n = 3360$; 1.2%). These were excluded, leaving 264,617 (92.6%) for analysis. Fourth, thermometer type was not recorded.

Although each data source has limitations, their limitations are different. Despite having different limitations, they both showed the same main findings, supporting the validity of these findings.

Main Analyses

For both datasets, we analyzed time, body temperature, and body temperature classified as fever range vs non-fever range. Additionally, we analyzed age groups (18–64 and 65+ years) in the national data.

Sensitivity Analyses

Sensitivity analyses appear in Appendix 3. To confirm that the temperature exclusion criteria were reasonable for the Boston data, we checked that results were unchanged when using other intermeasurement times (5, 30, and 60 sec). We also confirmed that temperatures $<35.0^{\circ}\text{F}$ ($<95.0^{\circ}\text{C}$) were rare enough in national data (0.3% of temperatures) for their exclusion to be reasonable in the Boston data. Further, to confirm that using arrival times as measurement times was reasonable for the national data, we checked that results were largely unchanged when using times patients were seen instead.

We also investigated the sensitivity of results to differences between weekdays and weekends, autocorrelation in temperature measurements, and differences in the numbers of patients presenting across the day. Principal findings were not changed in any case. Finally, to confirm our results were not attributable to use of temporal artery thermometry, we checked they were similar in national data from 2002-2004, when temporal artery thermometry was rare in EDs.

Other Analyses

We analyzed national results for pediatric patients (Appendix 6) and infants (Appendix 7). We also evaluated a method proposed by Mackowiak et al to correct the fever threshold for the circadian cycle (Appendix 8).⁵

Statistical Methods

We analyzed temperature means, temperature standard deviations, and proportions of temperatures in the fever range by time of day. Cases with missing temperature or time were excluded (see *Data Quality* section). For the Boston data, we obtained 95% confidence intervals (CIs) from exact binomial tests or bootstrapping. For the national data, we used different methods because it was necessary to account statistically for the multistage survey design of NHAMCS, as recommended by NHAMCS guidelines.^{14,15} Using the R “survey” package,^{25,26} we obtained point estimates and 95% CIs from the incomplete beta function for proportions and maximum pseudolikelihood estimation of normal distribution fits for means and standard deviations. For both Boston and national data, smooths of trends in means and standard deviations were obtained using moving averages with approximate inverse-variance weighting.

In national analyses, we also applied multivariable logistic regression to account for the effects on the observed fever incidence of differences in the composition of patients who are triaged at different times of day (Appendix 2). In more technical detail, to allow time-of-day comparisons of the observed incidence of fever while controlling for time-of-day differences in the distributions of 12 patient characteristics, we fit multivariable regressions with the observed incidence of fever as the dependent variable and the 12 patient characteristics as independent variables; we then obtained average marginal predictions by time of day using the approach described by Bieler et al,²⁷ as applied in the “survey” package^{25,26} using the quasibinomial family. For

our age group comparisons, this procedure was modified by removing the controlling for age, but continuing to obtain average marginal predictions over the entire analyzed cohort for other characteristics (i.e., over all ages combined).

RESULTS

General Characteristics

Of 115,149 records from the Boston ED, 21,924 (19.0%) were filtered out as described in the methods. We analyzed the remaining 93,225 (81.0%). Of 285,798 records from the nationally representative survey of EDs, 21,181 (7.4%) were excluded due to missing temperature or time values. The remaining 264,617 (93.6%) were analyzed. For the national data, results in the main text and figures are reported for adults only (ages ≥ 18 , $n = 202,181$), and results for pediatric and infant patients are given in Appendices 6 and 7. Median age was 49 years (interquartile range, 32-66) in the Boston ED and 43 years (interquartile range, 29-59) for adults in the national EDs. Mean body temperature was 36.7°C (98.1°F) in both data sources (95% CI, 36.7 - 36.7°C , 98.1 - 98.1°F for both). Patient demographics are summarized in Appendix 1, and temperature distributions are summarized in Appendix 4.

Fever Incidence Changes Over the Day

Figure 1 shows how the observed incidence of fever changed over the day. In practice, $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$) may be the most common cut-off used in definitions of fever. Overall, 2.9% of triage temperatures (1 in 35) were in this range at the Boston ED. The percentage of triage temperatures in this range was about 2.5 times higher in the evening as in the morning (7:00-8:59 PM vs 7:00-8:59 AM: 4.1% vs 1.6%; risk ratio [RR] 2.5, 95% CI, 2.0-3.3). Similarly large variations were also seen for more extreme definitions of fever: temperatures $\geq 39.0^{\circ}\text{C}$ ($\geq 102.2^{\circ}\text{F}$) and $\geq 40.0^{\circ}\text{C}$ ($\geq 104.0^{\circ}\text{F}$) were respectively 2.4- and 3.6-times more common in the evening than in the morning (7:00-8:59 PM vs 7:00-8:59 AM: incidences = 0.95% vs. 0.39% and 0.30% vs. 0.08%, respectively; RRs [95% CIs] = 2.4 [1.5-4.3] and 3.6 [1.5-17.7], respectively). For all definitions, the times when fever-range temperatures were least and most common were similar to the times when the circadian cycle results in lowest and highest body temperatures.^{1,5}

The national data confirmed the presence of strong cyclic variation in the observed incidence of fever, including after using multivariable logistic regression to adjust for 12 potential confounders (Figure 1). For the same fever definitions and times of day mentioned above, the fever incidence observed in the morning and evening were 4.2% and 2.3%, 1.00% and 0.54%, and 0.11% and 0.04%, respectively, while the unadjusted RRs (95% CIs) were 1.8 (1.6-2.1), 1.9 (1.4-2.5), and 2.8 (0.8-9.3), respectively, and the adjusted RRs were 1.8 (1.5-2.1), 1.8 (1.3-2.4), and 2.7 (0.8-9.2), respectively. Overall, the fever incidence changed similarly over the day in the national and Boston data, but the morning decline in fever incidence was not as deep in the national data.

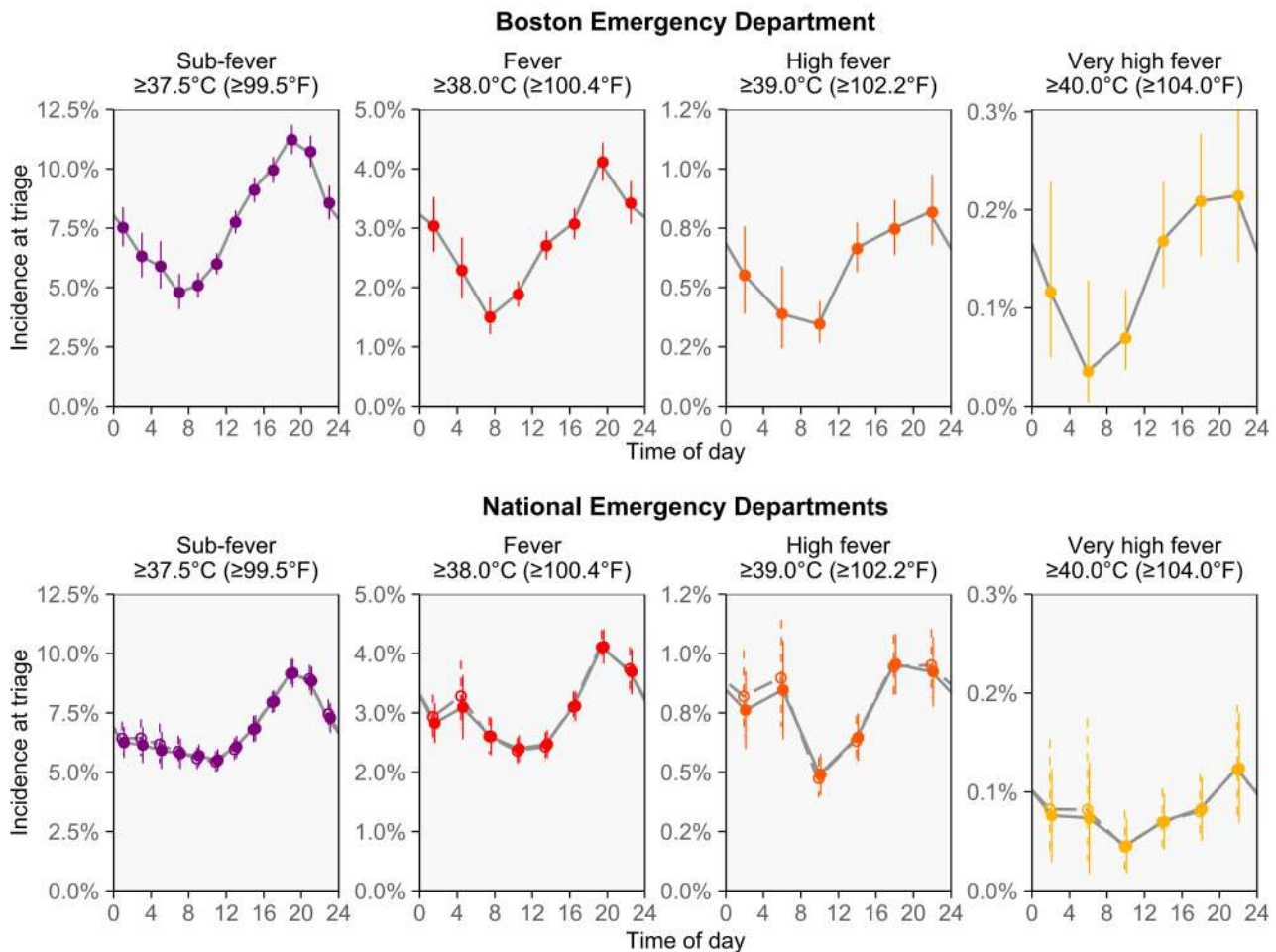


Figure 1. Cyclic changes in the incidence of fever observed across the day. For all investigated definitions of fever, lower fever incidence is observed at morning triages and higher fever incidence is observed at evening triages. The pattern of changing fever incidence resembles the circadian cycle of body temperature and may be caused by it. For the national analyses of US emergency departments, we used multivariable logistic regression to adjust for 12 potential confounders when estimating the incidence of fever observed at triage. Adjusting for the potential confounders led to almost no change in the results; thus, the unadjusted results (hollow points with dashed lines) and adjusted results (solid points with solid lines) often overlap. All confidence intervals are 95%.

Relationship Between Fever Incidence and the Daily Cycle of Mean Body Temperature

To help us understand why fever incidence changes so much over the day, we also analyzed diurnal variation in the mean and standard deviation of body temperature. Historically, it is not entirely clear how $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$) was established as a temperature range for fever. However, the mean plus 2 standard deviations is used as a cut-off to differentiate between normal and abnormal values in many scientific settings, and this value was indeed 38.0°C (100.4°F) in the Boston ED (95% CI, $38.0\text{--}38.0^{\circ}\text{C}$, $100.3\text{--}100.4^{\circ}\text{F}$). It was similar in the national data, too (37.9°C , 100.3°F).

Analysis of both datasets showed that the mean plus 2 standard deviations followed a substantially larger daily cycle than the mean temperature itself (Figure 2, Appendix 5). These findings may help to explain why the time-of-day variations in triage fever incidence (Figure 1) are unexpectedly large: Because

daily, cyclic variations are larger for unusually high temperatures than for mean temperatures, the proportion of patients who meet the definition of fever also varies more than would be anticipated based on experience with commonplace temperatures.

Fever Incidence and Body Temperature in Younger vs Older Adults

To examine how fever incidence was affected by age-associated body temperature changes, we performed comparative analyses of younger adults (ages 18–64, $n = 163,478$) and older adults (ages 65+, $n = 38,703$).

As shown in Figure 3A, overall fever incidence was higher in older than younger adults (difference: 1.3 percentage points, 95% CI, 1.0–1.5; ages 18–64, 2.8%; ages 65+, 4.1%), but differences largely disappeared after adjustment for potential confounders (adjusted difference: 0.3 percentage points, 95% CI, 0.0–0.7), which included characteristics related to case severity and use of

diagnostic testing (Appendix 2). Fever incidence followed a large daily cycle in both age groups, although older adults appeared to have heightened fever incidence after midnight.

As shown in Figure 3B, mean body temperature was slightly lower in older than younger adults, (difference: 0.1°C [0.1°F], 95% CI $0.1\text{-}0.1^{\circ}\text{C}$ [$0.1\text{-}0.2^{\circ}\text{F}$]; ages 18-64, 36.7°C [98.1°C]; ages 65+, 36.6°C [98.0°C]), a difference that persisted after confounder adjustment (adjusted difference: 0.1°C [0.1°F], 95% CI, $0.0\text{-}0.1^{\circ}\text{C}$ [$0.1\text{-}0.2^{\circ}\text{F}$]). Older adults also had a slightly smaller diurnal cycle of mean body temperature, but temperatures that were multiple standard deviations above the mean followed large diurnal cycles in both age groups.

Other Analyses

Analyses of pediatric patients showed much higher incidence of fever overall, as well as a different pattern of diurnal temperature variation that reached its minimum at around 8:00-

10: AM and its maximum after midnight (Appendix 6). Analyses of infants were consistent with an increasing circadian cycle of body temperature during early weeks of life, which matches previous studies^{28,29} (Appendix 7).

Appendix 8 investigates a proposal⁵ that recommended correcting for the circadian cycle by changing fever thresholds to $>37.2^{\circ}\text{C}$ ($>98.9^{\circ}\text{F}$) and $>37.7^{\circ}\text{C}$ ($>99.9^{\circ}\text{F}$) for oral temperatures taken during mornings and evenings, respectively. In comparison with the common $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$) fever threshold, the proposal classified more than twice as many patients as having fever (Boston data: 7.4% vs 2.9%; national data: 6.7% vs 3.0%). Additionally, the proposal appeared to overcorrect substantially for the circadian cycle, producing a reversed pattern of much higher incidence of fever during mornings than evenings.

DISCUSSION

This study establishes that there are large daily cycles in the incidence of fever-range temperatures seen at adult triage. The cycles were observed in a Boston ED and confirmed using a large, nationally representative sample of US EDs. The cycles remained after using multivariable regression to control for 12 potential confounders, and they also continued to be observed in age group comparisons and sensitivity analyses.

In the daily cycles, fever-range temperatures were generally least common at morning triages and most common at triages in the late afternoon and evening. This pattern parallels the usual pattern of diurnal variation of body temperature.^{1,4-6} Moreover, it is consistent with the longstanding hypothesis that the fixed temperature thresholds for fever are incompatible with the diurnal variation of body temperature, and that the incompatibility causes the detection of fever-causing disease to be artificially diminished in the morning and artificially inflated in the late afternoon and evening.⁵⁻⁹ Our results provide support for this hypothesis from a real-world healthcare setting. Our results also add to the current understanding by showing that cycles in the observed incidence of fever are larger, and therefore more consequential, than would be anticipated from the diurnal variation of mean body temperature alone.

The large daily cycles in the observed incidence of fever raise the concern that cases of fever-causing disease could be missed or underappreciated in the morning, and that false-positive fevers may be diagnosed in the late afternoon and evening. In practice, then, it is best to evaluate body temperature together with other signs and symptoms of fever, which can include chills and shivering (especially at the start of fever) and sweating (especially at its end).^{9,30} The other signs and symptoms of fever may be especially important during mornings, since body temperatures are usually lower at this time and may fail to reach the temperature ranges that are used to identify fever, even when fever is physiologically present. Relatedly, patients who do have fever-range temperatures in the morning may be in worse-than-expected condition because the lower values of morning temperatures in health mean that larger temperature increases are needed to reach the fever range.

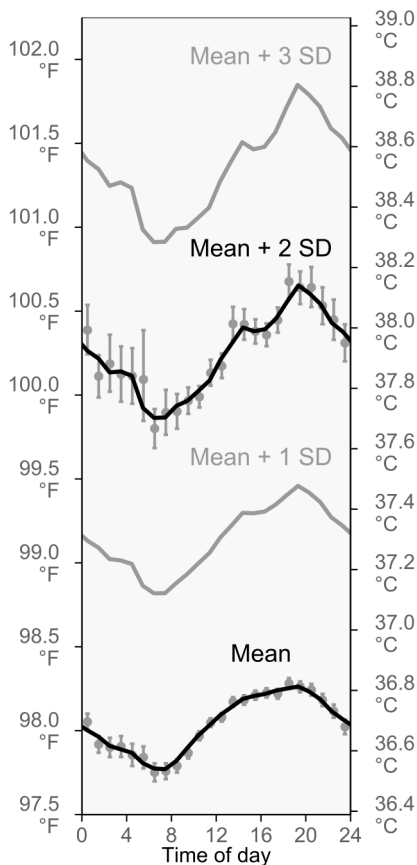


Figure 2. Daily cycles of the mean body temperature at triage, and the mean + 1, 2, and 3 standard deviations. The diurnal pattern of mean body temperature at triage resembles the well-known circadian rhythm of human body temperature. However, we observed that the amplitude of the cycle becomes larger for temperatures that are farther above the mean. Curves are 3-hour moving averages. Error bars are 95% confidence intervals. Results are shown for the Boston emergency department (ED). Similar results for the national EDs are in Appendix 5.

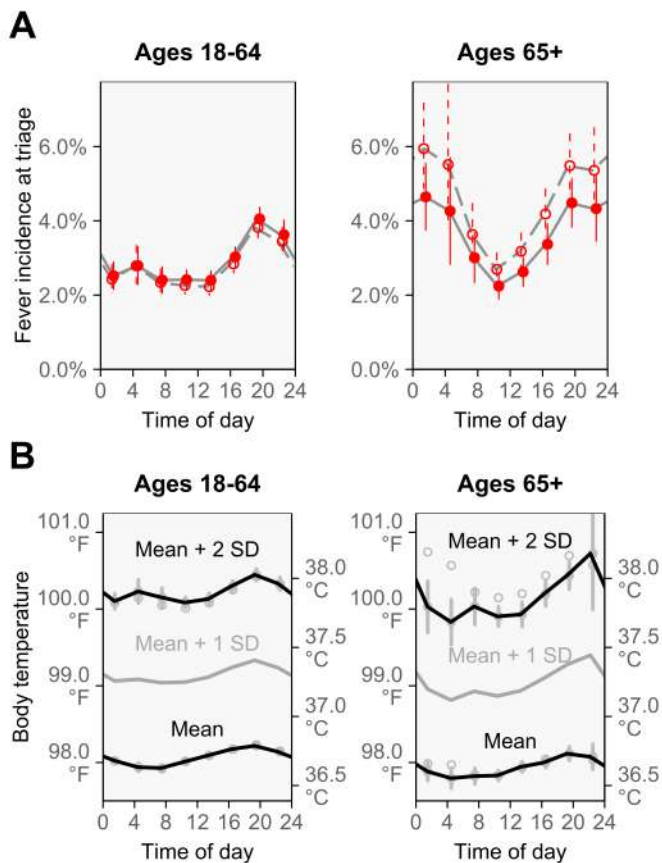


Figure 3. For ages 18-64 and 65+, the cycles of fever incidence and body temperature. (A) The incidence of fever followed large daily cycles in both age groups. Although the older age group had higher fever incidence before adjustment for potential confounders (hollow points and dashed lines), the difference largely disappeared after this adjustment (solid points and solid lines). Fever was defined as body temperature $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$). (B) Diurnal cycles of body temperature were present in both age groups, with temperatures that were multiple standard deviations above the mean following larger cycles. Mean body temperature was slightly lower in the older age group, both before (hollow points) and after (solid points) adjustment for potential confounders (unadjusted and adjusted difference: 0.1°C [0.1°F]). Results are for national US emergency departments. All confidence intervals are 95%.

Previous studies do not provide enough information to quantify the effects of diurnal body temperature variation on the observed incidence of fever. However, it is possible to take published values and use them in crude, back-of-the-envelope estimates. For example, in analyses of convenience samples, Musher et al⁴ observed that 72% and 84% of patients with fever-causing disease followed an exaggerated version of the usual diurnal cycle of body temperature. So, supposing that three-quarters of patients with fever-causing disease follow an exaggerated version of the usual diurnal cycle, and supposing also that one-third of these patients have temperatures below the $\geq 38.0^{\circ}\text{C}$ fever threshold in the morning, then a quarter of

all patients with fever-causing disease will not have fever-range temperatures in the morning. On the other hand, using a mean healthy temperature of 36.8°C ,⁵ an inter-individual standard deviation of 0.15°C ,³¹ and a mean (range) circadian amplitude of 0.25°C ($0.05\text{-}0.65^{\circ}\text{C}$),⁵ simulation suggests that perhaps a quarter of the ostensibly fever-range temperatures recorded at evening triage may be false positives supplied by nonfebrile patients who cross the $\geq 38.0^{\circ}\text{C}$ cutoff when reaching highpoints of their healthy circadian rhythms. However, we emphasize that these are crude, back-of-the-envelope estimates, rather than dependable evidence. Their purpose is to illustrate the logic of how the diurnal variations of body temperature are capable of producing large daily cycles in the observed incidence of fever, like those we found. It remains to be determined how much of the cycles are attributable to the lower morning temperatures of patients with fever-causing disease and how much of the cycles are attributable to false-positive fevers in the afternoons and evenings. We leave this to future research.

The incidence of fever seen at triage is not only determined by changes in body temperature, but also by changes in the mix of patients who show up to the ED across the day. In the current study, we applied multivariable regression to account for time-of-day differences in the patient mix seen at triage, which did not remove or reduce the cycle of adult fever incidence, despite including 12 patient characteristics in the analysis. However, it remains possible that the 12 characteristics were not sufficient to control for all important differences in patient mix across the day, and therefore that some of the fever incidence cycle is due to changes in patient mix. (See Appendix 2 for more detail on strengths and limitations of the multivariable approach.) We also observed that the large cycles of fever incidence occurred on both weekdays and weekends (Appendix 3), which suggests the cycles are not a consequence of differences in patient mix associated with people's work hours or the hours that alternative sources of care are open. Nonetheless, it remains possible that changes in patient mix contribute to the daily cycle of fever incidence and a different study design would be needed to address this possibility conclusively, likely by including many temperatures collected from the same individuals across the day.

Because mean body temperature is lower among older adults ("older is colder")¹³ and because fever responses can be blunted at older ages,¹² we also compared findings for 18-64 and 65+ year-olds (Figure 3). Mean body temperature was 0.1°C (0.1°F) lower in the older age group, which is a smaller difference than found in some studies,¹² but agrees with others, including several large-scale investigations (ages 20-59 – ages 60+: 0.1°C ;¹³ 0.02°C reduction per decade;³¹ ages 20-64 – ages 65-95: $+0.1^{\circ}\text{C}$ to -0.1°C , seasonally³²). Moreover, our results show that the lower mean body temperature of older adults did not translate to lower triage fever incidence, and that the blunted fever responses that have been reported previously¹² do not eliminate the daily cycle of fever incidence. Instead, fever incidence was higher in the older age group, and only became concordant with incidence at younger ages after statistical adjustment for differences in case

mix between the age groups. This suggests that the higher fever incidence among older adults reflected the different ED case mix in this group, instead of being a biological consequence of age.

For all age groups, we suggest investigating how the daily cycle of fever incidence affects diagnosis and outcomes. Triage decisions are upgraded by temperature and other vital signs in an important minority of cases.³³ We specifically suggest studying sepsis, for which delays in diagnostic maneuvers and management can be especially consequential.³⁴ Although body temperature can be an unreliable sign in sepsis,³⁴ sub-fever-range body temperature correlates with less-prompt treatment and much greater mortality in sepsis and septic shock.^{35,36} For example, among intensive care unit-admitted patients with severe sepsis and septic shock, each 1°C reduction in body temperature was associated with a five percentage-point increase in in-hospital mortality rates, with patients in the highest and lowest temperature brackets having mortality rates of 9% and 50%, respectively.³⁶ Seen alongside our results, these findings suggest the hypothesis that lower patient temperatures in mornings could hinder management and perhaps worsen outcomes by delaying recognition of sepsis. It may also be worth accounting for lower morning body temperatures during thermometer-based screenings for outbreaks of fever-causing disease, to reduce the possibility that disease cases are missed during morning screenings.

For both clinical and disease-screening purposes, it may ultimately be worth correcting fever definitions for the diurnal variation of body temperature. To date, one method of correction has been proposed.⁵ The proposal is currently recommended in *Harrison's Internal Medicine*,⁹ *UpToDate*,³⁰ and other medical references, but it appeared to perform poorly in our datasets (Appendix 8). This may be attributable to the small sample size that was originally used to derive the correction, as well as the absence of fevers in the originating study.⁵ Further work should also investigate fever cycles and definitions by age, since we observed differences between adults (main paper), children (Appendix 6), and infants (Appendices 7) in our study, which could also affect corrections. As an alternative to correcting fever thresholds, in some settings it is possible to chart patient body temperature over time and use the appearance of spikes to identify fever, instead of absolute thresholds.

Generalizability

Because the survey data are nationally representative, the findings likely have good generalizability to US EDs as a whole. However, individual EDs may show somewhat different findings because they use different thermometry methods and serve different populations, which have different age structures, gender ratios, and local climates, each of which can affect body temperature.³⁷

LIMITATIONS

Our study has several limitations. The study design was cross-sectional and there was no patient follow-up. Therefore, we were unable to investigate whether individuals without fever

at triage developed it at later times or had it earlier in the day. Similarly, we were unable to evaluate how the temperatures of individuals with fever changed over time. Our analyses do not distinguish between elevated temperatures attributable to fever, hyperthermias (such as heat stroke), or other conditions, and we did not investigate non-temperature symptoms of fever or antipyretics use. For the national data, arrival times had to be used as a surrogate marker for measurement times. Additionally, we did not investigate inter-individual differences in temperature baselines, which depend on age, gender, ovulation, and other characteristics.^{31,37} Both of the data sources used in this study also have several limitations (see Methods). However, we note that their limitations are different. Despite having different limitations, they both showed the same main findings, supporting the validity of these findings.

CONCLUSION

This study of US EDs demonstrates that triage temperatures are lower in the morning than in the afternoon or evening, and that adult patients are much less likely to have triage temperatures that meet the definition of fever in the morning. Clinically, the large difference between the observed incidences of fever during morning and evening triages suggests that it is worth investigating whether the diagnosis, management, and screening of fever-causing diseases are obstructed during mornings, including in cases of sepsis and infectious disease outbreaks.

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Conflicts of Interest: By the WestJEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. Funding, thermometers, and technical support were provided by Exergen, Corp., including for CH and DB's participation. The data-logging thermometer systems used in this study were designed by Exergen, which also played roles in design, collection, analysis, and interpretation of data; writing of the manuscript; and the decision to submit for publication. CH and DB report receiving payment from Exergen for work on this study and related research. FP is CEO and founder of Exergen, and holds patents related to the contents of this work. There are no other conflicts of interest to declare.

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Rabies Vaccination Compliance and Reasons for Incompletion

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Introduction: Rabies is a fatal disease with a 91% mortality rate in the United States. Current treatment of rabies consists of post-exposure prophylaxis treatment involving a complicated vaccination regimen. Studies conducted in other countries have found that patients do not complete their rabies vaccination treatment due to forgetting about their treatment, lack of time for visits, and the financial burden of treatment. However, little is known about why patients do not complete the rabies series in the US. The objective of this study was to determine the reasons why patients in the US do not complete rabies treatment.

Methods: We performed a retrospective study to evaluate rabies post-exposure prophylaxis completion in the emergency department of an academic suburban hospital between June 2014–July 2017. Further review was performed for patients who received inadequate vaccination to determine the cause of treatment incompletion. We conducted additional follow-up by phone survey for those patients who did not complete their rabies treatment but had no explanation for discontinuation available in the medical chart review.

Results: Results indicated 198 patients received rabies post-exposure treatment during the inclusion period. Of these, 145 patients completed the rabies vaccination regimen. Reasons for treatment incompletion were found for 29 patients, and 24 patients were lost to follow-up. Of the 29 patients for which discontinuation was assessed, 23 patients (79.3%) stopped treatment due to appropriate reasons – either the animal involved tested negative for the rabies virus or the patient had prior rabies treatment and only required two booster shots. Reasons for not completing the series when medically indicated included the patient deciding to not return for treatment, lack of awareness of the full vaccination regimen, and the patient declining initiation of rabies vaccination.

Conclusion: Most patients in the US discontinue their rabies vaccination treatment for appropriate reasons; however, there is a proportion of patients who discontinue rabies vaccination when further treatment is medically indicated. This subset of patients is particularly at risk of rabies-related mortality, and additional measures need to be taken to ensure increased treatment compliance. [West J Emerg Med. 2020;21(4)918-923.]

INTRODUCTION

Globally, there are an annual estimated 59,000 deaths due to rabies,¹ most of which are attributed to domesticated dogs. Fortunately in the United States, the prevalence of rabies in

domestic animals has been drastically reduced due to mandatory vaccination of pets. However; the Centers for Disease Control and Prevention (CDC) still report 1-3 rabies cases each year in the US despite 30,000-60,000 prophylaxis treatments given

annually.¹ This is because many variants of the rabies virus can still be found in various wildlife, particularly among bats and raccoons.⁵ According to the *Pennsylvania Animal Rabies 2017 Report*, thousands of animal are tested for rabies annually in Pennsylvania and on average 392 animals per year have tested positive in the past 10 years.⁶ Despite the precautions taken, 23 cases of rabies in humans were reported to the CDC between 2008–2017, resulting in 21 deaths.¹ These statistics show that there is still a risk of rabies infection for patients in the US, especially during the warmer months due to increased encounters with wildlife.

The current standard of care for rabies is administration of the rabies vaccination after potential exposure. The current rabies post-exposure treatment regimen in the US is one dose of human rabies immune globulin plus one dose of the rabies vaccine immediately after the exposure. Three additional doses of the rabies vaccine are administered three, seven, and 14 days after the initial dose.⁷ Unfortunately, this is a complicated regimen and previous investigations within our emergency department (ED) have revealed that some patients do not return to complete the recommended treatment.

Multiple studies have been performed in other countries, including China and Thailand, evaluating the reasons why patients do not complete their rabies treatment. Some results reported patients forgetting about their treatment, lack of time for visits, and the financial burden of treatment.^{2,3,4} However, no studies have been conducted in the US to evaluate causes for failure to complete the rabies vaccination regimen. Our objective was to determine the reasons why patients in the US discontinue rabies vaccination treatment. The results of this study can be used to help formulate countermeasures for increasing treatment compliance and reduce the risk of fatalities.

METHODS

This study was a single-center, retrospective cohort analysis designed to assess the completion rate and reason for discontinuation of post-exposure rabies treatment in patients seen in the ED. The study was performed in an academic, suburban hospital ED with an annual census of 70,000 visits per year. All procedures for this study were approved by the institutional review board. Training was provided to the primary author (TS) to review charts and collect data using a standardized abstraction form. The research team met frequently to discuss discrepancies and maintain consistency in data abstracted.

We obtained patient data from the Enterprise Information Management (EIM) office. The EIM is tasked with structuring and governing information across the organization, management of health records, and acquisition of patient charts for quality improvement and clinical research. The data obtained from EIM included patients of all ages who initiated rabies post-exposure treatment in the ED between June 2014–July 2017. We conducted an additional search for all animal bites seen in the ED within the same timeframe. These

Population Health Research Capsule

What do we already know about this issue?
Rabies is a preventable viral disease when treated with post-exposure prophylaxis vaccination. Some patients do not complete treatment and are at risk of rabies-related mortality.

What was the research question?
What are the reasons patients do not complete post-exposure prophylaxis treatment?

What was the major finding of the study?
While the majority of patients appropriately stopped treatment, a few discontinued treatment when not indicated.

How does this improve population health?
Patients inappropriately discontinue vaccination due to inadequate knowledge of treatment course and illness severity. Increased education and follow-up care is needed for these patients.

patients were cross-matched with patients who initiated rabies post-exposure prophylaxis treatment. The results show that all patients seen for an animal bite were offered post-exposure prophylaxis treatment.

Records identified by the EIM then underwent chart review. The chart review involved utilization of each patient's "immunization history" section and the "chart search" functionality of the electronic health record. The search term "rabies" was used to bring up all notes mentioning the term, and each individual note was reviewed to evaluate completion of rabies treatment. Patients who received the four CDC recommended doses were considered to have completed treatment and were included in the "completed vaccination" group without further analysis.

We conducted a retrospective chart review for patients without record of treatment completion in the immunization history. The initial post-exposure encounter note was evaluated to determine the animal involved in the exposure and initial treatment. Medical notes for later encounters were reviewed to evaluate reasons why patients did not return for completion of their rabies vaccine treatment and the number of vaccine doses each patient received prior to termination of treatment. If an explanation was provided for incompleteness of treatment, the chart review was considered to be complete for that patient and the reason for discontinuation was recorded.

If a reason for incompleteness was not found through chart review, the patient was subsequently contacted via

phone. A phone script was followed to determine the reason why patients did not complete the rabies vaccine treatment. Multiple attempts to contact each patient were made, altering days and times to maximize responses; patients were considered lost to follow-up if they did not answer their phone after 10 attempts. Verbal consent for inclusion in a research study was obtained from each subject according to the phone script. For underage subjects, verbal consent was obtained from parents and/or guardians. Subjects who were unable/unwilling to provide consent or unable to speak English were considered lost to follow-up. Patients who confirmed receipt of the four recommended doses were included in the “completed vaccination” group.

Patients who did not complete treatment were categorized into two groups: patients whose treatment termination was medically indicated (ie, animal involved tested negative for rabies or patient had received previous vaccination and only required two booster shots), and those whose treatment termination was not medically indicated.

RESULTS

A total of 198 patients received rabies treatment between June 2014–July 2017. The study population was representative of the larger patient population seen in this ED (Table 1). Of these patients, 145 (73.2%) completed treatment, 29 (14.6%) had incomplete treatment, and 24 (12.1%) were lost to follow-up (Figure).

Of those patients who discontinued treatment early, the majority (79.3%) were found to have terminated their treatments appropriately (Table 2). The remaining patients

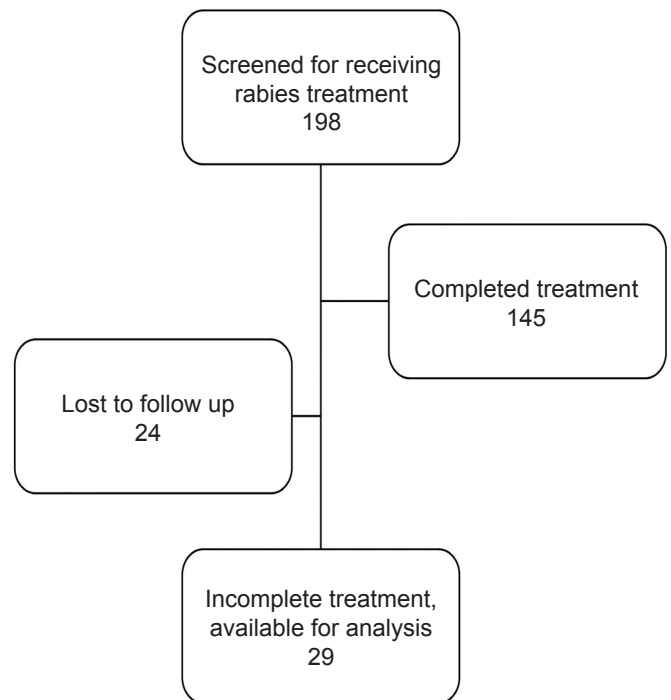


Figure. Treatment outcome grouping of patients who did or did not complete rabies vaccination regimen.

(20.7%) terminated rabies treatment when it was not medically indicated. Results show that dogs were involved with the majority of incidents with bats as the second most

Table 1. Treatment outcome and patient demographics of patients exposed to possible rabies infection.

Feature	Completed vaccination	Incomplete vaccination	Lost to follow up
Total patients	145 (73.2%)	29 (14.6%)	24 (12.1%)
Age group			
Pediatric	35 (24.1%)	12 (41.4%)	11 (45.8%)
Young adults	48 (33.1%)	4 (13.8%)	6 (25.0%)
Middle-aged adults	38 (26.2%)	9 (31.0%)	5 (20.8%)
Older adults	24 (16.6%)	4 (13.8%)	2 (8.3%)
Average age	34.3	29.9	26.2
Gender			
Male	67 (46.2%)	8 (27.6%)	12 (50.0%)
Female	78 (53.8%)	21 (72.4%)	12 (50.0%)
Race			
Caucasian	136 (93.8%)	25 (86.2%)	19 (79.2%)
African American	2 (1.4%)	2 (6.9%)	0 (0.0%)
Hispanic	5 (3.4%)	1 (3.4%)	5 (20.8%)
Asian	0 (0.0%)	1 (3.4%)	0 (0.0%)
Other	2 (1.4%)	0 (0.0%)	0 (0.0%)

Pediatric: < 18; young adults: 18-35; middle-aged adults: 36-55; older adults: >55.

frequently associated animal (Table 3). Of the six patients who stopped treatment when it was not medically indicated, three cases involved dogs, two cases involved bats, and one case involved a deer. Results demonstrate that the majority of patients (65.5%) who discontinued treatment received only one dose of the vaccine prior to discontinuation (Table 4). A second investigator reviewed 20 charts selected at random. The percent agreement between the two abstractors was 90% for treatment completion.

DISCUSSION

Rabies is a fatal disease that is easily preventable when appropriately treated with post-exposure prophylaxis. However, a previous investigation at our institution demonstrated that many patients seen in our ED for rabies post-exposure prophylaxis do not complete the recommended treatment course. Multiple studies have reported reasons why patients do not return to complete their rabies vaccination treatments, but all of these have been performed in developing countries where resources are limited. There has not yet been a study dedicated to evaluation of patients in the US.

This study specifically examined the reasons why patients at a single, academic institution in the US discontinue rabies vaccination treatment. Results show that the majority of patients do not return for completion of the vaccination regimen due to appropriate reasons (ie, the animal involved tested negative for the rabies virus or the patient had completed prior rabies treatment and only required two booster shots). This varied from prior studies performed in other countries (eg, Thailand and China), in which the main reasons for rabies vaccination incompleteness were patients not remembering their treatment, lack of time for visits, and the financial burden of treatment.^{2,3,4}

This difference is likely due to higher accessibility of resources available to patients in the US, particularly the opportunity to have the involved animals tested to determine the need for further medical treatment. This is especially noteworthy in the state of Pennsylvania where in-state residents are offered free animal testing, providing an opportunity for patients to avoid the financial cost and

Table 2. Reasons for incompleteness of vaccination regimen.

Reasons for incomplete	n (%)
Animal tested negative	18 (62.1%)
Received prior vaccination, only require booster shots	5 (17.2%)
Patient decided not to return to complete vaccination	3 (10.3%)
Patient unaware of vaccination regimen	2 (6.9%)
Patient declined initial vaccination	1 (3.4%)
Total	29

Table 3. Animals involved in rabies bites.

Animals involved	n (%)
Dog*	18 (62.1%)
Bat*	7 (24.1%)
Deer*	2 (6.9%)
Cat	1 (3.4%)
Raccoon	1 (3.4%)

*Animals involved in cases where patients terminated treatment when not medically indicated.

physical discomfort associated with rabies vaccinations.⁸ Additionally, the extensive treatment course allows ample time to obtain animal testing results before further vaccination treatment is indicated. This was highlighted by the fact that the majority of patients who stopped treatment only received one dose of the vaccine.

Additionally, our results show that dogs were involved with the majority of the incompleteness cases. Cats and dogs are considered low risk and less likely to transmit rabies to humans due to mandatory vaccination of domesticated animals.⁷ However, patients seen in our ED were offered treatment as a precaution because of unknown vaccination status of these animals. Furthermore, there is a small chance of transmission given that 50–60 dogs and over 250 cats test positive for rabies in the US each year, many of which were unvaccinated and infected by wildlife.¹ The animals were available for testing in some of these cases and were more likely to test negative given their lower risk of infection, thereby increasing the chances of appropriate treatment termination.

Nevertheless, there is still a proportion of patients who stopped vaccination treatment when further treatment was indicated. Additionally, it is reasonable to infer that some patients who were lost to follow-up did not receive the full vaccination regimen when medically indicated. Even though these patients only represent a small proportion of all patients receiving rabies treatment, this specific subset of patients is particularly at risk of rabies-related mortality despite rabies being an illness that is easily preventable with the right interventions. Therefore, it is important that additional steps be taken to increase treatment compliance.

Patient education and close follow-up are integral steps to increasing vaccination treatment compliance. With the prevalence of technology in everyday life, we propose the potential of electronic messaging to help increase vaccination completion rates. In many institutions, patients can sign up for patient portals that allow electronic communication between patients and medical providers. This provides a platform to educate patients about rabies and the potential harms of inadequate treatment. Additionally, previous studies have shown the utility of text messaging for increasing patient follow-up after ED visits.⁹ Therefore, these are two

Table 4. Number of vaccines received by patients with suspected rabies exposure.

Number of vaccines	n (%)
Zero	1 (3.4%)
One	19 (65.5%)
Two	5 (17.2%)
Three	4 (13.8%)

approaches that can facilitate communication between patients and providers to improve treatment compliance.

Our results show the average age of patients to be 34.3 years old among the completed vaccination group and 29.9 years old among the incomplete vaccination group. These values highlight the prevalence of younger patients being treated for post-exposure rabies treatment. The age distinction is hypothesized to be representative of the population that is more likely to encounter unfamiliar animals. Younger individuals spend more time outdoors and are more likely to encounter wildlife, leading to higher chances of exposure. When separated by age, treatment completion rates were similar for younger patients (93.2% among young adults) and older patients (85.7% among older adults). Nevertheless, additional studies can stratify patients by completion rate among different patient age groups to identify patients who are at a higher risk of non-compliance with post-exposure treatment.

LIMITATIONS

There are multiple factors in this study that limit the generalizability of the results. The main limiting factor is that this study is a single-center study. It was conducted in a rural/suburban area with a predominantly Caucasian population; therefore, our findings may not be generalizable to other parts of the country where the demographics are different. Additionally, reasons for inappropriate incompletion of treatment were determined for only six patients. Due to such a small sample size, no distinct conclusions can be made for recommendation of change. Lastly, a large number of patients were lost to follow-up, which could have potentially skewed the final results of the study. We postulate that the patients lost to follow-up reflect the results obtained from the study, given that three of these patients had the animal involved tested or quarantined and many other patients could have completed their treatment elsewhere. However, these are not certain and therefore limit the final results of our study.

No blinding was involved in data abstraction because chart reviews were performed by the primary investigator. Patient consent for communication other than via phone survey was unable to be obtained due to the retrospective nature of this study. Therefore, no additional measures were taken to contact patients, leading to high number of patients lost to follow-up.

CONCLUSION

Results show that the majority of patients received the appropriate post-exposure treatment (ie, completed the vaccination regimen or stopped treatment when medically indicated). However, a proportion of patients was found to have stopped their rabies treatment prior to completion and at increased risk of rabies-related mortality. This demonstrates that current medical practice leads to proper rabies management for the majority of patients, but there is a small subset of patients who do not complete their vaccination regimen and are at higher risk of rabies-related mortality. Therefore, additional measures need to be taken to ensure increased treatment compliance, mainly in the form of patient education to increase awareness of the high mortality associated with improper treatment.

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Practice Gap in Atrial Fibrillation Oral Anticoagulation Prescribing at Emergency Department Home Discharge

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Introduction: Current U.S. cardiology guidelines recommend oral anticoagulation (OAC) to reduce stroke risk in selected patients with atrial fibrillation (AF), but no formal AF OAC recommendations exist to guide emergency medicine clinicians in the acute care setting. We sought to characterize emergency department (ED) OAC prescribing practices after an ED AF diagnosis.

Methods: This retrospective study included index visits for OAC-naïve patients ≥ 18 years old who were discharged home from the ED at an urban, academic, tertiary hospital with a primary diagnosis of AF from 2012-2014. Five hypothesis-blinded, chart reviewers abstracted data from patient problem lists and medical history in the electronic health record to assess stroke ($\text{CHA}_2\text{DS}_2\text{-VASc}$) and bleeding risk (HAS-BLED). The primary outcome was the provision of an OAC prescription at discharge in OAC-naïve patients with high stroke risk. Descriptive statistics and multivariable logistic regression assessed associations between OAC prescription and patient characteristics.

Results: We included 138 patient visits in our analysis, of whom 39.9% ($n = 55$) were low stroke risk ($\text{CHA}_2\text{DS}_2\text{-VASc} = 0$ in males and 1 in females), 15.9% ($n = 22$) were intermediate risk ($\text{CHA}_2\text{DS}_2\text{-VASc} = 1$ in males), and 44.2% ($n = 61$) were high risk ($\text{CHA}_2\text{DS}_2\text{-VASc} \geq 2$). Of patients with high stroke risk and low-to-intermediate bleeding risk ($n = 57$), 80.7% were not prescribed an OAC at discharge. Cardiology consultation and female gender, but not stroke risk ($\text{CHA}_2\text{DS}_2\text{-VASc}$ score), were predictors of an ED provider prescribing an OAC to an OAC-naïve AF patient at ED discharge.

Conclusion: The majority of OAC-eligible patients were discharged home without an OAC prescription. In OAC-naïve patients discharged home from the ED, cardiology consultation and female gender were associated with OAC prescription. Our findings suggest that access to expert opinion may improve provider comfort with OAC prescribing and highlight the need for improved guidelines specific to ED-management of AF. [West J Emerg Med. 2020;21(4)924–934.]

INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia presenting to emergency departments (EDs) and accounts for more than 500,000 annual ED visits; up to one quarter of all new AF diagnoses are made in the ED.¹⁻² The related costs for these patients total more than \$26 billion annually.³ Importantly, AF has significant associated morbidity and mortality,⁴ with a fivefold increase in an individual's lifetime risk of stroke when compared to a non-AF reference population.⁵⁻⁷ Compared to estimates from 2010, the prevalence and incidence of AF are both expected to double by the year 2030, when over 12 million Americans will be affected.⁸

Although studies show that oral anticoagulation (OAC) therapy with traditional agents such as warfarin or non-vitamin K oral anticoagulants (NOACs) can reduce stroke risk by 64% in non-valvular AF, providers hesitate to prescribe OACs for reasons that include increased bleeding risk.^{7,9-11} Professional guidelines recommend the use of CHA₂DS₂-VASc, a validated scoring system that stratifies patients' annual stroke risk based on age, gender, and comorbid conditions, and HAS-BLED, a complementary scoring system that predicts the likelihood of a major bleeding event in anticoagulated patients, to determine appropriate OAC recommendations.¹²⁻¹⁵

Multiple studies show a net positive clinical benefit for OAC prophylaxis in AF patients with at least one additional risk factor for stroke.^{7,16-22} With rising pressure to decrease unnecessary hospitalizations, up to 89% of patients with new-onset AF may be discharged from the ED.¹⁷ ED providers may defer OAC initiation for a patient with new AF to an outpatient provider, but more than half of AF patients discharged from the ED fail to achieve outpatient follow-up within 90 days of hospital discharge.^{17,19} Thus, ED management at discharge may determine the trajectory of care and impact clinical outcomes.

The objective of this study was to describe baseline ED OAC prescribing rates for eligible OAC-naïve AF patients, characterize predictors of OAC prescribing, and identify variation from established guidelines and risk-stratification tools. This information will inform future interventions to improve prescribing in the ED and, ultimately, clinical outcomes for AF patients.

METHODS

Study Design and Setting

This retrospective study took place at an academic, tertiary care hospital ED with an affiliated emergency medicine (EM) residency program staffed by 43 board-certified faculty and EM residency-trained fellows with an annual ED volume of 50,000 adult patients. The study was approved by the Oregon Health & Science University Institutional Review Board.

Population Health Research Capsule

What do we already know about this issue?

Up to one quarter of all new atrial fibrillation (AF) diagnoses are made in the emergency department (ED), and AF accounts for more than 500,000 annual ED visits.

What was the research question?

What factors influence emergency physician oral anticoagulant (OAC) prescription rates for patients with a primary diagnosis of AF at home discharge?

What was the major finding of the study?

The majority of patients were not prescribed an OAC. Cardiology consultation and female gender were associated with OAC prescription.

How does this improve population health?

ED-specific guidelines and access to expert opinion may improve time to OAC prescription for OAC-naïve AF and reduce the associated morbidity and mortality.

Selection of Participants

A query of the electronic health record (EHR) identified patients ≥ 18 years old who were evaluated in the ED between January 1, 2012–December 31, 2014, and given a primary diagnosis of AF (International Classification of Disease-9 code 427.31) and discharged home from the ED. We excluded patients who were taking warfarin or a NOAC at the time of presentation. Patients taking aspirin at the time of presentation were considered OAC-naïve, as aspirin is not recommended for those at high risk for stroke.¹⁵ Only the first eligible visit during the study period was included.

Data Collection and Processing

We collected patient data for all qualifying patient encounters using the abstraction criteria described by Kaji et al.²³ Four chart abstractors blinded to the study hypotheses performed the chart review. The principal investigator trained each abstractor and provided them with standardized data collection procedures and definitions. A random sample of 10 encounters was selected for re-abstraction to determine inter-rater reliability. We assessed Fleiss' kappa and intraclass correlation statistics.

