Effect of Bedside Ultrasonography on the Certainty of Physician Clinical Decisionmaking for Septic Patients in the Emergency Department

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Study objective: Sepsis protocols promote aggressive patient management, including invasive procedures. After the provision of point-of-care ultrasonographic markers of volume status and cardiac function, we seek to evaluate changes in emergency physician clinical decisionmaking and physician assessments about the clinical utility of the point-of-care ultrasonographic data when caring for adult sepsis patients.

Methods: For this prospective before-and-after study, patients with suspected sepsis received point-of-care ultrasonography to determine cardiac contractility, inferior vena cava diameter, and inferior vena cava collapsibility. Physician reports of treatment plans, presumed causes of observed vital sign abnormalities, and degree of certainty were compared before and after knowledge of point-of-care ultrasonographic findings. The clinical utility of point-of-care ultrasonographic data was also evaluated.

Results: Seventy-four adult sepsis patients were enrolled: 27 (37%) sepsis, 30 (40%) severe sepsis, 16 (22%) septic shock, and 1 (1%) systemic inflammatory response syndrome. After receipt of point-of-care ultrasonographic data, physicians altered the presumed primary cause of vital sign abnormalities in 12 cases (17% [95% confidence interval {CI} 8% to 25%]) and procedural intervention plans in 20 cases (27% [95% CI 17% to 37%]). Overall treatment plans were changed in 39 cases (53% [95% CI 41% to 64%]). Certainty increased in 47 (71%) cases and decreased in 19 (29%). Measured on a 100-mm visual analog scale, the mean clinical utility score was 65 mm (SD 29; 95% CI 58 to 72), with usefulness reported in all cases.

Conclusion: Emergency physicians found point-of-care ultrasonographic data about cardiac contractility, inferior vena cava diameter, and inferior vena cava collapsibility to be clinically useful in treating adult patients with sepsis. Increased certainty followed acquisition of point-of-care ultrasonographic data in most instances. Point-of-care ultrasonography appears to be a useful modality in evaluating and treating adult sepsis patients. [Ann Emerg Med. 2012;60:346-358.]

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INTRODUCTION

Background

Patients with sepsis commonly present to the emergency department (ED). In the United States alone, more than 750,000 cases of sepsis occur annually, resulting in 215,000 deaths.[1] Reported mortality rates for this condition have ranged from 40% to 60%.[1-3] However, there has been an encouraging decrease in sepsis-related mortality in recent years, in large part because of the development and implementation of protocols resulting in the early identification and aggressive management of these patients.[4]

A notable advance in the management of this patient population has been the early goal-directed therapy initiative.[2] Although not without its critics, strict adherence to the recommendations of this protocol enables physicians to quickly identify patients with suspected sepsis and initiate interventions that have been shown to decrease patient morbidity and mortality.[5] As a result of this protocol, more severely ill patients often receive invasive interventions such as central venous catheterization. These interventions, when indicated, are thought to augment timely and accurate physiologic monitoring (eg, serial central venous pressure and oxygen saturation measurements) and allow more efficient therapeutic interventions (eg, rapid intravascular volume resuscitation and the administration of vasoactive medications and blood products). However, strict adherence to the protocol has been

Editor's Capsule Summary

What is already known on this topic

Sepsis management protocols use central venous pressure monitoring to evaluate volume status. Bedside ultrasonography can provide similar information noninvasively.

What question this study addressed

Physicians were queried before and after bedside ultrasonography of the heart and inferior vena cava on 74 patients with suspected sepsis about treatment plans and certainty about volume status and treatment.

What this study adds to our knowledge

Bedside ultrasonography led to a change in treatment plan in about half of the cases. Physician certainty about the cause of clinical findings increased in 71% and decreased in 29%.

How this is relevant to clinical practice

Bedside ultrasonography may provide clinically useful information in suspected sepsis and could replace more invasive methods.

met with limited success, and there is concern about the potential of iatrogenic harm.[6-8]

Importance

Point-of-care ultrasonography performed at the bedside in the ED has the potential to provide emergency physicians with intravascular volume status information similar to that obtained from central monitoring. This has significant clinical implications because point-of-care ultrasonography could spare some patients the risk of more invasive procedures. We sought to determine whether providing emergency physicians with point-of-care ultrasonographic surrogate markers of volume status and cardiac function would demonstrate clinical utility and affect clinical decisionmaking for adult patients with sepsis.