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture

tools. REDCap is a secure, web-based application designed to support data capture for research studies that is endorsed for clinical research purposes by institutions including Oregon Health & Science University.²⁴ Abstracted data included patient demographics, risk factors for stroke/bleeding,^{12,15,25} other comorbidities documented within one year of the ED encounter, substance use (alcohol, tobacco, illicit drug use), current medication use (OACs, antiplatelets, diuretics, heart rate-controlling medications), and disabilities or trouble with activities of daily living documented within the last year. Abstracted data related to management in the ED included chief complaint at time of presentation, arrhythmia management attempted in the ED, provision of OAC/antiplatelet prescription or adjustment to antiplatelet, specialty consultations obtained by the ED provider and recommendations for anticoagulation, reason from provider for management decisions, patient disposition, and follow-up international normalized ratio (INR) (if applicable). (See Appendix for further details of data captured.)

Outcome Measure

The primary outcome was the provision of an OAC prescription at home discharge in OAC-naïve patients with AF and a high stroke risk ($\text{CHA}_2\text{DS}_2\text{-VASc} \geq 2$). OACs included warfarin and NOACs (factor Xa and thrombin inhibitors). Based on investigator consensus, we simplified the indications for stroke prophylaxis to those who would be most acceptable by ED providers: AF patients with high stroke risk by $\text{CHA}_2\text{DS}_2\text{-VASc}$ ¹² (scores ≥ 2) and low bleeding risk by HAS-BLED²⁵ (scores 0-2), where AF patients would derive the greatest benefit and the least amount of harm from an OAC prescription. Although a high HAS-BLED score does not preclude the use of OACs, we chose to exclude them from the OAC indicated cohort to simplify the analysis to the most obvious cohort needing OACs with minimal concerns of adverse events for the risk-averse emergency provider.

Variables

We identified predictor variables to compare patients prescribed an OAC upon discharge from the ED to those who were not prescribed an OAC. Variables were selected based on the reviewed literature and factors thought to impact clinical decision making, and included the following: calculated $\text{CHA}_2\text{DS}_2\text{-VASc}$ and HAS-BLED scores stratified into low, intermediate and high risk; health insurance; gender; disabilities; cardiology consultation; return to normal sinus rhythm at disposition; whether cardioversion was attempted in the ED; and first method of rate or rhythm control attempted. All were identified through review of the ED provider and consultant notes as well as encounter registration data.

We also compared patients who received a cardiology consult in the ED to those who did not in order to

identify predictors of specialty consultation. Selected variables included the following: duration of symptoms; health insurance; and comorbidities used to calculate the $\text{CHA}_2\text{DS}_2\text{-VASc}$ score (congestive heart failure, hypertension, age, diabetes, gender, stroke/transient ischemic attack [TIA], vascular disease). For the patients who received a cardiology consultation, we determined whether cardiology's recommendation regarding OAC provision agreed with whether the emergency physician prescribed an OAC and identified any documented reason for discrepancy.

We documented whether or not the emergency physician cited use of a clinical guideline (such as $\text{CHA}_2\text{DS}_2\text{-VASc}$ or HAS-BLED) in his or her clinical decision-making process. Similarly, we identified emergency physicians' reasons for lack of OAC prescription in OAC-eligible patients. Lastly, we evaluated OAC and NOAC prescribing trends to investigate whether physician familiarity with newer drugs influenced prescribing of an anticoagulant.

Statistical Analysis

Descriptive statistics were used to summarize age, race, ethnicity, insurance, the reason for evaluation, medications at the time of the encounter, CHADS₂ score, $\text{CHA}_2\text{DS}_2\text{-VASc}$ score, HAS-BLED score, and follow-up instructions. We used multivariable logistic regression to identify factors associated with provision of OAC prescription at ED discharge and also to identify factors associated with cardiology consultation. Model diagnostics were visually inspected for outliers and leverage values. All tests were two-sided with a significance level of 0.05. The analysis was conducted with SAS 9.4 (Cary, NC, USA).

RESULTS

Characteristics of Study Subjects

During the study period, 317 patients were identified, with 138 ultimately meeting inclusion criteria (Figure 1). Their baseline characteristics are reported in Table 1.

Their mean age was 59 years, 39.1% were female, and 39.9% had no history of AF. Overall, 39.9% (n = 55) were low risk for stroke ($\text{CHA}_2\text{DS}_2\text{-VASc} = 0$ in males and 1 in females), 15.9% (n = 22) were intermediate risk ($\text{CHA}_2\text{DS}_2\text{-VASc} = 1$ in males), and 44.2% (n = 61) were high risk ($\text{CHA}_2\text{DS}_2\text{-VASc} \geq 2$)¹² for stroke. About half (49.3%) of included patients were taking aspirin at the time of presentation.

Main Results

Among the 138 OAC-naïve patient-visits, 14.5% (n = 20) received a new prescription of warfarin or NOAC at discharge for stroke prophylaxis (Table 1). Other medications were not included in the analyses, but usage is detailed in Appendix Table A1.

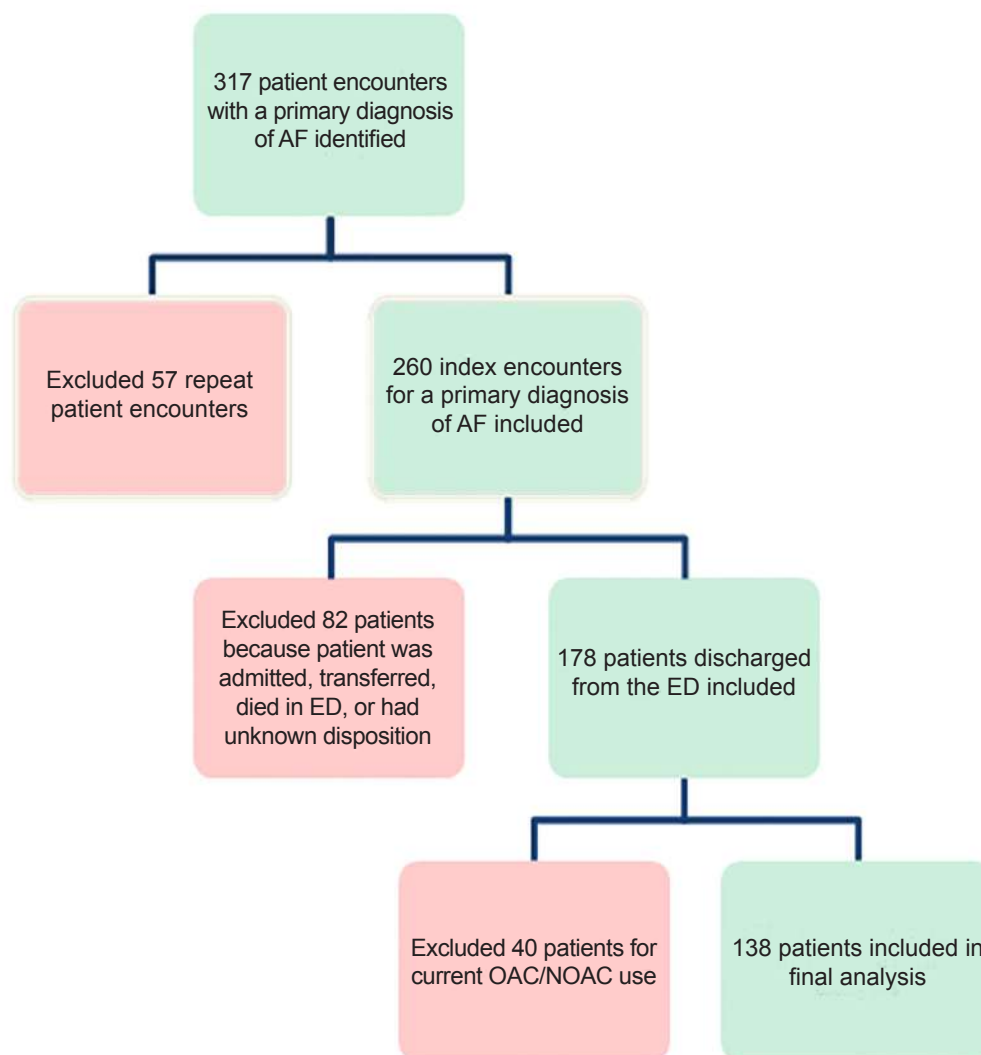


Figure 1. Cohort selection of patients with atrial fibrillation. *AF*, atrial fibrillation; *ED*, emergency department; *OAC*, oral anticoagulant; *NOAC*, non-vitamin K oral anticoagulants.

Provision of an Oral Anticoagulant Prescription Stratified By OAC-Naïve Patients' CHA₂DS₂-VASc and HAS-BLED Scores

OAC prescriptions were provided for 10.9% ($n = 6$) of patients with low stroke risk (CHA₂DS₂-VASc = 0 in males and 1 in females); 9.1% ($n = 2$) of patients with intermediate stroke risk (CHA₂DS₂-VASc = 1 in males); and 19.7% ($n = 12$) of patients with high stroke risk (CHA₂DS₂-VASc ≥ 2) (Table 2).

When stratified by HAS-BLED scores, OAC prescriptions were provided for 12.4% ($n = 10/81$) of patients with low bleeding risk, 22.6% ($n = 7/31$) of patients with intermediate bleeding risk, and 11.5% ($n = 3/26$) of patients with high bleeding risk. When stroke risk and bleeding risk were considered together, we found that patients with a high stroke

risk and low bleeding risk ($n = 13$) were prescribed an OAC 15.4% ($n = 2$) of the time (Figure 2).

Among all those prescribed an OAC (any risk) ($n = 20$), 10.0% ($n = 2$) were at intermediate risk and 60.0% ($n = 12$) were at high risk for stroke. Among those at low risk of stroke ($n = 55$), 36.3% ($n = 20$) received aspirin and 10.9% ($n = 6$) received OACs. Of these low-risk patients prescribed aspirin, 95.0% ($n = 19$) were in normal sinus rhythm when they were discharged from the ED. Compared to the intermediate and high stroke risk patients who received an OAC prescription, we found that the low stroke risk patients prescribed an OAC were more likely to be younger (49.6 years vs 58.7 years), to be female (83% vs 57% male), to have private or commercial insurance (67%

Table 1. Patient characteristics and calculated stroke and bleeding risk scores for 138 OAC-naive atrial fibrillation patients who were discharged home from the ED.

Characteristic (n, %)	Overall (n=138,100%)	OAC Prescription (n=20,14.5%)	No OAC (n=118,85.5%)	p-value*
Age (years), mean (SD)	58.7 (17.1)	61.4 (13.8)	58.2 (17.6)	0.69
Female gender	54 (39.1%)	13 (65.0%)	41 (34.7%)	0.01
Race				
White	128 (92.8%)	20 (100.0%)	108 (91.5%)	1.00
Black or African American	3 (2.2%)	0 (0.0%)	3 (2.5%)	
Asian or Pacific Islander	2 (1.4%)	0 (0.0%)	2 (1.7%)	
Other	2 (1.4%)	0 (0.0%)	2 (1.7%)	
Not reported	3 (2.2%)	0 (0.0%)	3 (2.5%)	
Insurance				
Commercial	59 (42.8%)	10 (50.0%)	49 (41.5%)	0.24
Medicare/Medicaid	64 (46.4%)	10 (50.0%)	54 (45.8%)	
Other	15 (10.9%)	0 (0.0%)	15 (12.7%)	
History of AF	81 (58.7%)	10 (50.0%)	71 (60.2%)	0.29
Symptom onset				
< 6 hours	64 (46.4%)	11 (55.0%)	53 (44.9%)	0.05
6–48 hours	28 (20.3%)	3 (15.0%)	25 (21.2%)	
> 48 hours	10 (7.2%)	4 (20.0%)	6 (5.1%)	
Unknown	36 (26.1%)	2 (10.0%)	34 (28.8%)	
Heart rate on arrival, mean (SD)	118 (31.5)	112 (30.3)	119 (31.7)	
Rate-controlling medication PTA	63 (45.7%)	12 (60.0%)	51 (43.2%)	0.16
On aspirin prior to presentation	68 (49.3%)	12 (60.0%)	56 (47.5%)	0.30
CHA ₂ DS ₂ -VASc group [†]				
Low stroke risk	55 (39.9%)	6 (30.0%)	49 (41.5%)	0.30
Intermediate stroke risk	22 (15.9%)	2 (10.0%)	20 (16.9%)	
High stroke risk	61 (44.2%)	12 (60.0%)	49 (41.5%)	
HAS-BLED group [§]				
Low bleeding risk	81 (58.7%)	10 (50.0%)	71 (60.2%)	0.42
Intermediate bleeding risk	31 (22.5%)	7 (35.0%)	24 (20.3%)	
High bleeding risk	26 (18.8%)	3 (15.0%)	23 (19.5%)	
Number of methods of control attempted				
0	57 (41.3%)	10 (50.0%)	47 (39.8%)	0.19
1	52 (37.7%)	4 (20.0%)	48 (40.7%)	
2	21 (15.2%)	4 (20.0%)	17 (14.4%)	
3	6 (4.3%)	1 (5.0%)	5 (4.2%)	
4	2 (1.4%)	1 (5.0%)	1 (0.8%)	
First method of control				
Rhythm	16 (11.6%)	1 (5.0%)	15 (12.7%)	0.52
Rate	65 (47.1%)	9 (45.0%)	56 (47.5%)	
None	57 (41.3%)	10 (50.0%)	47 (39.8%)	
Cardioversion attempted	18 (13.0%)	4 (20.0%)	14 (11.9%)	0.30

*t-tests for continuous data, chi-square tests for categorical data, and Fisher's exact tests for sparse categorical data.

[†]CHA₂DS₂-VASc (congestive heart failure, hypertension, age≥75, diabetes mellitus, prior stroke or transient ischemic attack, gender, age 65-74 years, and vascular disease). 0 in males, 1 in females = low risk for stroke, 1 in males = intermediate risk, and ≥ 2 high risk.

[§]HAS-BLED (hypertension, abnormal renal function or liver function, stroke, bleeding, labile international normalized ratio [excluded as all patients not on warfarin prior to inclusion], elderly >85 years old, and drugs and alcohol): 0 = low risk, 1 to 2 = moderate risk, >2 = high risk. OAC, oral anticoagulant; AF, atrial fibrillation; SD, standard deviation; PTA, prior to arrival.

Table 2. Provision of OAC prescription by CHA₂DS₂-VASc and HAS-BLED score.

CHA ₂ DS ₂ -VASc score [†]	HAS-BLED score [§]	OAC Prescription		
		Yes (n=20)	No (n=118)	Total (n=138)
Low stroke risk	Low bleeding risk	6 (11.1%)	48 (88.9%)	54 (100%)
	Intermediate bleeding risk	0 (0%)	1 (100%)	1 (100%)
	High bleeding risk	0 (0%)	0 (0%)	0 (0%)
	Total	6	49	55
Intermediate stroke risk	Low bleeding risk	2 (14.3%)	12 (85.7%)	14 (100%)
	Intermediate bleeding risk	0 (0%)	5 (100%)	5 (100%)
	High bleeding risk	0 (0%)	3 (100%)	3 (100%)
	Total	2	20	22
High stroke risk	Low bleeding risk	2 (15.4%)	11 (84.6%)	13 (100%)
	Intermediate bleeding risk	7 (28.0%)	18 (72.0%)	25 (100%)
	High bleeding risk	3 (13.0%)	20 (87.0%)	23 (100%)
	Total	12	49	61

[†]CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥ 75, diabetes mellitus, prior stroke or transient ischemic attack, gender, age 65-74 years, and vascular disease). 0 in males, 1 in females = low risk for stroke, 1 in males = intermediate risk, and ≥ 2 high risk.

[§]HAS-BLED (hypertension, abnormal renal function or liver function, stroke, bleeding, labile international normalized ratio [excluded as all patients not on warfarin prior to inclusion], elderly >85 years old, and drugs and alcohol): 0 = low risk, 1 to 2 = moderate risk, >2 = high risk. OAC, oral anticoagulant; AF, atrial fibrillation.

vs 43%), to present with a higher heart rate on arrival (137 vs 112), and have a shorter duration of symptoms, to have multiple methods of control attempted, to have cardioversion attempted (50% vs 7%), and were less likely to be on aspirin at the time of presentation (66.7% vs 33.3%).

Predictors of OAC Prescription

Multivariable logistic regression showed that cardiology consultation and female gender were significant predictors of prescribing (Table 3). Females had 2.9 (95% confidence interval [CI], 1.0-8.5) times the odds of receiving an OAC prescription as compared to males, and patients with a cardiology consult had 12.5 (95% CI, 1.5-100.5) times the odds of receiving an OAC prescription as compared to patients without a cardiology consult.

Predictors of Cardiology Consultation

Cardiology was consulted in 64.5% of all cases. We identified hypertension as a significant predictor of cardiology consultation after controlling for duration of symptoms, insurance status, and comorbidities associated with CHA₂DS₂-VASc score calculation (Appendix Table A2). Patients with a diagnosis of hypertension had 2.7 (95% CI, 1.0-7.2) times the odds of having a cardiology consult compared with patients without hypertension.

Cardiologists' Recommendations for Oral Anticoagulant Prescription

For the 89 patients who received a cardiology consultation, we examined whether cardiology's recommendation regarding OAC provision agreed with whether the ED provider prescribed an OAC. Cardiology recommended an OAC prescription for 10 (11.2%) patients, recommended against an OAC prescription for 40 (45.0%) patients, or opted to discuss OAC management at a later time for 19 (21.3%) patients (Appendix Table A3). Their recommendation was recorded as "unknown" for 20 (22.5%) patients. Other recommendations made by cardiology regarding patient management are specified in the appendix (Appendix Table A3).

Agreement Between Cardiologists' Recommendation for OAC And ED Provider Prescribing Patterns

For the 89 patients who received a cardiology consultation (36 of whom [40.5%] were high stroke risk), there were 12 cases in which cardiology's recommendation was not congruent with the emergency physician's decision (Appendix Table A4).

Cardiology recommended an OAC prescription for 10 of the 89 patients (11.2%), of whom seven were not prescribed an OAC. Cardiology did not recommend an OAC be prescribed

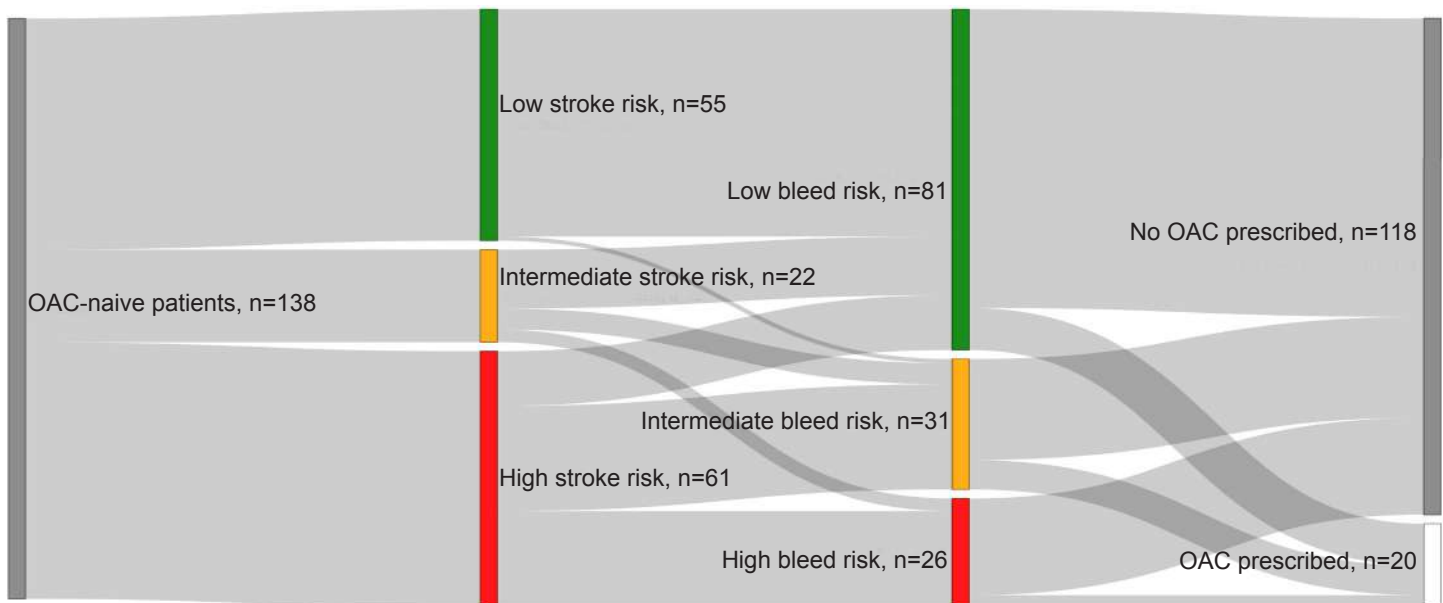


Figure 2. Patients who met exclusion criteria were stratified into low, intermediate, and high stroke risk by CHA₂DS₂-VASc score. They were then further stratified into low, intermediate, and high bleed risk by HAS-BLED scores. Next, they were stratified by prescription of oral anticoagulant (OAC) or not.

to 40 patients, although five (12.5%) of these patients were prescribed an OAC by the emergency physician. We attempted to identify reasons for these discrepancies within the patients' charts and identified one instance in which the ED provider opted against the recommended OAC prescription due to the patient's low stroke risk, and another in which the ED provider prescribed an OAC after citing the patient's high CHADS₂ score (Appendix Table A1). Interestingly, patients who did not receive an OAC prescription despite cardiology's recommendations were more likely to have a high HAS-BLED score (2/7 patients vs 0/5 patients who received an OAC prescription despite cardiology's recommendation).

Guidelines Cited by Provider

Of the 138 patient visits included, ED providers cited use of a clinical guideline such as CHA₂DS₂-VASc or HAS-BLED in AF management in 20.3% (n = 28) of visits. Use of a guideline was cited in 20.0% (n = 4) of visits where the patient was given an OAC prescription, and in 31.2% (n = 24) of visits where the patient was not prescribed an OAC or antiplatelet. Of all guidelines cited, CHADS₂ was the most cited guideline, both for or against an OAC prescription. All patient visits were reviewed for evidence of reasons for/against OAC prescription other than use of a guideline.

Identified Reasons for not Prescribing Oral Anticoagulant

We identified one visit in which the provider referenced

the patient's inability to follow up as an outpatient as a reason to support OAC prescription in the ED. Reasons against OAC prescription included low stroke risk (n=17), advanced age (n=4), lack of primary care physician management and/or follow-up (n=4), and "other" reasons (n=21). In patients perceived to be low stroke risk by the provider, 64.7% (11/17) were classified as low stroke risk by CHA₂DS₂-VASc. The most common "other" reason cited was that the patient was already taking aspirin (n=7).

Oral Anticoagulant Prescribing Patterns

To evaluate changes in OAC prescribing patterns over time, we compared the types of OACs prescribed stratified by year in which the ED visit occurred (Appendix Table A5). There was no variation in warfarin vs NOAC prescriptions provided throughout the study period.

DISCUSSION

In this study, we found that less than a quarter (15.3%) of OAC-naive AF patients at high risk for stroke and low risk for bleeding received a new prescription of warfarin or NOAC for stroke prophylaxis at the time of ED home discharge. This is consistent with findings from a previous study.²⁶ Reasons for underutilization of OACs by emergency physicians for AF management are likely multifactorial.²⁷⁻³⁰ A recent qualitative study by our group found that physicians were uncomfortable with prescribing and had a sense of futility in prescribing due to concerns that included low

Table 3. Factors associated with the provision of oral anticoagulant prescription at ED home discharge to 67 (48.2%) of 138 OAC-naïve AF patients.

Characteristic	OR (95% CI)	P-value
Gender, Female	2.9 (1.0-8.5)	0.05
CHA ₂ DS ₂ -VASc stratification		
High risk	1.9 (0.7-5.7)	0.21
Low/intermediate risk	referent	
Cardiology consultation	12.5 (1.5-100.5)	< 0.01

Significant values are bolded.

OR, odds ratio; CI, confidence interval; AF, atrial fibrillation.

adherence rates by patients prescribed anticoagulation and bleeding risks associated with anticoagulation,³¹ which are further magnified by an emergency physician's inability to follow up with patients.

A longitudinal cohort study of United States and Canadian patients with new-onset AF found that use of warfarin decreased from 65% at study enrollment to 44% 30 months later.²⁹ However, Atzema et al demonstrated that patients who received a prescription for warfarin in the ED had a higher frequency of long-term warfarin use than patients who were referred to another provider for OAC management.³² This suggests that there is longitudinal value in the initiation of a prescription associated with a significant event—an acute care encounter—and that more resources should be directed toward the initial acquisition of the medication for the patient. One potential solution by Barrett et al is the “provision of a protective tail of stroke prevention for a limited duration until they can follow up.”³³

Interestingly, 10.9% (n = 6/55) of patients were over-prescribed OACs when they had a low stroke risk. This may be driven in part by the increased frequency of cardioversion attempted in this group (50% vs 7%), as anticoagulation is often continued for four weeks after electrical cardioversion and recommended by the American Heart Association.¹⁵ We also found that these patients were more likely to be younger, female, and have private or commercial insurance. However, these findings contradict those from a study of the Practice Innovation and Clinical Excellence (PINNACLE) Registry, which found that older age, male gender, and Medicare insurance were associated with increased likelihood of OAC prescription among AF patients with a CHA₂DS₂-VASc score of 0.³⁴ The reason for this discrepancy is unclear, although our small sample size of six patients limits our ability to draw a statistically meaningful conclusion.

We found that cardiology consultation was a predictor of whether or not OAC-naïve patients were prescribed

an OAC on home discharge. These findings are in accordance with recently-published data from the non-oral vitamin K inhibitor era.³⁵ Similarly, the TREAT-AF study found significant, specialty-dependent differences in anticoagulation use, with cardiologists being more likely to prescribe OACs than primary care physicians.³⁶ This is likely due to provider comfort and familiarity with OAC prescribing. Additionally, having a cardiology consult may overcome barriers to outpatient follow-up as it directly connects the patient with a follow-up provider. Concern regarding lack of follow-up has been previously identified as a barrier to OAC prescription in the ED,³¹ and a lack of follow-up after ED discharge has been associated with increased mortality in AF patients.^{26,30,37}

However, we also found that ED providers did not always abide by cardiology's recommendations regarding OAC management, as management in the ED was incongruent with cardiology's recommendations for 12 of 89 (13.5%) patients who received a cardiology consult. Although ED providers did not provide reasons for these discrepancies, patients who did not receive an OAC prescription, despite cardiology's recommendations, were more likely to have a high-risk HAS-BLED score. While our simplified outcome maximized benefit and minimized harm (high stroke risk and low bleeding risk), we must acknowledge that a high bleeding-risk score does not preclude patients from being on OACs, and in fact, may still be indicated as the two risk scores share many features.

It is important to note that cardiology consults occurred in roughly two-thirds of encounters in our study population. This is higher than cardiology consults obtained in non-academic settings, with a recent study of Northern California Kaiser Permanente AF patients showing that cardiology was consulted 37.5% of the time.³⁵ This reinforces the importance of improving emergency physician comfort with OAC prescribing independently of cardiology consultation.

Despite the fact that CHA₂DS₂-VASc and HAS-BLED risk scores are well-validated tools in the AF population, we found that they did not influence OAC prescribing. This reflects findings from a previous study that found only a modest correlation between CHADS₂ score and warfarin prescribing in an elderly AF population.³⁸ This may be because emergency physicians underutilize the tools (potentially due to unawareness of the guidelines), or because they overvalue the risk of adverse events (eg, major bleeding events) when considering OAC initiation. However, a recent multicenter prospective cohort study in Spain showed that anticoagulation initiated in the ED for AF patients with high stroke risk was not associated with an increase in major bleeding event by one year and was in fact associated with a decrease in mortality.³⁹

We reviewed the reasons documented by physicians either for or against OAC prescription and found that use of

a guideline was cited in only 20.3% of visits. This finding may suggest physicians' unfamiliarity with risk-stratification tools not specifically intended for ED populations. A recent study reflected similar results, finding that among 1200 patients hospitalized at a community teaching institution with documented AF, only 14% had a CHA₂DS₂-VASc score documented in their charts.^{13,40} Those with a documented score were significantly more likely to have appropriate anticoagulation therapy, regardless of rate or rhythm control.^{13,40} Expanded efforts to educate emergency physicians on the use of these clinical decision-making tools may improve comfort with prescribing OACs, and thus improve time to appropriate anticoagulation.

This study contributes to the literature base describing NOAC-era ED prescribing practices for AF in OAC-naive patients.^{26,35} ED studies were limited to the use of warfarin until recently, but also show inappropriately low rates of OAC provision at ED discharge, ranging from less than one-quarter to nearly one-half of patients deemed eligible by calculation of stroke and bleeding risks.^{26,32,35,41} The number of patients prescribed NOACs is rapidly increasing, and it is critical to understand how this can inform clinical recommendations specific to the ED setting.^{24,42} Because our study took place over two years, we were able to evaluate changes in the rate of NOAC prescriptions over time and did not observe a significant change (Appendix Table A5). This is supported by a recent study showing the use of NOACs gradually increased over a three-year span (2012-2014); however, the use of warfarin was still 10-50 times more common than dabigatran, rivaroxaban, and apixaban as of 2015.⁴³ In part, this may be due to challenges of prescribing NOACs from the ED as they often require prior authorization from a patient's insurance.

Our work has again demonstrated an ED prescribing practice gap for anticoagulants in patients with a primary diagnosis of AF.^{26,32,35,41} However, it also showed that ED providers initiate OAC prescribing that may be incongruent with a cardiology consultation. Of note, while cardiology consultations influenced prescribing, they did not always correlate with the ED provider's decision at the time of discharge. The inconsistencies in OAC prescribing are likely in part due to the lack of consensus guidelines for acute, ED-specific AF management, and has been previously noted in a qualitative study interviewing providers who were concerned about the lack of ED-specific guidelines as current guidelines use data from outpatient, chronic care populations.^{14,31,44} With no formal ED recommendations in place, it is not surprising that more than half of patients with AF and high stroke risk do not receive an OAC prescription at the time of home discharge.⁴¹

A lack of guideline utilization by providers may include (1) wariness of using scoring tools that are not specifically validated in ED populations; (2) hesitancy to start aggressive anticoagulation therapy without definitive

follow-up; (3) over-reliance on cardiology consultants; and (4) lack of education regarding clinical decision-making tools (CHA₂DS₂-VASc and HAS-BLED), as well as other reasons.³¹ There is an opportunity to engage emergency physicians to validate existing clinical algorithms for AF management in ED populations. Systems-specific interventions and electronic clinical decision support could include improved methods for establishing outpatient follow-up after ED evaluation. These are several of many ways emergency clinicians can be empowered to contribute to multidisciplinary efforts to prevent strokes in patients with high-risk AF.⁴⁵

LIMITATIONS

Patients were included only if they had a primary ED diagnosis of AF, and therefore the conclusions from this study may not be applicable to patients with a different primary diagnosis accompanied by AF (e.g., a patient with pneumonia noted to have incidental AF). Patients with related diagnoses such as atrial flutter were not included. The degree of valvular disease was not abstracted. In addition, we included only patients who were discharged home from the ED. As a result, our patient population may have reflected patients with lower stroke and/or bleeding risk (determined by CHADS₂, CHA₂DS₂-VASc, and HAS-BLED tools), fewer co-morbidities, and a more favorable disposition status.

This retrospective study is limited to one academic, tertiary care, urban hospital and our results may be influenced by regional and/or institution-specific practice patterns, and our analysis is limited by what was available in the EHR. Prospective validation and external validation at other EDs is needed.

CONCLUSION

Our study suggests that current risk stratification tools for AF management are ineffectively used in the ED. Cardiology consultation and female sex were the only variables associated with OAC prescription at discharge. This may be explained by ED providers' unfamiliarity with risk-stratification tools, lack of comfort with OAC prescribing, or inability to facilitate patient follow-up. Clear guidelines for ED providers are critical in this high-risk and undertreated population. Possible solutions include new algorithms, expanded educational dissemination of existing guidelines, or collaborating with cardiology departments to create protocols for initiation of anticoagulation by ED providers coupled with automatic and timely outpatient follow-up for longitudinal management.

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Risky Behavior: Hospital Transfers Associated with Early Mortality and Rates of Goals of Care Discussions

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Introduction: Inter-hospital transfer (IHT) patients have higher in-hospital mortality, higher healthcare costs, and worse outcomes compared to non-transferred patients. Goals of care (GoC) discussions prior to transfer are necessary in patients at high risk for decline to ensure that the intended outcome of transfer is goal concordant. However, the frequency of these discussions is not well understood. This study was intended to assess the prevalence of GoC discussions in IHT patients with early mortality, defined as death within 72 hours of transfer, and prevalence of primary diagnoses associated with in-hospital mortality.

Methods: This was a retrospective study of IHT patients aged 18 and older who died within 72 hours of transfer to Wake Forest Baptist Medical Center between October 1, 2016–October 2018. Documentation of GoC discussions within the electronic health record (EHR) prior to transfer was the primary outcome. We also assessed charts for primary diagnosis associated with in-hospital mortality, code status changes prior to death, in-hospital healthcare interventions, and frequency of palliative care consults.

Results: We included in this study a total of 298 patients, of whom only 10.1% had documented GoC discussion prior to transfer. Sepsis (29.9%), respiratory failure (28.2%), and cardiac arrest (27.5%) were the top three diagnoses associated with in-hospital mortality, and 73.2% of the patients transitioned to comfort measures prior to death. After transfer, 18.1% of patients had invasive procedures performed with 9.7% undergoing major surgery. Palliative care consultation occurred in only 4.4%.

Conclusion: The majority (89.9%) of IHT patients with early mortality did not have GoC discussion documented within EHR prior to transfer, although most transitioned to comfort measures prior to their deaths, highlighting that additional work is needed in this area. [West J Emerg Med. 2020;21(4)935–942.]

INTRODUCTION

Adults with serious illnesses often visit an emergency department (ED) several times in their last year of life. Studies have shown that 75% of adults aged 65 and older with significant pre-existing conditions visit an ED within the last six months of life and 51% in the last month.¹⁻³ Many of these patients receive aggressive and invasive intensive care interventions at the end of life, sometimes without clear benefit.⁴⁻⁷ This is especially true for patients subject to inter-hospital transfer (IHT) to a tertiary medical center, which occurs regularly and in up to 1.5% of all Medicare patients.^{8,9} Studies have shown that IHT patients have up to 2.7-fold increased risk of in-hospital mortality compared to non-transferred patients.¹⁰⁻¹² In addition, up to 50% of these patients undergo inappropriate repeated procedures and tests.¹³ One study showed that IHTs was the most expensive non-therapeutic intervention performed in the acute setting.¹⁴

While a transfer may be necessary to ensure proper and timely care, transfers also can move patients to a location far from their families and may be associated with significant cost.^{8,15} In addition, studies have shown that IHT patients experience worse outcomes compared to non-transferred patients.¹⁶ Thus, given the increased cost, high mortality, and worse outcomes associated with IHT patients, having goals of care (GoC) discussions with patients and/or their loved ones prior to transfer is essential to ensure goal-concordant care.

Patients often choose less aggressive care if they anticipate a shorter life expectancy, lack of perceived benefit, and increased physical burden.¹⁷ One study demonstrated that aggressive end-of-life care just prior to death is later viewed as undesirable by bereaved families, compared to earlier transition toward comfort-focused measures.¹⁸ GoC discussions are associated with improved patient satisfaction, reduced healthcare costs, and reduced treatment burdens.¹⁹⁻²¹ However, there is a limited understanding of how often GoC discussions occur prior to transfer to a tertiary medical center. Our primary aim was to assess the prevalence of GoC discussions documented within the EHR and to assess the primary diagnosis associated with early mortality (defined as death within 72 hours of transfer) in patients who were transferred to a tertiary medical center.

METHODS

Study Design and Setting

This was a retrospective cohort study. We reviewed the EHR for all adults aged 18 years or older who had been transferred from an outside hospital to a tertiary medical center, Wake Forest Baptist Medical Center (WFBMC), between October 1, 2016–October 1, 2018 and expired within 72 hours of transfer. WFBMC is a Level 1 trauma center and serves the Piedmont Triad area of North Carolina, which is the north-central part of the state and contains 12 counties.²² The population is estimated at 1.69 million, making it the 30th largest metropolitan area in the US. In the

Population Health Research Capsule

What do we already know about this issue?
Patients transferred from community hospitals to tertiary medical centers are typically higher acuity, and at higher risk of mortality than non-transferred patients.

What was the research question?
How often were goals of care (GoC) documented prior to transfer in patients who died within 72 hours of transfer?

What was the major finding of the study?
GoC were documented prior to transfer in 10% of cases, but was more likely in patients with a do-not-resuscitate order.

How does this improve population health?
Interhospital transfer can be a costly and potentially non-beneficial intervention. When possible, GoC should be explored prior to transfer.

region, 22.2% of residents are African American and 15.9% are aged 65 and older.²² WFBMC is the only academic medical center in this 12-county region. This project was approved by the Wake Forest Institutional Review Board, with a waiver of requirement of informed consent.

Population

This study included all patients aged 18 and older who were transferred from any outside hospital to WFBMC between October 1, 2016–October 1, 2018, and expired within 72 hours of transfer. IHT patients under the age of 18 were excluded along with those who did not expire within 72 hours of transfer. A total of 298 patients met the inclusion criteria out of 16,506 admitted adult patients transferred from outside hospitals during the study period. One physician author verified the accuracy of the patient selection.

Methods and Measurements

All data, with the exception of documented GoC discussions, primary diagnoses associated with mortality, and rates of palliative care consultation, were directly extracted from the EHR by a blinded data abstractor with training in biomedical informatics. We used Research Electronic Data Capture (REDCap) to record all study data.²³ Demographic data collected included date of birth, age, gender, ethnicity, ZIP code, and marital status. The following

information was also collected: transferring hospital name; date of admission; date of mortality; length of stay; primary diagnoses most contributing to death based on chart review; GoC discussion documentation in transfer medical records; utilization of palliative care consultation; use of mechanical ventilation; use of pressor agents; and code status prior to and after transfer.

GoC discussion documentation was obtained through manual chart review, and was defined as documentation of a discussion with the patient or surrogate decision maker(s) related to a “crisis communication.” This was further specified as any discussion about treatment decisions and goals related to what had brought the patient to the hospital.^{3,24} Each chart abstractor was instructed regarding documentation that would be considered as a documented GoC discussion, as just described. In cases of ambiguous documentation regarding GoC discussion, the chart was reviewed by a second chart abstractor to determine whether a GoC discussion was adequately documented to meet this description.

Manual chart review was performed to assess the primary diagnoses associated with in-hospital mortality. We pooled diagnosis categories to assess illness categories most associated with early mortality based on initial review of all encounter diagnosis codes. Contributing diagnosis determination was based on review of the admission and discharge notes, progress notes, and encounter diagnosis. In cases of ambiguous documentation, charts were reviewed by a second chart abstractor to determine primary and secondary contributing diagnosis for mortality. We calculated the Charlson Comorbidity Index (CCI) score based on hospitalization encounter diagnoses and patient problem list.²⁵

Charts were manually reviewed to assess code status before and after transfer. If no documentation regarding pre-transfer code status was available, then we considered the pre-transfer code status to be full code as long as the initial documented code status was also full code after transfer. WFBMC currently has four tiers of scope of treatment orders: full code; do not resuscitate (DNR)-F (full scope of treatment); DNR-L (limited scope of treatment), and DNR-C (comfort care scope of treatment).²⁶ There were two instances where documentation revealed patient/surrogate requests specifically for do-not intubate status. We compared pre-transfer and post-transfer code status for each patient to determine the frequency of change prior to death.

Rates of invasive procedures and major surgery after hospital transfer were also recorded based on manual chart review. We defined invasive procedures as diagnostic or therapeutic procedures other than mechanical ventilation or central line placement, as these were considered separately, and did not constitute major surgical procedures. Examples of invasive procedures include cardiac catheterization; cerebral angiography; direct intracranial pressure monitoring; inferior vena cava filter placement; mechanical

thrombolysis; or tissue plasminogen activator administration. Major surgery was defined as any invasive operative procedure in which an extensive resection is performed (eg, a body cavity is entered, a partial or full organ is removed, or normal anatomy is altered). In-hospital cardiopulmonary resuscitation (CPR) rates after transfer and rates of palliative care consultation were also recorded based on manual chart review. The frequency of palliative care consultation was manually assessed through review of transfer documentation, consultation orders, and progress notes.

Statistical Methods

We used descriptive statistics of means and standard deviations (SD) for panel demographic and encounter data. Microsoft Excel, version 16.0 (Microsoft Corporation, Redmond, WA) was used for all analyses; $p < 0.05$ was assumed to be significant. We used chi-squared test to compare proportion of GoC discussions between institutions, and from referral ED or referral inpatient settings, as well as correlation between frequency of documented GoC discussions and code status prior to transfer. Chi-squared test was also used to assess aggregated code status outcomes following transfer. We used test of proportion to compare percentage of males to females in patient cohort, as well as prevalence of change in code status before and after transfer.

RESULTS

Patient Demographics

A total of 298 patients were transferred from inpatient settings and EDs at 51 outside community hospitals to WFBMC between October 1, 2016–October 1, 2018 and expired within 72 hours of transfer. The majority (57.7%) of patients were aged 65 or older, with 53% being male (Table 1). The median unadjusted CCI score for patients 18 and older to less than 65 years of age was 1 (SD 2.4), while the median unadjusted CCI for patients age 65 and older was 3 (SD 2.1).

Goals of Care Documentation

GoC discussions were documented in 10.1% ($n = 30$) of patients prior to transfer to the tertiary medical center. In those patients transferred directly from the ED 8.5% ($n = 19$) had GOC documentation, and in those transferred directly from inpatient settings, including floor and intensive care unit, 14.7% ($n = 11$) had documented GoC discussions. There was no significant difference ($p = 0.12$) between the frequency of documented GoC discussions prior to transfer for patients coming directly from the ED vs inpatient settings (Table 2).

Primary Diagnoses Associated with In-Hospital Mortality

The median length of stay was 32.9 (SD 19.46) hours with 41.9% and 72.5% of patients dying within 24 and 48 hours after transfer, respectively. Sepsis (29.9%), respiratory failure (28.2%),

Table 1. Baseline demographic data of study cohort of patients transferred to a tertiary care hospital.

Variable	N (%)
Age	
18 to <65	126 (42.3)
≥ 65	172 (57.7)
Gender	
Male	158 (53.0)
Female	140 (47.0)
Race/Ethnicity	
White	260 (87.2)
African-American	26 (8.7)
Hispanic or Latino	5 (1.7)
American Indian or Alaskan Native	3 (1.0)
Other/unknown	4 (1.3)
Marital status	
Single, never married	67 (22.5)
Married	150 (50.3)
Divorced	32 (10.7)
Widowed	46 (15.4)
Separated	3 (1.0)
Comorbidities	
Diabetes mellitus	88 (29.5)
Liver disease	30 (10.0)
Cancer	76 (25.5)
HIV/AIDS	1 (0.3)
Chronic renal disease	47 (15.8)
Congestive heart failure	66 (22.1)
Coronary artery disease	45 (15.1)
COPD	69 (23.1)
Peripheral vascular disease	15 (5.0)
Cerebrovascular accident/TIA	54 (18.1)
Dementia	15 (5.0)

HIV, human immunodeficiency virus; *AIDS*, acquired immunodeficiency syndrome; *COPD*, chronic obstructive pulmonary disease; *TIA*, transient ischemic attack.

Table 2. Frequency of goals of care discussions prior to transfer from emergency department and inpatient settings.

Pre-transfer location	Patients per setting N (%)	GoC discussions by setting N (%)	P-value
Emergency department	223 (74.8%)	19 (8.5%)	p= 0.12
Inpatient settings	75 (25.2%)	11 (14.7%)	
Total GoC discussions		30 (10.1%)	

GoC, goals of care.

and cardiac arrest (27.5%) were the top three primary diagnoses associated with in-hospital mortality (Figure). Cardiac arrest was only included as a contributing diagnosis to the patient's transfer mortality for patients who were transferred to the hospital following return of spontaneous circulation from a pre-transfer cardiac arrest event, and not solely as a terminal event of tertiary hospitalization. Notably, hemorrhagic stroke was the most specific diagnostic category after sepsis, respiratory failure, and cardiac arrest, affecting 10.4% of patients.

Code Status and Scope of Treatment Changes

The majority (90.3%) of patients were full code prior to transfer, and in 85.9% (N = 231) their code status was changed to DNR within 72 hours of transfer. In 73.2% (N = 218) of patients, their status was transitioned to comfort measures prior to death (Table 3). Thirty percent (N = 89) of patients underwent in-hospital CPR after transfer. Of the patients (N = 29) who were not full code prior to transfer, 72.4% (N = 21) were further de-escalated to comfort measures (DNR-C) prior to death. Only one patient had escalated care after transfer from DNR-F initially to full code prior to death.

Patients with a DNR prior to transfer were more likely to have a documented GoC discussion prior to transfer compared with patients who were full code prior to transfer (Table 4).

There was no significant difference between groups with aggregated code status outcomes following transfer. The data suggested a trend towards higher prevalence for comfort care among patients who had documented discussions prior to transfer, but this was not significant (Table 5).

Invasive Procedures, Surgery, and Palliative Care Consultation Rates

A total of 18.1% (N = 54) of patients underwent invasive procedures, and 9.7% (N = 29) underwent major surgery prior to death. Palliative care was consulted for only 3.4% (N = 10) of patients after transfer and 1.0% (N = 3) of patients prior to transfer.

DISCUSSION

This study revealed that only 10.1% of patients had documented GoC discussions prior to transfer, although the majority (73.2%) of patients had a de-escalation of code status within 72 hours of transfer to comfort measures. GoC discussions are critical, allowing patients and their families to be well informed of proposed therapies along with their risks and benefits. GoC discussions are associated with improved patient satisfaction, reduced healthcare costs, and reduced treatment burdens.¹⁹⁻²¹ Patients commonly present to an ED because there has been an acute change in their overall health, often representing an inflection point in their trajectory of illness. Emergency physicians are called upon to conduct initial GoC discussions particular to that crisis situation.^{3,27,28} Shared decision-making can only occur after GoC discussions have examined the patient's preferences and values.^{3,29} Unfortunately, our study

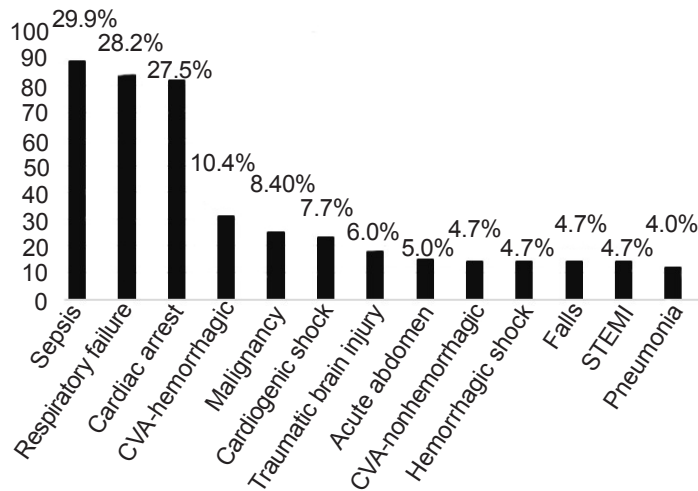


Figure. Primary diagnoses associated with in-hospital mortality. CVA, cerebrovascular accident; STEMI, ST-elevation myocardial infarction.

highlighted that these discussions occur infrequently, resulting in patients possibly receiving unwanted and unnecessary aggressive care in the last days of life. Further research is needed to investigate the best strategies for training emergency physicians in conducting GoC discussions and implementing standardized ways to document these discussions within the EHR.

There was a predominance of mortality associated with sepsis, respiratory failure, post-cardiac arrest care, and acute neurologic conditions including hemorrhagic stroke in this cohort. These patients suffered early in-hospital mortality despite receiving aggressive care interventions, including IHT, possibly due to lack of early predictors for poor prognostic outcome. It is also possible that recognition of patients at a high risk of mortality despite transfer was missed by transferring physicians and that further training in this area is needed.

Research has shown that early palliative care consults in the ED can decrease hospitalization cost, in-hospital mortality, and length of stay while improving quality of care and availability of acute bereavement support for families.³⁰⁻³² Unfortunately, only 4.4% of patients in this study had a palliative care consult. These results are not dissimilar to other studies showing that emergency physicians are less likely to refer patients to palliative care, representing only 3% of palliative care referrals.²⁹ Given the severity of disease and poor prognosis in this patient cohort, we expected a higher consultation rate.³³⁻³⁸ It is possible that providers did not consider involvement of palliative care until all life-prolonging measures had been attempted or exhausted. This is supported by the low rates of documented GoC discussions, leaving little time to involve palliative care providers prior to a patient’s death. The high mortality rate associated with IHT, especially in those with sepsis, respiratory failure, recent cardiac arrest, and neurologic emergencies, highlights the need for early GoC discussions with these patients to ensure quality and goal-concordant end-of-life care.

While transfers to tertiary care centers are ostensibly pursued to give patients access to resources, treatments, or procedures that are not available at the referring institution, we were surprised to see the relatively small portion of patients in this study who underwent surgeries or invasive procedures (9.7% and 18.1%, respectively). We are not aware of similar prior studies comparing rates of GoC discussions in patients with early mortality with rates of intervention following transfer. Multiple inferences can be made regarding the low rates of invasive or surgical procedures. The majority of patients had diagnoses that were medical in nature, but presumably even patients with medical diagnoses were transferred with the potential for specific invasive interventions. It is also possible that due to disease progression throughout the transfer period, many patients were poor candidates for these therapies at presentation to our tertiary care center.

Disease progression may have also impacted the GoC for the patient or family, rendering these invasive therapies no longer goal concordant. Further study is needed to differentiate the factors contributing to differences in pre-transfer assessment of the need for a higher level of care with subsequent care or interventions offered following transfer. Given the expanding availability of detailed medical record exchange through EHR networks, specialist evaluation of

Table 3. Code status before transfer and after transfer prior to death.

Code Status	Before transfer N (%)	After transfer N (%)	P-value
Full Code	269 (90.3%)	38 (12.8%)	p < 0.00001
DNR Status	29 (9.7%)	258 (86.6%)	p < 0.00001
DNR/Full SOTO	14 (4.7%)	22 (7.4%)	p = 0.168
DNR/Limited SOTO	15 (5.0%)	18 (6.0%)	p = 0.589
DNR/Comfort Care SOTO	0 (0.0%)	218 (73.2%)	p < 0.00001
Do Not Intubate	0 (0.0%)	2 (0.7%)	p = 0.156

DNR, do not resuscitate; SOTO, scope of treatment order.

Table 4. Frequency of goals of care discussions prior to transfer compared to code status prior to transfer.

GOC Documentation Prior to Transfer	DNR Prior to Transfer N (%)	Full Code Prior to Transfer N (%)	P-value
Documented GoC Discussion	8 (26.7%)	22 (73.3%)	p = 0.002
No Documented GoC Discussion	20 (7.5%)	248 (92.5%)	

GoC, goals of care discussion; DNR, do not resuscitate.

Table 5. Code status after transfer compared to documentation of goals of care discussion prior to transfer.

GOC Documentation Prior to Transfer	Full Code	DNR-F N (%)	DNR-L N (%)	DNR-C N (%)	P-value
Documented GoC Discussion	3 (10.0%)	1 (3.3%)	1 (3.3%)	25 (83.3%)	p = 0.591
No Documented GoC Discussion	37 (13.8%)	21 (7.8%)	17 (10.1%)	193 (72.0%)	

GoC, goals of care; *DNR-F*, do not resuscitate-full scope of treatment; *DNR-L*, DNR-limited scope of treatment; *DNR-C*, DNR-comfort scope of treatment.

candidacy for invasive procedures prior to transfer may become standard practice in the future.

The vast majority of patients (84.6%) had a change in their code status and scope of treatment after transfer with 73.2% of patients receiving comfort measures only prior to death. We suspect that this was multifactorial. Some patients may have been deemed poor candidates for aggressive therapies upon transfer or additional diagnostic information may have been available to providers leading to more accurate prognostication that was communicated to patients and their surrogate decision makers. More study is needed to determine the specific aspects of communication or prognostication that may have influenced decision-making following transfer, all of which can be documented in varying detail by medical providers. Standardized documentation of code status changes, preferences regarding care goals, stipulations of management, quality of life considerations, and other aspects of care in the EHR can help address dynamic changes in condition and goals that may occur during hospitalization.³⁹

LIMITATIONS

There are several potential limitations in our study. This was a single-center study, which may affect the generalizability of the results; and external validity is lacking. We assessed rates of GoC discussions based on documentation within the EHR, which likely has high inter-provider variability, particularly given the busy nature of the ED. The different transferring institutions use multiple EHR systems that may not communicate with the receiving hospital; thus, review of GoC discussions included review of available records provided at the time of transfer, which may not have been complete. The rates of these discussions could have been higher although just not documented in EHR.

The retrospective nature of this study can result in potentially ambiguous baseline data. Also, based on chart review, we suspect that the CCI of this population was not adequately captured. This is possibly due to a lack of thorough history of patient comorbidities given acuity of presenting condition, inaccurate recording of significant comorbidities in a patient's problem list, patients being too ill to adequately relay their history to providers, and patients being transferred by outside hospitals and health systems which may not have EHR systems capable of communicating with the receiving institution's EHR. Additionally, any informal guidance provided by palliative care providers via phone or after regular consultation hours would not

be captured in review since consultation was only considered if there was a consult order placed during hospitalization or direct documentation of consultation by a palliative care provider.

We assessed whether or not a GoC discussion took place, based on minimum specific criteria, but the depth or utility of such discussions may vary widely among medical providers. The chart abstractors were not blinded to study hypothesis. While a secondary review of charted GoC conversations and contributing diagnoses was undertaken in cases of ambiguous documentation, we did not perform review of each chart by a second reviewer to evaluate inter-rater reliability.

CONCLUSION

Goals of care discussions were infrequent in this cohort of IHT patients. Based on prior research on the outcomes of IHT patients and the effects of GoC discussions we suspect that early delivery of prognostic information and GoC discussions may have prevented some of these transfers from occurring, thereby possibly improving patient and family satisfaction, reducing treatment burden, and reducing costs.¹⁶⁻²¹ The majority of patients in this study came from ED settings. Barriers to GoC discussions occurring in ED settings likely include time limitations, provider comfort level with these discussions, lack of training in conducting GoC discussions, and availability of palliative care resources for potential care transitions.

Further study is needed to better understand the complexity of this issue and potential solutions. Based on this data, we suspect that facilitating early involvement of palliative care in patients at high risk of mortality prior to transfer could help identify patients who may not benefit from or want an inter-hospital transfer. In settings that lack direct access to a palliative care provider, targeted education for providers as well as telemedicine-based palliative care support may help bridge this gap.

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Necrotizing Fasciitis Within 72 hours After Presentation with Skin and Skin Structure Infection

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Introduction: A small percentage of patients with skin infections later develop necrotizing fasciitis (NF). Diagnostic testing is needed to identify patients with skin infections at low risk of NF who could be discharged from the emergency department (ED) after antibiotic initiation. Elevated lactate has been associated with NF; existing estimates of the frequency of NF are based on retrospective reviews, and cases often lack testing for lactate. We present the incidence of patients with skin infections who developed NF and their baseline lactates.

Methods: In four phase-3 trials, 2883 adults with complicated or acute bacterial skin and skin structure infections were randomized to dalbavancin or comparator, with early and late follow-up visits through Day 28. We prospectively collected baseline plasma lactates in one trial to assess an association with NF.

Results: NF was diagnosed in 3/2883 patients (0.1%); all three survived. In the study with prospectively collected baseline lactates (n = 622), 15/622 (2.4%) had a lactate ≥ 4 millimoles per liter (mmol/L), including 3/622 (0.5%) with a lactate ≥ 7 mmol/L. NF was not seen in patients with a lactate < 4 mmol/L; NF was seen in 1/15 (6.7%) with a lactate ≥ 4 mmol/L, including 1/3 (33.3%) with lactate ≥ 7 mmol/L.

Conclusions: NF incidence within 72 hours of antibiotic initiation in patients with complicated or acute bacterial skin and skin structure infections was extremely low (0.1%) and occurred in 6.7% with a lactate ≥ 4 mmol/L. Lactate < 4 mmol/L can be used to identify patients at low risk of NF who could be safely discharged from the ED after antibiotic initiation. [West J Emerg Med. 2020;21(4)943–948.]

INTRODUCTION

A small percentage of patients with serious skin infections later develop life-threatening necrotizing fasciitis (NF). NF has an annual incidence ranging from 0.3–15.5 cases per 100,000 population.¹ It involves the epidermis, dermis, subcutaneous tissue, fascia, and muscle, and is a surgical diagnosis, characterized by friable superficial fascia and dishwater-gray exudate.¹ NF can occur after minor or major breaches in skin or mucosa and requires emergent and extensive

surgical debridement.¹ It is defined as polymicrobial (type I) involving aerobic and anaerobic organisms with gas in the tissue in patients with underlying conditions such as diabetes, while monomicrobial NF (type II) most commonly involves *Streptococcus pyogenes*, followed by methicillin-resistant *Staphylococcus aureus* (MRSA), and can occur in persons without underlying conditions.¹ In invasive skin infections caused by *S. pyogenes*, the initial lesion may be mildly erythematous and swollen but progress to extensive inflammation over the next 24

to 72 hours with the skin appearing as dusky, then purplish with bullae, crepitus and/or subcutaneous gas, and with an associated mortality of 30-80%.¹⁻³

Since the initial clinical presentation may be benign and not suggestive of NF, a common clinical question in the emergency department (ED) is whether patients with skin infection can be discharged after antibiotic initiation, or if they may be at higher risk of NF and therefore require a brief hospital admission for observation while receiving intravenous (IV) antibiotic therapy. Adjunctive diagnostic testing is therefore needed to triage patients with skin infections at low risk of NF, who could potentially be safely discharged from the ED. Elevated lactate has been associated with NF and mortality (lactate level >2 or ≥ 6 millimoles per liter [mmol/L]),^{4,5} mortality in patients with infection (lactate level ≥ 4 mmol/L),⁶ and septic shock (lactate level >2 mmol/L).⁷ Existing estimates of the frequency of NF are based on retrospective reviews, and cases often lack prospective testing for lactate.

Dalbavancin is a long-acting lipoglycopeptide antibiotic approved by the US Food and Drug Administration and European Medicines Agency as a single- and two-dose treatment for adults with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible Gram-positive organisms, including MRSA.⁸⁻¹⁰ Dalbavancin has a terminal half-life of 15.5 days and is administered as a single IV infusion in the inpatient or outpatient setting to provide a complete two-week course of therapy for ABSSSI, eliminating the need for a peripherally inserted central catheter. Clinicians may be concerned about the risk of NF developing after patients present with skin infection in the ED, and many patients may be admitted unnecessarily to the hospital for IV antibiotics and observation.

In this analysis, we present the incidence of patients initially presenting with skin and skin structure infections (SSSI) who later developed NF, with available baseline lactate levels from four global phase-3 clinical trials of dalbavancin in SSSI, including 386 patients treated completely in the outpatient setting.¹¹

METHODS

This analysis evaluated data from four phase-3, double-blind, placebo-controlled multicenter trials of 2883 adults with complicated (cSSSI) or ABSSSI. Detailed methods for those trials have been described previously; patients were randomized to receive dalbavancin or linezolid (VER001-9, no registry number – study was completed prior to establishment of Clinicaltrials.gov),⁸ dalbavancin or vancomycin (with oral switch to linezolid) (DUR001-301, NCT01339091, and DUR001-302, NCT01431339)¹⁰ or dalbavancin single-dose or two-dose regimen (DUR001-303, NCT02127970).⁹ The study protocols included multiple early and late follow-up visits through Day 28. Based on an observation of two prior cases in studies VER001-9 and DUR001-302 of patients who presented with symptoms of cSSSI or ABSSSI and later developed NF, including one from DUR001-302 with an elevated baseline

Population Health Research Capsule

What do we already know about this issue?

A simple diagnostic tool is needed to triage patients with skin infection at low risk of necrotizing fasciitis (NF), who could be discharged from the emergency department (ED) after antibiotics.

What was the research question?

We prospectively collected baseline lactates in patients presenting with skin infections, to assess an association with NF.

What was the major finding of the study?

Lactate <4 millimoles per liter can identify patients at low risk of NF, who could be safely discharged from the ED after antibiotic initiation.

How does this improve population health?

A lactate level in the ED could identify patients at low risk of NF, to avoid unnecessary hospital admissions.

lactate level (4.4 mmol/L), the most recent study, DUR001-303, was designed to prospectively collect baseline plasma lactate levels as an exploratory analysis to assess an association with NF in all patients presenting with SSSI. The protocols for all studies were approved by the institutional review board or ethics committee at each study site, and all patients provided written informed consent.

Key Inclusion Criteria

Patients ≥ 18 years of age with cSSSI or ABSSSI involving deeper soft tissue or needing significant surgical intervention (major cutaneous abscess *or* surgical site *or* traumatic wound infection *or* cellulitis) were enrolled into the trials. Patients must have presented with at least one of the following systemic signs of infection: an elevated body temperature *or* increased white blood cell count *or* white blood differential count with $\geq 10\%$ band forms. In addition to erythema, at least two of the following signs of ABSSSI were required: purulent drainage/discharge; fluctuance; heat/localized warmth; tenderness to palpation; or swelling/induration.

Key Exclusion Criteria

We excluded patients if they had evidence of NF at enrollment, gas gangrene, or gangrene, or if infections were expected to require more than two surgical interventions for the cSSSI or ABSSSI. Patients were also excluded from studies DUR001-301, -302, and -303 if they had sustained shock at enrollment, defined as systolic blood pressure <90 millimeters

mercury for >2 hours despite adequate fluid resuscitation, with evidence of hypoperfusion or need for sympathomimetic agents to maintain blood pressure.

Study Outcomes

Patients were selected for this analysis from the four trials if they had baseline lactate levels available (DUR001-302 and DUR001-303) and/or if they developed NF. If signs or symptoms of NF were observed at the prior site of skin and soft tissue infection after enrollment, the treating physicians and surgical team established the diagnosis by surgical exploration in the operating room.

Statistical Analysis

We used sensitivity, specificity, positive predictive value, and negative predictive value to determine the predictive value of lactate in determining NF.^{12,13} Confidence intervals (CI) for sensitivity and specificity are “exact” Clopper-Pearson CIs;¹² CIs for positive predictive value and negative predictive value are the standard logit CIs.¹³

RESULTS

NF was diagnosed in 3/2883 patients (0.1%) within 72 hours of presentation for skin infection; all three had surgical debridement and survived (Figure 1). Clinical features of the patients who developed NF are presented in Table 1. None of these patients had evidence of NF or hemodynamic compromise consistent with septic shock at enrollment. In the DUR001-303

study, 622 patients had prospectively collected baseline plasma lactate levels per protocol: 15/622 patients (2.4%) had a lactate level ≥ 4 mmol/L, including 3/622 patients (0.5%) with a lactate level ≥ 7 mmol/L, one of whom developed NF (Figure 2). In patients with lactate levels >2 mmol/L (162/622 [26.0%]), there was no evidence of septic shock at enrollment. NF was not seen in patients with a lactate level <4 mmol/L. One of 15 patients (6.7%) with a lactate level ≥ 4 mmol/L had NF (lactate = 7 mmol/L); this patient constituted 1/3 patients (33.3%) with a lactate level ≥ 7 mmol/L. A lactate cutoff of ≥ 4 mmol/L in the DUR001-303 study provides a sensitivity of 100%, specificity of 97.8%, positive predictive value of 6.7%, and negative predictive value of 100% for NF (Table 2). In the earlier study (DUR001-302), the patient who developed NF had a serum sample collected at baseline that was later tested for lactate and was found to be 4.4 mmol/L (Table 1). Among the three patients with NF across the four clinical trials, 2/3 (67%) had type 1 diabetes, and 2/3 (67%) had *S. pyogenes* isolated from intraoperative specimens at the site of infection.

DISCUSSION

Our findings suggest that initial lactate levels <4 mmol/L may identify SSSI patients at low risk of NF. The high negative predictive value of 100% for a lactate <4 mmol/L may be relevant for ruling out NF, since no patient from our studies with available lactate levels developed NF with a baseline lactate <4 mmol/L. Our results also support an association between elevated lactate levels and NF, as previously reported.^{4,5} One existing tool

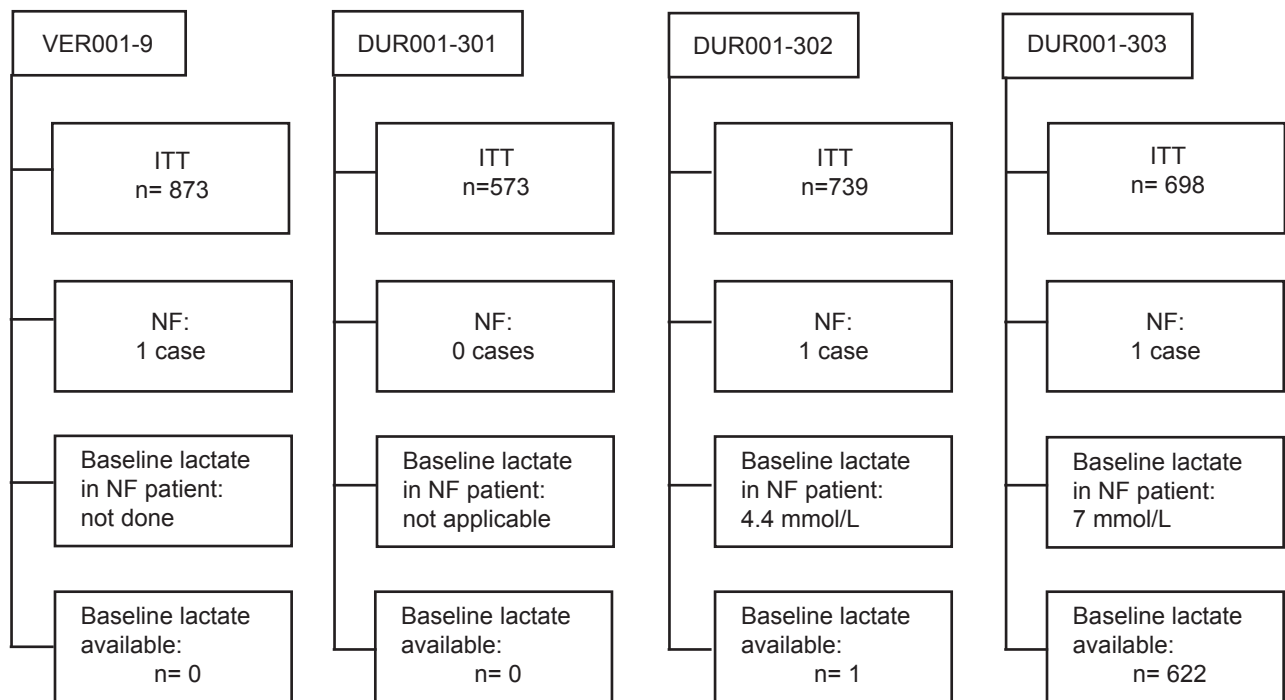


Figure 1. Incidence of necrotizing fasciitis and baseline lactate levels in intent-to-treat population. ITT, intent-to-treat; NF, necrotizing fasciitis; mmol/L, millimoles per liter.

Table 1. Characteristics of individual patients who developed necrotizing fasciitis.

Variable	VER001-9	DUR001-302	DUR001-303
Age (years)	37	32	31
Gender	Male	Female	Male
Race/ethnicity	Asian	Other ^a	White
Infection type	Abscess	Cellulitis/Erysipelas	Cellulitis
Location of infection	Right forearm	Right arm and hand	Left buttock
C-reactive protein, mg/L	ND	>300 ^b	>300 ^c
WBC count, cells/mm ³	35.3	19.1	22.2
Hemoglobin level, g/dL	15.6	13.5	11.9
Sodium level, mmol/L	127	138	135
Creatinine level, mg/dL	1.3	1.22	0.78
Glucose level, mg/dL	538	97	252
Lactate (mmol/L)	ND	4.4	7
SIRS criteria	Yes	Yes	Yes
Temperature	38.4°C	38.1°C	38.2°C
Baseline pain score	Moderate	10/10	5/10
Pathogen (infection site)	MRSA	<i>Streptococcus pyogenes</i>	<i>Streptococcus agalactiae</i>
	<i>Streptococcus pyogenes</i> (baseline wound culture)	(Day 2 intraoperative specimen from fasciotomy for NF)	(growth from baseline skin culture and intraoperative specimen during debridement on Day 4)
Clinical course prompting OR evaluation	Severe swelling, erythema and tenderness on Day 1	Worsening cellulitis on Day 2 with increased lesion area, severe pain, edema, hyperemia, a necrotic area with hemorrhagic border, new fluctuance, elbow in forced flexion, a 10 cm purulent, denuded area surrounded by hyperemia, with symptoms of fever, chills and nausea.	Worsening cellulitis 67 hours after study drug initiation, spread of infection from left buttock to left upper leg with injury of the fascia, severe fluctuance, and purulent drainage on dressing changes.
Intraoperative findings at diagnosis of NF	Surgical incision and drainage and debridement revealed copious purulence and significant necrosis of SQ tissues down to major fascia investing muscle bundles; NF diagnosed on Day 4. Required wound vac dressing, wet-to- dry dressing changes, and skin graft.	Upper extremity SQ fasciotomy; NF diagnosed on Day 2. Required additional debridements, wound revision, and skin graft.	Surgical incision and drainage and wide surgical debridement of necrotic tissue revealed putrid liquefaction and necrosis of SQ fat and fascia; NF diagnosed on Day 4.
Baseline blood culture	No growth	No growth	<i>Micrococcus luteus</i> , <i>Cutibacterium acnes</i>
Randomization arm	Linezolid	Dalbavancin (two-dose)	Dalbavancin (two-dose)
Infection area at baseline	375 cm ²	1452 cm ²	1139.7 cm ²
Medical history	Type 1 diabetes Hypertension Hyperlipidemia	Right hand eczema Deep venous thrombosis Demyelinating process of right elbow	Type 1 diabetes Pancreatic necrosis

^aOther race as noted in clinical study report: Gypsy; ^bLRINEC score = 6; ^cLRINEC score = 7.

LRINEC, Laboratory Risk Indicator for Necrotizing Fasciitis; MRSA, methicillin-resistant *Staphylococcus aureus*; ND, not done; NF, necrotizing fasciitis; cm, centimeter; vac, vacuum-assisted closure; OR, operating room; SIRS, systemic inflammatory response syndrome; SQ, subcutaneous; WBC, white blood cell.

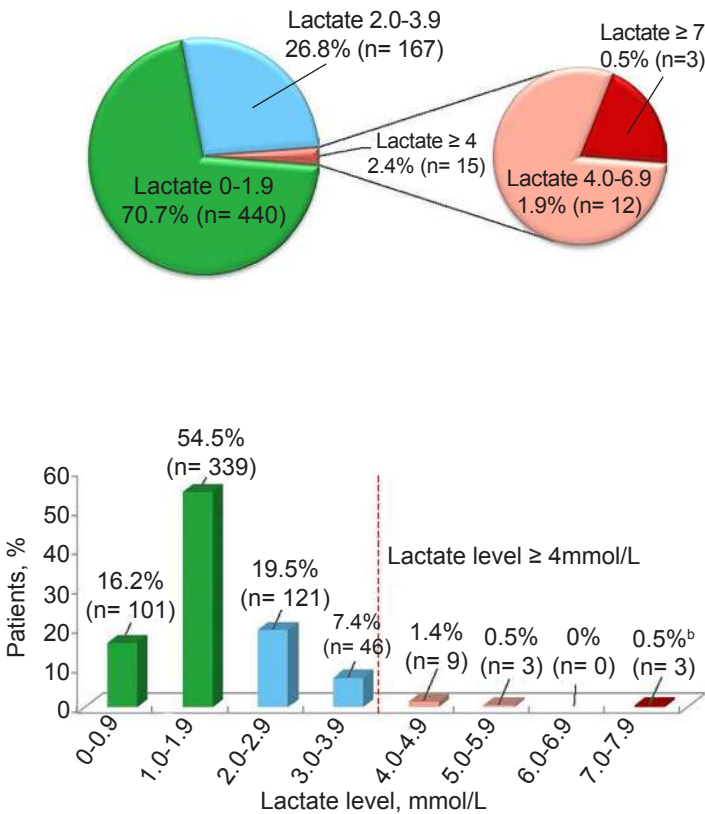


Figure 2. Baseline lactate levels in DUR001-303 (N = 622).^a
^a622 ITT patients had available baseline plasma lactate levels (normal range, 0.5–2.2 mmol/L). Figure includes 20 patients with lactate = 2.0 mmol/L.
^bCase of necrotizing fasciitis in DUR001-303 (lactate = 7 mmol/L).
 ITT, intention-to-treat; mmol/L, millimoles per liter.

to assist in the earlier diagnosis of NF is the Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score, which uses six serum values to distinguish between soft-tissue infections and NF: C-reactive protein, total white blood cell count, hemoglobin, sodium, creatinine, and glucose.¹⁴ A LRINEC score of ≥ 6 in adults should raise the suspicion of NF, while a score of ≥ 8 is strongly predictive.¹⁴ The positive predictive value of a LRINEC score of ≥ 5.8 for NF ranged from 57-92% in three studies, with negative predictive values of 86% and 96% in two studies.¹ In our studies, two of the three NF patients had all six serum values available, with LRINEC scores of 6 and 7, and corresponding lactate levels of 4.4 and 7.0 mmol/L, respectively. Using an initial lactate level to help rule out NF in patients presenting with SSSI may be easier than a scoring system requiring six serum values and may also provide a higher negative predictive value.

LIMITATIONS

A limitation of this analysis is that lactate levels were not available in all 2883 patients enrolled in the four trials; rather, they were available in patients enrolled in the most recent clinical trial, DUR001-303, where baseline lactates

Table 2. Evaluation of baseline lactate Level ≥ 4 millimoles per liter as predictor of necrotizing fasciitis.¹²

Test characteristic	Outcome, % (95% CI)
Sensitivity	100 (2.5–100)
Specificity	97.8 (96.3–98.8)
Positive predictive value	6.7 (4.1–10.7)
Negative predictive value	100

CI, confidence interval.

were required by the protocol. This limitation may have been unavoidable as the DUR001-303 protocol was designed to collect baseline lactates in all patients after the observation of a high baseline lactate in the NF patient from a prior study (DUR001-302) who had a serum sample retrospectively tested with value of 4.4 mmol/L. The number of baseline samples tested in the most recent study (n = 622) is robust and allows the calculation of a meaningful sensitivity (100%), specificity (97.8%), and negative predictive value (100%) for lactate as a predictor of NF; the low prevalence of NF may be a limitation in the interpretation of NPV and PPV. Due to the small number of cases of NF, it may not be possible to draw definite conclusions, and larger analyses with more cases of NF may be useful to confirm the association.

CONCLUSION

Overall, the incidence of necrotizing fasciitis within 72 hours of antibiotic initiation in cSSSI or ABSSSI patients was extremely low (0.1%). Patients with a lactate ≥ 4 mmol/L may be considered at significantly higher risk for NF. Lactate levels < 4 mmol/L may identify cSSSI or ABSSSI patients at low risk of NF, who could be safely discharged from the ED after antibiotic initiation with careful follow-up. Further investigation of initial lactate levels as a predictor of NF risk are needed in patients presenting with SSSI.

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Social Determinants of Hallway Bed Use

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Introduction: Hallway beds in the emergency department (ED) produce lower patient satisfaction and inferior care. We sought to determine whether socioeconomic factors influence which visits are assigned to hallway beds, independent of clinical characteristics at triage.

Methods: We studied 332,919 visits, across 189,326 patients, to two academic EDs from 2013-2016. We estimated a logistic model of hallway bed assignment, conditioning on payor, demographics, triage acuity, chief complaint, patient visit frequency, and ED volume. Because payor is not generally known at the time of triage, we interpreted it as a proxy for other observable characteristics that may influence bed assignment. We estimated a Cox proportional hazards model of hallway bed assignment on length of stay.

Results: Median patient age was 53. 54.0% of visits were by women. 42.1% of visits were paid primarily by private payors, 37.1% by Medicare, and 20.7% by Medicaid. A total of 16.2% of visits were assigned to hallway beds. Hallway bed assignment was more likely for frequent ED visitors, for lower acuity presentations, and for psychiatric, substance use, and musculoskeletal chief complaints, which were more common among visits paid primarily by Medicaid. In a logistic model controlling for these factors, as well as for other patient demographics and for the volume of recent ED arrivals, Medicaid status was nevertheless associated with 22% greater odds of assignment to a hallway bed (odds ratio 1.22, [95% confidence interval, CI, 1.18-1.26]), compared to private insurance. Visits assigned to hallway beds had longer lengths of stay than roomed visits of comparable acuity (hazard ratio for departure 0.91 [95% CI, 0.90-0.92]).

Conclusion: We find evidence of social determinants of hallway bed use, likely involving epidemiologic, clinical, and operational factors. Even after accounting for different distributions of chief complaints and for more frequent ED use by the Medicaid population, as well as for other visit characteristics known at the time of triage, visits paid primarily by Medicaid retain a disproportionate association with hallway bed assignment. Further research is needed to eliminate potential bias in the use of hallway beds. [West J Emerg Med. 2020;21(4)949-958.]

INTRODUCTION

When emergency department (ED) patient volume exceeds room capacity, patients may be seen in hallway beds rather than in dedicated examination rooms. Hallway bed use increases with overall hospital crowding.¹ Because hallway beds lack privacy compared to dedicated rooms, patients

assigned to hallway beds may receive inadequate history-taking, particularly on sensitive subjects, or may be less willing to disclose information to providers. Providers may be less inclined to perform a thorough physical examination in the hallway, and patients may be less comfortable with any examination performed. In a recent survey, emergency

physicians reported diagnostic errors and delays associated with hallway beds, with particular deficits for the diagnosis of self-harm, domestic violence, human trafficking, and substance abuse.²

Treating sick patients in hallway beds has been identified as a risk for preventable adverse outcomes, and disciplinary and legal action against providers.³ Even hand hygiene among ED staff has been found to be poorer in hallway care areas than in dedicated rooms.⁴ Placement in an ED hallway bed is associated with lower patient satisfaction, lower likelihood of recommending the ED to others, and a poorer assessment of a patient's overall hospital experience.^{5,6} Because satisfied patients are more likely to comply with medical advice, to return for recommended follow-up, and to communicate effectively with their physicians,^{7,8} patients seen in hallway beds may also be at risk of poorer downstream outcomes.

Because of the provisional nature of hallway beds, hospitals may lack objective policies guiding the assignment of patients to hallway beds, risking bias in the selection of patients for these less desirable and clinically inferior beds. Clinical appropriateness dictates that, if hallway beds are to be used, patients should be assigned to these beds solely on the basis of complaints amenable to adequate care in the hall rather than in a dedicated room.⁹ In reality, factors other than clinical appropriateness affect patient trajectories throughout the healthcare system, with racial and ethnic minorities and the poor less likely to receive appropriate care in a number of venues.¹⁰ Patients' insurance status (eg, private, Medicare, Medicaid, or uninsured) both directly affects the services and dispositions available to patients, and additionally serves as a proxy for socioeconomic status (ie, patients on Medicaid are more likely to be poor than patients with private insurance). Insurance status has been identified as a significant predictor of outcomes ranging from stroke treatment and recovery,¹¹ to the length of ED boarding for patients requiring psychiatric hospitalization, with Medicaid patients having significantly longer ED stays than privately insured patients.¹²

Our objective was to determine whether socioeconomic factors influence which visits are assigned to hallway beds, independent of patients' clinical characteristics at triage. In particular, we investigate whether a visit's primary payor (as a marker of patient socioeconomic status) and patient race affect the likelihood of being triaged to a hallway bed rather than to a dedicated room, and the extent to which any such disparities may be attributed to clinical or nonclinical characteristics of visits at the time of triage. Our secondary aim was to characterize the effect of hallway bed assignment on length of stay (LOS).

METHODS

Study Design, Setting, and Participants

We performed a retrospective study of all visits to the adult acute care areas of two large, academic EDs from January 1, 2013–December 31, 2016. The adult acute care

Population Health Research Capsule

What do we already know about this issue?
Hallway beds in the emergency department (ED) are associated with lower patient satisfaction and inferior care.

What was the research question?
What determines which patients are placed in ED hallway beds, rather than in dedicated exam rooms?

What was the major finding of the study?
Medicaid patients are more likely than comparable privately insured patients to be placed in hallway beds.

How does this improve population health?
Hallway beds disproportionately burden the poor through multiple mechanisms. Further research can help reduce any inappropriate bias in bed assignment.

area of ED A had 52 roomed beds and a flexible number of hallway spaces. The adult acute care area of ED B consisted of 23 dedicated beds in private or semiprivate rooms, and five hallway spaces. In both EDs, visits were assigned to hallway beds when roomed beds were not available. The majority of patients assigned to hallway beds were seen in the hallway bed for the duration of their visit. At both sites, hallway beds were used as final sites of patient workup and management, rather than as areas for patients to wait for roomed beds.

We included all visits to the adult acute areas of the two EDs from January 1, 2013–December 31, 2016, for which basic demographic data (age, gender, race), chief complaint, and primary payor (Medicaid, Medicare, or private insurance) were recorded. We excluded 12.2% of all visits due to absence of an unambiguous primary payor (including no insurance).

Measurements and Outcomes

For each visit, we observed patient age, gender, race, ethnicity, and insurance status (ie, Medicaid, Medicare, or private insurance), as well as time and date of arrival, illness acuity level at triage (1-5), chief complaint, and final diagnosis by *International Classification of Disease*, 9th revision, (ICD-9) code and category. For each visit, we calculated the number of same-ED arrivals in the preceding three hours, as a dynamic measure of ED volume. We also calculated the number of preceding visits by the same patient during the study period (2013-2016). The primary outcome was the bed type to which

each visit was first triaged (roomed or hallway). Because only a small proportion (under 4%) of visits moved from a hallway bed to a roomed bed or vice versa during a visit, we used first assigned bed as our primary outcome. Our secondary outcome was LOS in the ED (arrival to departure, with auxiliary analyses for bed assignment to disposition decision).

Statistical Analysis

We calculated the proportion of acute care visits of a given triage acuity level (1-5, where 1 is most urgent and 5 is least urgent) initially triaged to a hallway bed. We stratified this analysis by primary payor (Medicaid, Medicare, or private insurance), and assessed for differences in proportions of visits assigned to hallway beds by payor, using two-sample tests for equality of proportions. We performed analogous analyses stratifying by chief complaint, and by patient-stated primary race (Asian, Black, White, or other). We calculated confidence intervals (CI) for the ratios of binomial parameters (such as rates of assignment to hallway beds) using a skewness-corrected likelihood score-based method.¹³ We calculated Pearson's correlation coefficients between visit number for a given patient (ie, the number of visits including the present visit for a given patient, 2013-2016), and the probability of hallway bed assignment, separately for each payor category. As described below, we controlled for a wide range of factors that might confound these associations.

In a logistic model of ED visits, we regressed hallway bed assignment on patient- and visit-level factors including the following: patient age; gender; race; ethnicity; and payor (indicator variables for Medicare, Medicaid, or private insurance); triage acuity (in reverse ordinal specification, such that a higher value in the model reflects greater clinical acuity); chief complaint (indicator variables for the 40 most common complaints, and an 'Other' category encompassing all other complaints); the number of same-ED arrivals in the three hours preceding a given visit (as a measure of momentary ED volume); and the number of visits to date from the patient associated with a given visit (as a dynamic, patient-level measure of ED use). We estimated robust standard errors, clustered by patient.

We calculated median LOS (time from ED arrival to departure) in the ED by triage acuity and bed type (roomed vs hallway), and used the Wilcoxon rank-sum test to assess for differences in median LOS. We estimated a Cox proportional hazards model for the effect of hallway bed assignment on LOS, controlling for triage acuity, age, gender, race, Hispanic ethnicity, ED volume, and chief complaint. In auxiliary models, we assessed the robustness of this result to different specifications of LOS (arrival to departure vs bed assignment to disposition decision).

In auxiliary analyses, we assessed for differences in hallway bed assignment by diagnosis, coded by ICD-9 diagnostic category. Because these diagnoses are assigned after triage decisions are made, we did not include diagnosis

in our primary analyses of hallway bed assignment, as this would entail conditioning on post-triage variables, and thus induce post-exposure bias.¹⁴

All analyses were performed in *R*, version 3.6 (R Project for Statistical Computing). The study was approved by the institutional review boards of Stanford Health Care and Beth Israel Deaconess Medical Center.

RESULTS

Subject Characteristics

We observed 332,919 adult visits, across 189,326 patients, to our two EDs from January 1, 2013–December 31, 2016. Of these visits, we studied the 292,170 encounters for which a clear primary payor was identified in one of three categories (private, Medicaid, or Medicare), and for which relevant visit characteristics (triage acuity, chief complaint, time and date of visit) and patient demographics (gender, age, race, ethnicity) were recorded. The median age of patients at time of visit was 53 years, and 54.0% of visits were by female patients. Of the total visits, 42.1% had a private primary payor, 37.1% were primarily paid by Medicare, and 20.7% were primarily paid by Medicaid. With regard to race, 57.3% of patients identified as White, 18.1% as Black, 7.2% as Asian, and 17.4% identified as a different race or did not identify a race.

Main Results

The proportion of adult acute care visits assigned to hallway beds was 16.2% overall, ranging from a mean of 4.2% on Mondays between 5-6 AM, to 25.6% on Mondays between 3-4 PM (Figure S1). The proportion of visits assigned to hallway beds was strongly correlated with the number of same-ED arrivals in the preceding three hours, with an additional 10 arrivals in the preceding three hours associated with a 5.5% increase in the probability of a new arrival being assigned to a hallway bed (Figure 1). Acuity level 1-2 (higher acuity) visits were more likely to be triaged to roomed beds, and level 3-5 (lower acuity) visits were more likely to be triaged to hallway beds (Figure S2). There were very few level 5 visits in these data because level 5 visits were not generally seen in the acute care areas of the study EDs, but were instead triaged to separate "fast track" areas.

At triage acuity levels 2-5 (95.1% of visits), visits paid primarily by Medicaid were more likely to be assigned to hallway beds, compared to visits paid by Medicare or private insurance (Figure 2). For instance, at triage acuity level 3 (58.5% of visits), Medicaid visits were 25.9% more likely (95% CI, 23.2% - 28.8%) to be assigned to hallway beds, compared to pooled Medicare and privately insured visits. The pattern was similar at both sites (Figure S3). We interpreted Medicaid status as a proxy for patient socioeconomic status, rather than as a direct causal factor itself, since payor is not generally known at the time of bed assignment, but is highly correlated with socioeconomic status and its potentially observable markers.

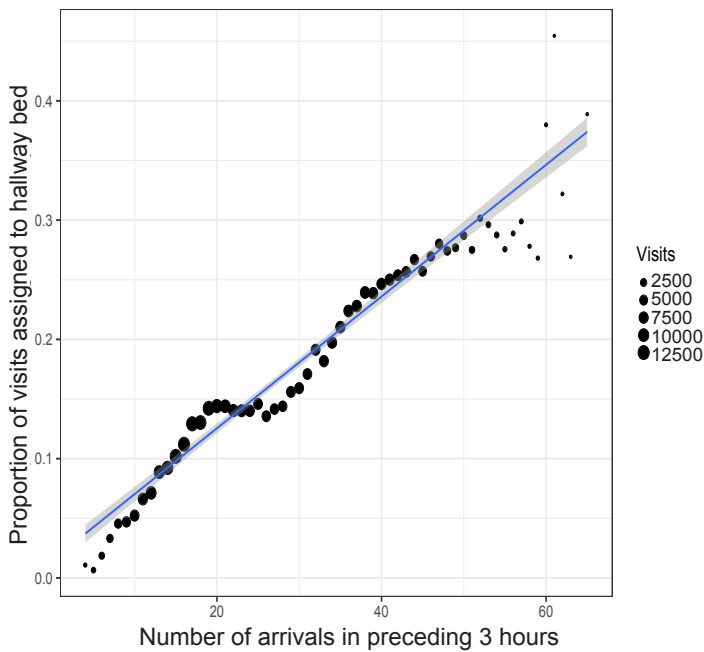


Figure 1. Hallway bed use and recent ED arrivals. For each visit, we calculated the number of same-ED patient arrivals in the preceding three hours. The likelihood of hallway bed assignment increases linearly with the number of recent ED arrivals, which reflects overall demand for beds. The blue line gives a visit-weighted line of best fit, and the shaded gray band shows the 95% confidence band around this estimate. On average, an additional 10 arrivals in the preceding 3 hours is associated with a 5.5% increase (95% confidence interval, 5.2% – 5.8%) in the probability of a new arrival being assigned to a hallway bed.

In analogous unadjusted comparisons, visits of Black patients were more likely than visits by patients of other races to be assigned to hallway beds at triage acuity levels 2-4: at level 3, Black patients were 20.7% more likely (95% CI, 18.0% - 23.5%) than patients of other races to be assigned a hallway bed, although the effect of race was more variable than the effect of insurer across our sites (Figure S4). Although Black patients were more likely than Asian or White patients to be insured by Medicaid (Figure S5), the relationship between race, insurance status, and hallway bed assignment was complex (Figure S6), and Black race was not an independently significant predictor of hallway bed use after accounting for all observable visit characteristics (Table 1), as detailed below.

Because chief complaints may be differentially amenable to evaluation in hallway beds, and because different populations have different distributions of chief complaints, chief complaint may mediate the bivariate relationship between insurance status and hallway bed assignment we describe above. Figure 3 shows the proportion of ED visits accounted for by each of the 40 most common chief complaints, as well as the proportion of visits with a given chief complaint assigned to hallway beds, with both sets of

analyses stratified by primary visit payor (Medicare, Medicaid, or private insurance). Medicaid patients were more likely than patients insured by Medicare or private insurance to present with certain complaints including abdominal pain, psychiatric problems or anxiety, headache, alcohol intoxication, and back, leg, flank, or knee pain. For some of these complaints, such as psychiatric problems, Medicaid patients were not more likely to be assigned to hallway beds, conditional on complaint. For these complaints, higher rates of assignment of Medicaid patients to hallway beds may be explained by their presenting at higher rates with hallway-amenable complaints. For other complaints, such as alcohol intoxication, Medicaid patients were more likely to be assigned to hallway beds, even accounting for higher prevalence of the complaint.

Because differently insured populations have differential access to non-ED options for care, frequency of ED use may also confound the relationship between insurance status and hallway bed assignment. If Medicaid patients are more frequent users of ED services, for instance, and if “frequent fliers” of any insurance status are more likely to be placed in hallway beds, then a higher number of frequent ED users may account for some of the apparent relationship between Medicaid status and hallway bed assignment. Figure 4 shows the relationship between hallway bed assignment and “visit number,” ie, the number of visits preceding and including the visit of interest from the same patient, in our study period. More frequent ED users were indeed more

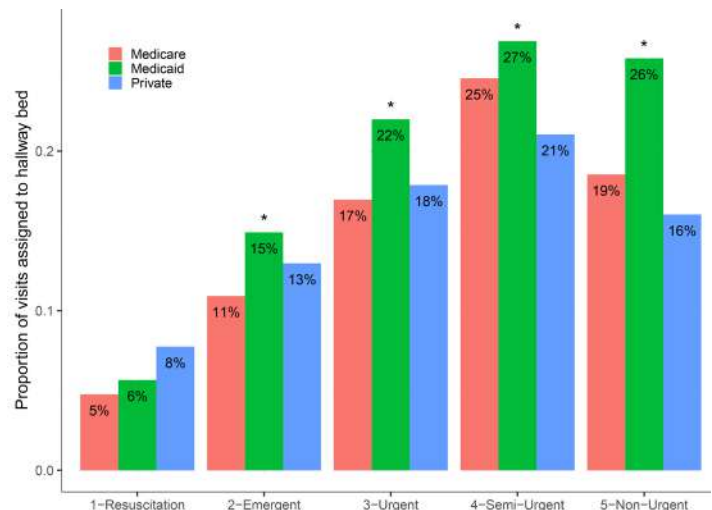


Figure 2. At triage acuity levels 2-5 (95.1% of visits), visits paid primarily by Medicaid were more likely to be assigned to hallway beds, compared to visits paid by Medicare or private insurance. Asterisks denote significant differences in proportions at $p < 0.01$, comparing Medicaid visits to pooled Medicare and privately insured visits. The small proportion of Emergency Severity Index 1 visits assigned to hallway beds were predominantly stroke code activations, which are assigned to hallway beds in anticipation of imminent transportation to radiology.

Table 1. Logistic regression model of hallway bed assignment.

	OR (95% CI)
Intercept	0.19 (0.18 - 0.21)
Age	1.00 (0.99 - 1.00)
Male	1.10 (1.08 - 1.13)
Triage acuity	0.60 (0.59 - 0.61)
Medicare	1.04 (1.00 - 1.07)
Medicaid	1.22 (1.18 - 1.26)
Asian	0.93 (0.89 - 0.98)
Black	1.01 (0.98 - 1.05)
Other race	1.06 (1.01 - 1.11)
Hispanic	0.92 (0.87 - 0.97)
Site B	1.51 (1.46 - 1.57)
3h arrivals	1.06 (1.06 - 1.06)
Patient visit	1.03 (1.02 - 1.03)
CC: Abdominal pain	0.87 (0.84 - 0.91)
CC: Chest pain	0.66 (0.62 - 0.70)
CC: Dyspnea	0.55 (0.51 - 0.60)
CC: Fall	1.35 (1.26 - 1.44)
CC: Psych problem	1.63 (1.50 - 1.76)
CC: Back pain	1.38 (1.29 - 1.48)
CC: Leg pain	1.57 (1.46 - 1.69)
CC: Flank pain	1.04 (0.96 - 1.13)
CC: Headache	1.15 (1.06 - 1.25)
CC: MVC	1.13 (0.98 - 1.31)
CC: Alcohol intoxication	8.50 (7.76 - 9.30)
CC: Fever	0.43 (0.38 - 0.49)
CC: Emesis	0.84 (0.76 - 0.93)
CC: Dizziness	1.09 (0.98 - 1.21)
CC: Weakness	0.91 (0.82 - 1.01)
CC: Knee pain	1.70 (1.55 - 1.86)
CC: Syncope	0.85 (0.76 - 0.96)
CC: Foot pain	1.80 (1.63 - 1.99)
CC: Wound evaluation	0.88 (0.79 - 0.98)
CC: Neurologic problem	1.56 (1.37 - 1.78)
CC: AMS	0.79 (0.69 - 0.92)
CC: Seizure	1.24 (1.10 - 1.40)
CC: Breathing problem	0.47 (0.39 - 0.57)
CC: Abnormal lab	0.96 (0.84 - 1.09)
CC: Cough	0.80 (0.70 - 0.92)
CC: Palpitations	0.59 (0.49 - 0.71)
CC: Allergic reaction	2.05 (1.81 - 2.34)
CC: Rash	0.64 (0.54 - 0.75)
CC: Vaginal bleeding	0.34 (0.27 - 0.42)

Standard errors clustered by patient. Entries denote odds ratios (OR) and 95% confidence intervals (CI).
 CC, chief complaint; MVC, motor vehicle collision; AMS, altered medical status.

Table 1. Continued.

	OR (95% CI)
CC: Sore throat	0.60 (0.50 - 0.71)
CC: BRBPR	0.71 (0.59 - 0.86)
CC: Flu-like illness	0.21 (0.16 - 0.28)
CC: Anxiety	3.12 (2.70 - 3.59)
CC: Neck pain	1.54 (1.31 - 1.81)
CC: Hypertension	1.10 (0.93 - 1.30)
CC: Diarrhea	0.65 (0.53 - 0.79)
CC: Melena	0.52 (0.41 - 0.67)
CC: Head injury	1.50 (1.26 - 1.80)
CC: Bicycle accident	0.59 (0.41 - 0.86)
CC: Urinary retention	0.43 (0.33 - 0.56)
N	281,183
AIC	228,397

Standard errors clustered by patient. Entries denote odds ratios (OR) and 95% confidence intervals (CI).
 CC, chief complaint; BRBPR, bright red blood per rectum; AIC, Akaike information criterion.

likely to be assigned to hallway beds. Medicaid patients were likelier than patients with Medicare or private insurance to be frequent users of the ED (bottom panel). Notably, however, the correlation between visit number and hallway bed assignment was stronger for visits paid by Medicaid ($r = 0.83$) than for those paid by Medicare ($r = 0.67$) or private insurance ($r = 0.75$). Compared to first or second visits from a given patient, third or later visits from the same patient were likelier to be from older patients, from patients with Medicaid or Medicare, and for chief complaints including abdominal pain, chest pain, dyspnea, psychiatric problems, alcohol intoxication, and altered mental status (Table S1). We accounted for all of these features in our models of hallway bed assignment.

Table 1 presents a logistic model of ED visits, regressing hallway bed assignment on patient- and visit-level factors including age, gender, race, Hispanic ethnicity, payor, triage acuity, chief complaint, number of same-ED arrivals in the three hours preceding a given visit (as a measure of momentary ED volume), and the number of visits to date from the patient in question. We estimated robust standard errors, clustered by patient. Controlling for these factors, we found that visits paid primarily by Medicaid had 22% greater odds of being assigned to a hallway bed (odds ratio [OR] 1.22 [95% CI, 1.18-1.26]), compared to visits paid by private insurers. In this fully specified model, Black race was not independently predictive of hallway bed assignment (OR 1.01 [95% CI, 0.98-1.05]), compared to visits of White patients. In this model, an additional patient arrival in the preceding three hours was associated with 6% greater odds

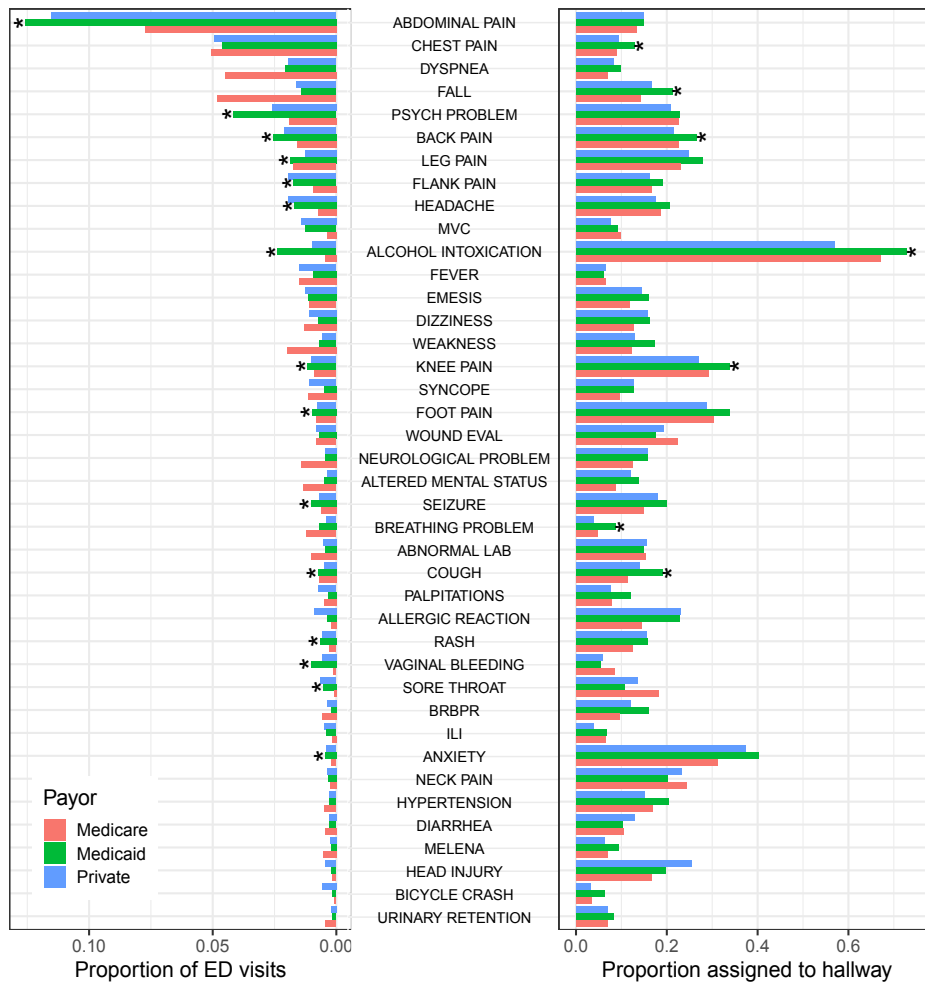


Figure 3. Rates of emergency department visits and hallway bed assignment, by payor and chief complaint. The 40 commonest chief complaints are shown, which collectively account for half of all visits. The left panel shows the proportion of ED visits accounted for by each complaint, stratified by payor. The right panel shows the proportion of visits of a given chief complaint assigned a hallway bed, again stratified by payor. Asterisks denote differences in proportions significant at $p < 0.001$ (to account for multiple comparisons), comparing Medicaid patients to Medicare and privately insured patients, pooled. Medicaid patients are more likely than patients insured by Medicare or private insurance to present with certain complaints including abdominal pain, psychiatric problems or anxiety, headache, alcohol intoxication, and back, leg, flank, or knee pain (left panel). For some of these complaints, such as psychiatric problems, Medicaid patients are not more likely to be assigned to hallway beds, conditional on complaint. For others, such as alcohol intoxication, Medicaid patients are more likely to be assigned to hallway beds, even accounting for higher prevalence of the complaint (right panel). MVC, motor vehicle collision; ILI, influenza like illness; BRBPR, bright red blood per rectum.

of hallway bed assignment (OR 1.06 [95% CI, 1.06 - 1.06]), and an additional prior visit from the same patient predicted 3% greater odds of hallway assignment (OR 1.03 [95% CI, 1.02-1.03]). Chief complaints associated with increased odds of hallway bed assignment included the following: alcohol intoxication; psychiatric complaints; fall; and back, neck, knee, and leg pain.

Table S2 shows a hierarchy of models of increasing complexity, of which Model 4 is the final model described above. The attenuation of the estimated OR associated with Medicaid status with the sequential introduction of chief complaint (Model 1 to Model 2), and prior patient visits (Model 3 to Model 4) supports the interpretation above, i.e.,

that the aggregate association between Medicaid status and hallway bed assignment, as depicted in Figure 2, is mediated in part by differential distributions of chief complaints (Figure 3), and by more frequent ED use by the Medicaid population (Figure 4), but that even after accounting for these factors, as well as for other visit characteristics known at the time of triage, visits paid primarily by Medicaid retain a disproportionate association with hallway bed assignment.

We did not condition on final diagnosis in our primary analyses to avoid introducing post-exposure bias (unlike chief complaint, final diagnosis is not known at the time of bed assignment).¹⁴ Nevertheless, an auxiliary analysis stratifying by ICD-9 diagnostic category showed that visits by Medicaid

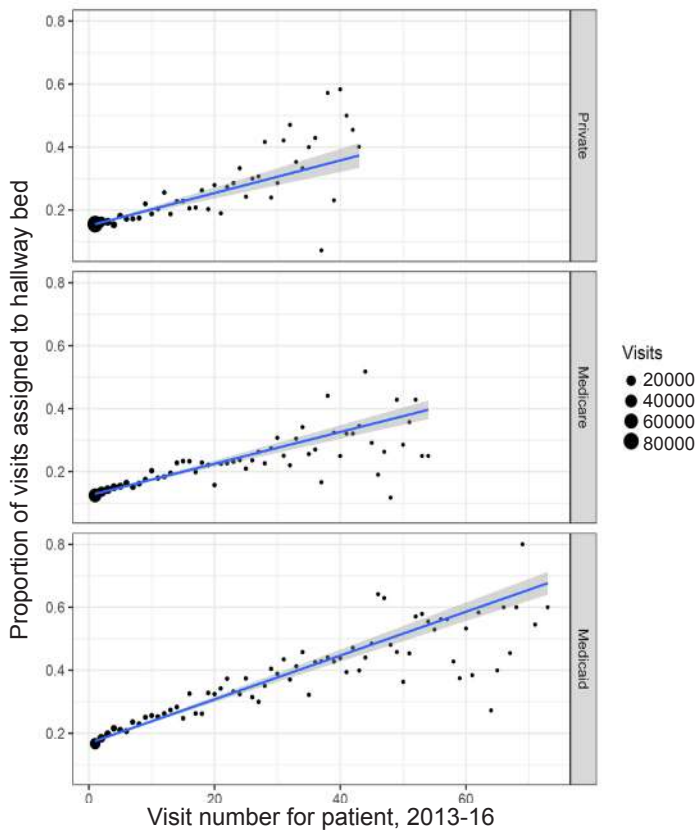


Figure 4. Proportion of visits assigned to hallway bed, by emergency department (ED) visit number for a given patient, 2013-2016. More frequent ED users are more likely to be assigned to hallway beds. Plots depict the proportions of visits of a given “visit number” (the number of visits up to and including the present visit by the patient associated with the present visit, in the study period, 2013-2016) assigned to hallway beds. Medicaid patients are likelier than patients with Medicare or private insurance to be frequent users of the ED (eg, with many more patients with 40 or more visits during the study period, bottom panel). Still, the correlation between visit number and hallway bed assignment is stronger for Medicaid patients ($r = 0.83$) than for patients with Medicare ($r = 0.67$) or private insurance ($r = 0.75$). Blue lines denote visit-weighted lines of best fit. Point size is proportional to the number of visits of a given type.

patients were more likely to be seen in the hallway across diagnostic categories, with particularly marked disparities for injury and poisoning, mental illness, and musculoskeletal disease (Figure S7). This analysis also recapitulates the previously described finding of prolonged “boarding” of psychiatric patients in ED hallway beds,^{12,15} with patients presenting with psychiatric diagnoses more likely than any other diagnostic category to be assigned to hallway beds.

Length of Stay

Visits assigned to hallway beds had significantly longer LOS than roomed visits of the same acuity level (Figure 5, Figure S8). In a visit-level Cox proportional hazards model of visit duration, controlling for age, gender, race, triage acuity,

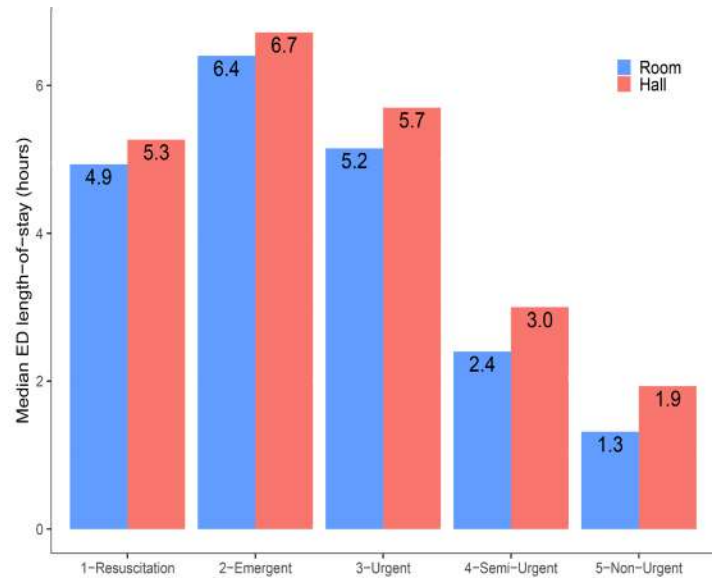


Figure 5. Patients assigned to hallway beds have significantly longer lengths of stay than roomed patients of the same acuity level. All differences are significant at $p < 0.01$ by Wilcoxon rank-sum test.

volume of recent arrivals, and chief complaint (Table 2), visits assigned to hallway beds had significantly longer LOS than comparable roomed visits, with a hazard ratio for ED departure of 0.91 (95% CI, 0.90-0.92). Complaints associated with significantly prolonged LOS included alcohol intoxication, psychiatric complaints, abdominal pain, and chest pain. In auxiliary models, in which we compared arrival-to-departure time and bed-assignment-to-disposition time as outcomes in otherwise identical Cox proportional hazards models estimated on the subset of patients with available times of first bed assignment and disposition decision, hazard ratios associated with hallway bed assignment were very similar with either outcome (Table S3).

DISCUSSION

Our findings provide evidence for socioeconomic determinants of hallway bed use at two large, academic EDs. The magnitude of the association is considerable, with visits paid by Medicaid having 22% greater odds of being assigned to a hallway bed, compared to otherwise comparable visits paid by private insurance. Although Black patients were more likely than patients of other races to be assigned to hallway beds, race was not a significant predictor of hallway bed assignment after controlling for other features of visits observable at triage.

Both policy¹⁶ and legal precedent^{17,18} dictate that insurance or socioeconomic status should not affect ED triage, and that clinical personnel should not in general know the patient’s insurance status throughout initial screening and stabilization.

Table 2. Cox proportional hazards model for time to emergency department departure (admission or discharge).

	Hazard ratio (95% CI)
Hallway bed	0.91 (0.90 - 0.92)
Triage acuity	0.74 (0.74 - 0.75)
Age	0.99 (0.99 - 0.99)
Male	1.01 (1.01 - 1.02)
Asian	1.03 (1.02 - 1.05)
Black	0.94 (0.93 - 0.95)
Other race	1.01 (0.99 - 1.02)
Hispanic	0.96 (0.94 - 0.98)
ED B	1.04 (1.03 - 1.06)
3h arrivals	0.99 (0.99 - 0.99)
CC: Abdominal pain	0.77 (0.76 - 0.78)
CC: Chest pain	0.79 (0.78 - 0.81)
CC: Dyspnea	0.96 (0.94 - 0.99)
CC: Fall	0.97 (0.94 - 0.99)
CC: Psych problem	0.36 (0.36 - 0.37)
CC: Back pain	1.02 (0.99 - 1.05)
CC: Leg pain	0.92 (0.90 - 0.95)
CC: Flank pain	0.86 (0.83 - 0.88)
CC: Headache	1.05 (1.01 - 1.08)
CC: MVC	1.61 (1.52 - 1.69)
CC: Alcohol intoxication	0.63 (0.60 - 0.65)
CC: Fever	0.86 (0.83 - 0.88)
CC: Emesis	0.78 (0.76 - 0.81)
CC: Dizziness	1.07 (1.03 - 1.11)
CC: Weakness	0.80 (0.78 - 0.83)
CC: Knee pain	1.10 (1.06 - 1.14)
CC: Syncope	1.11 (1.07 - 1.16)
CC: Foot pain	1.21 (1.16 - 1.26)
CC: Wound evaluation	1.09 (1.04 - 1.13)
CC: Neurologic problem	1.01 (0.97 - 1.05)
CC: AMS	0.87 (0.84 - 0.91)
CC: Seizure	0.93 (0.89 - 0.97)
CC: Breathing problem	0.80 (0.77 - 0.84)
CC: Abnormal lab	0.91 (0.87 - 0.95)
CC: Cough	1.20 (1.15 - 1.26)
CC: Palpitations	1.19 (1.14 - 1.25)
CC: Allergic reaction	1.84 (1.75 - 1.94)
CC: Rash	2.04 (1.94 - 2.16)
CC: Vaginal bleeding	1.15 (1.09 - 1.21)

Standard errors clustered by patient. Entries denote hazard ratios and 95% confidence intervals (CI).

ED, emergency department; CC, chief complaint; MVC, motor vehicle collision; AMS, altered medical status.

Table 2. Continued.

	Hazard ratio (95% CI)
CC: Sore throat	1.35 (1.27 - 1.43)
CC: BRBPR	1.24 (1.17 - 1.31)
CC: Flu-like illness	1.07 (1.01 - 1.14)
CC: Anxiety	0.78 (0.73 - 0.83)
CC: Neck pain	1.22 (1.15 - 1.30)
CC: Hypertension	1.48 (1.39 - 1.58)
CC: Diarrhea	0.97 (0.91 - 1.03)
CC: Melena	0.90 (0.84 - 0.95)
CC: Head injury	2.22 (2.07 - 2.39)
CC: Bicycle accident	1.19 (1.08 - 1.32)
CC: Urinary retention	1.39 (1.30 - 1.49)
N	281,143
R ²	0.12

Standard errors clustered by patient. Entries denote hazard ratios and 95% confidence intervals (CI).

CC, chief complaint; BRBPR, bright red blood per rectum.

Because evaluation in a hallway bed is associated with poorer patient satisfaction as well as with potentially inferior care,³⁻⁶ any bias in hallway bed assignment risks compounding the known disadvantages faced by the poor and by racial minorities throughout the healthcare system.

The association between Medicaid status and hallway bed assignment is likely enacted via mechanisms at different levels of analysis, of which bias in bed assignment decisions may be only one. Medicaid status is not generally known at the time of triage, and so is unlikely to directly dictate bed assignment. In our analyses, a substantial portion of the aggregate association was accounted for by higher burdens of psychiatric and substance use presentations among the Medicaid population, which likely reflect consequences of poverty, and by frequent ED users, which may reflect poorer access to primary care and specialty services among Medicaid patients. Although upstream issues of poverty and access to care cannot be solved by changes to bed assignment policies, our analysis suggests that, in many cases, a patient's being assigned to a hallway bed can be a proxy for unmet social needs, and patients in hallway beds may be particularly likely to benefit from social work and case management services. Notably, the association between Medicaid status and hallway bed assignment persisted even after controlling for features such as chief complaint and visit frequency, suggesting other mechanisms not directly observed in our data.

We propose three avenues for further research. First, because a patient's insurance status is not generally known before triage decisions are made, Medicaid status per se is unlikely to affect hallway bed assignment, and a qualitative study of providers making triage decisions can help identify

the visit characteristics associated with insurance status that may affect bed assignment, beyond chief complaint, triage acuity level, and demographics.

Second, we propose estimating the predilection of individual triage providers to assign Medicaid patients to hallway beds. Although adequately controlling for variation in patient characteristics would require selection of only those providers triaging large numbers of visits, finding consistent and longitudinal differences among triage providers in the likelihood of assigning Medicaid patients to hallway beds would support an element of discretionary bias at the level of triage, rather than the effect of clinically relevant but unmeasured features associated with insurance status, which over large numbers of visits would be expected to be distributed similarly across the patients triaged by different providers.

Finally, to whatever extent the association between insurance status and bed assignment is driven by non-clinical bias, corrective interventions are needed. The simplest way to mitigate the inferior care and patient experience associated with hallway beds is to reduce the need for these temporary beds altogether, via hospital-wide strategies to improve the efficiency of admissions, discharges, and transfers.¹⁹ Since this analysis was performed, one of our study sites has moved to a new ED with only individual patient rooms and no hallway beds. Clearly, however, new facilities are not a general remedy for the use of hallway beds. To improve equity in the use of hallway beds that cannot be eliminated, triage personnel could be encouraged to consider only clinical characteristics in making bed assignments, or required to give brief justification for a decision to assign a patient to a hallway bed. A more targeted intervention would quantify the degree of possible bias in bed assignment decisions for all triage personnel, and provide each triage provider with a “scorecard” illustrating his or her historical propensity to assign Medicaid patients to hallway beds, compared to the mean propensity for triage personnel to do the same. Such an approach has been shown to reduce opioid prescribing among ED providers.²⁰ After a predetermined period (e.g., one year or more), the present analyses could be repeated, including at the provider level, to assess for reductions in socioeconomic disparities, and to design more effective bias-reduction interventions in turn.

LIMITATIONS

Our study has limitations. Although the sample size is large, the study was conducted at two centers, both large teaching hospitals, and our findings regarding hallway bed use may not generalize to other sites. Although we control for patient demographics, acuity level at triage, chief complaint, frequent visitors, and ED volume, it is conceivable that insurance status could correlate with other unrecorded but clinically relevant characteristics on which triage decisions are made. We did not observe rates of ED “boarding,” which is likely a major driver of the overall use of hallway beds. More generally, although we identify a robust association between

Medicaid status and assignment to hallway beds, we do not identify all mechanisms whereby insurance status affects triage decisions. Part but not all of the association is explained by acuity, demographics, chief complaints, and frequent ED users. In general, payor is not known until patients are registered, typically after triage decisions are made. Thus, Medicaid status itself is unlikely to bias triage decisions, but rather to be correlated with some set of observable patient characteristics that affect these decisions.

CONCLUSION

The determinants of hallway bed use are complex. Patients insured by Medicaid, a proxy for low socioeconomic status, are more likely to be assigned to hallway beds for multiple reasons. These mechanisms require further investigation to reduce the possibility of inappropriate bias in the use of hallway beds.

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Food Insecurity and Insulin Use in Hyperglycemic Patients Presenting to the Emergency Department

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Introduction: The prevalence of food insecurity (FI) and insulin rationing among patients with diabetes who present to the emergency department (ED) is unclear. We examined the prevalence of food insecurity and subtherapeutic insulin use among patients who presented to the ED with a blood glucose level of greater than 250 milligrams per deciliter.

Methods: This was a single-center, cross-sectional survey of clinically stable, hyperglycemic adults in the ED for food insecurity using the Hunger Vital Sign screening tool. Patients who were insulin dependent were asked about insulin usage and rationing.

Results: Of the 85 eligible patients, 76 (89.4%) were enrolled; 35 (46%) screened positive for food insecurity. Food insecure patients were 1.9 times more likely to be hospitalized than non-food insecure patients (relative risk = 1.90 [1.21-2.99], $p < .01$). Food insecure patients were younger than non-food insecure patients (50.4 vs 57.5 $p < .02$), and had significantly higher hemoglobin A1c (HgbA1c) levels (11.2% vs 9.9% $p = 0.04$). Of the 49 patients prescribed insulin, 17 (34.6%) stated they had used less insulin during the prior week than had been prescribed, and 21 (42.9%) stated they had used less insulin during the prior year than had been prescribed. Food insecure patients were more likely to have used less insulin than prescribed in the prior year (odds ratio = 3.60 [1.09-11.9], $p = 0.04$).

Conclusion: Our exploratory findings suggest almost half of clinically stable adults presenting to our inner-city ED with hyperglycemia experience food insecurity. More than one-third of those prescribed insulin used less than their prescribed amount in the prior year. [West J Emerg Med. 2020;21(4)959–963.]

INTRODUCTION

Food insecurity (FI) is defined as “limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways.”¹ Previous research has suggested that food-insecure patients are more likely to have diabetes than those who are not food insecure, adjusting for other socioeconomic factors and physical activity.² Those living with diabetes

and food insecurity are at high risk of poor outcomes due to the struggle of deciding whether to spend limited financial resources on food or medication.^{3,4}

Insulin prices have increased 300% in the past decade, leading to reports of patients rationing insulin.⁵ The prevalence of insulin rationing to save money has not been well described among the general diabetic population. Herkert et al reported their experience at the Yale Diabetes Center and found that

25.5% reported cost-related insulin underuse. Among these patients, more than one-third did not inform their physician.⁶

Existing data on the prevalence of FI are variable and are likely dependent on a number of factors including the clinical environment in which patients are surveyed. Data from DC Hunger Solutions demonstrated that 15% of the general population in Washington DC is food insecure.⁷ In a single-center study performed at a large, urban Minneapolis emergency department (ED), more than a fifth (22%) of patients were food insecure.⁸ Among diabetic patients in urban safety net clinics in San Francisco, 60% were food insecure.⁹ Currently there are no published data on the rate of FI among high-risk groups such as diabetic patients who present to the ED.

Efficiently screening for FI may provide an opportunity to mitigate this social determinant of health. In this study we aimed to quantify the prevalence of FI and subtherapeutic insulin usage among diabetic patients who present to the ED with hyperglycemia. We hypothesized that the prevalence of FI was higher among patients with hyperglycemia treated in the ED compared with the general population.

METHODS

We conducted a single-center, cross-sectional exploratory study and report in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Guidelines.¹⁰ The study protocol was reviewed and approved by our institutional review board. Subjects were enrolled from June 11–July 26, 2019, between the hours of 8 AM and 10 PM Monday through Friday at an urban, adult, tertiary care teaching hospital ED with ~90,000 annual visits. Trained and supervised research assistants were electronically notified when any patient in the ED had a blood glucose > 250 milligrams per deciliter (mg/dL) using a screening tool built into the electronic health record. After confirming medical stability with the clinical team, research assistants verbally consented subjects and provided an information sheet detailing involvement. Non-English speakers were excluded because we did not have the resources to reliably consent these patients.

Consenting subjects were verbally administered the previously validated Hunger Vital Sign screening tool for FI.¹¹ A response from the patient with “Often True” or “Sometimes True” from either question was categorized as a positive screen. Insulin-dependent subjects were also asked questions regarding insulin rationing adapted from Herkert et al. (Figure 1).⁶ In addition, we recorded baseline characteristics (including age, gender, race/ethnicity, weight, height, pre-existing comorbid conditions); vital signs at presentation, pertinent laboratory variables (including basic metabolic panel, anion gap, beta-hydroxybutyrate, venous/arterial blood gas, urinalysis); years since diagnosed with diabetes; outpatient insulin regimen (insulin types, dose, timing); how many doses missed in the past week or month; and disposition

Population Health Research Capsule

What do we already know about this issue?
Food insecurity (FI) is associated with poorer health outcomes. Screening for FI may provide an opportunity to mitigate this social determinant of health.

What was the research question?
What is the prevalence of FI in hyperglycemic patients presenting to the emergency department (ED)?

What was the major finding of the study?
Forty-six percent of patients presenting to our inner-city ED with hyperglycemia experienced FI.

How does this improve population health?
There are no known simple clinical markers for FI for screening in the ED. Hyperglycemia may be an objective marker for FI, but this data requires external validation.

from the ED. Data were collected via an encrypted, standardized, REDCap data collection tool. If patients screened positive for FI, they were given an information sheet of resources to contact for emergency food and other public services based on their ZIP Code of residence.

The primary outcome was percentage of patients who screened positive for FI in the past 12 months. Secondary outcomes included percentage of patients who reported using less insulin than prescribed in the past week and the percentage who reported using less insulin than prescribed in the past year. Patient characteristics were assessed with descriptive statistics and frequency distributions. We compared categorical variables using the chi-square test or Fisher’s exact test. Continuous variables were compared using the independent samples t-test or Wilcoxon’s rank-sum test.

RESULTS

In total, 153 patients presented with a blood glucose greater than 250 mg/dL. Of those, 85 were eligible of whom nine declined, resulting in 76 subjects enrolled in our study (Figure 2). Mean age was 53.7 years, 58% were female, and 91.7% were Black. Of the 76 patients enrolled, two were homeless and two were housed in skilled nursing facilities. Refer to Table 1 for additional demographics. Of 76 subjects, 35 (46.1%) reported FI in the prior year.

I'm going to read you two statements that people have made about their food situation. For each statement, please tell me whether the statement was often true, sometimes true or never true for your household in the last 12 months.

"We worried whether our food would run out before we got money to buy more." Was that often true, sometimes true or never true for your household in the last 12 months?	<input type="radio"/> Often True <input type="radio"/> Sometimes True <input type="radio"/> Never True
--	--

"The food that we bought just didn't last, and we didn't have money to get more." Was that often true, sometimes true, or never true for your household in the last 12 months?	<input type="radio"/> Often True <input type="radio"/> Sometimes True <input type="radio"/> Never True
--	--

The next set of questions are about insulin. Are you prescribed insulin?	<input type="radio"/> Yes <input type="radio"/> No
--	---

Do any of the following statements apply to you in the past week: 1. I used LESS insulin than prescribed 2. I tried to stretch out my insulin 3. I stopped using insulin 4. I did not fill an insulin prescription	<input type="radio"/> Yes <input type="radio"/> No
--	---

What was the reason for using less insulin this week?	<input type="radio"/> Cost of Insulin <input type="radio"/> Insurance Authorization Issue <input type="radio"/> Traveling and forgot to bring insulin <input type="radio"/> Embarrassment of using insulin <input type="radio"/> Pain or Side Effects Associated with Insulin Use <input type="radio"/> Other Reason
---	---

Figure 1. Questionnaire items including the Hunger Vital Sign and screen for insulin use.

Forty-nine of the 76 subjects reported they had been prescribed insulin. Of these, 34.7% (17 of 49) reported using less insulin than prescribed in the past week and 42.9% (21 of 49) in the past year. Three of the 17 subjects (17.6%) reporting using less insulin than prescribed in the past week due to cost. All of these subjects also reported FI (Table 2). Other reasons for not using insulin as prescribed included traveling and forgot insulin; undesirable side effects; and prescription filling/authorization issues. There was no majority in the reasons for patients reporting insulin underuse.

Hyperglycemic patients who reported FI were 1.9 times more likely to be admitted to the hospital than discharged than hyperglycemic patients who did not report being food insecure (Table 3).

DISCUSSION

In this exploratory study, we sought to determine the prevalence of FI and insulin underuse in hyperglycemic patients in an urban ED. The prevalence of FI in our study is similar to that described in diabetic patients in safety net clinics in San Francisco,⁹ but more than double the rate described by Miner et al among all clinically stable patients presenting to their urban ED in Minneapolis.⁸ Furthermore, our study found that the rate of FI among those with a

glucose > 250 mg/dL in our ED was triple the rate of the general population in Washington, DC, as reported by DC Hunger Solutions (15%) suggesting that those who use our ED and those who are hyperglycemic are more likely to be food insecure.⁷

Patients who screened positive for FI were significantly more likely to be admitted to the hospital and have significantly higher HgbA1c levels. These results suggest that those who are food insecure have worse control of their diabetes leading to complications and hospitalization. It is unclear how much FI contributes to the lack of control vs

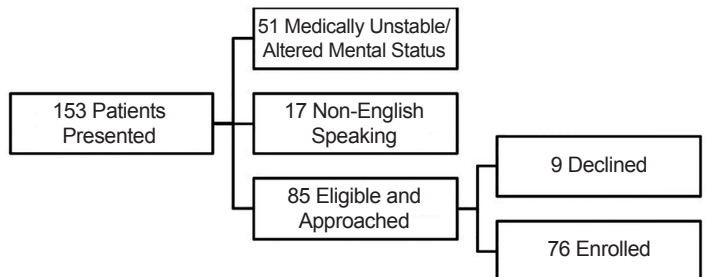


Figure 2. Patient enrollment in study of insulin use and food insecurity.

Table 1. Demographics.

	Food insecure	Non-food insecure	Total
Number of patients enrolled	35 (46.1%)	41	76
(Average Age \pm SD) p=.05	(50.4 \pm 12.6) n= 33	(56.5 \pm 13.2) n=39	(53.7 \pm 13.2) n=72
% Female	55%	60%	58%
Race (N=72)			
Black	29	37	66
Non-Hispanic White	1	1	2
Hispanic	1	1	2
Other	2	0	2
Annual income (N = 66)			
Less than \$12,490	13	11	24
\$12,490-\$25,000	11	3	14
\$25,000-\$50,000	3	11	14
\$50,000-\$75,000	1	3	4
\$75,000-\$100,000	2	2	4
>\$100,000	0	6	6
Education level (N = 73)			
High school/GED	20	28	48
Associates	5	2	7
Bachelors	3	5	8
Masters/Doctorate	2	3	5
Trade school	0	1	1
None of the above	3	1	4
Prescription Coverage Through Medicare, Medicaid or Private Health Insurance (N = 73)			
Coverage	32	36	68
No coverage	1	4	5
(Average HgbA1c \pm SD) p = 0.04	(11.2 \pm 1.9) n = 25	(9.9 \pm 1.9) n = 15	(10.7 \pm 2.0) n = 40

SD, standard deviation; GED, general education development.

being associated with poor control. It is plausible that if one is unsure what and when their next meal may be, they may be less likely to use their prescribed dose of diabetic medication(s). It is also possible that those with FI may have fewer healthy food choices, exacerbating their glycemic control and contributing to the observation that food-insecure patients were almost twice as likely to be admitted than those with food security.

Many studies have looked at possible interventions to address FI, but little is known about the efficacy of these interventions. One study interviewed a group of food-insecure patients who received written or verbal information about local resources and interviewed another group of food-insecure patients who received active, clinic-guided enrollment with a food resource program.⁹ In this clinic-guided enrollment, clinic staff would complete the program application and connect the patient with the program. This clinic-guided method had a much

higher success rate than sharing written or verbal information about local resources based on follow-up interviews (31% vs 0-4%).⁹ These data suggest that an intervention for food-insecure patients should include active support to enroll patients into food assistance programs.

FI is an important social determinant of health; it is insidious and has a profound impact on patient well-being. The ED may be the only point of care for many disadvantaged patients. There are no known simple clinical markers for FI that can be used for screening in the ED. The results of this study suggest that hyperglycemia may be an objective predictive clinical marker for FI. This hypothesis will need to be validated in a larger cohort of ED patients and among diverse ED settings. If our preliminary findings are validated, blood glucose levels, and specifically the presence of hyperglycemia, could be employed as a simple screening tool to identify FI, the next step in addressing this important social determinant of health.

Table 2. Insulin use in the past week and year.

	Used less insulin than prescribed in the past week		Used less insulin than prescribed in the past year	
	YES	NO	YES	NO
Food insecure	11	13	14	10
Non-food insecure	6	19	7	18
	OR =2.68 (0.79-9.07) p =0.11		OR = 3.60 (1.09-11.9) p = 0.04	

OR, odds ratio.

Table 3. Patient disposition: admitted to the hospital or discharged to home.

Disposition	Admitted to the hospital	Discharged to home
Food insecure (35)	25 (71.4%)	10 (28.6%)
Non-food insecure* (40)	15 (37.5%)	25 (62.5%)
	RR = 1.90 (1.21-2.99), p<.01	

*One patient who was non-food insecure left against medical advice. RR, relative risk.

LIMITATIONS

There were several limitations to this observational study. Patients had to be clinically stable and awake to be screened, which could have biased the patient population to those who were healthier. Answers were patient reported; therefore they were subject to recall bias. Patients may have had reservations about answering that they indeed had FI, which may have led to under-reporting and a falsely low reported prevalence of FI. We used a prior study’s ED FI rate,⁸ and did not include non-hyperglycemic patients. It is possible the prevalence of FI is high in our ED population and may not be unique to hyperglycemic patients.

Results from this convenience sample may not be generalizable to populations that were excluded, including non-English speakers and those presenting overnight and on weekends who may have differed in their prevalence of FI. In addition, we did not record reason for presentation and, therefore, were unable to determine what portion of the study subjects presented with issues related to diabetes. Finally, our institution is a large, safety-net hospital as represented by more than half of responding participants noting an annual household income of ≤ \$25,000. This may overestimate the prevalence of FI in locations with less poverty.

CONCLUSION

Our data suggest almost half of clinically stable, hyperglycemic adults in our inner-city ED experience food insecurity. More than one-third of those prescribed insulin used less than prescribed for various reasons. The prevalence of

food insecurity in an undifferentiated population and the use of hyperglycemia as a screening tool for food insecurity warrant further study.

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Patient and Community Organization Perspectives on Accessing Social Resources from the Emergency Department: A Qualitative Study

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Introduction: Social risks adversely affect health and are associated with increased healthcare utilization and costs. Emergency department (ED) patients have high rates of social risk; however, little is known about best practices for ED-based screening or linkage to community resources. We examined the perspectives of patients and community organizations regarding social risk screening and linkage from the ED.

Methods: Qualitative interviews were conducted with a purposive sample of ED patients and local community organization staff. Participants completed a brief demographic survey, health literacy assessment, and qualitative interview focused on barriers/facilitators to social risk screening in the ED, and ideas for screening and linkage interventions in the ED. Interviews were conducted in English or Spanish, recorded, transcribed, and coded. Themes were identified by consensus.

Results: We conducted 22 interviews with 16 patients and six community organization staff. Three categories of themes emerged. The first related to the importance of social risk screening in the ED. The second category encompassed challenges regarding screening and linkage, including fear, mistrust, transmission of accurate information, and time/resource constraints. The third category included suggestions for improvement and program development. Patients had varied preferences for verbal vs electronic strategies for screening. Community organization staff emphasized resource scarcity and multimodal communication strategies.

Conclusion: The development of flexible, multimodal, social risk screening tools, and the creation and maintenance of an accurate database of local resources, are strategies that may facilitate improved identification of social risk and successful linkage to available community resources. [West J Emerg Med. 2020;21(4)964–973.]

INTRODUCTION

Emergency department (ED) patients have high rates of non-medical but health-related needs, including both food and housing instability.¹ A number of different terms have

been used to describe these individual-level, adverse social determinants of health. For the purposes of this paper, we will term these “specific adverse social conditions that are associated with poor health” as *social risk*.² Social risks are

associated with higher disease prevalence, worse disease control, and resultant patterns of hospital utilization that include increased ED utilization^{3,4} and higher healthcare costs.⁵ Recent policy changes, including the creation of accountable care organization (ACO) models, are increasing emphasis on social risk by mandating screening and allowing organizations to use payments to address social risk.⁶ Both the Accountable Health Communities project⁷ and several Medicaid ACO demonstration studies are currently studying strategies for social risk screening and referral to community resources.^{8,9}

Thus far, most of the policy emphasis has been on screening and linkage to resources in the primary care setting, and existing programs have demonstrated significant challenges in improving health outcomes and reducing healthcare utilization. A recent large evaluation of a phone-based screening and navigation program found only small decreases in healthcare utilization in the intervention group.¹⁰ Interventions directly targeting community-based organizations have also had little impact on healthcare utilization.¹¹ Other studies, including one in the ED, have used a help-desk model of undergraduate volunteer navigators, and found no difference in ED utilization or need resolution.¹² Similar interventions requiring significant staffing, potentially including community health workers, have shown promise but may be more challenging to scale outside of academic centers.^{13,14}

With the increasing emphasis on social risk screening in novel payment models such as the ACO, and the high prevalence of social risk in ED patients who may not be accessing primary care, institutions are beginning to pilot screening and linkage interventions in the ED.¹⁵ However, little is known about best practices for linking ED patients to community resources in a time- and staff-efficient manner that is both useful for patients and feasible for the receiving community organizations.⁶ In particular, the perspectives and preferences of ED patients and receiving community organizations have not been well described. Therefore, the goal of this study was to examine the perspectives of patients and community organizations regarding social risk screening and linkage from the ED.

METHODS

Study Design and Setting

We conducted an in-depth, qualitative interview study with a purposively selected sample of ED patients as well as staff from regional community organizations, including homeless shelters and food banks. We chose in-depth interviews to identify the range of opinions regarding ED-based, social risk screening and linkage programs and elucidate new ideas and concepts.¹⁶ As is standard in qualitative studies, we used purposive sampling to “select representatives from various cross-cutting status positions that are relevant to individual experiences and beliefs with respect to the topic at hand”¹⁶ and concluded when thematic saturation was reached, or no new information was provided on the topic of interest in each of the

Population Health Research Capsule

What do we already know about this issue?

Emergency Department (ED) patients have high rates of social risk, however little is known about best practices for ED-based screening or linkage to community resources.

What was the research question?

To examine the perspectives of patients and community organizations regarding social risk screening and linkage from the ED.

What was the major finding of the study?

Participants felt it was important to screen, were concerned about linkage, and provided suggestions for program development.

How does this improve population health?

Participants highlighted the potential of ED social risk screening to reach vulnerable patients, identified barriers, and generated ideas for improvement to optimize population health.

prespecified status positions or groups.

Qualitative interview guides were developed by the study team, piloted, and then refined. Interviewers received qualitative methods training, and direct feedback following each round of interviews. Interviews were conducted until thematic saturation was reached. This was deemed to have occurred when subsequent interviews failed to provide new information in each of the predefined groups (English speakers, Spanish speakers, community organization staff).¹⁶ This study was approved by the Partners Healthcare institutional review board.

Selection of Participants and Participant Categories

Patients were recruited from a large, urban, academic ED. Bilingual research assistants (RA) screened patients for eligibility. Eligible patients included adults or parents/guardians of pediatric patients, who spoke either English or Spanish and were expected by the clinical team to be discharged at the conclusion of their ED visit. Patients on an involuntary mental health hold or with active intoxication were excluded. Community organizations were identified through hospital directories, social work, and use of the United Way 211 website. Community organizational staff were contacted for participation using a standard email. Community organization interviews were conducted at the organization and in English. (Please see Methodological Appendix for more details).

Measurements

Patient participants completed a brief demographic survey and a health literacy assessment (Newest Vital Sign)^{17,18} in either English or Spanish. Qualitative interviews focused on barriers and facilitators to social risk screening in the ED, choice of ED as a care location, and ideas for screening and linkage interventions in the ED (Table 1).

All patient participants received an ED resources sheet outlining community resources for social risks. Community organization participants completed a brief demographic survey and a qualitative interview in English covering the same domains, with slightly modified questions (Table 2).

Analysis

All interviews were recorded and professionally transcribed. A coding tree was developed based on the interview guide, and refined with input from the entire team. Transcripts were coded by two independent members of the research staff, with differences resolved by team consensus.

Spanish-language transcripts were coded by bilingual study team members, and Spanish-language quotes are presented in the manuscript verbatim with translations from the study team following. Coding and theme development were ongoing throughout the study process, with adjustment of the coding tree and interview guide as themes emerged. Analyses used a modified grounded theory framework.¹⁹ Interviews were conducted until thematic saturation, as identified by consensus, was reached among patients within each predefined group (English speakers, Spanish speakers, community organization staff).

RESULTS

Characteristics of Study Subjects

Twenty-two interviews were conducted, of which 16 were with patients and six were with community organization staff. Of the patient participants, 11 (69%) spoke English and five (31%) spoke Spanish. Eleven (69%) had adequate health literacy and five (31%) had limited health literacy. Table 3 summarizes

Table 1. Patient interview questions regarding screening for social risk in the emergency department.

Topic	Domain	Sample questions
Social risk screening	Experience	Would you like to share anything else about your experience with the survey we just walked through?
	Barriers Facilitators	Were there parts that you yourself or others may not want to answer? That you found or others would find hard to answer? That you found or others would find easy to answer?
		Suggestions for improving
	Resource linkage	Experience
Barriers		What might make it hard to access those resources? (probe for ED- and PCP- provided resources)
Facilitators		What might help you access those resources? (probe for ED- and PCP- provided resources)
Suggestions for improving		How could ED staff do a better job connecting people in the ED with community resources?
Choice of ED as care location	Barriers	Do you have a primary doctor or clinic? Is there anything that might make it hard for you or others to go there when you need care?
	Facilitators	Is there anything that makes it easier to go there when you or others need care?
	Decision making	Tell me about why you chose to come to this location today? (not reason for seeking care/but why this location) Did you seek care anywhere else for this problem before this visit?
	Barriers to ED use	What makes it hard for you or others to receive care in the ED? (probe for domains of social risk)
	Facilitators of ED use	What makes it easier for you or others to receive care in the ED? (probe for domains of social risk)

ED, emergency department; PCP, primary care provider.

Table 2. Community organization interviews regarding how emergency department staff connects patients to community resources.

Topic	Domain	Sample questions
Social risk screening	Suggestions for improving	How can we improve patients' experience answering these questions? What information would be helpful for you to get about patients referred from the ED?
Resource linkage	Experience	Can you tell me about how people get referred to your organization? Specifically, from the healthcare system? From the ED?
	Barriers	What challenges do patients face accessing community resources?
	Facilitators	What makes it easier for patients to access community resources?
	Suggestions for improving	How could ED staff do a better job connecting people in the ED with community resources?
	Logistics	What would be the best way to connect a patient with your organization? Please tell me about your intake for new participants. Is there anyone else you think we should talk with about this?

ED, emergency department.

the demographic characteristics for patient participants. Of the six community organization participants, positions ranged from community health worker to director of a community health coalition, with a range of 3-31 years of experience in their respective sectors.

Main Results

Three categories of themes emerged. The first related to drivers of ED utilization and emphasized the importance of screening for social risk in the ED. This category included themes around challenges accessing primary care providers (PCP) and inconsistent screening at PCP offices. The second category related to challenges around screening and linkage to community resources. Themes in this category included concerns around fear and mistrust of the healthcare system, the collection, maintenance, and transmission of accurate information, as well as time and resource constraints. In the third category, both patients and community organization staff provided suggestions for improvement and program development.

In each of the three categories, there were few differences in perspectives between patients by language or health literacy. Overall, resource scarcity was emphasized more by community organization staff. Staff also highlighted the importance of bidirectional and multimodal communication strategies with users of their services, whereas patients had more variation in preferences for specific verbal vs electronic strategies.

Challenges in Primary Care Access and the Resulting Importance of ED Screening

Many patients reported challenges accessing primary care related to timing, cost, and availability of appointments, although a few patients highlighted the potential of the PCP in addressing social risk (Table 4).

Patient participants reported a broad range of experiences with social risk screening in the primary care setting. Some participants reported being screened for specific social risks in the clinic setting either verbally ["Somebody asked me...

It was a type of questionnaire like this if I will need help with the utilities so I just answered yes" (limited literacy) or electronically ["Well when you go there and you check in they just give you a little tablet with some questions and then you answer the questions with what type of resources you think you will need. So I answer through that" (limited literacy)]. Others reported seeing posters with information but had not been asked directly.

Community organization staff also emphasized the importance of the ED as a screening location: "It's like you're often seeing people at a really critical time and they may be more down and out...if they had a plan for access to counseling for their mental health needs and potential medication and stuff like that. And direction to food and shelter. And having that all laid out and have someone as a point of contact for them even if it's only during business hours or whatever just having-- I mean, caseworkers exist and all that stuff, but having more of that through the hospital could be good" (community organization staff).

Challenges Around Screening and Linkage

Fear and Mistrust

Community organization staff and patient participants alike raised concerns around trust in both the healthcare and social services systems, in addition to fear of using resources. Participants reported concerns about stigmatization: "I would definitely say social discrimination is a huge barrier as well in many ways...People with different diagnoses might have barriers as well like substance use disorders, getting housing might be difficult if you have any kind of criminal record" (community organization staff). In addition, several staff participants discussed barriers related to recent policy changes, particularly for immigrants: "I think fear, immigration fear is a giant, giant concern right now that we see people aren't coming out for services and they're not signing up for services that they might be eligible for. So the political climate has really been an issue" (community organization staff).

Table 3. Demographics of patient participants.

Age†	Primary language		Total n (%)
	English	Spanish	
30-40	8	2	10 (67)
41-50	3	1	4 (27)
51+	0	1	1 (6)
Gender			
Male	3	0	3 (19)
Female	9	4	13 (81)
Race/Ethnicity			
Hispanic	1	4	5 (32)
Non-Hispanic White	8	0	8 (50)
Non-Hispanic Black	1	0	1 (6)
Asian	1	0	1 (6)
Non-Hispanic Other	1	0	1 (6)
Insurance			
Private	8	0	8 (50)
Public/ state	4	4	8 (50)
Total			16 (100)

†One participant preferred not to not provide an age.

Although most participants focused on recipient mistrust, one patient reported concerns about whether the health system or social service providers could trust the patients, who might be lying to access resources: “Por lo que--Tú sabes que muchas veces la gente puede omitir información, o muchas veces mienten para tener o conseguir más...Entonces no sé de qué manera podría llegar, o de qué manera--O sea, es una simple encuesta, yo sé; pero de qué manera comprobar de lo que están diciendo sea verídico” [*So—You know that many times people can omit information, or many times they lie to have or get more...So I don't know in what way it could get to, or in what way—That is, it's a simple survey, I know; but in what way to verify that what they are saying is truthful*] (adequate literacy).

Collection, Maintenance, and Transmission of Accurate Information

Patient participants emphasized the importance of providing accurate information about resources: “Yo pienso que muchas veces las informaciones son ya un gran recurso, es decir, existen estos recursos que se pueden utilizar en ciertas condiciones, porque hay mucha gente como yo que no la conoce toda, y por eso muchas veces uno se encuentra en grandes dificultades” [*I think that many times the information is already a great resource, that is to say, these resources exist that can be utilized in certain conditions, because there are many people like myself that do not know it all [the information], and because of that many times one finds oneself in great difficulties*] (limited literacy). The importance of accurate information was repeatedly emphasized with regard to

resource availability and cost: “Providing as much information as possible so people know what services are there and know that it's not going to cost them anything, or at least have an idea of what it would if there was a cost” (adequate literacy). Community organization staff discussed the importance of establishing accurate resource databases and being very clear with patients about the type of help that is available.

Patients discussed the challenges of obtaining information from hospital posters. In particular, they highlighted difficulties with remembering or retaining the information: “It's just like it's not really pamphlets, so it's not really anything that I can take with me...It's in the bathroom when you're sitting in a stall and it says, ‘Are you in danger?’...I mean, so the stuff is there, but unless you're writing it down or you take a picture of it with your phone...I might see it and go like, ‘Oh, wow. I would really like to do that,’ but remembering to take a picture, remembering to grab that information could be hard” (adequate literacy). Others identified challenges understanding information when it was provided only in English: “No. Yo no he visto, es que muchas veces se llega con tanta preocupación y la otra cosa es que podrían estar en inglés, no comprendo el inglés y bueno” [*No. I have not seen, it's that many times you arrive with a lot of worry and the other thing is that they could be in English, I don't understand English, and well...*] (limited literacy).

Time and Resource Constraints; Complexity of Navigation

Community organization staff, in particular, spoke repeatedly about the challenges of navigating the complex social service infrastructure to obtain resources: “Because I know someone came in looking for a detox bed and I tried to sit down with him and talk to him but I had no idea where to start. And I called all these different centers and they had all these different policies. ...I don't know how to navigate this? I'm very literate on a computer. I know how to use a computer. I'm very comfortable making phone calls. I'm a fluent English speaker and I still can't figure this out. So I definitely had just a moment of frustration with how complex the system is and if there was a way to get other information really accessible, I think that that would be amazing and really change how things were working” (community organization staff). Others emphasized the importance of knowing what resources are actually available: “They may have a five-year waiting list. And the provider in the ER may not know that. And it's hard to know what all the capacity is for a different agency” (community organization staff).

Community organization staff, as well as some patients, referenced time and attention constraints within the ED visit as potential barriers to screening effectively: “I think, yeah, I don't at all disagree with you but I also think people in the emergency room, by the time they've been in the emergency room and seen a doctor can be so ready to leave but they're not going to sit around and wait for a social worker to come down and talk to them even if that would be great. I've seen it in the

ER a lot of times, that people are just like, ‘I’m out of here. I’m not sticking around. I’m not interested in going through my complex care plan with you. I just want to leave’” (community organization staff).

Improvements and Next Steps

When asked about new tools for screening, participants reported mixed preferences for verbal vs electronic screening: “because they’re personal questions. Someone might feel more comfortable answering them through text, but at the same time they feel like they’re very personal questions, so it feels weird answering them through text. So kind of the same answer for both. Opposite reasons” (adequate literacy).

Regarding novel strategies for linkage, participants emphasized the importance of having a centralized directory of resources (Table 4) and being able to access information easily on-demand across modalities: “I think it would be really good if there were multiple points of entry and multiple points of access. So I don’t think it -- I think if it’s not an either -- or but if it’s somehow both. That you can have access to resources right then but then there’s also ways to engage at later points that are really accessible maybe through texting. I think that that’s awesome” (community organization staff).

Patients Compared to Community Organizations

As compared to the patient participants, community organization staff were more skeptical about resource availability and more focused on bidirectional and multimodal communication. Community organization staff emphasized the challenges around accessing scarce social resources: “I think you just should be careful about offering housing resources because waitlists are 5, 10 years long. I just talked to somebody last week. I was doing an interview myself with someone last week who works with housing issues and she said she even has somebody on the emergency housing list that’s been on it for five years. So to be offering. I think you have to be careful when you say do you want resources with housing because people will jump on that because there’s really not much out there. So I think not over-promising” (community organization staff).

More than the patient participants, staff focused on the follow-up for positive screens: “I think it’s great that people are asking these questions because they’re so important. I would just want to make sure that they’re doing it for a reason and that it’s not just out there in the atmosphere. That somebody actually follows up and goes over the answers with them if their answers show that it needs follow up” (community organization staff). Finally, staff were also more concerned about the loss of information in transfer and translation between hospital providers and patients, emphasizing the importance of personal communication and the direct transmission of information: “So if you have somebody who could make that connection and connect patients, do a warm handoff, what we say warm handoff to resources.

Sometimes, in the healthcare system, we’re used to like, ‘Oh, here is the sheet. There you go. Oh, it’s translated,’ but it could not be clear in that language... So there could be very simple thing that people don’t know about that you can help them brainstorm how to access that resource. And they just sometimes won’t unless somebody is there cheerleading them to do that” (community organizer staff).

DISCUSSION

Screening for social risk among ED patients is an area of increasing interest across many healthcare systems. In this study, we sought to better understand the facilitators and barriers to social risk screening in the ED, as well as opportunities to develop mechanisms to link ED patients with social risks to community organizations. Through in-depth interviews, ED patients and community organization staff confirmed the importance of social risk screening in the ED, while also identifying several important barriers to screening and referral. Participants also identified strategies for improvement.

Overall, study participants felt that ED screening for social risk was important and valuable. However, they also raised concerns around fear and mistrust – particularly in the current political environment. Establishment of systems for social risk screening in the ED must take into consideration the particular concerns and needs of each hospital’s patient population, including fears of stigmatization based on social risk. To address concerns about fear and mistrust, programs must take appropriate measures to ensure secure collection and storage of patients’ social risk information and provide transparency around how and with whom the information is shared, particularly for immigrants and other vulnerable groups.

Patient participants had mixed preferences for the modality of screening, with some strongly preferring verbal and others recommending electronic. Given differing patient preferences about screening modalities, programs will need to consider their specific patient population to determine the acceptability of in-person vs technology-based screening. The development of multimodal, multilingual screening tools with systems that allow for flexibility even within a single healthcare facility may foster improved acceptance among both patients and healthcare providers.

Additional barriers to acceptable and efficient social risk screening in the ED identified in this study included time and resource constraints of both patients and providers, the collection and transmission of accurate information, and the complexity of the social service infrastructure into which patients are referred. While time and resource constraints for ED patients and staff can vary considerably across different care environments, the development of screening strategies that do not require clinical provider time and involvement may help increase feasibility and acceptability.

Both patients and community organization staff highlighted the importance of developing and maintaining

Table 4. Themes and representative quotes from patients facing social risks and community organizers regarding access to aid.

Category	Theme	Patient participant	Community organization participant
Importance of ED screening	PCP access	Their hours. They close at three ...I get out of work at 3:00. They get out of school at 3:00. You can't see them during the week. And they only see very sick babies on the weekends. So basically, in order to go with these kids for anything, I need to take a day off from work. They need to take time off from school, which is kind of not right. (Adequate literacy)	
	Inconsistent PCP screening	I see them all over the walls. Posted. Oh, I need help with...I don't recall being asked directly, I guess...If you need help to quit smoking. For domestic violence or something, you can call this number. Bunch of random stuff. (Adequate literacy)	
Challenges around screening and linkage	Fear and trust	Not knowing where and who to go to and even being afraid of asking questions mostly. (Adequate literacy)	Specifically, it's the fear of receiving any help from anybody if you're undocumented. ... It's just the fear of what it is and how much information do I have to provide in order to receive the benefits...especially with the fear of immigration and deportations. Even people who are documented, who are in the path to receiving green cards, and who are eligible to receive green cards, they say, "No, thank you" because now there's that fear that if I'm using public benefits, that public charge clause would apply.
	Collection, maintenance, and transmission of accurate information.	I think he was a social worker from the Massachusetts General Hospital. I don't know. But he called me. Yeah, he called me and he spoke with me over the phone and just -- he give me all the information and I wrote it down. And also he said that he was going to send me a mail with resources. And I got that in the mail as well. So that was good. (Limited literacy)	But if you don't have access to a phone or internet regularly, then keeping track in your head when all these different things are open and when you can go and get services I think is probably really challenging.
	Time and resource constraints	Just thinking back about my local hospital and how I'm pretty sure that they have pamphlets for any sort of needs or feeling endangered in any way, but they're not really prominent in the areas. (Adequate literacy)	But that is what we find is always the biggest issue is that just handing someone a pamphlet or handing somebody a phone number is not always very effective. I'm sure you've heard the term warm hand-off. I think those are far more successful. So when somebody is actually helping the patient make the connection and make sure it's a referral that's appropriate and works.
		So I'd be like, "Hey I can't pay for this. What do I need to do to get some help?" And then if they had all the information you needed. You're good. But if they're like, "Oh, you need this. You need three month's worth of utility bills, your three months of pay stubs--" if you need a whole bunch of stuff to get it done then people are going to get frustrated. (Adequate literacy)	But there are almost 12,000 patients, and there's me. And so I can't talk to everybody. But I know where the people can get free clothes and food and there's always help there for the basic, basic things.
		I've been in the emergency room in more difficult situations and I probably wouldn't be answering questions in that moment. Yeah. But definitely before or after. I don't see why not. So maybe if you could get the contact information and then, just text them after. (Adequate literacy)	A lot of times that leads them to a little bit of disappointment when they think that you're going to give them something, and they're like "Oh, you're just here to give me paper. I don't need paper."

ED, emergency department; PCP, primary care provider.

Table 4. Continued.

Category	Theme	Patient participant	Community organization participant
Strategies for improvement	Modality (electronic vs. verbal)	Just because everyone's on their phone all the time, and it's probably a good way to get at people, and maybe it won't make them nervous if they don't have to answer face-to-face or be embarrassed (Adequate literacy)	Somebody who could connect them to resources, who looks like them and speaks like them. I would say that that's been not necessarily like all of that combined, but it has to be some kind of a connection because really we're looking at a lot of mistrust between either for the healthcare system or well, just not a lot of trust.
		Talking is extremely easy. But for me to understand it's good. I understand what it was you was asking (Limited literacy)	I mean, I think in person would be so much more effective. But I understand the cost of that is probably not something that people are willing to take on. I mean, I hope that an organization with the resources that engage has or other hospitals would move in that direction. I think texting is a really good start for it. Yeah. But I think that in-person follow-up is so much more effective.
	Centralized resource information and coordination	Like a centralized location or yeah, a resource area. You know what I mean? If there was a place that we could go where those questions were asked, like, "Are you struggling with homelessness? Are you struggling to provide food?" If there was a certain area or resource place, I think that would be good because, from my recollection, it's just posters and things that I see and little pamphlets that are over here, but it's kind of spread throughout the healthcare center. (Adequate health literacy)	If there is some way for the hospital or some organization the hospital is working with to hold all the knowledge of all the organizations in the city and be able to share that. And be able to be updated on what places have beds and what their hours are and when their hours change.
	On demand information and navigation	Well, I think because you're worried about so much else going on, and then if you're just getting a quick text message that here we can help you with something that's troubling you so much. I mean, if somebody has no food they're really going to be worried, or they're about to lose their utilities, and so they could say I can get your text and give you an answer and help you. I think that's extremely useful. (Adequate literacy)	It really just depends on the need of the patient because if they are in need, and you give them the information they'll be grateful. But some people, for example, the elderly, or if they have some sort of disability, they might need the advocate to help them. So it really depends on the person.
			But if there is a way to text and be like, "Where can I go right now to get food?" And if there was an automatic response, "Where can I go right now to get food in 02116?" Or, whatever. I think that would be really cool. If there was just something that was some sort of computer system that could just generate responses to questions. And if patients could be educated about how that works before they leave the ED so that then they have that information on hand. That's one thing that comes to mind.

ED, emergency department; PCP, primary care provider.

a centralized resource directory in order to allow users to access accurate resource information at multiple times and in multiple ways. Compared to patient participants, community organization staff were more focused on the limitations of available resources and the importance of in-person navigational assistance to ensure that patients did not get lost in the transition from referral to resource. Interestingly, while community organization staff raised concern about the fear of resource utilization in relation to becoming a public charge, no patient participants identified this concern. However,

we intentionally did not include any questions related to immigration status or citizenship in our study. Therefore, it is impossible to know whether the absence of this concern related to the public charge rule is a result of having interviewed only patients for whom this is not a concern, or whether they were reluctant to raise this concern with study staff.

In the setting of increasing policy emphasis on addressing social risk,^{8,9} a variety of screening and linkage programs have been developed. However, as mentioned previously, most have focused on screening in the primary care setting and many

have struggled to successfully connect patients to resources. Notably, a recent large study of over 34,000 patients found that 53% screened positive, but only 10% were able to connect with resources to address their needs.¹⁰ Another study found that only 19% of patients with a health-related social need reported in the electronic health record had a documented referral placed.²⁰ These studies further underscore the importance of developing interventions that not only identify social risk, but successfully link patients to adequate resources in their communities.

Our study's participants also emphasized the need to create systems that establish true linkages between patients and community resources. Community organization staff in particular highlighted the need for personalized, repeated contact between individuals with social risk and those with the knowledge of how support systems operate in that individual community. Developing a robust system for linkage to community resources must incorporate accurate, timely, and confidential information-sharing between programs and community organizations. Ideally, such a system would be supported by a centralized resource directory. While further research is needed to understand optimal linkage strategies from the ED (eg, direct information provision vs hands-on navigation, follow-up mechanisms to ensure linkage and assist with troubleshooting, etc.), ED-based, social risk screening and linkage programs should be built on a foundation of understanding local resource availability and community organization capacity.

LIMITATIONS

As with all qualitative studies, this work is hypothesis generating, not hypothesis testing. Due to staff capabilities, we were only able to enroll in English and Spanish, and, reflecting underlying demographics of hospital usage, we had limited racial diversity in our sample. In addition, we deliberately did not screen for social risk in our sample as we did not want to bias participant opinions by the use of one particular tool. As a result, however, we did not know the social risk status of the patient participants and thus cannot know how that might have affected their perspectives on screening and linkage.

CONCLUSION

In this qualitative study, we examined perspectives of both ED patients and community organizations regarding ED-based screening for social risk and linkage to community resources. Participants highlighted the potential of ED-based social risk screening to reach vulnerable patients, who may otherwise not be identified through PCP-based screening programs. They also highlighted important barriers to successful screening and linkage, and generated ideas for optimizing such programs. The development of flexible, multimodal screening tools as well as the creation and maintenance of an accurate centralized database of local resources may facilitate improved identification of vulnerable patients and successful linkage to available community resources.

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Documentation Displaces Teaching in an Academic Emergency Department

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Introduction: Adverse effects of administrative burden on emergency physicians have been described previously, but the impact of electronic health record documentation by academic emergency attendings on resident education is not known. In this observational study of a quaternary care, academic emergency department, we sought to assess whether the amount of time attending physicians spent on documentation affected the amount of time they spent teaching.

Methods: A fourth-year emergency medicine (EM) resident observed 10 attending physicians over 42 hours during 11 shifts, recording their activities every 30 seconds. Activity categories were developed iteratively by the study team and validated through co-observation by an EM education fellow with a kappa of 0.89. We used regression analysis to assess the relationship between time spent documenting and time spent teaching, as well as the relationship between these two activities and all other attending activity categories.

Results: Results demonstrate that time spent documenting was significantly and specifically associated with less time spent teaching, controlling for patient arrivals per hour; every minute spent on documentation was associated with 0.48 fewer minutes spent teaching ($p < 0.05$). Further, documentation time was not strongly associated with time spent on any other activity including patient care, nor did any other activity significantly predict teaching time.

Conclusion: Findings suggest that academic attendings may face a trade-off between their documentation and teaching duties. Further study is needed to explore how administrative expectations placed on academic emergency physicians might interfere with trainee education. [West J Emerg Med. 2020;21(4)974-977.]

INTRODUCTION

Academic emergency physicians are asked to balance a myriad of demands during shifts. In addition to providing clinical care and completing administrative tasks, they must find time to teach trainees. Prior studies suggest that time spent teaching correlates with perceived teaching quality by trainees,¹ and that expert academic physicians find creative ways to incorporate education into clinical shifts.² Previous

studies from over a decade ago found that clinical work load did not significantly affect teaching quality during shifts.^{3,4} However, with increasing administrative tasks and the introduction of (EHR) health records, it may be that modern demands on academic physicians do interfere with teaching opportunities.

Documentation burden in particular has been shown to affect many facets of physician life;⁵⁻⁷ it may follow that

documentation impacts education in the clinical setting as well. However, there is no study to our knowledge that has examined the direct impact of documentation on teaching in an emergency medicine (EM) setting. In this observational study, we therefore sought to assess how time spent on documentation activities affected time spent on teaching by attending physicians in one academic emergency department (ED). We also examined whether documentation time was associated with time spent on direct patient care or other attending activities, and whether activities other than documentation impacted time spent teaching.

METHODS

This study was conducted in an urban, quaternary care, academic center with an EM residency that receives approximately 110,000 patient visits per year. It was considered quality improvement by the institutional review board and therefore exempt from review. All observations were conducted in the 25-bed critical care area of the ED, which sees 52 patients per day of whom 60% are admitted. This area is supervised by one attending at all times of day, with varying levels of staffing by residents and physician assistants depending on time of day. In general, all patients in our ED are seen by a resident or physician assistant; only very rarely do attendings see patients on their own.

A fourth-year EM resident observed attendings during shifts, writing down all activities they performed in 30-second intervals. Forty-two total clinical hours were observed in 10 four-hour blocks and one 2-hour block, all between the hours of 10 AM and 7 PM. Specific shifts to be observed were chosen at random without regard to who the covering attending would be. One attending was observed in each period, and 10 different attendings were observed over the course of 11 observation blocks (one attending was observed twice by chance). Attendings were not aware of the aims of the study and were therefore unlikely to have systematically altered any particular behaviors in response to being observed.

Attending activity categories were developed iteratively by the study team and then validated through co-observation by a second observer (an ED education fellow) over two separate two-hour co-observation sessions. During these sessions, each observer simultaneously and independently used the iteratively designed rater scale to record and code attending activities in 30-second intervals. Subsequently, observations were compared by 30-second increment for agreement.

Teaching categories included bedside teaching, procedural teaching, case-based teaching, didactic teaching, and implicit teaching through case discussion, all explicitly defined and then identified by the observers. Time spent on any teaching category was then summed to create a total teaching time variable. Documentation time consisted of all time a physician spent creating a patient care note, which included typing, dictating using computer software, or dictating to a scribe. This was separate from “chart review,” which consisted of

attendings reviewing results data or previous medical history on the computer. Direct patient care consisted of all time attendings spent in patient rooms.

The primary outcome was the relationship between teaching, documentation, and patient care during shifts. This was assessed using univariate regression analyses between these variables and multivariate regression controlling for patient arrivals per hour. In the area where observations were performed, attendings must see all patients upon arrival; attendings do not have discretion over which patients they see. Therefore, arrivals per hour captured the number of patients that attendings saw, and attendings could not modulate their patient load based on other factors. Secondary outcomes involved further regression analyses to assess the association of other attending activities with teaching time and documentation time, respectively. Finally, a sensitivity analysis with removal of outliers assessed the potential impact of outliers on results.

RESULTS

Co-observation

The two observers had a Cohen’s kappa of 0.89. Of note, they achieved 90% agreement on teaching categories specifically.

General Characteristics

On average, attendings in our study spent 32% (standard deviation [SD] 9%) of their time on direct patient care, 25% (SD 7%) on teaching, and 12% (SD 8%) on documentation. They spent 7% (SD 6%) of time on socializing and breaks, 6% (SD 2%) on chart review, 6% (SD 2%) receiving sign-out, and the remaining time on other activities including taking emergency medical services calls, communicating with non-trainee team members, walking, and speaking with consultants. Attendings saw a median of 2.9 (SD 0.59) patients per hour and spent a median of 5.8 (SD 2.6) minutes in each patient’s room.

Outcomes

Increased time spent on documentation was associated with significantly decreased time spent teaching in our sample (Figure). In a univariate regression model, every additional minute of documentation time predicted 0.48 fewer minutes of teaching during a shift ($p = 0.04$). This relationship was not affected by controlling for the number of patient arrivals per hour (Table), suggesting patient volumes did not explain the inverse relationship between time spent documenting and teaching. In further univariate analyses, patient care time was not significantly associated with teaching time (coefficient 0.12, $p = 0.6$), nor was time spent on chart review (coefficient 1.5, $p = 0.13$), breaks and socializing (coefficient -0.21, $p = 0.57$), or any other observed activity. Documentation time was also not significantly associated with time spent on direct patient care (coefficient 0.13, $p = 0.66$) or any activity other than teaching.

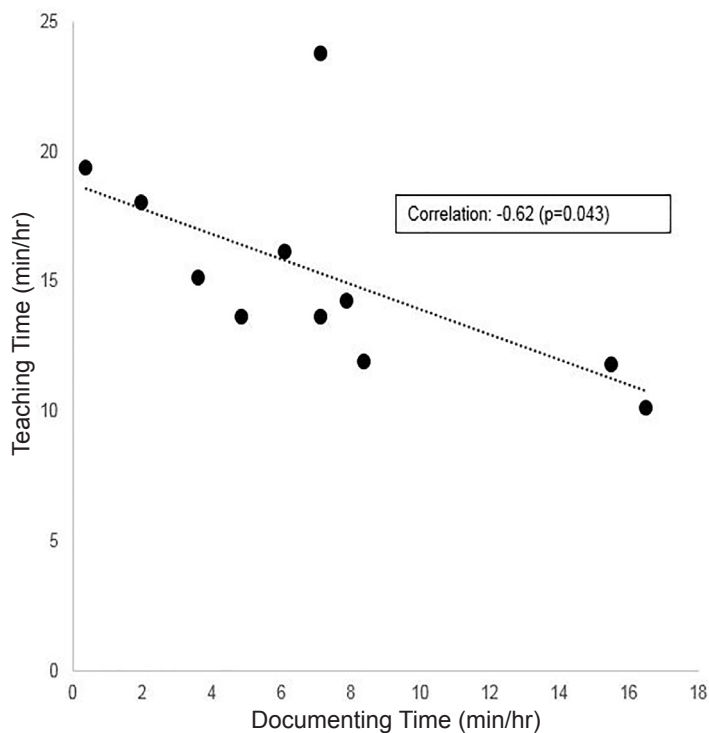


Figure. Relationship between time spent teaching versus documenting during an hour of on-shift time ($n = 11$). *Min*, minute; *hr*, hour.

Through sensitivity analysis, we identified and removed one outlier (involving an unusually high amount of teaching for our sample). Removal of this outlier strengthened the findings; the direction and magnitude of the coefficient between teaching and documentation was unaffected, but the p value on this coefficient decreased from 0.04 to 0.0007. The relationship remained robust to controls for all other activities. This suggests outliers did not drive our main outcome, and, in fact, weakened it.

DISCUSSION

Our results suggest that time spent on documentation by attendings was specifically associated with decreased time spent on teaching in this academic ED, while time spent on direct patient care, chart review, breaks, and other activities was not significantly associated with teaching time. This may indicate attendings face a particular trade-off between documentation and teaching demands. A recent study found that introducing residents into a community ED setting did not slow attending productivity because increased time spent teaching and supervising was balanced by the completion of administrative tasks by residents; this suggested a trade-off between education time and administrative time (one assumes these community physicians spent only as much time teaching as the decrease in administrative tasks allowed, since productivity was unaffected).⁸ Our results fit with this pattern;

Table. Univariate regression analysis results for the associations of time spent teaching with time spent documenting, and patient arrivals per hour with time spent teaching, along with a multivariate regression of the association of time spent teaching with time spent documenting, controlling for patient arrivals per hour.

Relationship of interest	Coefficient (Standard Error)
Association of minutes spent documenting with minutes spent teaching	-0.48 (0.18)**
Association of patients per hour with minutes spent teaching	-0.006 (0.56)
Association of documenting with teaching, controlling for patients per hour	-0.5 (0.21)**

** $p < 0.05$

when attendings spent less time on documentation they spent more time teaching, and vice versa. As academic departments weigh documentation expectations for faculty, they may wish to consider potential educational effects.

Of course, we do not know whether increased documentation caused less teaching or was simply associated with less teaching; it may be that documenting directly interferes with teaching or that attendings who devote more time to documentation simply tend to teach less. While the latter remains possible, documentation may plausibly impact teaching at multiple junctures. If attendings are documenting during or immediately after patient presentations by trainees, they may not seek opportunities to probe or teach. An attending with a moment of free time may face a choice between gathering trainees to discuss a case and finishing notes. An attending documenting in a patient room may more likely miss out on opportunities for bedside teaching.

In our department, attendings write their own patient care notes. Recent EHR data from our department suggests attendings spend an average of more than one hour working on the medical record after shifts. The 12% of shift time we observed attendings spend documenting, therefore, likely underestimates total time spent on documentation. It may be that attendings who spent more time teaching pushed their documentation duties until later; if so, attendings who taught more paid a price with more uncompensated time spent documenting after shifts.

LIMITATIONS

Our study was small and occurred in a single academic department with particular documentation requirements for attendings. This may limit the generalizability of our findings. Our sample size did not allow for analysis by attending characteristics, such as tenure. More research is certainly needed to assess whether patterns observed persist with larger samples across institutions. We were also unable to assess perceptions of teaching quality and whether increased time spent teaching was associated with better

teaching. While prior research has suggested an association between time spent teaching and teaching quality, only time spent teaching could be captured in our study. In addition, we were unable to assess time spent documenting after shifts were finished. We were therefore only able to capture time spent documenting during shifts, rather than total time spent on documentation by attendings.

CONCLUSION

Our study suggests that documentation demands placed on attending emergency physicians may be associated with less time for teaching in academic departments. Further work should examine how this may affect teaching quality, as well as the amount of off-shift administrative time required of attendings. It will be important to better understand how administrative burden on attendings impacts resident education, and what can be done to optimize ED educational environments in the face of administrative responsibilities.

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Assessment of Emergency Medicine Residents' Clinical Reasoning: Validation of a Script Concordance Test

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Introduction: A primary aim of residency training is to develop competence in clinical reasoning. However, there are few instruments that can accurately, reliably, and efficiently assess residents' clinical decision-making ability. This study aimed to externally validate the script concordance test in emergency medicine (SCT-EM), an assessment tool designed for this purpose.

Methods: Using established methodology for the SCT-EM, we compared EM residents' performance on the SCT-EM to an expert panel of emergency physicians at three urban academic centers. We performed adjusted pairwise t-tests to compare differences between all residents and attending physicians, as well as among resident postgraduate year (PGY) levels. We tested correlation between SCT-EM and Accreditation Council for Graduate Medical Education Milestone scores using Pearson's correlation coefficients. Inter-item covariances for SCT items were calculated using Cronbach's alpha statistic.

Results: The SCT-EM was administered to 68 residents and 13 attendings. There was a significant difference in mean scores among all groups (mean + standard deviation: PGY-1 59 + 7; PGY-2 62 + 6; PGY-3 60 + 8; PGY-4 61 + 8; 73 + 8 for attendings, $p < 0.01$). Post hoc pairwise comparisons demonstrated that significant difference in mean scores only occurred between each PGY level and the attendings ($p < 0.01$ for PGY-1 to PGY-4 vs attending group). Performance on the SCT-EM and EM Milestones was not significantly correlated ($r = 0.12$, $p = 0.35$). Internal reliability of the exam was determined using Cronbach's alpha, which was 0.67 for all examinees, and 0.89 in the expert-only group.

Conclusion: The SCT-EM has limited utility in reliably assessing clinical reasoning among EM residents. Although the SCT-EM was able to differentiate clinical reasoning ability between residents and expert faculty, it did not between PGY levels, or correlate with Milestones scores. Furthermore, several limitations threaten the validity of the SCT-EM, suggesting further study is needed in more diverse settings. [West J Emerg Med. 2020;21(4):978–984.]

INTRODUCTION

A primary goal of residency training is to develop competence in clinical reasoning; however, there are no instruments that can accurately, reliably, and efficiently assess clinical decision-making ability. Current methods of

clinical reasoning assessment such as simulation, written tests, clinical shift evaluations, and standardized patient encounters lack the optimal combination of fidelity (emulates real life), feasibility (easily reproduced), and content validity (evidence that the assessment measuring what it is intended

to measure). Multiple-choice exams force learners to select single, predetermined “correct” answers, but fail to capture the uncertainty surrounding clinical scenarios.¹ Essay-based examinations are time-intensive and have poor evaluator inter-rater reliability.²

Simulated clinical scenarios are an excellent means of assessing clinical reasoning skills; and due to their high-fidelity nature, they may assess a more realistic level of competence. However, simulation sessions cannot offer a wide array of clinical scenarios during a brief encounter due to the extensive need for time and resources. A single simulation session for 30 residents may take 15 hours of preparation time for faculty and technicians.³ Standardized patient encounters allow for assessment of clinical reasoning in a more realistic setting but are resource-intensive and time consuming.⁴ Finally, the frequently used end-of-shift evaluations are subject to bias, may be subjective, and may result in grade inflation.⁵

The script concordance test (SCT) is designed to measure clinical reasoning ability in the context of uncertainty.⁶ The advantages of the SCT in comparison to the aforementioned strategies are that it is more congruent with actual clinical practice in emergency medicine (EM), in which decisions are often made in the face of ambiguity. In addition, the SCT has the ability to assess examinees' responses to several clinical scenarios yet is easy to administer and score.⁷ The SCT accomplishes these tasks by presenting the trainee with multiple clinical scenarios and comparing their responses to an expert panel, rather than selecting one correct option. In 2011, Humbert et al developed and assessed a SCT in EM (SCT-EM), which evaluated clinical reasoning skills among EM residents and medical students.⁷ The SCT-EM was able to discriminate among examinees with varying levels of clinical experience (ie, medical students vs residents vs experts). To establish convergent validity, the authors compared the SCT-EM to the American Board of Emergency Medicine (ABEM) in-training exam and the United States Medical Licensing Examination (USMLE) Step 2-Clinical Knowledge (CK) exam. However, the in-training exam only measures one dimension of clinical reasoning (knowledge), while the Step 2-CK exam is not specific to EM and is typically completed before residency training. Furthermore, it is unknown whether the SCT-EM can be used to measure an EM resident's progression during training.

We aimed to expand upon evidence supporting the validity of the SCT-EM by determining whether it could reliably distinguish clinical reasoning ability between EM residents by postgraduate year (PGY) level. We also attempted to validate Humbert's SCT instrument by comparing SCT-EM results to the EM Milestones, a method endorsed by the Accreditation Council for Graduate Medical Education (ACGME) to assess and benchmark clinical competency.⁸⁻¹⁰

Population Health Research Capsule

What do we already know about this issue?
Assessing clinical reasoning in emergency medicine (EM) residents is difficult. Many methods of doing so exist, each with its own pros and cons.

What was the research question?
Is a script concordance test an accurate and reliable tool to assess EM residents' clinical reasoning skills?

What was the major finding of the study?
The script concordance test for EM has limited utility in reliably assessing clinical reasoning among EM residents.

How does this improve population health?
By assessing the crucial skillset of clinical reasoning during residency, the ability for future emergency physicians to effectively manage patients may be improved.

METHODS

Study Design

We performed a cross-sectional study of EM residents comparing SCT-EM scores among and between EM residents of different PGY years and expert attending emergency physicians. We then correlated EM residents' SCT-EM scores to their subsequent ACGME “Patient Care” Milestones scores 1-6, which focus on emergency stabilization, diagnostic studies, diagnosis, pharmacotherapy, and observation and reassessment, respectively.

Study Setting and Population

We enrolled EM trainees and board-certified attending faculty physicians (“experts”) in three residency programs (two PGY 1-3 format, one PGY 1-4 format) in an urban academic setting. While the three residency programs evaluated were all part of a single health system, each program had distinct faculty, clinical sites, and conference structures.

Study Protocol

The SCT-EM is a 59-question assessment consisting of 12 clinical vignettes typically encountered in the emergency department, originally developed by two test-writers (AJH and BB) in Humbert et al 2011.⁷ The questions were

categorized as diagnostic, investigational, or therapeutic. Based on previous evidence on how to optimally construct a SCT, Likert-scale response choices were attached to each question.^{11,12} For example, take a hypothetical patient who presents with a chief complaint of headache. The clinical decision-making process (i.e., what differential diagnoses to entertain, what studies to order, what therapeutic options to consider) is dependent on information obtained from the history, physical exam, and investigational studies. The SCT-EM is developed such that elements from the history and physical exam as well as investigational studies are introduced to the examinee in the context of a clinical vignette; and this new information may or may not be useful in his or her clinical decision-making process. Respondents indicate via a five-point Likert scale (-2, -1, 0, 1, 2), the degree of effect that a new piece of information has on the clinical decision they are to make. An example of an SCT-EM item is provided in Appendix A.

As eight years have elapsed since the original SCT-EM exam was developed, two reviewers (ES and EC) examined the SCT-EM scenarios to assess face validity, that is, to ensure that there were no major changes in diagnostic, investigational, or therapeutic principles regarding the test items. Neither reviewer believed that any of the questions required alteration or removal. As per the original study protocol, a scoring key was derived by administering the examination to an expert panel consisting of board-certified EM faculty from all three residency training sites.

Residents were recruited on a voluntary basis to take the exam during a weekly educational conference in November 2018. Instead of expanding the enrollment period to collect more responses, we deliberately recruited in this very narrow timeframe to minimize variability in residency experience between the subjects of the same PGY year. After obtaining verbal consent by a co-investigator who did not have a leadership role within the residency program, the test was administered with paper and pencil. Residents and members of the expert panel were given 45 minutes to complete the examination. Upon completion of the exam, examinees voluntarily completed a brief survey assessing their attitudes toward the SCT-EM. The study was reviewed and approved by a single institutional review board that reviews research for the health system and medical school.

Data Collection

To score the SCT-EM, one full credit (one point) was awarded to a response that correlated to the modal answer provided by the expert panel. Partial credit was also obtainable on the SCT-EM, by calculating the ratio of congruent expert responses to that of the modal response. For example, of a 10-person expert panel, if eight answered "0" and two answered "-2" for a particular item, those examinees with the modal response, "0," would receive one full point, those who

responded "-2" would receive 0.2 (2/10 experts with the same answer), and all other responses would receive no credit. An example of our scoring matrix is available in Appendix B.

ACGME EM Milestones "Patient Care (PC)" competency scores were obtained from the Fall 2018 clinical competency committees' semi-annual meetings from each residency training program. Data were recorded in an electronic database by a co-investigator blinded to the study outcomes using Microsoft Excel (Microsoft Corp., Redmond, WA). SCT-EM responses were de-identified by assigning each participant a unique code to ensure participant confidentiality. Once SCT-EM scores had been matched to the Milestone scores, all identifying information was removed.

Data Analysis

We analyzed baseline characteristics of the groups using descriptive statistics. Mean and standard deviations were calculated for normally distributed continuous variables and proportions for categorical variables. We analyzed normality of SCT scores and Milestones using Shapiro-Wilk normality tests and graphical methods. Mean SCT scores were compared using pairwise comparison of means. Tukey's procedure was used to adjustment for multiple comparisons. The alpha level was set at 0.05.

We performed correlation between SCT and milestone scores by calculating Pearson's correlation coefficients. Simple linear regression was used to produce a fitted correlation line and R-squared value to overlay onto a scatterplot comparing SCT exam scores to Milestone scores. Inter-item covariances for SCT items were calculated using Cronbach's alpha statistic. Sample size was based on the total pool of eligible residents in the three surveyed residency programs. We analyzed all statistical data using Stata, Version 15.1 (StataCorp, College Station, TX).

RESULTS

Population and Program Characteristics

Of 138 eligible residents from three different EM residency programs, a total of 68 (49%) completed the SCT-EM. One resident did not indicate a PGY year and was not included in the final analysis. Of the residents completing the SCT, 22 (32%) were PGY-1s, 21 (31%) were PGY-2s, 19 (28%) were PGY-3s, and six (9%) were PGY-4s. For the two PGY 1-3 programs 62% and 51% of residents completed the SCT-EM, respectively. For the one PGY 1-4 program 46% of residents completed the SCT-EM. Of the 15 attending physicians from three different programs asked to compile the expert panel, 13 (87%) completed the SCT-EM. Each member of the expert panel completed all 59 questions.

Script Concordance Test-EM Scores

Mean SCT scores for each group are shown in Table 1. Mean differences in SCT scores between all groups (PGY-1,

Table 1. Descriptive statistics by group.

Group	Mean (%)	SD	Sample Size	Range (%)
PGY-1	58.5	4.1	22	44.7-69
PGY-2	62.2	3.5	21	52.5-73.7
PGY-3	60.5	4.1	19	43.1-71.8
PGY-4	61.5	4.5	6	51.3-73.2
Experts	72.8	4.9	13	57.5-85.7

PGY, postgraduate year; SD, standard deviation.

2, 3, 4, attending) was statistically significant ($p < 0.001$). Post hoc pairwise testing demonstrated no significant difference in SCT scores between PGY groups. The difference between SCT scores between the attending group and all PGY groups except the PGY-4 group was statistically significant ($P < 0.001$, Table 2).

Milestones Scores and Convergent Validity

There was no correlation between performance on the SCT exam and Milestone scores ($r = 0.12$, $p = 0.35$), as demonstrated on the Figure.

Test Performance

The Cronbach's alpha for correlation of SCT scores among all test takers was 0.68 ($n = 81$). Among the panel of experts, the alpha increased to 0.89.

Survey Results

Of the 65 respondents, 45 (73%) agreed that the test was easy to understand; 57/61 (93%) respondents felt that there was enough time to complete the test; and 56/62 (90%) agreed that the clinical scenarios were realistic.

DISCUSSION

This is the first study to stratify SCT-EM scores among EM residents by PGY year, as well as the first to compare SCT-EM scores to ACGME Milestones scores. While the SCT-EM did not differ between PGY levels, the exam was able to differentiate clinical reasoning skills between residents and expert physicians. This confirms prior study results across various specialties.^{7, 13-31} Considering the expert panel achieved significantly higher scores than all resident groups, yet there was no significant difference between resident groups, our findings raise the possibility of an inflection point of clinical reasoning ability that occurs sometime between graduating residency and practicing independently. Literature suggests that more experienced emergency physicians "differ from novices in clinical decision-making strategy by their ability to focus and be selective."³² In addition, it has been suggested that expert physicians take advantage of their accumulated knowledge and experiences to make clinical decisions in a more purposeful manner.³³

In terms of assessing convergent validity, performance on the SCT-EM did not correlate with ACGME Milestones scores, a universally accepted framework of assessment. Specifically, we chose sub-competencies "PC 1-6," which focuses on patient care and clinical decision-making. This raises the concern that ACGME Milestones scores may not be associated with clinical reasoning ability, or that the SCT-EM may measure another important aspect of clinical reasoning assessment that is not encompassed by Milestones. Humbert et al noted a modest positive correlation between SCT-EM scores and USMLE Step 2-CK performance, establishing convergent validity.⁷ Higher performance on the USMLE Step 2-CK may predict higher first-time pass rates on oral board examinations, and ABEM qualifying exams.^{34,35} Further research is needed to establish the association between written board examination scores and clinical reasoning ability and/or quality of patient care.

Table 2. Post-hoc testing: pairwise mean comparisons demonstrating mean differences in script concordance test scores between groups.

Group	Mean Difference	Standard Error	Tukey 95% CI
PGY-2 vs PGY-1	2.1	1.3	-1.4 to 5.5
PGY-3 vs PGY-1	1.1	1.3	-2.5 to 4.7
PGY-4 vs PGY-1	1.7	1.9	-3.6 to 7.0
Attending vs PGY-1*	8.4	1.4	4.4 to 12.4
PGY-3 vs PGY-2	-0.9	1.3	-4.6 to 2.7
PGY-4 vs PGY-2	-0.3	1.9	-5.6 to 5.0
Attending vs PGY-2*	6.3	1.5	2.3 to 10.4
PGY-4 vs PGY-3	0.6	1.9	-4.5 to 6.0
Attending vs PGY-3*	7.3	1.5	3.1 to 11.4
Attending vs PGY-4	6.6	2.0	1.0 to 12.3

(*) indicates $p < 0.001$.

PGY, postgraduate year; CI, confidence interval.

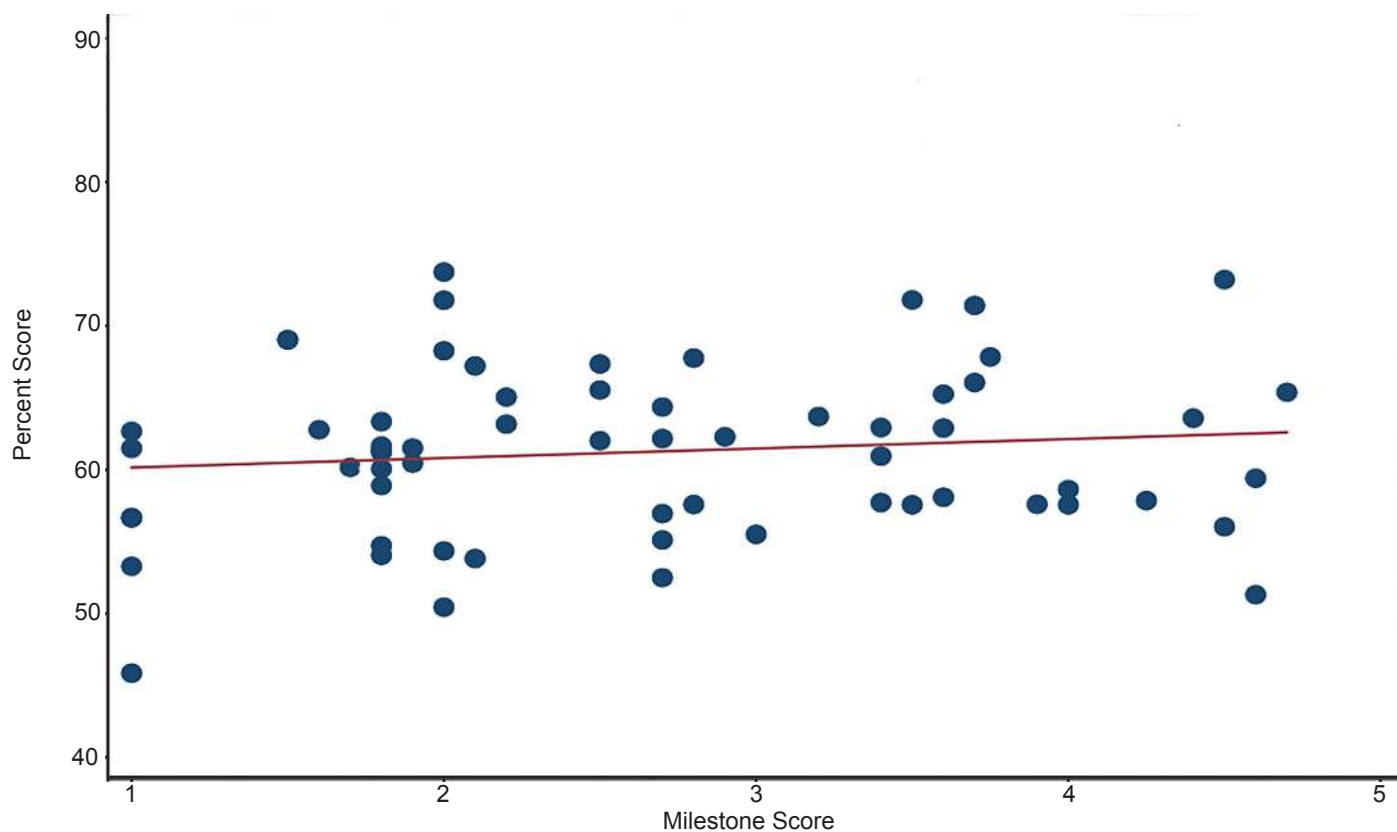


Figure. Scatterplot showing a fitted regression line comparing Accreditation Council of Graduate Medical Education Milestone scores to script concordance test (SCT) scores. $r = 0.12$, $p = 0.35$, $R\text{-squared} = 0.01$. SCT, Script Concordance Test.

Our study also establishes the feasibility and acceptability of administering the SCT-EM. A majority of the participations agreed that the test was easy to understand, that there was enough time to complete the test, and that the scenarios were realistic. These findings comport with prior studies that SCTs are easy to administer and represent clinical situations that translate into real practice.

Although SCTs are typically regarded as an assessment tool, there is great potential for their use as a unique instructional modality.⁷ The SCT-EM could be used to facilitate a scenario-based dialogue between residents and an expert panel of attendings, justifying and challenging each other's rationales behind their thought processes and decisions. These discussions could add valuable qualitative information to a quantitative exam. One prior study applied a "think aloud" approach in which examinees reflected upon their reasoning in written form as they completed a SCT. The authors found that this strategy enhanced the examinees' ability to critically evaluate their own clinical reasoning skills compared to interpreting their SCT results alone.³⁶ Another study in which an SCT was used for a continuing medical education curriculum found high rates of learner satisfaction and self-assessed knowledge acquisition and change

in practice.³⁷ Further research is needed to evaluate the SCT as an instructional strategy for resident education.

LIMITATIONS

While our study was limited by the convenience sample and response rate, all PGY levels were well represented. This 49% response rate may instill a substantial risk of responder bias. The lack of a difference in mean SCT-EM scores between PGY years may be due to sample size, as a power analysis was not performed to determine the sample size necessary to produce statistically significant results. Our findings may have limited generalizability because it was conducted in three urban residency programs in close proximity to each other, under one GME hospital system. However, the three programs represent a broad range of clinical settings, including community and academic.

We assessed convergent validity using the residents' ACGME Milestones scores; however, ACGME Milestones scores have been suggested to lack inter-rater reliability, and consistency between GME programs.³⁸⁻³⁹ Moreover, the ACGME Milestones are not a complete determination of residents' abilities nor do they assess all areas essential to unsupervised

practice.⁴⁰ Finally, the ACGME Milestones were not designed to be an assessment tool in this context. Despite these limitations, Milestone scores are endorsed by the ACGME to assess and benchmark clinical competency and used by all EM residency programs.

The SCT itself may have several implicit weaknesses. For one, respondents may perform significantly better on the exam by avoiding extreme responses (i.e., -2 or 2).^{41,42} Secondly, critics posit that SCT reliability evidence essentially ignores inter-panelist and test-retest measurement error by simply using levels of coefficient alpha as a surrogate for reliability.⁴² Next, it is impossible to determine whether an examinee has an awareness of divided expert opinion or probability beliefs regarding cases prior to the exam.⁴² In addition, the face validity of the SCT may be dependent on the quality of the exam questions, particularly the amount of context offered in each clinical vignette.⁴³ Finally, our study was based on an assumption that clinical reasoning could be adequately measured using one assessment tool. Young et al highlight the extent of this misconception, stating that standardized tests may not properly capture how well trainees perform in setting of uncertainty.⁴⁴ Considering these limitations, the utility of the SCT-EM may lie with formative assessment rather than high-stakes evaluation.

CONCLUSION

Clinical reasoning ability is difficult to reliably and feasibly assess. Although our findings demonstrate that the SCT-EM had ability to differentiate clinical reasoning ability between residents and expert faculty, it was unable to differentiate clinical reasoning between PGY levels. There are several proposed limitations inherent to the script concordance test, calling into question its overall ability to assess clinical reasoning. Future studies examining differences among residents as they progress during and after residency training, or in different residency settings, may elucidate the utility of the SCT-EM.

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Clinical Teaching: An Evidence-based Guide to Best Practices from the Council of Emergency Medicine Residency Directors

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Clinical teaching is the primary educational tool use to train learners from day one of medical school all the way to the completion of fellowship. However, concerns over time constraints and patient census have led to a decline in bedside teaching. This paper provides a critical review of the literature on clinical teaching with a focus on instructor teaching strategies, clinical teaching models, and suggestions for incorporating technology. Recommendations for instructor-related teaching factors include adequate preparation, awareness of effective teacher attributes, using evidence-based-knowledge dissemination strategies, ensuring good communication, and consideration of environmental factors. Proposed recommendations for potential teaching strategies include the Socratic method, the One-Minute Preceptor model, SNAPPS, ED STAT, teaching scripts, and bedside presentation rounds. Additionally, this article will suggest approaches to incorporating technology into clinical teaching, including just-in-time training, simulation, and telemedical teaching. This paper provides readers with strategies and techniques for improving clinical teaching effectiveness. [West J Emerg Med. 2020;21(4)985–998.]

BACKGROUND

Emergency medicine (EM) is a dynamic specialty that requires not only an acquisition of vast amounts of medical knowledge, but also the ability to prioritize and task switch efficiently and effectively to combat the chaos, high patient volume, and variable acuity within a given shift. Additionally, mounting pressures are placed on EM faculty to use less time to care for a larger volume of patients while increasing patient satisfaction scores, documentation, billing, and academic productivity.^{1,2} All of these factors can make the emergency department (ED) a challenging environment for clinical

teaching.³ Moreover, EM faculty concerns over time constraints and patient census variability are reflected in a decline of bedside teaching in the clinical setting.^{2,4-6} There is mounting evidence that clinician educators often feel ill prepared to teach in this dynamic clinical environment due to a lack of a consolidative resource.⁷⁻¹³ A set of guidelines may help assist in the development of skills for educators to help bridge this gap.

However, the ED environment provides unique opportunities for clinical teaching due to the breadth of pathology, spectrum of acuity, and large number of clinical encounters. When surveyed, students rated the ED as the

most valued rotation for learning opportunities.¹⁴ Therefore, it is essential that all emergency clinicians who work with learners develop strong clinical teaching skills to maximize this educational opportunity. This article provides a narrative summary of the literature and best practice recommendations for clinical teaching in medical education with a focus on their application within the ED environment.

CRITICAL APPRAISAL OF THE LITERATURE

This article is the fourth in a series of evidence-based best practice reviews from the Council of Emergency Medicine Residency Directors (CORD) Best Practices Subcommittee.¹⁵⁻¹⁷ With assistance of a medical librarian, we performed a search of Embase, CINAHL, Ovid MEDLINE, and PsycINFO for articles published from inception to April 23, 2018, using keywords and medical subheadings (MeSH) terms focused on teaching at the patient's bedside. The full search strategy is available in the Appendix. Bibliographies of all relevant articles were reviewed for additional studies. We used social media to further augment the search by placing several calls on Twitter among the #FOAMed and #MedEd communities to gather additional article recommendations. Articles were screened independently by two of the authors to evaluate for any papers addressing the following three themes, which were determined a priori: instructor teaching strategies, clinical teaching models, and incorporation of technology. We included articles if either author recommended inclusion.

The search yielded a total of 2,514 articles, of which 123 were deemed to be directly relevant for inclusion in this review. When supporting data were not available, recommendations were made based upon the authors' combined experience and consensus opinion. The level and grade of evidence was provided for each best practice statement according to the Oxford Centre for Evidence-Based Medicine criteria (Tables 1 and 2).¹⁷ Prior to submission, the manuscript was reviewed by the entire CORD Best Practices Subcommittee. It was subsequently posted to the CORD website for two weeks for review and feedback from the entire CORD community.

INSTRUCTOR TEACHING STRATEGIES

1. Preparation

As in most areas in life, preparation is the key to success in clinical and bedside teaching. Adequate planning and preparation by the instructor, learner, and even the patient will result in a much more effective learning experience for all involved.¹⁸ Preparing for didactic teaching, development of teaching scripts, and review of physical examination skills prior to a shift can help alleviate instructor uncertainty and improve instructor confidence.^{5,6,18-22}

Educators should consider priming the learner for the anticipated shift. Prior to the beginning of each teaching shift, the instructor should work with the learner to set clear expectations and goals.³ This includes orienting the learner to the plan for clinical teaching, getting buy-in from the learner,

Table 1. Oxford Centre for Evidence-Based Medicine levels of evidence.¹⁷

Level of evidence	Definition
1a	Systematic review of homogenous randomized control trial (RCT)
1b	Individual RCT
2a	Systematic review of homogenous cohort studies
2b	Individual cohort study or a low-quality RCT*
3a	Systematic review of homogenous case-control studies
3b	Individual case-control study**
4	Case series or low-quality cohort or case-control study***
5	Expert opinion

*<80% follow-up; **includes survey studies; ***studies without clearly defined study groups.

Table 2. Oxford Centre for Evidence-Based Medicine Grades of Recommendation.¹⁷

Grade of evidence	Definition
A	Consistent level 1 studies
B	Consistent level 2 or 3 studies or extrapolations* from level 1 studies
C	Level 4 studies or extrapolations* from level 2 or 3 studies
D	Level 5 evidence or troublingly inconsistent or inconclusive studies of any level

*"Extrapolations" indicate data were used in a situation that has potentially clinically important differences than the original study situation.

and setting relevant and achievable learning objectives by aligning the instructor's and learner's goals.^{3, 18-21, 23-29}

Patients are integral to bedside teaching by delivering a unique perspective into their illness and educating learners about their disease course. The incorporation of patients into clinical teaching adds a level of complexity for preparation and planning.¹⁸ For bedside teaching, the instructor should help prepare the patient and teaching team. This should be done by setting expectations for the interaction with the patient, such as maintaining a respectful and professional tone, avoiding medical jargon, and involving the patient and his or her family.^{30,31} When incorporating a patient into bedside teaching, one should seek the patient's permission first and set expectations prior to the encounter.^{6,20,21,23,25,26,30,32,33} However, care must be taken not to create a blind spot in clinical teaching by only focusing on specific sets of patients while avoiding others (e.g., those with communicable diseases or those deemed

“difficult” patients).³³ Patients’ autonomy should be respected at all times and they should be explicitly encouraged to ask questions, clarify or amend data, and to provide feedback to their medical team.^{34,35}

2. Instructor Characteristics

Trust and support are important in clinical teaching. Establishing a collegial and supportive teacher-learner relationship is essential to create a culture that promotes effective knowledge acquisition, professional growth, and lifelong learning habits.^{20,27,36-38} Learners have a tendency to mirror the behavior of instructors they feel are professional and competent. In knowing this, instructors should demonstrate empathy and compassion, teaching both medical knowledge and professionalism skills. Learners value instructors who can push them to their zone of proximal development (the difference between what a learner can do without help and what they can do with help) while maintaining a safe learning environment.^{19,20,30,39-41} To help achieve this, educators should avoid “read my mind” questions.^{19,42} If a learner is struggling with a question, it can be beneficial to ask whether they understand the question at hand or if it was too ambiguous. An appropriate balance should be maintained between autonomy

and supervision to help foster a supportive relationship with the learner while providing an opportunity for growth.^{40,43,44} Additionally, learners appreciate a positive attitude and enthusiasm for teaching, as well as candor from teachers about their own knowledge deficits.^{18,27,45,46} Table 3 provides a summary of qualities considered by learners to be essential in an effective clinical teacher.^{18,19,31,47,48}

3. Knowledge Integration Strategies

Learners, while very eager and enthusiastic, may struggle with knowledge integration and retention. As an instructor, it is important to be cognizant of barriers to learning and how to overcome them. Several theories and strategies can be applied to clinical practice to help with knowledge acquisition and retention.

A. Cognitive Load Theory

The theory that the human brain can process only a finite amount of information at one given time, creating a bottleneck effect for learning is known as cognitive load theory.⁴⁹⁻⁵¹ When the cognitive load is exceeded, learning and performance are both impaired. This can be avoided by selecting relevant teaching pearls that correspond to your learner’s level while avoiding teaching too much information at one time. In addition

Table 3. Features of an effective clinical teacher.^{18,19,31,47,48}

Quality	Example
Attitudes	<ul style="list-style-type: none"> • Efficient • Enthusiastic about medicine and teaching • Good bedside manner • Obviously interested • Positive attitude • Professional • Stimulates learners to think about topics
Content Knowledge	<ul style="list-style-type: none"> • Broad knowledge base • Clinical and technical skill competence • Challenges accepted dogma while admitting gaps in own factual knowledge • Clinical reasoning • Teaching ability
Humanistic	<ul style="list-style-type: none"> • Can admit limitations and say “I don’t know” • Compassionate and kind • Concerned • Fosters positive and supportive relationships with learners • Outgoing and friendly • Role model
Leadership skills	<ul style="list-style-type: none"> • Clear communication • Encourages active participation and team involvement • Establishes rapport with the group • Inclusive • Respects individuals • Sets goals and provides feedback • Supportive
Learner-centered instructional strategies	<ul style="list-style-type: none"> • Balance between didactics and bedside approaches • Challenges learners to continue to grow and think independently • Encourages learners to develop life-long learning skills

to the quantity of knowledge, educators should strive to reduce extraneous load. Extraneous load is the part of the working memory that engages in work that is not crucial to completing the learning task.⁵⁰⁻⁵³ Another technique in the clinical realm is to reduce extraneous activities to let the resident or student focus more on specific tasks.

B. Interleaving

Interleaving is when the learner alternates between semi-related topics rather than exclusively focusing on a single area for an extended period of time.^{54,55} One practical clinical application of interleaving would be for the learner to first see a patient with shortness of breath who has congestive heart failure, followed by a patient with shortness of breath due to chronic obstructive pulmonary disease. The learner can then compare and contrast the two different presentations.

C. Spaced Repetition/Retrieval Practice

Spaced repetition is when the learner spreads out studying or recall of information over time to enhance retrieval and retention.^{54,55} Retrieval practice is another strategy focused on knowledge retention, wherein the learner is asked to bring learned information from long-term memory back into use.⁵⁴ One example using this concept is having the learner reiterate teaching points later in the shift, at sign out, or even on a subsequent shift to help space the acquired knowledge and encourage recall of the information at a later time. Technology, in the form of flash card programs and applications (apps) (e.g., Quizlet, Anki, Flashcard Machine, Study Blue, Study Stack) or in email form can also serve to remind the learner of information at a later date.

D. Importance of “Wait-time” and “Think-time”

It is important to allow adequate time for the learner to process and recall information. When teaching, an instructor typically poses a question and then waits for the learner to reply, known as “wait time 1.” The time after the learner response is known as “wait time 2.” After proposing a question to a learner, previous studies have shown that an instructor typically waits an average of only 1.5 seconds prior to interjecting the answer.^{56,57} However, studies have found that waiting three seconds or longer (especially after “wait time 2”) allowed the learner time to process the question and decreased failure-to-respond rates, increased perception of caring (thereby encouraging the learner to engage more actively), and increased the total number of responses received.^{56,57}

4. Environmental and Timing Considerations

Clinical teaching should never hinder or delay care for patients, especially the critically ill; safety and the oath to “do no harm” take precedence over educational benefit.⁴¹ An instructor should select an appropriate “moment” for clinical teaching while minimizing distractions and engaging learners.^{6,23} In a busy ED environment, it is necessary to

remind learners that interruptions frequently occur based on patient care demands. The responsibility falls on both the learner and instructor to revisit any interrupted teaching interaction to complete open discussions and teaching points.⁵⁸ In caring for an acutely ill patient, it can be highly valuable for the learner to observe how a seasoned instructor provides medical care and communicates effectively with the patient, family, and team members.^{4,59} After the event, the instructor should debrief to allow discussion of medical decision-making, alternatives, and possible outcomes.³

It is important for the instructor to be aware of the learner’s mindset and select teaching opportunities for when the learner will be most receptive.³ If the learner is falling behind on his or her current patients and has several new patients to see, the instructor should select a different time to provide clinical teaching. Selecting a time when the learner is more receptive and has more available learning capacity will enhance knowledge retention.⁵⁰⁻⁵³ Allowing time after clinical teaching to answer clarifying questions and explain the thought process of decision-making are essential for learning and retention while providing guidance on future learning.^{19,41}

Several strategies can be used to make on-shift teaching more efficient.^{6,32,60} The teacher could ask the learner to briefly review the literature for a given illness and then teach this back to the instructor and other learners.^{23,30,31,37,60,61} This will instill lessons of lifelong learning, such as strategies for accessing the literature on shift, and provides an opportunity for the learner to develop advanced knowledge on a specific topic while freeing up the teacher to see the patient. However, asking the learner to review literature should not distract from the clinical experience or teaching, and care must be taken to not overuse this practice. Additionally, it is important for the teacher to set aside time for the learner to report back the information they learned on their search. Setting a time limit for the team (e.g., less than five minutes) to keep the teaching session brief will support the learning environment without compromising ED throughput.^{4,25} Additionally, this ensures that teaching points remain brief, thereby avoiding the tendency to over-teach (i.e., covering an excessive amount of material in a short time span).^{50,51} The use of a dedicated teaching shift to protect the teacher and learner from tasks and duties that may distract from an instructional goal is another effective strategy to optimize the time available for teaching in the clinical environment.⁶³

5. Interprofessional Considerations

Medicine has placed an increasing emphasis on the importance of interprofessional teams for the delivery of safe, efficient, cost-effective, and patient-centered care. Studies have found that non-physician colleagues who are actively involved in bedside teaching can help to improve communication around the care plan, enhance provider satisfaction with communication, reduce errors, aid in the diagnosis, shorten hospital length of stay, and reduce total

hospital charges.^{18,26,64} Even if other providers (e.g., nurses, technicians, and pharmacists) are unable to be physically present at the bedside, securing buy-in from interprofessional providers and institutions for the importance of clinical teaching can minimize distractions during clinical teaching, and improve the learning experience for all involved.^{6,25,65}

BEST PRACTICE RECOMMENDATIONS

1. Adequate preparation is crucial to the success of clinical teaching. This includes setting clear expectations, priming the learner, and seeking patient permission prior to bedside teaching (Level 2b, Grade B).
 2. Learners will emulate behaviors of physicians they perceive as competent and professional. Instructors should capitalize on teachable moments and model efficient bedside history and examination skills, communication styles, respect, compassion, and humanism (Level 2b, Grade B).
 3. Consider reducing cognitive load, interleaving, using spaced/retrieval practice, and increasing wait times after asking questions to allow the learner time to process and respond (Level 2a, Grade B).
 4. During critically ill patient encounters, allow time to debrief after the event. Also, consider incorporating short bedside teaching points during a patient's evaluation (Level 5, Grade D).
 5. Incorporate additional members of the care team (e.g., nurses, pharmacists, technicians) into clinical teaching encounters (Level 2b, Grade B).
-

CLINICAL TEACHING MODELS

It is important to use a variety of teaching strategies in the ED and tailor them to the individual learner and situation. Being creative and innovative with teaching techniques ensures that the sessions are memorable and meaningful for learners.²⁸ We highlight several, well-described teaching models and describe how they can be used in the ED including the Socratic method, Aunt Minnie, the One-Minute Preceptor (OMP), SNAPPS, ED STAT, teaching scripts, and bedside presentation/rounds. Table 4 includes a summary of each of these teaching techniques with a description and example of how to implement them clinically. Additional resources for those interested in learning more are available in the Appendix.

A. Socratic Method

In the Socratic method, the instructor poses a series of questions to a learner. One recent study found that this was the most frequently used teaching method in the ED and was used more often among higher-acuity patients, with more senior residents, and when multiple learners were present.⁶⁶ In contrast, “pimping” (as it has been colloquially known) is an alternate approach dating back to 17th century London and is frequently confused with the Socratic method.^{67,68}

The difference lies in the intent of the instructor toward the learner.⁶⁸ While the Socratic method is a well-established model for improving learning and recall, pimping has a less desirable intent. It is often viewed as a “sport” aimed at reinforcing the power dynamic and hierarchy of medical training.⁶⁹⁻⁷³ Using increasingly difficult questions until the learner is unable to answer, the teacher shames or embarrasses the learner. Not surprisingly, this tactic impairs the trust relationship and inhibits learning.

Questioning, in general, as a teaching method has been found to be very efficient and effective.^{54,56,57,74} Students have been shown to better recall knowledge if it is taught after asking a question.⁷⁵ Using this technique, advanced learners can be challenged while still teaching novices by targeting teaching and communication to meet the learner's specific needs.^{23,27,30,36,37,40,42,44,60,67,76} To determine a learner's existing knowledge, skills, and gaps, teachers can use probing questions (e.g., “why?” and “how would you approach...?”) to guide individualized, specific teaching to the learner, regardless of his or her level of training.^{4,18,19,23,28,41} Low-level questions can be used to assess factual recall, while higher-level questions assess problem-solving skills, analysis, and synthesis of the information.^{24,30,32,34,36,37,40,42,43} It is important to push a learner from basic knowledge into critical thinking and problem-solving skills through questioning. One strategy to help improve learning when approaching less familiar topics is to provide basic starting points to create the scaffolding for further problem-solving. However, when using questions as part of clinical teaching, it is essential that the learner feel safe to answer incorrectly with an emphasis on learning rather than “correct answers.”⁶⁸

Three types of questioning have been found to be the most effective for learning: broadening, targeting, and up-the-ladder.⁴⁴ Broadening involves asking “what if” scenarios to add educational examples beyond the current case. Targeting is the practice of asking specific questions to specific team members. The up-the-ladder technique (also referred to as “step-up questioning”) occurs when the teacher asks the same question to progressively more advanced learners. An advantage of the up-the-ladder technique is that it respects the educational advancement order and avoids the challenges of having a junior learner respond once a more senior learner has answered incorrectly.⁷⁷

When using the Socratic method, it is important to identify the avoidant learner and gently draw him or her into the discussion. This may be facilitated by beginning with simple questions or those that you previously have confirmed the learner is able to answer correctly. While it is important to incorporate evidence-based medicine into teaching, questions that are overly advanced or not familiar to the team should be minimized as they have been shown to be less effective.^{40,44,78}

Finally, lowering the stakes of the Socratic method may be accomplished by incorporating humor, explicitly stating expectations, and refraining from ego-driven discussions.

Table 4. Commonly described clinical teaching models.

Technique	Implementation	Pearls and Pitfalls
Socratic Method	<p>Types of Questions:</p> <ul style="list-style-type: none"> • Broadening: Asking “what if…” questions and changing the details of a case to make it more interesting. Example: “How would the management change if the patient were 25 versus 75 years old?” • Targeting Questions: Directing questions at specific team members based on their level of training. Example: For a student: “What are the most common bacteria that cause community-acquired pneumonia?” For a junior resident: “How do we decide if a patient with pneumonia needs to be admitted?” For a senior resident: “How do we recognize and manage complications of pneumonia?” • Up-the-Ladder Questions: Ask the same question of the medical student, junior resident, and finally the senior resident if needed. Example: “In this patient with a recent variceal bleed, what treatments should we consider (student)? What do you think (junior resident)? Any additional considerations (senior resident)?” 	<p>Best with higher patient acuity and flow, as well as team teaching with learners of different levels.</p> <p>Avoid alienating the learner with arcane questions.</p> <p>Avoid material that most/all of the team is unfamiliar with.</p>
Aunt Minnie	<p>Pattern recognition: “If the lady across the street walks like your Aunt Minnie and dresses like your Aunt Minnie, she probably is your Aunt Minnie, even if you cannot identify her face.”</p> <p>Steps:</p> <ol style="list-style-type: none"> 1. The learner evaluates the patient and then presents only the chief complaint and the presumptive diagnosis. 2. The learner begins the patient note while the teacher evaluates the patient. 3. The teacher discusses the case with the learner, gives feedback, and discusses pattern recognition for the presentation. 4. The teacher reviews the learner’s write-up and signs the medical record. 	<p>Best with lower patient volume and acuity, and with learners able to perform a history and physical examination in a timely manner.</p> <p>Efficient in teaching typical presentations in common illnesses.</p> <p>Avoid with rare or atypical presentations and complex cases.</p>
One-Minute Preceptor (OMP)	<p>Steps:</p> <ol style="list-style-type: none"> 1. Get a commitment from the learner on what they think is going on with the patient. 2. Probe for supporting evidence to explore the learner’s understanding. 3. Teach general rule(s) pertaining to the patient and case. 4. Reinforce what was done correctly and provide positive feedback to the learner. 5. Correct learner mistakes. 	<p>Best with high acuity patients and more advanced learners.</p> <p>Avoid in a busy ED with frequent task interruptions unless completed at the bedside.</p>
SNAPPS	<p>Steps:</p> <ol style="list-style-type: none"> 1. Summarize the history and physical examination. 2. Narrow the differential diagnosis to the most important. 3. Analyze the differential by discussing the diagnosis and probabilities. 4. Probe the preceptor by asking questions about uncertainties and alternative approaches. 5. Plan patient management together. 6. Select a related clinical issue for additional self-directed learning. 	<p>Facilitates active adult learning through dialogue with the preceptor, management planning, and identifying issues for further learning.</p> <p>Avoid in a busy ED with frequent task interruptions unless completed at the bedside.</p>
ED STAT	<p>Steps:</p> <ol style="list-style-type: none"> 1. Expectations: Orient the learner to the ED, how the teacher and learner will work together, and clarify expectations. 2. Diagnosis of the Learner: To make the teaching more relevant, determine their learning objectives. 3. Set-Up: Use a specific patient care scenario to pose a question that will be used as the foundation for the teaching point. 4. Teach: Focus teaching on high-yield, concise, and relevant information to the learner with generalizability to other similar patient case presentations. 5. Assess and Give Feedback: Provide constructive and nonjudgmental feedback, include self-assessment as the foundation for preceptor feedback. 6. Teacher Always (Role Model): Realize that the learner is always watching and implicitly learns a great deal. Be aware of verbal and non-verbal communication cues (body language). Acknowledge statements as facts or opinions. 	<p>Designed for the complex environment of the ED.</p> <p>Incorporates teaching and feedback into one tool.</p> <p>Determination of learner’s needs can help optimize clinical teaching.</p>

ED, emergency department; *STAT*, strategies for teaching any time.

Table 4. Continued.

Technique	Implementation	Pearls and Pitfalls
Teaching Scripts	Tips: <ul style="list-style-type: none"> Instructors should have quick and specific teaching talks readily available to review common topics. Scripts should be short teaching points prepared ahead of time. 	Avoid too much content to be covered in a concise manner. Preparation is essential.
Bedside Presentations	Tips: <ul style="list-style-type: none"> Set the stage for your learners, patient, and family beforehand. At the bedside, ask the patient and family to listen to the presentation first. Then provide any clarifications afterwards. Assign roles to team members such as providing feedback on presentations, entering orders, or starting the patient note while the presentation is given. Consider combining with the Socratic method, OMP, or SNAPPS at the bedside. 	Best when teaching team are able to all round together. Must set expectations. Avoid medical jargon.

The emphasis should be placed on positive reinforcement and framing questions as “learning opportunities.”⁷⁷ Trainees should be reminded that more can be learned from incorrect answers than correct ones, as incorrect answers shed light into the learner’s knowledge gaps. The Socratic method is frequently combined with many of the techniques that follow to enhance learning and retention.

B. Aunt Minnie

In the ED, many diagnoses occur through pattern recognition by aligning the history and physical examination with prior experiences and expertise. The “Aunt Minnie” approach is a teaching method focused on learning pattern recognition or heuristics for facilitating diagnostic efficiency. This is ideal for typical presentations of common, low-to-moderate acuity clinical complaints and allows learners to increase their repository of patient experiences as they develop their clinical gestalt. This strategy is based on the principle that, “if the lady across the street walks like your Aunt Minnie and dresses like your Aunt Minnie, she probably is your Aunt Minnie, even if you cannot identify her face.”⁷⁹ On a deeper level, this is informed by the concept of System 1 (e.g., unconscious, automatic) and System 2 (e.g., slow, effortful) thinking.⁸⁰ This method can be used in the ED to efficiently balance clinical care while incorporating clinical teaching of learners.^{79,81}

For an instructor, it is important to recognize when this technique is appropriate (e.g., common ambulatory complaints) and when the model should not be used (e.g., rare or complex diseases).^{82,83} In the latter, learners may need to use a more strategic approach (i.e., System 2 thinking).^{82,83} This also provides an opportunity for educators to teach learners how to develop their gestalt. The Aunt Minnie method relies on an instructor with a good foundation of clinical experience to help facilitate the formation of pattern-recognition skills for the learner. The instructor should not be afraid to share his or her own uncertainty and doubt with the learner in more complex cases to prevent the formation of incorrect associations.

C. One-Minute Preceptor (OMP)

The OMP model was initially described in 1992 by Neher and colleagues as a method to efficiently balance teaching while simultaneously providing effective patient care.⁸⁴ This model is particularly well-suited for the busy ED environment. The OMP is a learner-centered model of instruction that is based on five microskills, as described in Table 4.^{58,84-88}

The OMP model has shown high satisfaction among both learners and instructors with learners preferring the OMP model over the traditional precepting model.⁸⁶ When evaluating the OMP, instructors have stated that it was more effective and efficient than the traditional model, allowing them to provide more information in the same amount of time.⁸⁹ Multiple studies have demonstrated that teachers using the OMP feel more confident in their ability to assess the learner’s knowledge and clinical reasoning skills.^{86,89,90}

The OMP model depends on the accuracy and completeness of information gathered by the learner. With more experienced learners, such as a senior EM resident, this model may be implemented rapidly in one interaction from start to finish. With more novice learners, modifications may be necessary to allow the instructor the opportunity to assess the patient and gather any missing data. Regardless, the fundamental theme of encouraging learners to commit to a diagnosis and plan is crucial to help shape their critical thinking and decision-making skills.

D. SNAPPS (Summarize, Narrow, Analyze, Probe, Plan, Select)

The SNAPPS model emphasizes active learning by incorporating opportunities for the learners to ask the instructor questions regarding uncertainties and alternative approaches, as well as guiding self-directed, future learning. Although faculty training and ongoing commitment is required, SNAPPS does not require significantly more time than traditional teaching.^{91,92} A simple refinement of the SNAPPS technique incorporates the PICO (Patient, Intervention, Comparison, and Outcome) approach to frame

clinical questions to guide additional self-directed learning.⁹³

Multiple studies have reported that utilization of the SNAPPS model results in numerous benefits when compared with traditional teaching and the OMP model. These benefits include increases in learner satisfaction, differential diagnosis generation, expression of clinical reasoning, active engagement with teachers, generation of teaching points, opportunities for self-directed learning, and clinical skills development.^{91,92,94-98}

E. ED STAT (Emergency Department Strategies for Teaching Any Time)

ED STAT is the first tool specifically designed for the complex learning environment of the ED with easy-to-follow steps, allowing incorporation of clinical teaching and feedback into a single model. This model has been shown to increase the confidence in preceptors' teaching and is designed for educators of all experience levels and backgrounds.⁹⁹ Aside from demonstrating an increased knowledge of teaching strategies specific to the ED, this technique has also been associated with an increased satisfaction and confidence in teaching abilities by the individual.⁹⁹

F. Teaching Scripts

Teaching scripts are quick, specific, previously created teaching talks designed to review common complaints seen in the ED. Having these teaching scripts prepared ahead of time allows for efficient teaching during a busy ED shift.^{4,22,100} For example, when a patient presents with possible pulmonary embolism, being able to quickly summarize the diagnostic approach with a figure and references for additional reading can reduce the educator's workload while ensuring high-quality knowledge dissemination. Instructional content for teaching scripts can include medical knowledge, communication skills, procedural training, and time management strategies. To prevent cognitive overload, instructors should focus on one topic and limit the teaching to a short time period.⁴¹ While some teaching opportunities will present themselves based on a particular patient complaint, others can be created by asking learners about theoretical scenarios.¹⁰⁰

G. Bedside Presentations and Rounds

Although initially a clinical teaching approach used in inpatient medicine, bedside presentations and rounds can be incorporated into the ED environment and may prove beneficial for patient care. During bedside rounds, all team members should be introduced, and the comfort and privacy of the patient should be maintained at all times.¹⁰¹ The patient should be oriented to the goal of the clinical teaching session prior to the interaction and be informed that there may be theoretical discussions (e.g., differential diagnosis development, what-if scenarios) about their illness.^{19,20,30,32,42,102} Of note, some experts believe that hypothetical scenarios are best left for discussion away from the patient's bedside to avoid confusion.³⁰ Patient-centered communication (both verbal and non-verbal) should be used. As such, a body part should not be referred to as "it." The patient should be talked to

and not about, and there should be mindful physical positioning between the physician, learner, and patient.^{22,25,103}

With adequate preparation, an instructor can add structure and depth to the teaching session to maximize the learning opportunity, even if presenting patient complaints are limited.¹⁸ Several different models of bedside rounds exist that can be adapted to the ED, including basic science rounds (focus on pathophysiology, signs, and symptoms); problem-oriented rounds (focus on prioritizing and managing the presenting problem list); and clinical skills rounds (focus on history-taking and physical examination skills).¹⁸

There are several benefits to having learners present to the supervising clinician at the patient's bedside. By moving away from the computer or busy workstation, the focus shifts to the patient.¹⁰² Learners are able to directly observe how experienced clinicians interview, examine, reason, and communicate with patients and their families. In addition, supervising clinicians can immediately clarify presentations and physical examination findings.

However, this approach has potential challenges. Learners may feel increased pressure to present all of the facts and provide a comprehensive management plan while patients may not want more sensitive issues disclosed in group teaching sessions. Residents may also fear that answering questions incorrectly in front of their patients will jeopardize their patient-physician relationship and undermine their ability to care for that patient. To avoid this, the faculty can direct questions to learners not involved in direct care of that specific patient.⁴ Alternatively, instructors can help mitigate this by guiding learners to identify or by demonstrating a particular finding.³⁵

BEST PRACTICE RECOMMENDATIONS

1. Use questions to engage students and residents in active learning. Combine the use of low-level questions to assess knowledge and high-level questions to assess problem-solving skills. Make sure to create a supportive, safe learning environment (Level 2b, Grade B).
 2. Consider OMP to promote a learner-centered model of instruction. This tool is well-received by both learners and instructors due to its focus on five microskills while incorporating feedback (Level 2b, Grade B).
 3. Consider using SNAPPS to promote active participation and engagement for both learners and educators (Level 1b, Grade B).
 4. Considering using ED STAT to help foster an environment of learning in the complete ED environment. It is designed for educators of all experience and backgrounds and will increase preceptors' confidence in teaching. (Level 2b, Grade B)
 5. Prepare ahead by having brief, specific, pre-created teaching scripts designed to review common ED complaints to allow for efficient teaching during a busy ED shift (Level 2b, Grade B).
 6. For bedside presentations, always orient the patient to expectations prior to the interaction. Use patient-centered communication, while being cautious with hypothetical situations in front of the patient, to facilitate a successful experience (Level 2b, Grade B).
-

INCORPORATING TECHNOLOGY

The use of technology can help promote learning. As clinical teaching continues to evolve, the use of technology and innovative bedside teaching approaches will increase. Learners who are involved in simulation rather than traditional, paper-based learning have been shown to demonstrate better retention skills.¹⁰⁴ However, the use of technology is not just limited to formal didactics and can be used in a variety of formats, including just-in-time training, task trainers, in situ simulation, and telemedicine.

A. Just-in-Time Training

The learning needs and preferences of medical student and resident learners continue to evolve. Digital natives crave immediate information and prefer the integration of technology in the learning process.¹⁰⁵⁻¹⁰⁷ One particular teaching modality, just-in-time training (JITT), incorporates both technology and immediate, high-yield information to satisfy digitally-savvy learners. JITT is a method of training where topic-specific education occurs in a focused, concise manner just prior to performing the task. The literature most commonly focuses on using short, predefined educational content, such as a video with simulation for procedural-based competency.

The advantages of JITT include minimizing training time, the ability to visualize the procedure prior to performing it, and allowing prompt return to clinical duties.¹⁰⁸ As such, this is ideal for a high-volume ED setting. Additionally, JITT has demonstrated positive effects at the learner, patient, and system levels, while also generally being enjoyed by learners.¹⁰⁸ JITT has previously been studied for splint application.^{109,110} When compared with reading textbooks, watching a brief JITT instructional video before splinting was shown to yield faster learning times and more successful splint applications.¹¹⁰ Another study assessed JITT for intraosseous needle placement and defibrillator use in a pediatric ED. JITT significantly increased comfort levels and the ability to perform the procedure independently by the trainee. Moreover, the use of a dedicated JITT room in the clinical environment is both feasible, effective, and can lead to improved resident confidence with fewer supervisor-reported procedural interventions.^{108,111,112} However, JITT may not be helpful for all types of procedures and training with some research showing conflicting success rate for certain procedures, such as pediatric intubation and infant lumbar puncture.^{113,114}

Importantly, in the era of mounting technology and easy availability, it is vital to screen the JITT resources for quality and applicability prior to incorporation into clinical practice.^{115,116} One study performed a systematic search of YouTube™ to assess videos focused on teaching ophthalmoscopy.¹¹⁷ Out of more than 7,000 videos, they identified 27 (0.4%) that were suitable for teaching this skill; however, none of them included all of the elements for a thorough education on ophthalmoscopy. Pre-identifying resources and having them ready for learners, rather than

having to look them up and evaluate them in real time, can help ameliorate this.

B. Simulation (including Task Trainers and In Situ Simulation)

Clinical procedures have been identified as one core area to improve the efficiency and effectiveness of critical care education, specifically given the need to balance patient safety with opportunities for learners to practice procedures.⁶⁰ Strategies to bridge this gap include learning that uses computers, task trainers, and simulation. The use of simulation to enhance clinical teaching and learning continues to increase rapidly in the form of both in situ simulation and procedural training.

Task trainers can serve as a safe alternative for reinforcing the muscle memory necessary for many of the tasks required of an emergency physician. These can range from phantom limbs for peripheral intravenous line placement to transvenous pacing or pericardiocentesis models. Use of task trainers allows evaluation of procedural competencies, provides a safe environment for learning and fine-tuning skills, and allows for troubleshooting common errors that may occur in these high-stakes procedures without the added pressure of patient and time constraints. The learner can practice placing an ultrasound-guided peripheral line on an ultrasound phantom model prior to performing the procedure on a patient.

In situ simulation refers to simulation performed in the clinical care setting. Simulation offers the benefit of experiential learning in a realistic environment and can be run during any clinical shift. Simulation allows the opportunity for interdisciplinary interactions and communication training. This can range from high fidelity (e.g., mannequins) to low fidelity (e.g., mock cases in an empty patient room).¹¹⁸ Technology can facilitate these simulations by using stored images or videos, as well as a number of simulation smartphone apps.

C. Telemedicine

Wearable platforms enable learners to view how they are perceived by patients and facilitate novel debriefing approaches when attendings are not in the room during the initial patient encounter. Google Glass is a wearable platform with a head-mounted optical display that is lightweight, voice-activated, and provides the opportunity for technology-assisted education.^{119,120} This platform allows audiences and learners to visualize what the operator is seeing in real time, thereby allowing multiple learners to experience an educational benefit from a single experience.^{104,120} This can also be used by learners to review and engage in self-reflection based on the encounter.¹²¹ Many of the features that clinical learners deem as important to clinical education can be accomplished using this model.^{122,123} However, it is important to be conscious of patient privacy and the Health Insurance Portability and Accountability Act. Moving forward, it is imperative that medical educators keep abreast of emerging educational technologies including personalized learning,

mobile technologies, and learning analytics. Such technology has the potential to enhance learning and clinical competence within the clinical environment.⁶⁰

BEST PRACTICE RECOMMENDATIONS

1. Use just-in-time training instructional videos to facilitate asynchronous teaching and procedural skills (Level 1b, Grade B).
 2. Incorporate a variety of stimuli (eg, imaging, electrocardiograms, ultrasound videos) into clinical shifts to enhance teaching and engagement of the learner (Level 2b, Grade B).
 3. Consider employing *in situ* simulation as an effective educational strategy when teaching in the clinical environment (Level 2b, Grade B).
 4. Consider incorporating telemedicine and wearable platforms such as Google Glass to enhance teaching and feedback during clinical encounters (Level 2a, Grade B).
-

LIMITATIONS

This review has several important limitations to consider. First, while our search methodology was comprehensive, some articles may nevertheless have been missed in the current review. We minimized the risk by reviewing all related studies in the bibliographies of included articles, reaching out to content and topic experts, undergoing pre-submission review and approval by the CORD community, and placing several calls via social media for further resources. Another limitation is the dearth of experimental studies specifically within the ED setting. When robust, ED-specific educational outcomes data were not available, we used studies from other fields and expert opinions. Thus, some proposed interventions may not be as effective in the ED setting and further studies are needed to establish their efficacy in our learning environment.

CONCLUSION

Because clinical teaching is a critical tool in the education and development of all physician trainees, it is vital to have a strong foundation of the available techniques and methods for clinical teaching. Our work provides a critical review of the literature on clinical teaching for residency education with a focus on EM. Recommendations were given for instructor teaching considerations, clinical teaching strategies, and options for incorporating technology into clinical practice. We hope this manuscript will inform readers on strategies and techniques for successful clinical teaching.

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Conference Didactic Planning and Structure: An Evidence-based Guide to Best Practices from the Council of Emergency Medicine Residency Directors

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Emergency medicine residency programs around the country develop didactic conferences to prepare residents for board exams and independent practice. To our knowledge, there is not currently an evidence-based set of guidelines for programs to follow to ensure maximal benefit of didactics for learners. This paper offers expert guidelines for didactic instruction from members of the Council of Emergency Medicine Residency Directors Best Practices Subcommittee, based on best available evidence. Programs can use these recommendations to further optimize their resident conference structure and content. Recommendations in this manuscript include best practices in formatting didactics, selection of facilitators and instructors, and duration of individual sessions. Authors also recommend following the Model of Clinical Practice of Emergency Medicine when developing content, while incorporating sessions dedicated to morbidity and mortality, research methodology, journal article review, administration, wellness, and professionalism. [West J Emerg Med. 2020;21(4)999–1007.]

BACKGROUND

Graduate medical educators are responsible for training well-rounded physicians who are prepared to practice their specialty independently following graduation. A significant component of their education comes from “regularly scheduled didactic sessions” as prescribed by the Accreditation Council for Graduate Medical Education (ACGME) Common Program Requirements.¹ Specialty-specific ACGME requirements provide further recommendations regarding the amount of dedicated didactic time that must be provided and general themes that must be covered such as journal review, morbidity and mortality (M&M) conference, and research seminars.²

Beyond these general requirements, programs have the flexibility to develop their conference structure and content however they choose. This has led to much variation in conference structure, content, and how specific conferences

such as M&M are conducted at each individual program. This variation leads to very different experiences for residents based on the residency they attend and has the potential of producing graduates with uneven exposure to key didactic topics during their training. To our knowledge, no evidence-based guidelines or best practices exist to aid educators in the design or implementation of residency didactic curricula. This article provides an evidence-based summary of the literature and best practice recommendations for didactics as it pertains to conference structure and content with a focus on emergency medicine (EM) residency programs.

CRITICAL APPRAISAL OF THE LITERATURE

This is the fifth article in a series by the Council of Emergency Medicine Residency Directors (CORD) Best Practices Subcommittee.³⁻⁶ A medical librarian performed a

search of Medline, Embase, Web of Science, CINAHL, and ERIC for articles published from inception of each database through February 7, 2019, using keyword combinations of education level (medical, graduate, internship, house staff, PGY, and residency), as well as didactics (or conference or lecture) with differing frequency (daily, weekly, bi-weekly, and monthly). Two authors then screened each of the articles independently for papers addressing the three themes: conference structure; conference topics; and M&M sessions. Given the extent of M&M literature obtained, the authors decided to separate articles dedicated specifically to that topic.

The initial literature search yielded 1,199 articles, which were then categorized and provided to content experts for consideration of inclusion in this review. A total of 101 articles were selected for inclusion in this review. Each best practice statement has a corresponding level of evidence and grade based on the Oxford Centre for Evidence-Based Medicine criteria (Tables 1 and 2).⁷ When there was insufficient

supporting data, the authors based recommendations on their experience and consensus opinion. The entire CORD Best Practices Subcommittee reviewed the manuscript after which time it was posted on the CORD website for review by the entire CORD community.

OVERALL CONFERENCE STRUCTURE

Many factors may influence programmatic decisions regarding timing, frequency, and duration of didactic curricula in addition to the desire to optimize education. These may include regulatory requirements, clinical work schedules, locations of faculty and trainees, personnel (teachers and learners), and space availability. The concentrated blocked weekly didactic format (i.e., a single, dedicated conference half day per week) is highly prevalent in other specialties such as family medicine and neurology, in addition to EM.^{8,9}

Residents appreciate having protected educational time and, compared to shorter daily formats, the blocked weekly didactic structure has demonstrated higher learner satisfaction, improved attendance, and fewer interruptions.¹⁰⁻¹³ While learners perceive improved learning with this format, studies have failed to demonstrate differences in objective outcomes such as scores on standardized tests or board examinations.¹⁰⁻¹⁴ However, given the perceived and logistical benefits, including improved attendance, which is essential to maintaining accreditation, combined with the nature of EM clinical schedules, the authors recommend the blocked weekly format.

The ACGME places certain requirements on programs regarding faculty participation in didactics. These include that each core faculty member must attend at least 20% of planned didactic experiences and that EM faculty members must present at least 50% of resident conferences.² While there is limited data evaluating faculty conference attendance and objective learning outcomes, one study found that higher faculty conference attendance was associated with higher pass rates on EM oral boards for trainees.¹⁵ Additionally, residents perceive that faculty presence at conference facilitates learning.^{16,17} One approach to increase faculty presence at conference would be to offer incentives for attending conference.¹⁸ Providing continuing medical education credit for didactic conferences can also increase faculty attendance.¹⁹

Conference didactics are most often presented by faculty or residents.^{8,9,16,15,20} Some have advocated for residents to give didactic lectures to ease the burden on faculty time and sharpen resident public speaking skills.²¹ While residents perceive that faculty lectures greatly contribute to their educational experience,^{11,16} limited data has demonstrated that residents can learn from resident-given lectures, and that no difference in learning outcomes (e.g., test scores, board passage rates) were found between resident-given lectures vs faculty-given lectures.^{15,20,22} Additionally, it may be appropriate to incorporate other professionals (e.g., nurses, pharmacists) as lecturers depending on the topic. Smith et al found no difference between lecture evaluation scores for nurse-given lectures compared to

Table 1. Oxford Centre for Evidence-Based Medicine criteria.⁷

Level of Evidence	Definition
1a	Systematic review of homogenous RCTs
1b	Individual RCT
2a	Systematic review of homogenous cohort studies
2b	Individual cohort study or a low-quality RCT*
3a	Systematic review of homogenous case-control studies
3b	Individual case-control study**
4	Case series or low-quality cohort or case-control study***
5	Expert opinion

*<80% follow up; **, includes survey studies; ***, studies without clearly defined study groups.
RCT, randomized controlled trial.

Table 2. Oxford Centre for Evidence-Based Medicine grades of recommendation.⁷

Level of Evidence	Definition
A	Consistent level 1 studies
B	Consistent level 2 or 3 studies or extrapolations* from level 1 studies
C	Level 4 studies or extrapolations* from level 2 or 3 studies
D	Level 5 evidence or troublingly inconsistent or inconclusive studies of any level

*“Extrapolations” are where data is used in a situation that has potentially clinically important differences than the original study situation.

faculty- and resident-given lectures.²³

Given that the specialty of EM interfaces with many other disciplines, it may also be beneficial to incorporate multidisciplinary conferences with other medical professionals into the didactic curriculum to enable collaborative learning, coordinated patient care, and a better understanding of the roles of other professions.^{24–26} The ACGME recommends the inclusion of multidisciplinary conferences as part of the resident didactic experience.² Limited research suggests that trainees value this type of experience^{24,27}; however, robust objective data on learning outcomes are lacking.

Instruction should be tailored to the level of the learner.^{28,29} However, this may be especially challenging in program-wide didactic conferences in which the learners differ significantly in terms of stages of training and faculty are at varying career stages and experience. In recent years, we have seen the development of a national EM curriculum specific to the training level and the nearly universal presence of a dedicated intern orientation in residency programs.^{30,31} To date, there are no objective data evaluating training level-specific didactics on learning outcomes; however, faculty and residents have been shown to view this targeted instruction positively.^{32,33}

Resident didactic instruction has traditionally been delivered via lectures despite calls for alternatives.^{34,35} Common criticisms of lectures include lack of engagement due to an emphasis on passive learning,³⁶ overwhelming students' ability to learn by providing too much information,³⁷ and waning attention due to the duration of the session.³⁸ Despite calls to minimize the use of lectures, data support their continued effectiveness as a teaching modality.^{39–41} The common criticisms can be overcome through intentional learner-centered instructional design.

Cognitive load theory states that there are three main components involved in the creation of long-term memories: intrinsic load; extraneous load; and germane load.²⁸ While

intrinsic load and germane load are generally fixed, extraneous load is highly modifiable and heavily influenced by the manner in which material is presented to learners.²⁸ Since the amount of working memory is generally fixed for a given person at a set time, increases in extraneous load (i.e., presenting information in an overly complex manner) will detract from learning and retention.²⁸ Therefore, instructors should focus on ensuring that talks are focused on delivery of information, while limiting unnecessary information or overly complex presentations of the information. Multimedia learning theory informs principles of slide design and is one effective method that can be used to increase the long-term retention of taught material⁴² (Table 3).

With regard to the duration of lectures given at conference, the notion that shorter may be better is based on data of learner attention spans.⁴⁵ In a classic study of medical students, Stuart and Rutherford found that the attention span peaked at 10-15 minutes and fell steadily thereafter, with the authors recommending that lectures not exceed 25-30 minutes.⁴⁵ In more recent years, we have seen the implementation of shorter lectures in EM both at the local and national level.^{34,46} Limited studies have compared shorter (8- to 30-minute) segments compared to the more traditional 50- to 60-minute lecture and found the learners typically prefer the shorter format^{47–49}; however, few have looked at objective learning outcomes. One study by Bryner did evaluate knowledge acquisition and retention between 20-minute and 50-minute lectures and found no significant difference.⁵⁰ More research is needed to determine the optimal length of didactic sessions with an emphasis on outcome-based evaluations.⁵¹ When it is not possible to reduce the duration of a lecture, incorporating pauses, interactive questioning, and intermittent summarization can re-engage learners and improve attention to the content.⁵²

Handouts are an additional method to increase the effectiveness of lectures. While many lecturers will distribute copies of their presentations, a more effective technique is the

Table 3. Mayer's 12 principles of multimedia learning.^{43,44}

1. **Coherence Principle:** Avoid extraneous words, pictures, and sounds. They can detract from learning.
2. **Signaling Principle:** Add cues to highlight the essential materials.
3. **Redundancy Principle:** On-screen text can detract from learning. People learn better from graphics and narration alone as opposed to graphics, narration, and on-screen text.
4. **Spatial Contiguity Principle:** Corresponding words and pictures should be presented near each other rather than far from each other on the screen.
5. **Temporal Contiguity Principle:** Corresponding words and pictures should be presented simultaneously rather than successively.
6. **Segmenting Principle:** Multimedia lessons should be presented in learner-controlled segments rather than as a continuous unit.
7. **Pre-training Principle:** When students already know the names and behaviors of system components, they will learn more from the session.
8. **Modality Principle:** Learning is more effective when words are presented as narration rather than on-screen text.
9. **Multimedia Principle:** Learning is more effective when words are combined with pictures as opposed to include words alone.
10. **Personalization Principle:** Information delivery is more effective when words are presented in a conversational style rather than formal style.
11. **Voice Principle:** Learning is more effective when narration is spoken in a friendly human voice rather than a machine voice.
12. **Image Principle:** Learning is not necessarily more effective when the speaker's image is added to the screen

concept of guided notes. Guided notes are a hierarchical outline of the presentation with key information intentionally left blank. Learners will “fill in the blanks” as the lecture progresses, thus increasing attention and discovering the relationships in the presented material. Additionally, the fact that the notes are mostly complete allows for effective note-taking and allows attention to be directed at the presenter instead of the notebook.⁵³

While lectures can still be effective, active learning has been shown to positively impact objective learning outcomes, by incorporating other instructional techniques.⁵⁴⁻⁶³ Active learning is “any instructional method that engages students in the learning process”⁶⁴ and can include techniques such as games, flipped classroom, audience response systems, case-based problems, and team-based activities.⁶

Real-time electronic broadcasts of lectures and video conferencing can be another good use of technology to support resident education.⁶⁶ This has been demonstrated to be an effective educational model that is positively viewed by trainees and can improve access and attendance at didactic offerings for both residents and faculty.⁶⁷⁻⁶⁹ For training programs with multiple sites or that have struggled with maintaining the required attendance percentage for accreditation, this may be a valuable option to consider.

Our understanding of how learning occurs has evolved as cognitive scientists continue to refine effective methods for teaching and learning. Unfortunately, effective methods are often not incorporated into medical curricula. Educators should avoid using or encouraging the use of learner-initiated summarization, highlighting and underlining, mnemonics, imagery, and rereading as these techniques have not been shown to enhance learning.⁷⁰ Effective techniques with a strong effect size include practice testing and distributed practice. Additionally, there is likely some benefit from the use of elaborative interrogation, self-explanation, and interleaving.⁷⁰

Practice testing is the use of no- or low-stakes tests that can be completed independently by the learners. These can include recall via flashcards, practice problems, or traditional types of test questions.⁷⁰ Teachers may choose to implement this technique using shared card decks or applications (apps), or web-based asynchronous question banks. Anonymous audience-response systems are popular and have also been shown to improve student learning in medical education.^{71,72} Distributed practice (also known as spaced repetition) refers to the spreading out of learning over time as opposed to massed practice or “cramming.”⁷⁰ Implementation of this technique can be accomplished by content mapping that allows for repeated exposure to the concepts from prior didactics, the use of handouts or summarization materials between didactic sessions, or by using email to re-expose learners to the material.⁷³

Elaborative interrogation involves the use of self-questioning to enhance learning. This would involve the learner seeking out the underlying rationale or etiology using questions such as “why does this occur?” Similarly, self-explanation involves directing learners to explain their logic during task

completion.⁷⁰ Educators can easily incorporate this technique through simple questioning exercises during their lectures. Interleaving is an education organizational technique in which multiple topics and themes are mixed and covered over time instead of having discrete blocks dedicated to single topics.⁷⁴

The flipped classroom, also known as the reverse classroom,⁷⁵ is an instructional design method in which independent learning, often via previously-viewed video lectures or pre-reading, is combined with face-to-face classroom activities.⁷⁶ When studied, the flipped classroom appears to be effective⁷⁷⁻⁷⁹; however, caution should be exercised as recent systematic reviews have found high methodological diversity, inconsistent results, and risk of bias.^{76,80-82} Gamification is another active learning technique, which involves the utilization of games and competition to support learning.⁸³ As a technique, gamification may support learning of skills,⁸⁴ emergency department (ED) throughput,⁸³ decision-making,⁸⁵ and medical knowledge.⁸⁶⁻⁸⁹

Team-based learning (TBL) is an instructional method used with increased frequency in both undergraduate medical education and graduate medical education, which is often combined with the flipped classroom model.⁹⁰⁻⁹³ Prior to TBL, learners are expected to prepare and complete a pre-session test individually ahead of time. During the TBL sessions, learners then work in teams to solve a series of realistic, complex problems. Faculty serve as facilitators encouraging peer-learning, cooperation, and ensuring the discussion stays on track. This approach requires upfront training of faculty in discussion facilitation and learner buy-in to prepare for sessions.^{91,94}

BEST PRACTICE RECOMMENDATIONS:

1. Didactic lectures should be administered as blocked, weekly sessions (Level 2b; Grade B).
 2. Encourage faculty attendance and participation in conference (Level 3b; Grade B).
 3. Lecture can still be an effective method to present didactic content. When this technique is used, the lecturer should ensure that their presentation complies with cognitive load theory, multimedia learning theory, and active learning principles (Level 1a; Grade B).
 4. Real-time video conferencing can be considered to improve access and attendance (Level 3b; Grade C).
 5. Educators should incorporate the use of spaced repetition and no- or low-stakes testing into didactic instruction to increase long-term retention of content (Level 1a; Grade A).
 6. Utilization of recorded lectures, flipped classroom, and gamification can supplement or replace the traditional lecture (Level 1a; Grade B).
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Conference Topics

After a thorough review of the literature, we found no prospective studies evaluating which specific topics should be included in the conference didactic curriculum. For this reason,

the core content as described by the Model of the Clinical Practice of Emergency Medicine, or the “EM Model,”⁹⁵ is most commonly used as the de facto foundation of the conference curriculum in most residencies. While this was designed using expert consensus data, it is heavily informed by those areas most relevant to the emergency physician. In fact, during the creation of the EM Model, hospital data from over 90 million ED visits were compared to its content and found to have 82% overlap, validating the content of the EM Model.⁹⁶ The EM Model is further refined every three years to identify new areas to cover.⁹⁷ As it is used to inform board certification examinations, it is important for residents to be familiar with all of the topics covered and is a critical initial reference for most conference planners.⁹⁸ While there is no strong data to help prioritize specific subject matter during conference time, in-training examination coverage of various areas may help guide emphasis on high-yield topics.

While the EM Model may be used as a guide for resident education, conference didactics should be viewed only as one component of resident education with its unique strengths and weaknesses. As such, rather than focusing solely on “covering” all topics in the EM model, the priority of conference didactic design should be on maximizing the learning potential of this modality.⁹⁹ Additionally, some topics can best be taught through other components of resident education including clinical experience, outside reading, simulation and use of Free Open Access Medical Education (FOAM).⁴

The ACGME Program Requirements for Graduate Medical Education (GME) in EM mandate specific conference content to be taught as part of didactics.² These include five main components listed in Table 4.

Additionally, the ACGME requires a number of other specific themes to be included in residency training.² We suggest incorporating the following into your conference topics to assure completion of these requirements.

Patient Safety and Quality Improvement

Residents should be educated in a culture of safety, including understanding safety goals, diagnostic error, response to adverse events, continuous quality improvement, and ultimate accountability of the physician for the care of the patient. This can also be combined with M&M conference

Table 4. Main components of conference didactics.

1.	Curriculum presentations
2.	Quality improvement/morbidity and mortality
3.	Research seminars (including education on how to conduct and understand research in a clinical context)
4.	Journal review and evidence-based medicine concepts
5.	Administrative seminars (to include operations and administrative practices in emergency medicine)

sessions.¹⁰⁰*Professionalism*

Residents must be aware of their professional responsibilities toward their patients and peers, as well as their relationship with the health system on a local and national level. Residents should also appreciate the necessity of their own need for ongoing education after residency and how to obtain and maintain board certification.

Well-Being

In recognition of the prevalence of depression, burnout, substance abuse, and suicidality among residents and medical students, the ACGME now mandates teaching on the identification and mitigation of these concerning issues. While there is no set curriculum provided or recommended by the ACGME itself, materials are available, such as the Educational Toolkit provided by the 2017 Resident Wellness Consensus Summit.¹⁰¹ This incorporates modules on second victim syndrome, mindfulness and mediation, and positive psychology.

Fatigue mitigation

All residents must be able to recognize limitations in their ability to care for patients due to sleep deprivation and fatigue; they should be made aware of options for fatigue management and transition of care to another provider, should the need arise.

Given the limited evidence-based data on curricular content of didactics further dedicated research on possible curricular content and the weighting of topics taught may be beneficial.

BEST PRACTICE RECOMMENDATIONS:

1. Core content topics for conference should be derived from the conditions and skills described in the EM Model (Level 5, Grade D).
 2. Curriculum presentations, morbidity and mortality sessions, research seminars, journal review, and administrative seminars should be included as part of the conference design (Level 5, Grade D).
-

LIMITATIONS

There are several limitations to consider for this review. First, it is possible that some articles were not identified using our search strategy; however, an experienced medical librarian conducted the search with a broad search strategy using multiple databases. Additionally, we searched bibliographies of all included articles, contacted topic experts, and underwent pre-submission peer review by the entire CORD community.

Given the breadth of this topic, we were unable to address all aspects of conference planning and some components (e.g., simulation, journal club) were therefore not included in the current review. However, journal club was previously covered

in a prior best practice manuscript,³ and other topics may be covered in future best practice recommendations. Moreover, some areas did not have EM-specific data available. When data specific to EM residency conference didactics was limited, relevant data from other specialties and fields was also incorporated.

CONCLUSION

This article provides a summary of the best practice guidelines in developing resident didactic structure and content based on current literature and expert consensus. It offers a set of recommendations regarding the various didactic modalities, techniques to maximize the benefit from these sessions, and addresses effective incorporation of technology to improve participation. With regard to content, the authors recommend following the EM Model as a scaffold as well as incorporating other topics as specified by the ACGME such as research, professionalism, journal review, and wellness. More research is needed to better guide what content should be included in didactics and to what extent.

The authors hope that this review will serve as a blueprint for programs to optimize their conference curriculum, ensuring a more uniform, high-quality level of education for their residents. Ultimately, educational designers must create a curriculum in the context of their specific institution, balancing pedagogically robust didactic content and structure with the resources available to them including money, time, equipment, and space. It is our hope that this review can be used by educators to advocate for additional resources from their department or institution to better facilitate evidence-based education for residents.

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Diagnostic Accuracy of Point-of-Care Ultrasound for Intussusception in Children Presenting to the Emergency Department: A Systematic Review and Meta-analysis

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Introduction: Ileocolic intussusception is a common cause of pediatric bowel obstruction in young children but can be difficult to diagnose clinically due to vague abdominal complaints. If left untreated, it may cause significant morbidity. Point-of-care ultrasound (POCUS) is a rapid, bedside method of assessment that may potentially aid in the diagnosis of intussusception. The purpose of this systematic review and meta-analysis was to determine the diagnostic accuracy of POCUS for children with suspected ileocolic intussusception by emergency physicians (EP).

Methods: We conducted a systematic search on PubMed, Embase, CINAHL, LILACS, the Cochrane databases, Google Scholar, as well as conference abstracts, and assessed bibliographies of selected articles for all studies evaluating the accuracy of POCUS for the diagnosis of intussusception in children. We dual extracted data into a predefined worksheet and performed quality analysis with the QUADAS-2 tool. Data were summarized and a meta-analysis was performed.

Results: Six studies (n = 1303 children) met our inclusion criteria. Overall, 11.9% of children had intussusception. POCUS was 94.9% (95% confidence interval [CI], 89.9% to 97.5%) sensitive and 99.1% (95% CI, 94.7% to 99.8%) specific with a likelihood ratio (LR)⁺ of 105 (95% CI, 18 to 625) and a LR⁻ of 0.05 (95% CI, 0.03 to 0.10).

Conclusion: POCUS by EPs is highly sensitive and specific for the identification of intussusception for children presenting to the emergency department. [West J Emerg Med. 2020;21(4)1008-1016.]

INTRODUCTION

Ileocolic intussusception is the most common cause of gastrointestinal obstruction in children and represents a common abdominal emergency in early childhood.¹ As the ileum telescopes into the cecum, the mesentery is compressed, which leads to venous and lymphatic bowel congestion. As time passes, the process can lead to ischemia, perforation, peritonitis, and significant morbidity. Therefore, rapid diagnosis is paramount. Children with intussusception

may present with nonspecific symptoms such as vomiting, abdominal pain, or lethargy.¹ The classic triad of colicky abdominal pain, palpable abdominal mass, and bloody stool are present in less than 50% of children with intussusception, which can make the diagnosis challenging to make on history and physical examination alone.² Additionally, since the majority of cases are seen in children aged 6-36 months,¹ the history is often limited, which can compound the difficulty of diagnosis.

Ultrasound is considered the first-line diagnostic test of choice when evaluating children for intussusception because of its high accuracy and lack of harmful ionizing radiation.³ Radiology-performed ultrasound has been shown to have excellent test characteristics, with high sensitivity (98%) and specificity (98%),⁴ and is far superior to abdominal plain radiography in accurately evaluating children for intussusception.⁵ Moreover, ultrasound for the evaluation of ileocolic intussusception is relatively uncomplicated to learn and can be accurately performed by junior radiology trainees.⁶ Still, radiology-performed ultrasound requires a capable provider, often including a technician and/or radiologist. Such expertise may not be available 24 hours a day at many institutions. Delays from limited access to radiology-performed ultrasound may lead to increased morbidity and mortality.⁷

Point-of-care ultrasound (POCUS) is increasingly used in adult and pediatric emergency medicine for a wide range of applications.⁸⁻¹⁰ POCUS for the evaluation of ileocolic intussusception may allow EPs to make the diagnosis at the patient's bedside and avoid delays in diagnosis. However, it is important to determine the diagnostic accuracy of this approach prior to routine use. The purpose of this systematic review and meta-analysis was to determine the diagnostic accuracy of POCUS in children with possible intussusception by EPs.

METHODS

Our study conforms to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines and was conducted in accordance with best practice recommendations.¹¹ The study was also registered with PROSPERO, the international prospective register of systematic reviews (CRD42019122126).

We conducted a systematic search of PubMed, Embase, the Cumulative Index of Nursing and Allied Health (CINAHL), Latin American and Caribbean Health Sciences Literature database (LILACS), Google Scholar, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials to include citations from inception through January 14, 2019. A medical librarian assisted us in our search. In accordance with the recommendations by Bramer and colleagues, only the top 200 Google Scholar search terms were selected.¹² Details of our search strategy are included in the Appendix. In addition to the above, we also hand searched the last five years of conference abstracts from the American College of Emergency Physicians and the Society for Academic Emergency Medicine and the last three years of abstracts from the American Institute of Ultrasound in Medicine (only three years were available) for relevant abstracts. We also reviewed the references of identified studies and review articles for potentially missed articles.

Inclusion criteria consisted of all prospective or

retrospective studies assessing the accuracy of POCUS for intussusception in pediatric patients (defined as younger than 18 years of age). There were no language or date restrictions. All studies had to include a gold standard confirmatory test (ie, radiology-performed ultrasound, other radiology imaging, air enema, or patient follow-up). We excluded case reports, case series, studies on practice patients, and adult studies.

Two investigators (MLM, AEK) independently assessed studies for eligibility based on the above criteria. All abstracts meeting inclusion criteria underwent full-text review. Studies determined to meet criteria after full-text review by both investigators were included in the final data analysis. Discrepancies were resolved by consensus between the two investigators and a third party (MG). Two investigators (MLM, AEK) independently extracted data from the included studies. The investigators were trained on extraction and used a predesigned data collection form. The following information was extracted: first author; year; study design; type of publication (ie, abstract or full article); sample size; country; study location (ie, pediatric emergency department [PED], other); median/mean age of patients; number of male patients; ultrasonographer training level (ie, trainee, attending); ultrasound training protocol; ultrasound probe and machine; scanning protocol; gold standard; intussusception rate; true-positive results; false-positive results; true-negative results; and false-negative results. Studies were independently assessed for quality by two investigators (MLM, AEK) using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) Tool.¹³ Discrepancies were resolved by consensus between the two investigators and a third party (MG).

The results were pooled from the included studies using a bivariate mixed-effects model to calculate sensitivity, specificity, positive likelihood ratio (LR+), and negative likelihood ratio (LR-) with 95% confidence intervals (CI).¹⁴ We constructed a summary receiver operating characteristic (sROC) curve with observed study data, and calculated the area under the curve. We assessed heterogeneity between studies graphically by plotting their sensitivity/specificity points on the sROC grid, creating standard forest plots of sensitivity and specificity, and calculating I^2 .¹⁵ We also performed a sensitivity analysis after excluding one study¹⁶ that appeared to be an outlier due to physician training, index test, and reference test. We performed additional sensitivity analyses excluding retrospective studies as well as excluding studies that were reported as abstracts only. We assessed the possibility of publication bias using a scatter plot of the inverse of the square root of the effective sample size vs the diagnostic log odds ratio and reported the p-value for Deeks' funnel plot asymmetry test.¹⁷ Statistical analysis was completed with Stata/SE, version 15.1 (StataCorp LP, College Station, TX). We used the MIDAS module to perform analyses and construct the figures. For subgroups of fewer than four studies, we used MetaDTA (https://crsu.shinyapps.io/dta_ma/) to pool results.

RESULTS

We identified a total of 791 studies as follows: PubMed yielded 192; Embase 345; CINAHL 48; LILACS four; Google Scholar 200; the Cochrane Central Register of Controlled Trials two; and the Cochrane Database of Systematic Reviews yielded zero. After removal of duplicates, 549 abstracts were reviewed with 26 reviewed as full-text articles or conference abstracts (Figure 1).

Six studies comprising 1303 children were selected for the final analysis with a total of 155 cases (11.9%) of intussusception (Table 1).

Three studies were journal publications^{16,18,19} and three were meeting abstracts.²⁰⁻²² Studies were conducted from 2010-2017 with the number of children in each study ranging from 44-775. Five studies were conducted in the United States¹⁸⁻²² and one was performed in Taiwan.¹⁶ All studies were performed in pediatric EDs. Three studies were retrospective,^{16,19,21} while three were prospective.^{18,20,22} The average age of patients ranged from 12.3 months to 6 years, with studies reporting male gender ranging from 59-68%. In five studies, sonographers were pediatric emergency physicians who had various levels of ultrasound training,¹⁸⁻²² with some having received relatively brief training on ultrasound while others had performed over 100 POCUS scans. In one study, the pediatric emergency physician performing POCUS was also a board-certified pediatric gastroenterologist.¹⁶ A linear transducer was used in three

studies. The transducer type was not described in three studies. The reference standard varied between the six studies. Three studies^{18,20,22} used radiology-performed ultrasound as their gold standard, one study¹⁹ used radiology study (either computed tomography, ultrasound or barium enema), and another study¹⁶ used final diagnoses from the ED chart as well as chart review for admitted patients to the wards or return visits. Tryglidas et al²¹ used either radiology over-read of POCUS images or radiology-performed ultrasound as the reference standard.

Overall POCUS was 94.9% sensitive (95% CI, 89.9% to 97.5%) and 99.1% specific (95% CI, 94.7%-99.8%) with a LR+ of 105 (95 % CI, 18-625) and a LR- of 0.05 (95% CI, 0.03-0.10) (Table 2, Figure 2). The area under the sROC curve was 0.95 (95% CI, 0.93 - 0.97), suggesting excellent diagnostic accuracy (Figure 3).

We also evaluated the data for PEM-only trained physicians, by excluding Lin et al¹⁶ (Table 2, Appendix Figure 1), given that the pediatric emergency physician in the study was also a board-certified pediatric gastroenterologist, and found similar sensitivity and specificity: 94.2% sensitive (88.5% to 97.2%) and 97.8% specific (94.1%-99.2%) with a LR+ of 43 (16-117) and a LR- of 0.06 (0.03-0.12) and area under the ROC curve of 0.97.

The study by Lin et al¹⁶ was at high risk for bias (Table 3). In terms of patient selection, this study included all patients with acute abdominal pain rather than those just with suspected intussusception. Out of 775 patients only 15,

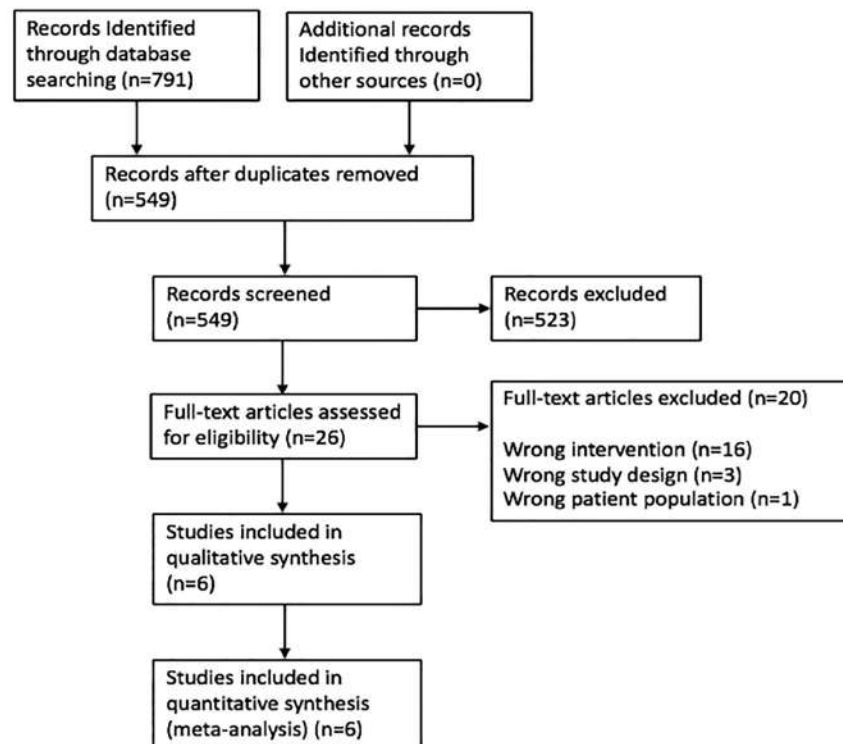


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram. No additional articles were identified through bibliographic review.

Table 1. Characteristics of studies that assessed the accuracy of point-of-care ultrasound for diagnosis of intussusception in children.

First author	Year	Study design	n	Country	Study location	Intussusception Rate	Average age (mean)	Male n (%)	Ultrasound training level	Ultrasound training protocol	Gold standard
Lam	2014	Retrospective	44	USA	PED	10 (23%)	31 months	30 (68%)	PEM Physicians	Minimum 1 hour of training on POCUS for ileocolic intussusception	Radiology study (CT, US or barium enema)
Muniz	2010	Prospective	198	USA	PED	30 (15.1%)	12.3 months	N/A	PEM physicians	N/A	Radiology US
Riera	2012	Prospective	82	USA	PED	13 (16%)	25 months (median)	48 (59%)	PEM attendings and fellows	1 month of clinical instruction POCUS, 100-150 adult exams, 1 hour focused bowel US training session by a pediatric radiologist	Radiology US
Trigylidas	2017	Retrospective	105	USA	PED	78 (74%)	22 months (mean)	67 (64.4%)	PEM Physicians	Trained in standard POCUS and underwent brief additional education in identification of ileocolic intussusception	Pediatric radiology direct overread of POCUS scan or radiology department ultrasound
Zerzan	2012	Prospective	99	USA	PED	9 (9%)	N/A	N/A	PEM attendings and fellows	PI gave brief in-service consisting of a didactic and hands-on ultrasound training session for all PEM attendings and fellows	Radiology US
Lin	2013	Retrospective	775	Taiwan	PED	15 (2%)	6 years (mean)	478 (62%)	PEM doctor also was Pediatric gastroenterologist	Exams done by board certified pediatric GI physician	Chart review

PEM, pediatric emergency department; PEM, pediatric emergency medicine; POCUS, point-of-care ultrasound; PI, principle investigator; GI, gastroenterology; CT, computed tomography; US, ultrasound; N/A, not available.

all under the age of three, were positive for intussusception, and it is unclear in how many children intussusception was suspected clinically. There were also applicability concerns for the index test, as the person who performed POCUS was board-certified in pediatric gastroenterology. Moreover, the diagnostic accuracy data included was for multiple different diagnoses including appendicitis, gastrointestinal infection, renal disease, gynecologic disease, gastrointestinal anomalies, extra-abdominal disease, and nonspecific abdominal pain, as well as for intussusception. Finally, for patients with negative POCUS, not all had received a follow-up radiology study and final diagnosis relied upon ED chart review, hospital course and possible revisits, which led to unclear bias in the reference standard. For these reasons, we also report pooled results after excluding this study (Table 2, Appendix Figure 1).

Additional sensitivity analysis of only prospective studies showed slightly lower sensitivity and similar specificity: 90.4% sensitive (79.0-96.8%) and 98.8% specific (96.9-99.7%) with a LR+ of 74 (28-197) and a LR- of 0.10 (0.04-0.22), and, sensitivity analysis of journal publications only, excluding abstracts, showed similar results to pooled data: 94.7% sensitive (82.3- 99.4%) and 99.5% specific (98.8-99.9%) with a LR+ of 204 (77-545) and a LR- of 0.05 (0.01-0.20).

DISCUSSION

This systematic review and meta-analysis demonstrates that POCUS for intussusception by pediatric emergency physicians is both highly sensitive and specific with accuracy similar to that of prior studies of radiology ultrasound for the diagnosis of intussusception.²³ POCUS has the potential to reduce the time to treatment and overall length of stay in the ED. In fact, one study found that the institution of a POCUS protocol for intussusception reduced length of stay by over 200 minutes and shortened the door-to-reduction time by 26 minutes.²⁴

A recent systematic review and meta-analysis by Tsou et al²³ evaluated combined radiologic ultrasound and

POCUS, demonstrating similar sensitivity and specificity to our study. However, our study differs in that we excluded radiology ultrasound and focused specifically on POCUS for intussusception. Additionally, the prior review included several studies with significant limitations, including one study²⁵ that reported diagnostic accuracy data for patients who did not necessarily receive an ultrasound. In this retrospective study, patients were divided into two groups, one that was treated by pediatric EPs trained in POCUS for intussusception and one that was treated by pediatric EPs without this training. However, not all patients in the POCUS-trained group actually received a POCUS. The overall sensitivity for the group is reported, but not for the POCUS itself. The authors do report combined sensitivity and positive predictive value for POCUS by pediatric EPs and gastroenterology-performed ultrasound (considered the standard ultrasound in this study), but do not specifically assess the sensitivity and specificity of POCUS by pediatric EPs in isolation. We chose not to include this study for those reasons. Furthermore, they included the study by Lin et al¹⁶ that had a high risk of bias in the patient selection as well as applicability concerns for the index test and that was likely subject to an extreme form of incorporation bias.²⁶ Given these concerns, we performed a sensitivity analysis excluding this study and report these results as well.

When performing POCUS for intussusception, there is not currently a single preferred technique, although multiple have been described.^{18,27} These varying techniques can also affect the diagnostic accuracy of a test. We include a protocol (Figure 5) that was developed with POCUS experts and pediatric radiology at our institution.

Begin in the right lower quadrant, using a high-frequency linear probe with the probe marker to the patient's right side. First, identify the psoas muscle and right iliac vessels as anatomical landmarks. Next, look for the transition from small bowel to large bowel and the ileocecal valve. Perform graded compression, with slow, steady pressure to displace bowel gas. Follow the colon from the right lower quadrant

Table 2. Diagnostic accuracy data from included studies and pooled results.

Study	Sensitivity (95% CI)	Specificity (95% CI)	LR+ (95% CI)	LR- (95% CI)
Lam	100.0% (69.2%-100.0%)	94.1% (80.3%-99.3%)	17 (4-65)	
Muniz	93.3% (77.9%-99.2%)	100.0% (97.8%-100.0%)		0.07 (0.02-0.25)
Riera	84.6% (54.6%-98.1%)	97.1% (89.9%-99.6%)	29 (7-117)	0.16 (0.04-0.57)
Trigylidas	96.2% (89.2%-99.2%)	92.6% (75.7%-99.1%)	13 (3-49)	0.04 (0.01-0.13)
Zerzan	88.9% (51.8%-99.7%)	97.8% (92.2%-99.7%)	40 (10-161)	0.11 (0.02-0.72)
Lin	100.0% (78.2%-100.0%)	100.0% (99.5%-100.0%)		
Pooled-ALL	94.9% (89.9%-97.5%)	99.1% (94.7%-99.8%)	105 (18-624)	0.05 (0.03-0.10)
PEM-trained only	94.2% (88.5%-97.2%)	97.8% (94.1%-99.2%)	43 (16-117)	0.06 (0.03-0.12)

PEM, pediatric emergency medicine; CI, confidence interval; LR+, positive likelihood ratio; LR-, negative likelihood ratio.

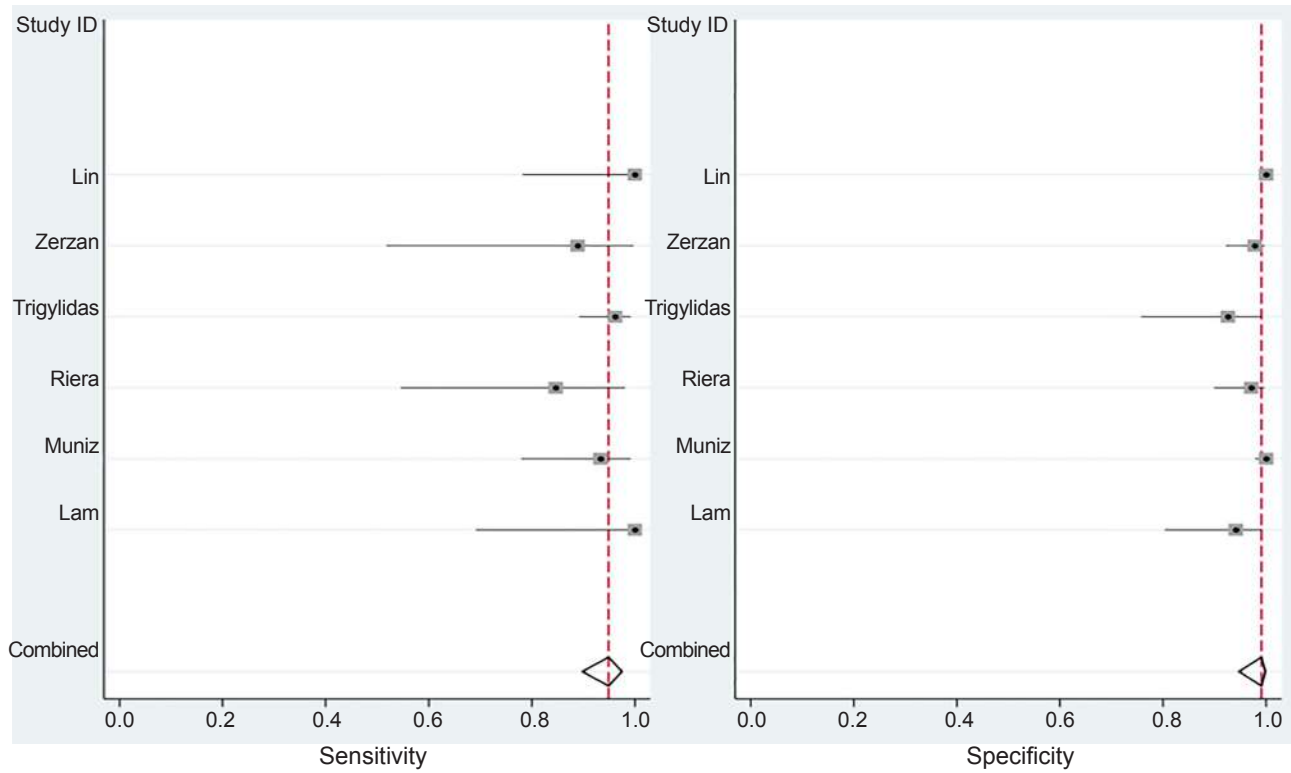


Figure 2. Forest plot with all included studies.

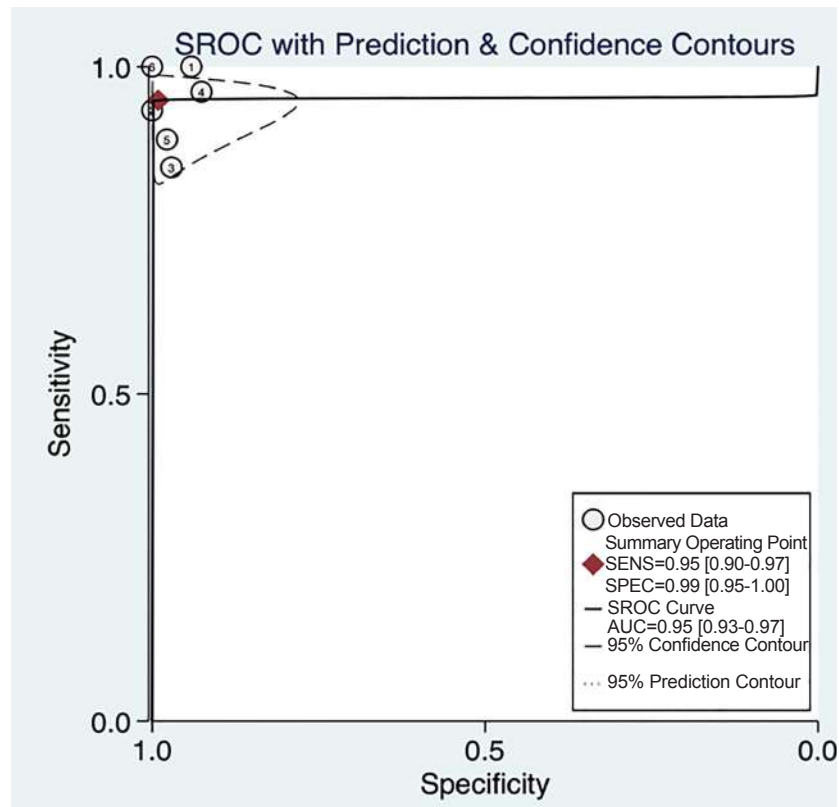


Figure 3. Summary receiver operating characteristic (SROC) curve with all studies.

1=Lam, 2=Muniz, 3=Riera, 4=Trigylidas, 5=Zerzan, 6=Lin.

SENS, sensitivity; SPEC, specificity; AUC, area under the curve.

to right upper quadrant until the liver and gallbladder are identified. Rotate the probe marker to patient’s head and scan entire length of transverse colon. Rotate the probe marker back to patient’s right and scan entire length of descending colon, making sure to scan all four quadrants and to rescan any possible lesions.

Typically, an ileocolic intussusception appears as a “target sign” lesion, with one part of bowel (intussusceptum) telescoping into another part of bowel (intussusciptens). In the transverse axis, the outer wall is thickened and hypoechoic. In the longitudinal axis, a “pseudokidney” sign has been described from the hyperechoic intussusceptum telescoping into the hypoechoic intussusciptens. Other typical findings of ileocolic intussusception include lymph nodes in mesenteric

fat noted in the intussusceptum.³

Based on our findings, POCUS could be considered for early diagnosis of intussusception. However, it is important to consider several limitations of POCUS for intussusception. These include operator dependence and the need for sufficient training. Future studies should establish the ideal training protocol and necessary number of POCUS exams for skill maintenance.

LIMITATIONS

This study has several limitations that are important to consider. First, most studies did not state their specific scanning protocol, so it is unclear whether their specific protocols may have differed. Ultrasound, in general, is user-dependent and can vary based on training, skill, and frequency of practice. In our included studies, there was significant heterogeneity in who performed the POCUS, with some studies having experienced sonographers and others having physicians who had received short trainings. However, we believe this risk is low as prior studies have shown that ultrasound for intussusception can be learned by junior trainees⁶ and do not necessarily have to be performed by experts. Future studies should use standardized scanning protocols to limit variation and assess the test characteristics of physicians using these protocols.

Half of the included studies were abstracts rather than journal articles, which can limit ability to analyze sources of bias. However, when a separate sensitivity analysis was performed on journal articles only, we found similar results for diagnostic accuracy.

Additionally, half of the studies included were retrospective, which can bias the results. To help control for bias from retrospective studies, we also performed a sensitivity analysis without these studies, and the diagnostic accuracy data without retrospective studies showed slightly worse sensitivity, with larger CIs, but similar specificity. This change in sensitivity could be due to bias. The prevalence of intussusception varied among the included studies. The two

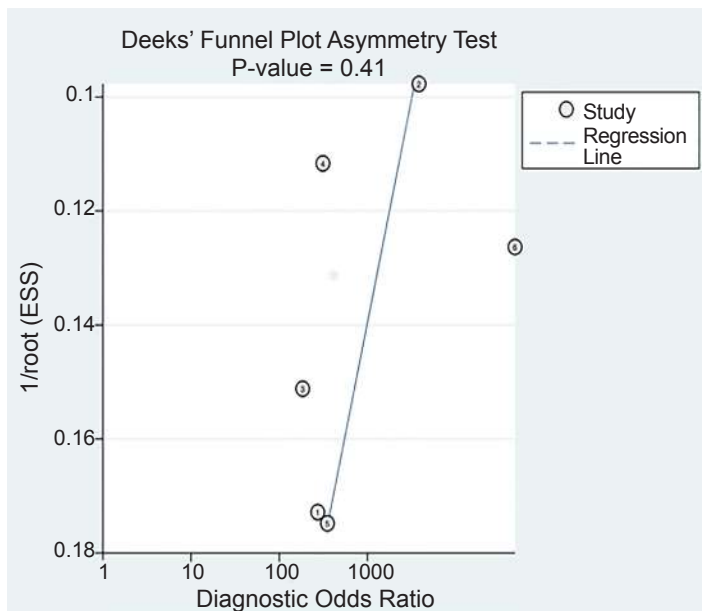


Figure 4. Funnel plot with all included studies. 1=Lam, 2=Muniz, 3=Riera, 4=Trigylidas, 5=Zerzan, 6=Lin. ESS, effective sample size.

Table 3. Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) for included studies.

First author	Year	Risk of bias				Applicability Concerns		
		Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
Lam	2014	U	L	L	L	L	L	L
Muniz	2010	U	L	L	U	L	L	L
Riera	2012	U	L	L	L	L	L	L
Trigylidas	2017	U	L	U	U	U	L	L
Zerzan	2012	U	L	L	L	L	L	L
Lin	2013	H	U	U	U	H	H	U

L, low; H, high; U, unclear.

studies, Lam et al¹⁹ and Trygylidas et al,²¹ with the highest prevalence of intussusception were both retrospective. This may suggest partial verification bias in the retrospective studies.²⁶ One exception to this is Lin et al,¹⁶ which was retrospective, but had a low prevalence of intussusception (2%). However, this study included patients who may not have been suspected to have intussusception initially. Typically, a high prevalence of disease suggests partial verification bias where patients with positive index tests are more likely to get the reference standard test and patients with negative index tests are excluded from the study, meaning that true negatives are excluded (biasing specificity down) and false negatives are excluded (biasing sensitivity up). And indeed, both Lam et al¹⁹ and Trigylydas et al²¹ had relatively high sensitivities and low specificities.

The variation in prevalence of disease also suggests risk of selection bias, where included patients may have been selected who were more or less likely to have intussusception than the typical population where POCUS would be used, which also limits the generalizability of the results. The prospective studies included used convenience sampling based on when a physician trained in POCUS for intussusception was available. This may also limit the generalizability of this data. Also, there was moderate statistical heterogeneity between studies, which may also

limit the generalizability of the data.

Larger, prospective studies, controlling for patient selection and physician training, are still needed for the accuracy of POCUS for intussusception. There was no data on patient outcomes or cost of care, and further trials are needed to determine the influence of POCUS on these factors. Finally, it is possible that some studies may have been missed with this search strategy. However, we used an extensive search strategy with the assistance of an experienced medical librarian, so we believe the risk of this is low.

CONCLUSION

POCUS performed by emergency physicians is a highly sensitive and specific test for diagnosis of intussusception in children and has potential to be used as a screening tool. However, additional larger, prospective studies limiting bias are needed to assess the accuracy of POCUS for physicians of various training levels, using standardized protocols, and evaluating how use of POCUS for intussusception correlates with clinical outcomes.

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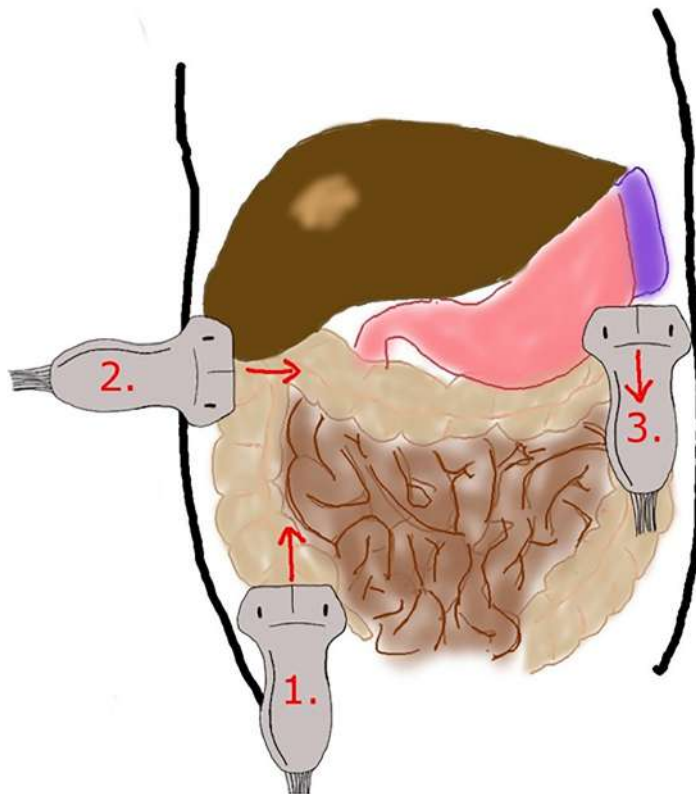


Figure 5. Intussusception scanning protocol.

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A Novel Multimodal Approach to Point-of-Care Ultrasound Education in Low-Resource Settings

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Point-of-care ultrasound (POCUS) enables physicians to make critical diagnosis and treatment decisions at the bedside. However, access to and expertise with this technology remain limited in Peru. Establishing longitudinal POCUS educational curriculums in remote, low-resource settings can be challenging due to geographical distances, encumbering the ability to provide ongoing hands-on support. Previously described educational interventions have focused on training individual users on clinical applications of POCUS, rather than training physicians how to teach POCUS, thereby limiting scalability and sustainable impact. We therefore describe our experiences establishing the first ultrasound fellowship curriculum in Peru, which incorporates tele-ultrasonography to circumvent traditional geographical barriers. [West J Emerg Med. 2020;21(4)1017-1021.]

INTRODUCTION

Point-of-care ultrasound (POCUS) is recognized as an integral skill set for emergency medicine (EM) providers working in the United States (US).¹ The World Health Organization considers ultrasound as one of the most important technologies for developing countries; however, a lack of education and training remains a limiting factor to widespread use.²

Prior studies have demonstrated the ability to teach clinical applications of emergency care POCUS to novices with adequate retention of knowledge and skills when longitudinal educational curriculums are employed.³⁻⁵ However, sustainability and scalability of longitudinal educational programs is resource intensive, and often not possible. International travel for instructors for hands-on education is expensive and time consuming. Also, prior studies have focused on training large groups of individual users, rather than educating future physician leaders on how to teach POCUS. Our novel model is an attempt to allow for scalability and ongoing impact.

Recent technological advances (both improved, broadband Internet access as well as ultrasound software advances) allow for

tele-ultrasonography to be used as an additional tool for providing ongoing supervision and mentoring of learners.⁶ Prior studies have demonstrated that tele-ultrasonography can be employed to direct image acquisition by novice providers⁷ and also increase diagnostic accuracy when combined with expert mentorship.⁸

EM has been a recognized medical subspecialty in Peru since 1993. While most emergency departments (ED) have access to an ultrasound system due to a national decree from the Ministry of Health in 2015 requiring all EDs treating critically ill patients to have access to an ultrasound, many remain unused due to lack of training. Given this identified need for further EM POCUS training, we formed a partnership with the Department of EM at the Hospital Nacional Dos de Mayo to establish the first EM ultrasound fellowship in Peru. The Hospital Nacional Dos de Mayo is a large, urban, public academic medical center that primarily serves the uninsured. Prior to the initiation of our educational project, the ED had an ultrasound system devoted to clinical care that was primarily used for focused assessment with sonography for trauma (FAST) examinations.

In this report we describe our experiences creating the first

ultrasound fellowship for emergency physicians in Peru. Our educational model leverages tele-ultrasonography to provide ongoing remote education and support, alongside traditional in-person hands-on education. Our model is aimed at providing fellows with sufficient depth of education and expertise to become educators and future leaders within the field of EM POCUS.

METHODOLOGY

Three Peruvian, EM-trained doctors were selected as the inaugural class of ultrasound fellows based on recommendations by faculty and residents at the Hospital Nacional Dos de Mayo. Participation in the fellowship was voluntary. The year-long fellowship is modeled after the ultrasound fellowship curriculum at our academic institution and incorporates traditional in-person, hands-on learning both in Lima and the US with real-time tele-ultrasonography, educational teleconferences, and academic journal reviews. The educational intervention was reviewed by the Alameda Health System Institutional Review Board and deemed to be exempt from any informed consent requirements.

Hands-on Education

The fellowship begins with a two-week interactive bootcamp course held in Lima covering basic and advanced ultrasound topics both with lectures and hands-on scanning component on models and patients. The course is taught by visiting ultrasound faculty from our academic institution. After the introductory course, fellows begin to perform clinically relevant ultrasounds in the ED at the Hospital Nacional Dos de Mayo. Fellows participate in three, four-hour-long weekly ultrasound scanning shifts during which they are protected from primary patient care

responsibilities. During the initial two months, ultrasound scanning shifts were led by visiting ultrasound instructors from our academic institution. Following this initial period, visiting instructors are not always present in Lima; however, fellows use the built-in tele-ultrasonography software to obtain guidance with image acquisition and interpretation.

Additionally, fellows travel separately as early as possible in their fellowship year to our US-based medical center to spend a one month-long rotation with our EM ultrasound division. They participate in daily ultrasound scanning shifts led by ultrasound faculty and learn advanced POCUS diagnostic and procedural skills. During the rotation, fellows also observe how POCUS education is incorporated into medical school and residency education, which is critical to our model's sustainability and scalability through the teaching of future educators.

Tele-ultrasonography

Fellows employ tele-ultrasonography to provide real-time, remote supervision and guidance using built-in software on the handheld ultrasound devices during scanning shifts. The tele-ultrasound software allows the fellows to join real-time video chat with a pool of on-call ultrasound faculty and alumni from our academic medical center in the US while performing ultrasound scans. Fellows are encouraged to call when there is diagnostic uncertainty or need for additional procedural support. Ultrasound faculty and alumni can connect to the tele-ultrasound application on their personal cell phone, tablet, or computer and have access to real-time footage of both the ultrasound images, as well as a video camera that can be used to visualize and direct placement of the ultrasound probe and/or guide procedures as shown in Figure 1.

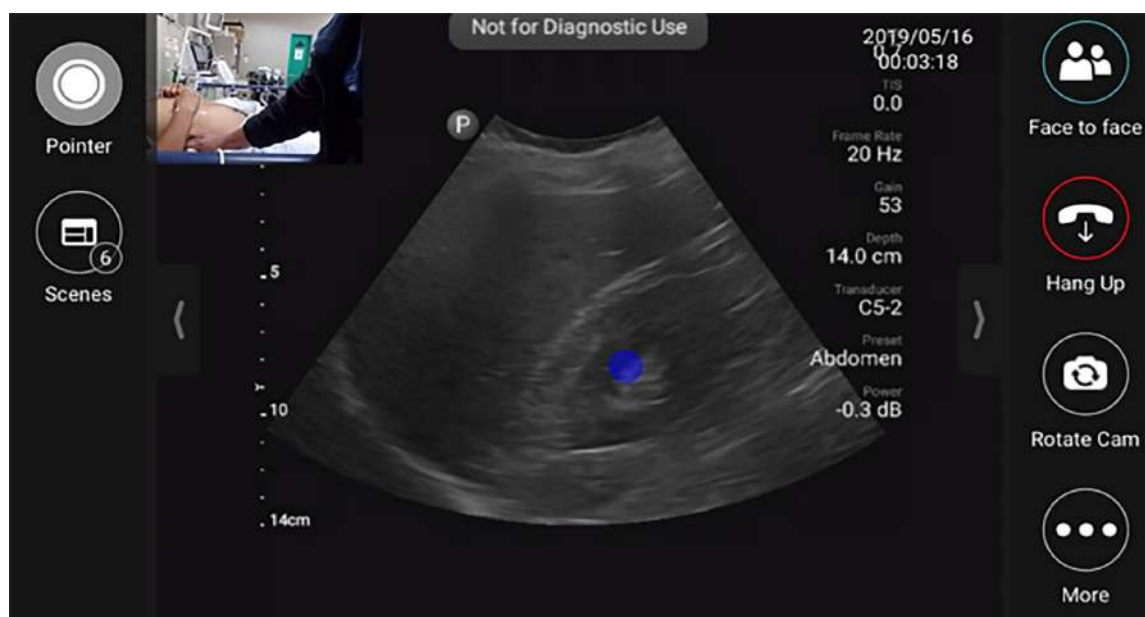


Figure 1. Tele-ultrasound platform as visualized by remote user providing diagnostic/procedural assistance. The blue dot is an indicator that can be manipulated by either user.

Educational Teleconferences

Educational teleconferences occur weekly in Spanish to review ultrasound images for quality assurance and to discuss scientific articles related to POCUS. Fellows upload de-identified ultrasound images and video clips onto an online storage database and videos are reviewed during the educational teleconferences. Fellows provide their initial ultrasound interpretations by annotating the media on the online data-storage platform, and the images are subsequently reviewed for both image quality and image accuracy of initial interpretation by faculty from our EM ultrasound division. Ultrasound faculty can also provide asynchronous feedback by annotating the uploaded media prior to the weekly educational teleconference.

After reviewing all of the Peruvian fellows' images, the fellows join in the division of ultrasound's weekly quality assurance conference at our academic institution. The discussion is in English; however, simultaneous translation is provided via the chat feature of the teleconferencing platform by one of our two native Spanish-speaking, ultrasound faculty members.

RESULTS

Our fellows uploaded over 1300 ultrasound studies to our online database during the year-long fellowship representing over 500 hours of clinically protected time dedicated to performing ultrasounds. The studies encompass multiple images and have been categorized into either diagnostic or procedural scans. Figure 2 provides a graphical representation of the total number of ultrasound studies performed by category for the entire fellowship year. Cardiac, inferior vena cava, and lung ultrasound represent over 70% of all studies performed. Fellows have additionally performed over 80 ultrasound-guided procedures as

evidenced in Figure 3. The most common ultrasound procedural application has been vascular access.

Each fellow has completed a one-month ultrasound rotation at our academic institution including more than 80 hours of ultrasound scanning time with experienced ED sonographers. Fellows have participated on average in over 190 hours of quality assurance and educational teleconferences with our local US division.

Fellows have presented at both national and international conferences on advanced POCUS applications such as regional pain anesthesia and management of cardiac arrest. Since completion of the fellowship, one of our graduates has published an ultrasound case report in a US-based EM journal on the POCUS features of late-stage Ebstein's anomaly findings. Additionally, the fellows created the first annual ultrasound procedural course for EM residents in Peru. Over 40 EM residents participated in the conference held at the Hospital Nacional Dos de Mayo in December 2018. They have also developed an elective ultrasound rotation for EM residents nationwide and have had a total of 12 rotators since the creation of the elective, with plans to begin to accept international rotators from throughout Latin America. In addition to developing a resident curriculum, the fellows are in the process of developing ongoing, one-on-one training sessions with local faculty to ensure a basic understanding of POCUS within the entire EM faculty.

The fellowship program has also led to interdepartmental collaborations with multiple specialties including general surgery, trauma, orthopedics, and cardiology. For example, the general surgeons have requested that our fellows perform POCUS on patients presenting with abdominal pain, since they previously primarily relied on history and exam findings due to limited

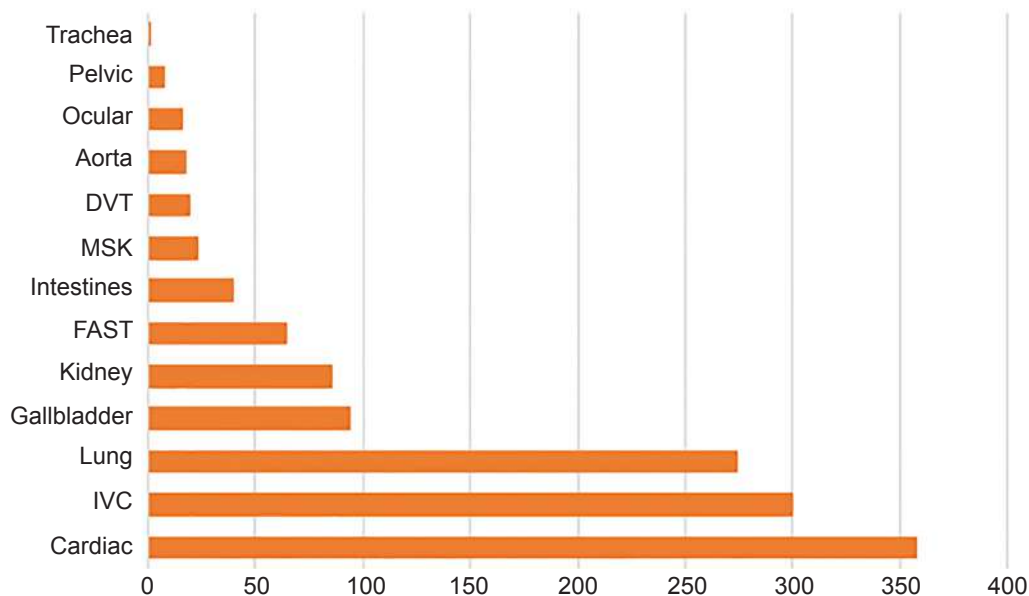


Figure 2. Graphical representation of total ultrasound studies performed by category by three fellows during the fellowship year. *DVT*, Deep venous thrombosis; *MSK*, musculoskeletal; *FAST*, focused assessment of sonography in trauma; *IVC*, inferior vena cava.

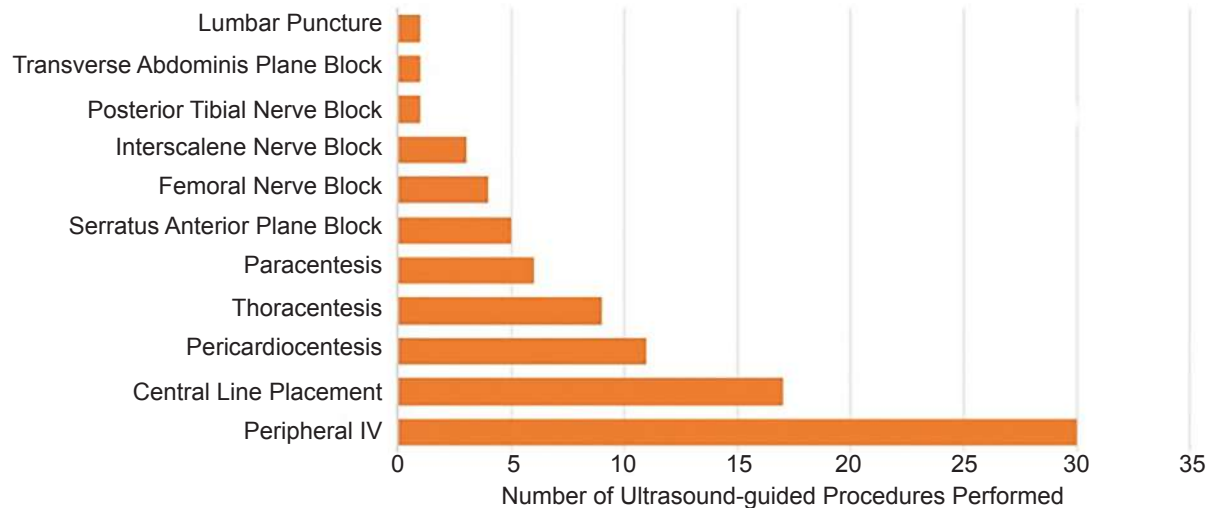


Figure 3. Graphical representation of ultrasound-guided procedures performed by inaugural class of three emergency medicine ultrasound fellows in Lima, Peru.

access to computed tomography. The trauma and orthopedic services have also embraced the use of ultrasound-guided regional nerve anesthesia for the treatment of acute pain in patients with traumatic injuries.

DISCUSSION

In this report we describe the unique aspects of our educational model for teaching POCUS to emergency physicians in Peru. While previous studies have primarily focused on teaching general practitioners POCUS applications using traditional hands-on education,³⁻⁵ we employ an innovative multimodal approach to train future POCUS educators and leaders. Our approach uses a novel multi-pronged approach using tele-ultrasonography to provide ongoing remote education and support, in addition to traditional hands-on education.

Previously described limitations with global health ultrasound education projects include geographical distances and language barriers.⁵ We have been able to limit the burden of international travel by recruiting multiple visiting instructors and employing tele-ultrasonography to provide ongoing remote education. Additionally, fellows spend one month of the year at our home institution in the US, which allows them to gain firsthand clinical experience in a setting where POCUS is already integrated within the clinical workflow of the ED. We have mitigated potential language barriers by developing a curriculum that is executed in Spanish. All of our visiting instructors are fluent in Spanish and teleconferencing sessions are held in Spanish with the exception of our division of ultrasound quality assurance conference, which has simultaneous translation provided.

We have been able to reduce financial costs associated with running our program by using ultrasound machines equipped with tele-ultrasonography software on loan for the initial year of the fellowship from Philips Healthcare. Travel costs for fellows

have been partially reimbursed by using scholarship funds from our local EM resident international group. While fellows do not receive an additional stipend for participating in the fellowship, they were able to reduce their overall clinical burden and obtain protected ultrasound scanning time due to our partnership with hospital administration at the Hospital Nacional Dos de Mayo.

LIMITATIONS

The ability to replicate this project is contingent on political buy-in from key stakeholders abroad. Part of our success has been due to the time and effort spent building relationships with the local hospital and the Peruvian national EM society. Thus, the generalizability of our project to other low-resource settings is contingent on building similar partnerships.

CONCLUSION

Our program is unique compared to other international POCUS educational interventions because fellows become POCUS experts and leaders in ultrasound education at the completion of their fellowship year. We expect fellows to become educational leaders for effecting curricular change and integration of POCUS within graduate medical education in Peru. To that extent, the graduates from the inaugural class are now our co-directors of the ultrasound fellowship program, helping us oversee the education of our second class of ultrasound fellows. We currently have four new ultrasound fellows and have expanded to three additional public academic hospital training sites. Two of the new sites are in smaller cities in more remote areas of Peru: Cusco in the Andean highlands and Iquitos in the Amazonian rainforest. We are now using tele-ultrasonography within Peru, employed by our inaugural class of graduates to provide remote support to our two new fellows outside of Lima. The scalability and sustainability of our program has been facilitated by training local champions who continue to grow the

POCUS community within Peru and by leveraging tele-ultrasonography to reduce geographical barriers to ongoing education.

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Visual Estimation of Tricuspid Annular Plane Systolic Excursion by Emergency Medicine Clinicians

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Introduction: Tricuspid annular plane systolic excursion (TAPSE) is an established echocardiographic marker of right ventricular (RV) systolic function. The objective of this study was to evaluate whether emergency clinicians can visually estimate RV function using TAPSE in a set of video clips compared to a reference standard M-mode measurement.

Methods: Emergency clinicians were shown a five-minute educational video on TAPSE. Participants then viewed 20 apical four-chamber point-of-care ultrasound (POCUS) echocardiography clips and recorded their estimate of TAPSE distance in centimeters (cm), as well as whether TAPSE was normal (>1.9 cm), borderline (1.5-1.9 cm), or abnormal (<1.5 cm). We calculated sensitivity, specificity, and overall accuracy of visual TAPSE categorization using M-mode measurement as the criterion standard. Participants also reported their comfort with assessing TAPSE on a five-point Likert scale before and after participation in the study.

Results: Among 70 emergency clinicians, including 20 postgraduate year 1-4 residents, 22 attending physicians, and 28 physician assistants (PA), the pooled sensitivity and specificity for visual assessment of TAPSE was 88.6% (95% confidence interval, 85.4-91.7%) and 81.6% (95% CI, 78.2-84.4%), respectively. The sensitivity and specificity for the clips in which the measured TAPSE was <1.5 cm or >1.9 cm was 91.4% (95% CI, 88.4-94.3%) and 90.8% (95% CI, 87.7-93.9%), respectively. There was no significant difference in sensitivity ($p = 0.27$) or specificity ($p = 0.55$) between resident and attending physicians or between physicians and PAs ($p = 0.17$ and $p = 0.81$). Median self-reported comfort with TAPSE assessment increased from 1 (interquartile range [IQR] 1-2) to 3 (IQR 3-4) points after participation in the study.

Conclusion: A wide range of emergency clinicians demonstrated fair accuracy for visual estimation of TAPSE on previously recorded POCUS echocardiography video clips. These findings should be considered hypothesis generating and warrant validation in larger, prospective studies. [West J Emerg Med. 2020;21(4)1022-1028.]

INTRODUCTION

Venous thromboembolism (VTE) including pulmonary embolism (PE) represents the third leading cause of vascular disease worldwide after myocardial infarction and stroke, with approximately 300,000 deaths each year from PE in the United States.¹⁻⁶ The timely diagnosis of PE in the emergency department (ED) is critical to the management of a condition that carries significant morbidity and mortality.⁶

Evidence of right heart dilation or impaired function on point-of-care ultrasound (POCUS) are findings that can be associated with the presence of PE. POCUS is a required competency in emergency medicine, should be available in the ED setting, and can be rapidly performed at the bedside. Evidence of right ventricular dysfunction (RVD) on ultrasound is both a predictor of PE diagnosis as well as PE severity and clinical outcomes.⁷⁻⁹ One of the markers of RVD on ultrasound is reduced tricuspid annular plane systolic excursion (TAPSE).¹⁰ The measurement of TAPSE involves obtaining an apical four-chamber ultrasound view, placing the M-mode line at the lateral tricuspid valve annulus (where the valve leaflet attaches to the wall of the right ventricle), obtaining an M-mode tracing and measuring the height of the annulus movement during systole.¹¹ Besides its utility in diagnosing PE, TAPSE has also been applied as a marker of pulmonary hypertension and, more recently, as a predictor for the development of cardiac tamponade in patients with malignant effusions.^{12,13} A prior study showed that investigators trained in echocardiography could visually estimate TAPSE as normal or abnormal with good agreement.⁹ However, to our knowledge, there is no prior literature examining whether emergency clinicians with a diverse level of training can accurately visually estimate TAPSE.

The primary aim of this study was to assess the sensitivity, specificity, and overall accuracy of emergency clinicians' visual estimation of TAPSE as compared to standard M-mode measurements. Secondary aims were to evaluate the accuracy of visual estimation of TAPSE compared to visual estimation of right ventricle (RV) to left ventricle (LV) ratio, as well as the self-reported comfort level of emergency clinicians with TAPSE assessment after a brief training intervention.

METHODS

The study was performed at an urban, university-affiliated, tertiary-care ED with a patient volume of approximately 70,000 per year. The institution has an emergency ultrasound division, emergency ultrasound fellows, and a resident ultrasound-training program. All attendings, residents, and mid-level clinicians in emergency medicine (EM) were eligible for enrollment in the study. The study was reviewed by the local institutional review board and determined to be exempt.

Study Participants

We approached all emergency clinicians (including 65 attendings, 58 residents and 33 physician assistants [PA]) in the department for study participation. Participation was solicited by

Population Health Research Capsule

What do we already know about this issue?
Tricuspid annular plane systolic excursion (TAPSE) is a marker of right heart function that can be a predictor of the diagnosis and severity of pulmonary embolism.

What was the research question?
Can emergency clinicians of diverse training levels accurately visually estimate TAPSE after brief training?

What was the major finding of the study?
Emergency clinicians had fair accuracy for the visual estimation of TAPSE, which is hypothesis generating.

How does this improve population health?
Incorporating visual TAPSE assessment to point-of-care ultrasound techniques in the emergency department may improve the assessment of right heart dysfunction.

an email sent to all EM-trained attendings, EM residents, and ED PAs. Participation was voluntary and uncompensated. There were no exclusion criteria.

Study Design

Study participants were shown a five-minute educational video on TAPSE. The educational video was comprised of PowerPoint™ slides with a concurrent audio recording outlining the concept of TAPSE and the definitions of normal and abnormal TAPSE, including ultrasound clips demonstrating examples of each. The video was produced and edited by the study authors. Participants then viewed 20 apical four-chamber ultrasound clips. Images were selected by a study investigator to have a wide range of TAPSE values spanning the normal, borderline, and abnormal categories. All images were obtained from our departmental POCUS database and had been reviewed by ultrasound fellowship trained division faculty. Images in the database were previously de-identified, and clinical data were therefore not available for review.

The TAPSE for each of the 20 apical four-chamber clips was measured by an ultrasound fellowship-trained emergency physician (EP) using the M.mode.ify application,¹⁴ an open-source software that generates an M-mode image from any B-mode ultrasound clip (Figure 1). The M.mode.ify application uploads a B-mode ultrasound clip and prompts the user to place an M-mode line. The application then crops and aligns still frames from the ultrasound clip corresponding to the location

of the user-placed line in order to splice together an M-mode image. In this study, the M-mode line was placed over the tricuspid annulus in the same manner as when measuring TAPSE on an ultrasound machine. The M-mode TAPSE for each clip was measured twice. If there was disagreement, a second ultrasound fellowship-trained EP performed a third measurement for final agreement. Only three clips required a third measurement due to differences between the first two measurements of 0.1 cm or 0.2 cm.

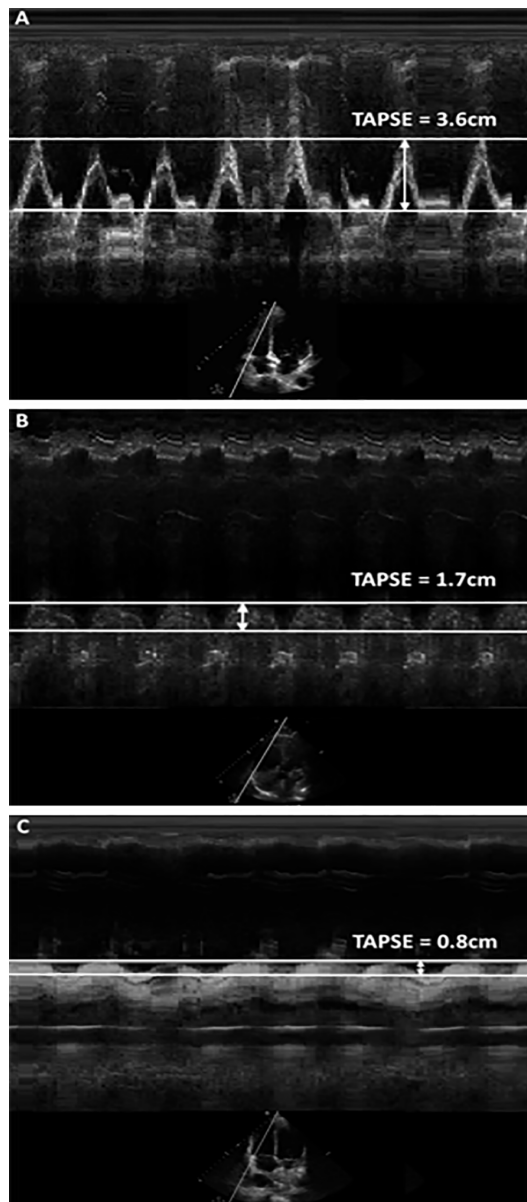


Figure 1. The measurement of tricuspid annular plane systolic excursion (TAPSE) from apical 4-chamber ultrasound clips by using the M-mode.ify open source software in normal (A), borderline (B), and abnormal (C) TAPSE. This technique was applied to determine the reference standard TAPSE measurement for each clip. M-mode images were not shown to the participants. TAPSE, tricuspid annular plane systolic excursion; cm, centimeter.

The M-mode.ify M-mode measurement performed by an ultrasound fellowship-trained EP was considered the gold standard of TAPSE assessment for each clip. A measured TAPSE of 1.7 centimeters (cm) or greater was accepted as normal per the recommendations from the American Society of Echocardiography (ASE).¹⁰ The reference standard for the RV to LV size ratio estimate was calculated by a registered diagnostic medical sonographer using the measured ratio of the diameter of the right ventricle vs the left ventricle at the level of the mitral and tricuspid valves at end diastole.¹⁵

Clips were displayed in random order. Each clip was six seconds long and was played for three consecutive loops, for a total of 18 seconds per clip. While viewing each video clip, participants recorded their visual estimate of TAPSE distance in cms. They were informed of the current ASE guideline cutoff of ≥ 1.7 cm, as well as the study categorizations of normal TAPSE as (>1.9 cm), borderline as (1.5-1.9 cm) and abnormal as (<1.5 cm). We chose these three-category cutoff numbers during the design of this study as some studies on RV dysfunction have used the ASE cutoff of 1.7 cm while others have proposed using a normal TAPSE cutoff of >1.9 cm.^{9,12} In addition, participants were asked to note whether the RV:LV ratio appeared normal (<0.9), borderline (0.9-1.1), or abnormal (>1.1), with standard normal defined as an RV size less than a 1:1 size of the LV. These categorizations were chosen based on literature proposing RV:LV ratio cutoffs between 0.9 and 1.12 for predicting PE severity.^{16,17}

Participants were asked how many previous TAPSE measurements they had performed. They were also asked to rate their comfort level with TAPSE assessment on a Likert scale from 1-5 with 1 indicating “not at all comfortable” with TAPSE and 5 indicating “very comfortable” with this concept, numbers 2 though 4 were not labeled. The Likert score was recorded both before and after the review of the educational video and the entire series of ultrasound clips. Enrollment for each subject took place in a single, in-person session.

Statistical Analysis

We performed a sample size calculation according to the methods described by Buderer (1996).¹⁸ For an expected sensitivity of 95% and specificity of 86% (assuming that accuracy of visual estimation of RV function would be similar to visual estimation of LV function), a positive finding prevalence of 50%, acceptable precision of 10% and a significance level of 0.05, the desired sample size was 82 participants for adequate power in calculating sensitivity and specificity.¹⁹ Participants’ visual estimation of TAPSE distance in centimeters was used to stratify their assessment into the two-category classification of normal or abnormal (≥ 1.7 cm or < 1.7 cm) as well as the three-category classification of normal, borderline or abnormal (>1.9 cm, 1.5-1.9 cm, or <1.5 cm).

We calculated the sensitivity and specificity of participants’ two-category TAPSE assessment using ultrasound expert-performed M-mode.ify measurement of TAPSE as the reference standard. The overall accuracy of the participants’ three-

category TAPSE estimate was also calculated. We calculated overall accuracy of the participants' three-category RV:LV ratio assessment by using the RV:LV ratio measurement performed by a registered sonographer as the reference standard.

We used Mann-Whitney U test to compare sensitivity and specificity between training levels. Wilcoxon signed-rank test was used to evaluate TAPSE comfort level before and after the intervention. We considered a p value <0.05 statistically significant. Data was analyzed using Stata 14.2 (Stata Corporation, College Station, TX).

RESULTS

A total of 70 emergency clinicians including 20 postgraduate year (PGY) 1-4 residents (7 PGY-1, 5 PGY-2, 5 PGY-3 and 3 PGY-4), 22 attending physicians, and 28 PAs participated in the study. While four (18%) of the attending physicians had previously completed an ultrasound fellowship, the majority of attendings (16, 73%) reported never previously having measured TAPSE. Half of the residents (10, 50%) and the majority of physician assistants (26, 93%) also reported no prior experience with TAPSE measurement. The range of TAPSE values in the 20 clips was 0.3-3.6 cm with 11 (55%) of the clips having abnormal TAPSE.

The pooled sensitivity and specificity for visual assessment of TAPSE was 88.6% (95% confidence interval [CI], 85.4-91.7%) and 81.6% (95% CI, 78.2-84.4%) respectively. The sensitivity and specificity for correct assessment of the clips (16/20) in which the measured TAPSE was not borderline (<1.5 cm or >1.9 cm) was 91.4% (95% CI, 88.4-94.3%) and 90.8% (95% CI, 87.7-93.9%), respectively.

The overall accuracy for the correct classification of TAPSE into the three categories of normal, borderline, and abnormal was 72.9% (95% CI, 70.4-75.3%). Table 1 shows the percent accuracy of TAPSE categorization within each of these three categories. The overall accuracy for correct categorization of non-borderline TAPSE into normal and abnormal was 91.2% (95% CI, 89.2-93.3%). The overall accuracy for the correct categorization of RV:LV ratio into the three categories of normal, borderline, and abnormal was 61.5% (95% CI, 59.6-63.5%). Table 2 shows the percent accuracy of RV:LV categorization within each of these three categories. The overall accuracy for the correct categorization of non-borderline RV:LV ratio into normal and abnormal was 71.4% (95% CI, 69.1-73.8%).

There was no significant difference in the sensitivity (88.9% vs 89.7%, p = 0.27) or specificity (83.33% vs. 80.8%, p = 0.55) of visual TAPSE assessment between resident and attending physicians or between physicians and PAs (89.3% vs 87.4%, p = 0.17 for sensitivity and 82.0% vs 80.9%, p = 0.81 for specificity) (Figure 2). Median TAPSE assessment comfort score increased from 1 (interquartile range [IQR] 1-2) to 3 (IQR 3-4) after participation in the study among all participants.

DISCUSSION

Assessment of RV function is an important aspect of the

emergent evaluation of patients presenting with cardiopulmonary complaints, particularly when there is concern for PE. In this study, emergency clinicians of diverse training levels were able to categorize TAPSE as normal or abnormal by visual assessment with fair sensitivity and specificity when compared to TAPSE M-mode measurement, after review of a brief educational video. The overall significance of these findings is limited by a slightly smaller than targeted sample size, which may have led to insufficient power of the study's results.

Although EPs have been shown to be able to use M-mode to measure TAPSE as a marker of RV systolic function, this measurement can be cumbersome for many users.⁹ It has been previously demonstrated that EPs can visually estimate left ventricular (LV) ejection fraction with good agreement as compared to cardiologists.¹⁹ If emergency clinicians could also estimate RV systolic function visually at the point-of-care without performing M-mode measurements, this could be a time efficient addition to the assessment of cardiac function the ED. We believe that our results provide early, hypothesis generating evidence that this may be the case.

Table 1. Percentage accuracy of visual categorization of tricuspid annular plane systolic excursion (TAPSE) into the categories of normal (>1.9 centimeters [cm]), borderline (1.5-1.9 cm) and abnormal (<1.5) as compared to measured TAPSE.

	Measured TAPSE Normal	Measured TAPSE Borderline	Measured TAPSE Abnormal
Visual TAPSE Normal	83%	4%	2%
Visual TAPSE Borderline	16%	42%	19%
Visual TAPSE Abnormal	2%	54%	79%

Darker shading indicates more accurate categorization.

Table 2. Percentage accuracy of visual categorization of right ventricle (RV) to left ventricle (LV) ratio into the categories of normal (<0.9), borderline (0.9-1.1), and abnormal (>1.1) as compared to measured RV:LV ratio.

	Measured RV:LV Ratio Normal	Measured RV:LV Ratio Borderline	Measured RV:LV Ratio Abnormal
Visual RV:LV Ratio Normal	64%	35%	1%
Visual RV:LV Ratio Borderline	28%	32%	19%
Visual RV:LV Ratio Abnormal	8%	34%	80%

Darker shading indicates more accurate categorization.

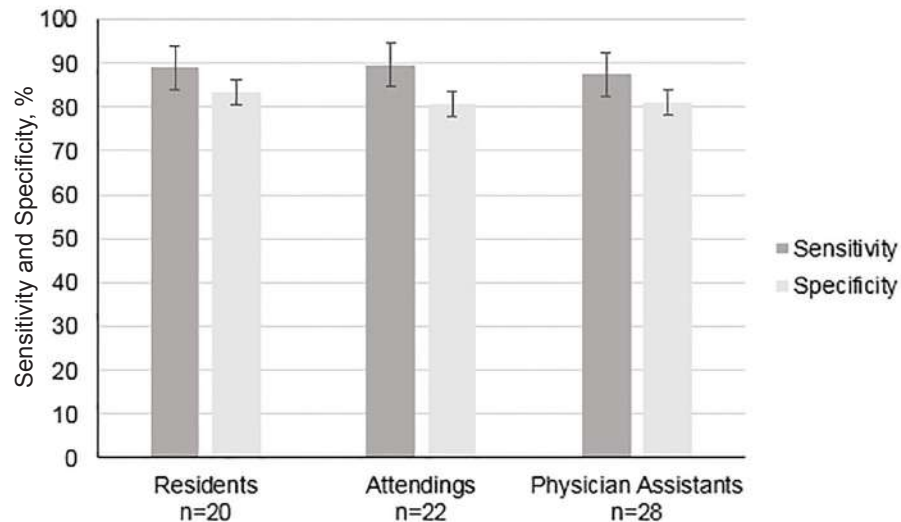


Figure 2. Comparison of sensitivity and specificity of tricuspid annular plane systolic excursion (TAPSE) visual estimation by training level.

In patients with PE, a finding of RV dysfunction as demonstrated by low TAPSE measurement has been associated with increased mortality, longer length of hospital stay, and the development of pulmonary hypertension.^{7,8} TAPSE has been shown to be the least user-dependent evaluation of RV dysfunction and has been shown to be a feasible measurement by emergency physicians.^{9,20} Prior literature also suggests that TAPSE is a sensitive marker for PE in patients with tachycardia or hypotension.^{9,21}

In the current study, there was superior sensitivity and specificity for assessing normal vs. abnormal at the more extreme ranges of TAPSE as compared to the overall sensitivity and specificity of TAPSE assessment as normal or abnormal. Patients with severely reduced TAPSE from conditions such as a massive or sub-massive PE would likely require the most time-sensitive clinical interventions.²¹ Therefore, the ability to correctly identify significantly impaired RV dysfunction with a quick visual assessment may represent a valuable clinical application. Our data implies that patients with severely reduced TAPSE are more accurately identified than those with borderline RV dysfunction.

Interestingly, visual estimation of RV to LV ratio had only fair accuracy across all participants in our cohort, despite this being the accepted POCUS method for evaluating for right ventricular dysfunction, and which is taught to emergency clinicians at our institution.^{22,23} Even excluding borderline RV size clips, the overall accuracy of correct categorization of RV as normal or abnormal was only 71.4%. This may have been due to the fact that RV size may be more difficult to estimate or due to the fact that the visual estimation of RV:LV size was not included in the educational video but assumed to be known by the study participants. The overall accuracy of correct categorization of non-borderline TAPSE was 91.2%. Paczyńska and colleagues demonstrated recently that TAPSE was a better predictor of

adverse outcomes in patients with acute PE than RV to LV ratio.²⁴ Our study suggests that visual TAPSE assessment could be a more accessible and accurate aspect of the POCUS assessment of right heart function than relative RV size for emergency clinicians in the acute care setting. Whether dedicated training in the assessment of RV size could improve emergency clinicians' accuracy in this measure warrants further investigation.

A prior study by Daley et al demonstrated that a small sample of three ultrasound fellowship-trained EM attendings, four ultrasound fellows as well as an EM resident and medical student with several weeks of training in TAPSE measurement could visually estimate its value with good agreement.⁹ In comparison, the majority of participants in our study had never previously measured TAPSE. To our knowledge, this is the first study to examine the visual estimation of TAPSE by non-physician clinicians. Advance practice providers (APP) such as PAs and nurse practitioners have become increasingly prevalent in EM, and the use of POCUS by APPs is a growing aspect of their practice.²⁵ Visual TAPSE assessment was easily learned by those who had little or no prior exposure to the concept of TAPSE. There was no significant difference in the overall sensitivity or specificity of visual TAPSE assessment between junior and senior residents, residents, and attendings, or physicians of all levels of training and PAs. Although a very brief training video appeared to increase participants' confidence in visual TAPSE assessment, more extensive education is likely required for this skill to be applied in clinical practice. Further study as to whether diverse groups of emergency clinicians in different types of hospital settings can visually assess TAPSE, and whether this correlates to clinically significant disease processes is warranted.

LIMITATIONS

This study was limited by smaller than targeted sample size

due to the lack of sufficient volunteers, which may have led to insufficient power of the study's results. Enrollment took place at a single academic institution with a robust ultrasound training program, which may limit generalizability to other institutions and practice settings. Emergency clinicians volunteered to participate in the study, which may have introduced a selection bias. The clips were selected from an ultrasound image database but may not have been representative of those encountered in clinical practice. Furthermore, because the clips were selected from a de-identified database, the clinical information for the patients (ie, whether they had a diagnosis of PE or other right heart pathology) is unknown. Results could vary when clinicians both obtain the POCUS images as well as estimate the TAPSE in clinical practice. Finally, description of the M.mode.ify software has been published in peer-reviewed literature, but independent validation of how well it corresponds to ultrasound machine M-mode measurements has not been established.

CONCLUSION

The ability to estimate RV systolic function visually at the point of care could represent a valuable addition to the assessment of cardiac function in the ED. This study suggests that visual TAPSE estimate is easy to learn and may be a feasible surrogate for measurements, particularly in non-borderline cases.

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Novice Physician Ultrasound Evaluation of Pediatric Tricuspid Regurgitant Jet Velocity

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Introduction: Pulmonary hypertension, associated with high mortality in pediatric patients, is traditionally screened for by trained professionals by measuring a tricuspid regurgitant jet velocity (TRJV). Our objective was to test the feasibility of novice physician sonographers (NPS) to perform echocardiograms of adequate quality to exclude pathology (defined as TRJV > 2.5 meters per second).

Methods: We conducted a cross-sectional study of NPS to assess TRJV by echocardiogram in an urban pediatric emergency department. NPS completed an educational course consisting of a didactic curriculum and hands-on workshop. NPS enrolled a convenience sample of patients aged 7-21 years. Our primary outcome was the proportion of echocardiograms with images of adequate quality to exclude pathology. Our secondary outcome was NPS performance on four image elements. We present descriptive statistics, binomial proportions, kappa coefficients, and logistic regression analysis.

Results: Eight NPS completed 80 echocardiograms. We found 82.5% (95% confidence interval [CI], 74.2-90.8) of echocardiograms had images of adequate quality to exclude pathology. Among image elements, NPS obtained a satisfactory, apical 4-chamber view in 85% (95% CI, 77.1-92.9); positioned the color box accurately 65% (95% CI, 54.5-75.5); optimized TRJV color signal 78.7% (95% CI, 69.8-87.7); and optimized continuous-wave Doppler in 55% (95% CI, 44.1-66.0) of echocardiograms.

Conclusion: NPS obtained images of adequate quality to exclude pathology in a majority of studies; however, optimized acquisition of specific image elements varied. This work establishes the basis for future study of NPS assessment of TRJV pathology when elevated pulmonary pressures are of clinical concern. [West J Emerg Med. 2020;21(4)1029-1035.]

INTRODUCTION

Background

Pulmonary hypertension, while rare in children and young adults, carries a 25% five-year mortality.¹ Pulmonary hypertension is a clinical consideration during various pediatric emergency department (PED) presentations including syncope and pulmonary embolism.^{2,3} Thirty-six percent of children with idiopathic or familial pulmonary

hypertension first present with syncope.¹ The gold standard for diagnosing pulmonary hypertension is cardiac catheterization.⁴ Alternatively, cardiologists estimate pulmonary artery pressure by measuring a tricuspid regurgitant jet velocity (TRJV) during transthoracic echocardiography. An elevated TRJV of > 2.5 meters per second (m/s) is a surrogate measure of elevated pulmonary artery pressure *in lieu* of invasive cardiac catheterization (TRJV pathology).^{5,6} While a pathologic

TRJV is rare in children and young adults, approximately 68-86% of healthy individuals will have a non-pathologic TRJV (detectable jet velocity up to 2.5 m/s).⁷⁻⁹ The remaining 14-32% of healthy children and young adults will have no tricuspid regurgitant jet.

To date, TRJV has only been reliably measured by cardiologists and ultrasound technicians with cardiologist oversight. Unfortunately, this level of expertise, which is the current standard of care, is often unavailable to emergency physicians at times when patients may have concerning clinical presentations.¹⁰ Emergency physician sonographers have previously been shown to accurately assess and measure many components of a point-of-care echocardiogram.¹¹⁻¹⁶ Point-of-care ultrasound, in comparison to comprehensive ultrasound, is an abbreviated examination performed by a medical professional at the bedside, which is used to identify either the presence or absence of specific pathologic findings. Previous studies have used a combination of didactic instruction and practical training to teach specific components of a point-of-care echocardiogram to emergency physicians.¹¹⁻¹⁶ To our knowledge, the ability of novice physician sonographers (NPS) to perform assessments of TRJV has not been previously studied. As a result, we performed this pilot study aimed at determining feasibility.

Goals of Investigation

Our study objectives were to 1) test the feasibility of NPS to perform echocardiograms in the PED of adequate quality to exclude pathology (defined as TRJV > 2.5 m/s) as determined by a blinded pediatric cardiologist, and 2) identify patient and NPS characteristics associated with adequately performed echocardiograms.

METHODS

Study Design

We conducted a prospective cross-sectional study from April 2018 to October 2018 in an urban, tertiary care facility with an annual census of 24,000 PED visits. The facility is a Level I trauma center with an accredited pediatric emergency medicine (PEM) fellowship and EM residency. The facility operates a separate PED that cares for patients through 21 years of age.

Patient Population

NPS screened and enrolled a convenience sample of patients aged 7-21 years who presented to the PED. Medical records were reviewed prior to approaching subjects for enrollment. We excluded patients who were critically ill, non-English speaking, or were younger than seven years of age. Patients less than seven years of age were excluded at the recommendation of the study's primary cardiologist to limit exclusions based on patient intolerance. All other patients were eligible for enrollment. The patient or patient's guardian (for minors under 18 years of age) provided informed consent

Population Health Research Capsule

What do we already know about this issue?
Emergency physician sonographers have previously been shown to accurately assess many components of a point-of-care echocardiogram.

What was the research question?
Are novice physician sonographers able to perform echos that exclude tricuspid regurgitant jet (TRJ) pathology

What was the major finding of the study?
Pediatric cardiologist rated 82.5% of echos performed to be of adequate quality to exclude TRJ pathology.

How does this improve population health?
This pilot study establishes the basis for future investigation of novice assessment of TRJ pathology when elevated pulmonary pressures are of clinical concern.

prior to enrollment. All patients less than 18 years of age provided verbal assent. The Boston University Medical Campus and Boston Medical Center Institutional Review Board approved this study.

Novice Physician Sonographer Population

We aimed to analyze the performance of NPS, which we defined as individuals who had performed fewer than 50 lifetime echocardiograms. This number was selected based on the 2016 ACEP policy statement.¹⁷ The primary investigator (PI) recruited EM residents, pediatric EM fellows, and pediatric EM attendings as unpaid volunteers to participate as NPS based on their limited echocardiography experience. All of the institution's first-year EM residents (14), eligible pediatric EM fellows (2), and eligible pediatric EM attendings (5) were first contacted by email, followed by in-person recruitment if interest in participation was expressed.

Educational Intervention

Prior to participation in the study, NPS completed a three-hour educational course combining a didactic curriculum (30 minutes) and hands-on workshop (2.5 hours). The educational course taught NPS the steps required to obtain TRJV images. The didactic curriculum used still-image and video-clip modalities to demonstrate a stepwise approach to obtaining a TRJV. As no curriculum for TRJV image acquisition exists, the study's principal investigator (PI) and primary pediatric cardiologist (SO) created a

curriculum through a comprehensive multistep process. A literature review of pediatric echocardiography reference materials led to the generation of an initial curriculum.¹⁸⁻²⁰ A panel of three independent pediatric cardiologists from outside the study institution reviewed the curriculum and provided feedback. These cardiologists had no role in curriculum generation, or image rating. We obtained consensus on all proposed modifications using modified Delphi methodology.²¹ The final curriculum contained four elements: 1) apical 4-chamber view; 2) color box positioning; 3) TRJV color signal optimization; and 4) continuous-wave Doppler interrogation (Figure 1 and Figure 2). The study's PI and primary pediatric cardiologist (SO) administered the didactic curriculum.

Immediately following the didactic curriculum, NPS participated in a hands-on workshop consisting of deliberate practice with direct feedback from experts (professional cardiac sonographer and certified pediatric cardiologist). All NPS were required to complete a proctored echocardiogram during the workshop where an expert assessed performance. The proctored examination required the successful completion of all four image elements. Proctored echocardiograms established the novice's ability to obtain TRJV images prior to his or her participation in the study.

Apical 4-Chamber View

1. Image orientation with cardiac apex at the top of screen and left ventricle to the right of screen
2. Outline of all four chambers simultaneously visualized
3. Image aligned with ultrasound beam parallel to intraventricular septum and perpendicular to tricuspid valve
4. Image saved of apical 4-chamber view

Color Box Positioning

5. Color box extending from the back wall of right atrium past the tricuspid valve leaflet tips
6. Color box width minimized to just include tricuspid valve orifice

Tricuspid Regurgitant Jet Velocity Color Signal Optimization

7. Clip saved showing a dynamic sweep through the tricuspid valve (anterior → posterior) or (posterior → anterior)
8. Select probe position that generates maximal regurgitant color signal

Continuous-wave Doppler

9. Doppler cursor placed in the middle of tricuspid regurgitant color jet
10. Doppler cursor aligned parallel to color jet flow
11. Doppler gain adjusted to maximize waveform
12. Baseline adjusted to maximize display of wave form
13. Image includes three full cardiac cycles
14. Image saved with continuous-wave Doppler applied

Figure 1. Tricuspid regurgitant jet velocity curriculum.

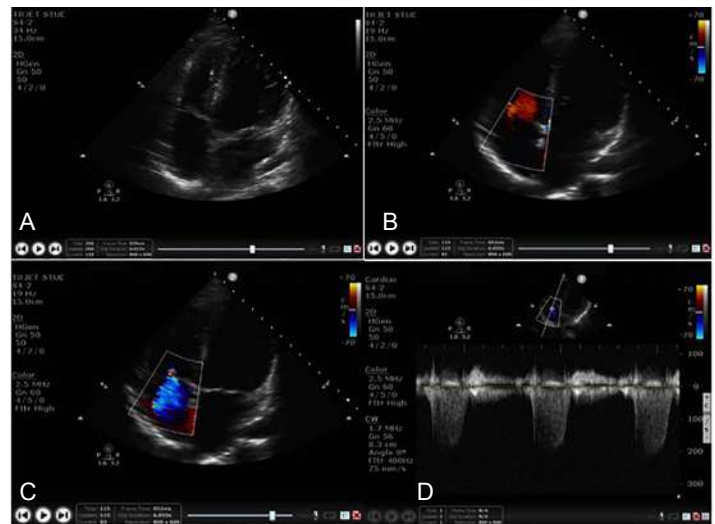


Figure 2. Tricuspid regurgitant jet velocity image elements. 2A. Apical 4-Chamber, 2B. Color box positioning, 2C. Tricuspid regurgitant jet signal optimization, 2D. Continuous-wave Doppler interrogation.

Image Rating

The study's primary cardiologist, SO, blinded to NPS and patient identity, reviewed each recorded study. The cardiologist first reviewed all images to determine whether they could confidently exclude pathology based on the images provide. The cardiologist then performed a secondary analysis where individual image elements were assessed (Figure 1). The cardiologist recorded these results on an electronic score sheet. To assess inter-rater reliability a second pediatric cardiologist, not otherwise involved in the study, independently reviewed 20% of all study echocardiograms.

Sample Size Estimation

We predicted 80% of echocardiograms would have images of adequate quality to exclude pathology (TRJV > 2.5 m/s). Based on this estimate, we required 80 echocardiograms to generate a 95% confidence interval (CI) with a lower bound percentage of 72.6%. Therefore, each of the eight NPS was asked to perform a minimum of 10 echocardiograms over a six-month period.

Data Collection

NPS recorded still images and video clips in a protocolized fashion using a Philips SPARQ (Philips Healthcare, Bothell, WA) ultrasound machine. Images automatically transferred wirelessly to Qpath (Telexy Healthcare, Maple Ridge, BC) software, a program for storage and management of ultrasound examinations. NPS obtained all images and clips using a standardized imaging preset with a phased array probe (S4-2). We de-identified all study images at the time of acquisition with a study identification.

NPS completed a standardized data collection form after each echocardiogram. The study's PI abstracted patient information including gender, age, ethnicity, vital signs, and body mass index (BMI) from the electronic health record. The study's PI transcribed clinical data into Research Electronic Data Capture (REDCap) (Nashville, TN).²²

Statistical Analysis

Descriptive statistics, binomial proportions, and kappa coefficients were performed to analyze the data. We tested for patient and NPS characteristics associated with adequately performed echocardiograms using logistic regression analysis. All statistical analyses were performed using SAS 9.4 software (SAS Institute, Cary, NC).

RESULTS

Demographics

NPS consented 75 eligible patients for participation during the six-month study period. Two consented patients did not have echocardiograms performed because of time constraints. Ultimately 73 patients, ages 7-21 years, provided 80 echocardiograms for analysis (seven patients provided two echocardiograms by different NPS). Table 1 details patient and NPS characteristics.

Primary Outcome

The study's primary pediatric cardiologist rated 66 of 80 (82.5%, 95% CI, 74.2-90.8) echocardiograms to have images of adequate quality to exclude pathology. The remaining 14 of 80 were deemed to be of too poor quality to assess for the presence of TRJV. Of 66 echocardiograms, 27 (40.9%) had no TRJ present, 21 (31.8%) had a present but not measurable TRJ, and 18 (27.3%) had a measurable TRJV less than or equal to 2.5 m/s. None of the echocardiograms had a TRJV greater than 2.5 m/s (Figure 3).

Secondary Outcomes

Of the four image elements, the proportion of satisfactorily completed elements ranged from 55% (95% CI, 44.1- 66.0) for the interrogation of continuous-wave Doppler to 85% (95% CI, 77.1- 92.9) for the acquisition of apical 4-chamber view (Table 2A). To complete the examinations, NPS took an average of 2.5 minutes (interquartile range [IQR] 1.6 - 4.7) from time of first to last saved ultrasound image timestamp. NPS performed an average of 11 echocardiograms (IQR 8-13) (Table 2B).

For the variables selected to test association with image quality, younger patient age was associated with improved echocardiogram adequacy (odds ratio [OR] 0.64; 95% CI, 0.41- 0.99; $p=0.04$). No association was found between patient gender or NPS level of clinical training and adequacy of images (Table 2C). There was fair agreement ($\kappa = 0.25$) between the two pediatric cardiologists when assessing the primary outcome, the ability to exclude pathology.

Table 1. Characteristics of patients and novice physician sonographers (NPS) in study to determine whether NPS could obtain point-of-care echocardiogram images of adequate quality to exclude pathology.

Patient characteristics (n = 73)	Median [IQR]
Age (years)	19 [17-20]
BMI (kg/m ²)*	23.9 [21.9-27.5]
Gender (female)	40/73 (54.8%; 95% CI, 43.3-66.3)
Ethnicity (Hispanic)	19/73 (26.0%; 95% CI, 15.9-36.1)
Patient vital signs (n = 73)	Median [IQR]
Temperature (°F)	99.0 [97.3-98.7]
Heart rate (beats/minute)	79 [68-88]
Respiratory rate (breaths/minute)	18 [16-18]
Systolic blood pressure (mmHg)	120 [112-124]
Diastolic blood pressure (mmHg)	74 [68-78]
Oxygen saturations (%)	99 [98-100]
Novice physician sonographer level of training (n = 8)	n (%)
Emergency medicine residents	2 (25.0%)
Pediatric emergency medicine fellows	2 (25.0%)
Pediatric emergency medicine attendings	4 (50.0%)

*N = 52 for this variable.

IQR, interquartile range; kg/m², kilograms per meter squared; °F, degrees Fahrenheit; mmHg, millimeters of mercury; BMI, body mass index; CI, confidence interval.

DISCUSSION

The study found 82.5% of echocardiograms to have images of adequate quality to exclude pathology, TRJV >2.5 m/s. We believe this provides preliminary evidence NPS can perform adequate TRJV studies following a brief educational intervention. This is in line with prior studies showing novices can accurately assess and measure other focused components of a point-of-care echocardiogram.¹¹⁻¹⁶

It is important to note for this study it was possible to obtain images of adequate quality to exclude pathology without performing each image element optimally. For example, NPS may have failed to adjust the display to produce a textbook image; however, the images may still have been adequate to exclude pathology when reviewed by the cardiologist. The objective of our secondary analysis was to determine which image elements were more difficult for NPS. They were most successful in acquiring an apical 4-chamber view (85%), and least successful in optimally interrogating continuous-wave Doppler (55%). The interrogation of continuous-wave Doppler is an advanced skill and this study likely represented the NPS's first exposure to this function. These results provide further support that

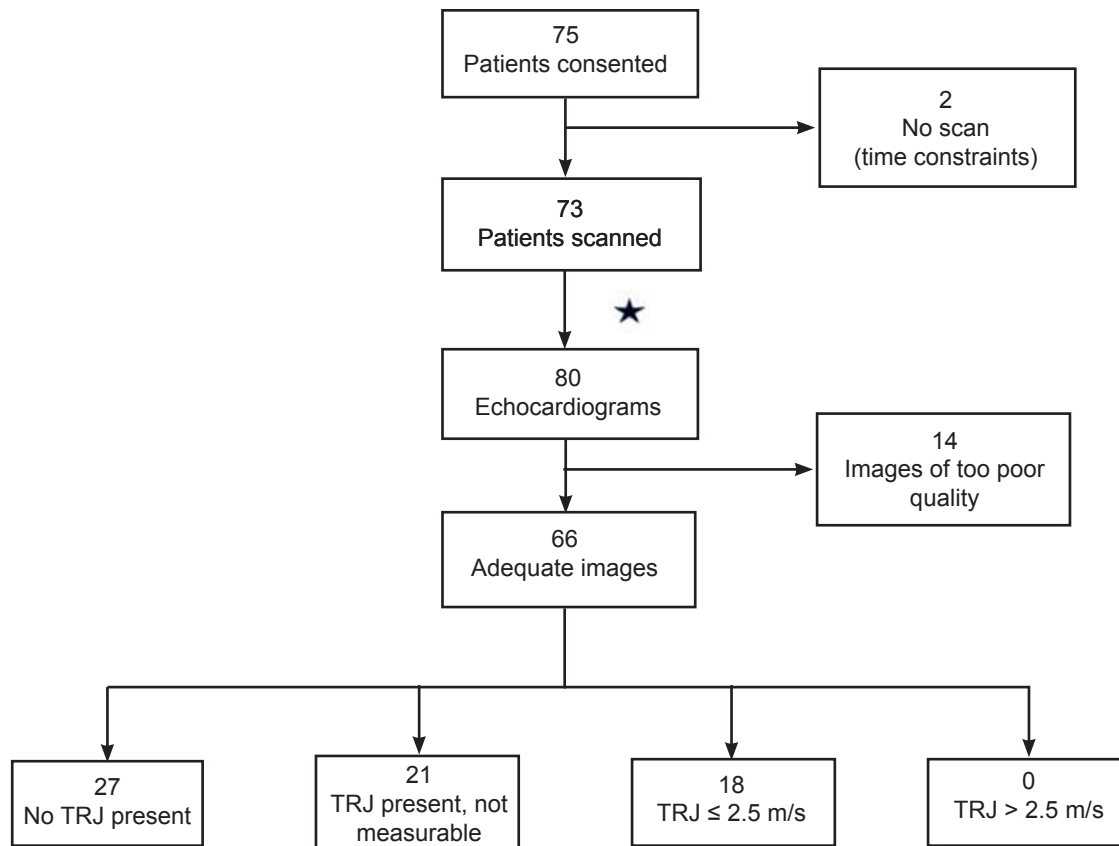


Figure 3. Flowchart demonstrating patient enrollment and image rating as determined by pediatric cardiologist.

★ Seven patients were scanned by two sonographers.
 TRJ, tricuspid regurgitant jet; m/s, meters per second.

ultrasound performance is dependent on repeated exposure and practice.^{17,23,24}

We found a statistically significant association between younger patient age and echocardiograms with images of adequate quality. This association may be explained by thinner chest walls in younger patients; however, the study was inadequately powered to evaluate this relationship. Furthermore, the study was inadequately powered to determine a relationship between patient BMI and image adequacy.

We found a fair level of inter-rater agreement. Liem et al demonstrated an inter-rater kappa of 0.45 (moderate agreement) when measuring TRJV.²⁵ Their study analyzed measurements obtained by expert sonographers that were then interpreted by cardiologists. It is possible that images obtained by novices have a greater range of quality leading to a lower inter-rater agreement. Both our study and that by Liem et al suggest expert agreement regarding the assessment of TRJV is varied.

It is notable that 82.5% of echocardiograms in our study had images of adequate quality to exclude pathology. As an initial pilot study, the first step was to determine ability regarding image acquisition. We recognize that future study of

NPS interpretation and incorporation of their echocardiograms into clinical care is needed.

LIMITATIONS

As a convenience sample of non-critically ill patients from a single center, this may limit the study's generalizability. Our findings will require external validation in a future larger study prior to clinical implementation. While no patients in the study had a TRJV greater than 2.5 m/s, this was not unexpected. NPS successfully detected TRJVs at lower velocities. Further study would be required to demonstrate a NPS's ability to rule in pathology. We feel that our patient population is representative of a general population because prior studies of healthy children and young adults found a similar distribution of TRJV findings.⁷⁻⁹

The primary study outcome, adequacy of images, is subjective and therefore subject to bias. We found no objective assessment tool available for the purposes of our study. In an attempt to limit bias, we blinded the raters to patient and NPS information. In prior studies on this subject, experts have only been able to generate moderate inter-rater agreement suggesting the lack of an ideal assessment mechanism.

Table 2. Echocardiography results.

2A. Rating of TRJV image elements	Ratio of satisfactory completion	95% CI
Apical 4-chamber	68/80 (85.0%)	(77.1-92.9)
Color box positioning	52/80 (65.0%)	(54.5-75.5)
TRJ signal optimization	63/80 (78.7%)	(69.8-87.7)
Continuous-wave doppler	44/80 (55.0%)	(44.1-66.0)
2B. Echocardiogram characteristics	Median	[IQR]
Scans per sonographer	11	[8-13]
Time to complete ultrasound study (minutes)	2.5	[1.6-4.7]
2C. Association with adequate echocardiogram*	OR [95% CI]	P-value
Patient age	0.64 [0.41-0.99]	0.04
Patient gender	0.58 [0.16-2.13]	0.41
Sonographer: resident vs attending	0.75 [0.15-3.78]	0.72
Sonographer: fellow vs attending	0.84 [0.17-4.18]	0.83

*Logistic regression analysis.

CI, confidence interval; TRJV, tricuspid regurgitant jet velocity; IQR, interquartile range; OR, odds ratio.

The study's primary cardiologist (SO) helped develop the initial curriculum and served as one of the study's image raters. Three independent cardiologists not involved in the study, via a modified Delphi approach, finalized this curriculum. It is possible that by having the primary cardiologist assist with the initial curriculum development and grading the images bias was introduced into this study. We believe this would be limited by having the external pediatric cardiologists provide consensus on approving the final curriculum. Additionally, the two cardiologists were blinded to both patient and NPS identity when rating images.

The study's protocol did not incorporate pulsed-wave Doppler prior to continuous-wave Doppler analysis. This is an accepted practice in echocardiography and has been used in prior studies on the topic.²⁶ The risk in excluding pulsed-wave Doppler is overestimating the TRJV through contamination of signal from extremely rare intracardiac shunting lesions. Identification of shunting lesions, while outside the scope of this study, represents pathology that one would ideally not miss. We do not believe the decision had an impact on our study's results.

CONCLUSION

There is currently no way to easily assess pulmonary hypertension in the PED setting. The ability to assess for pulmonary hypertension in the PED could assist in the management of multiple patient presentations including syncope and pulmonary embolism. While this study was performed in a PED, we believe the results and potential clinical implications would also apply to an adult population. It is important to note that in the era of the electronic health record, if an emergency physician could perform a study and review the images with a cardiologist it might improve the

quality of subspecialty input and referrals at the time of ED presentations. We acknowledge these evaluations are best done in consultation with cardiology colleagues and not as a replacement for their expertise. This study suggests that NPS can obtain images of adequate quality to evaluate TRJV in the absence of pathology (TRJV > 2.5 m/s) after a brief educational intervention. This work establishes the basis for future study of novice assessment of TRJV pathology when elevated pulmonary pressures are of clinical concern.

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