Goals of This Investigation

The primary objective of this study was to evaluate the effect that the provision of 3 bedside ultrasonographic measures (overall cardiac contractility and inferior vena cava diameter and collapsibility), obtained at the point of care by emergency physicians, has on the clinical decisionmaking process in adult patients with sepsis. Our secondary objectives were to (1) evaluate changes in physician certainty, as measured along a visual analog scale, about their clinical decisionmaking after provision of point-of-care ultrasonographic information; and (2) evaluate physicians' assessments of the clinical utility of point-of-care ultrasonographic information.

SIRS Criteria for Activation of Sepsis Bundle

Clinical or microbiologic evidence of infection, **along with** two or more of the following:

- Body temperature greater than or equal to 38ºC (100.4°F) or less than 36ºC (96.8°F),
- Heart rate greater than 90 beats per minute,
- Respiratory rate greater than 20 breaths per minute or partial pressure of arterial carbon dioxide less than 32 mm Hg,
- White blood cell count greater than 12,000 per cubic millimeter or less than 4,000 per cubic millimeter or the presence of more than 10 percent immature band forms (neutrophils).

Sepsis Severity Definitions for Subject Classification

SIRS
- The presence of at least one of the above SIRS criteria.

Sepsis
- The presence of at least two of the above SIRS criteria in addition to clinical or microbiologic evidence of infection.

Severe Sepsis
- Sepsis, as defined above, associated with evidence of organ dysfunction, hypoperfusion abnormality (lactic acidosis, oliguria, acute alternation in mental status), or sepsis-induced hypotension (systolic blood pressure of less than 90 mm Hg or a reduction from baseline systolic blood pressure of 40 mm Hg or more).

Septic Shock
- Severe sepsis, as defined above, associated with sepsis-induced hypotension that persists despite adequate fluid resuscitation, in addition to the presence of hypoperfusion abnormalities or organ dysfunction.

*American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference criteria and definitions.

Figure 1. Systemic inflammatory response syndrome criteria for activation of sepsis bundle.

MATERIALS AND METHODS

Study Design

We studied a prospective cohort, using a before-and-after design to evaluate our study hypotheses. Before initiation of the study, the hospital's institutional review board reviewed and approved it.

Setting

The study was conducted in the ED at Maine Medical Center, an academic tertiary care hospital located in Portland, ME. The ED houses an emergency medicine residency program and had an annual census of approximately 60,000 visits per year at the study. Resident emergency physicians at Maine Medical Center undergo formal training in focused ultrasonography, and all members of the faculty are required to obtain certification in this procedure. The study was conducted from July 2009 through March 2010.

Selection of Participants

Study participants consisted of a convenience sample of adult patients (aged ≥18 years) presenting to the ED with suspected sepsis, severe sepsis, or septic shock. Figure 1 provides the systemic inflammatory response syndrome criteria and sepsis definitions used during the study.

At study enrollment, an Adult Sepsis Alert Protocol provided the basis for the standard of care in the study ED (Appendix E1, available online at http://www.annemergmed.com). This protocol allowed the early identification of potentially septic

patients, most often by triage nursing staff. Activation of the protocol required the presence of 2 or more of the following criteria, in addition to clinical suspicion for infection: abnormal body temperature (greater than 38°C [100.4°F] or less than 36°C [96.8°F]), pulse rate greater than 90 beats/min, unstable blood pressure (systolic blood pressure less than 90 mm Hg or 40 mm Hg lower than baseline; mean arterial pressure less than 65 mm Hg), and respiratory rate greater than 20 breaths/min.

Once identified, patients were entered into the department's electronic patient tracking system and flagged as a "sepsis alert." Physician providers, when encountering a sepsis alert patient, could choose to activate the ED sepsis order set (Appendix E2 and E3, available online at http://www.annemergmed.com). This evidence-based, bundled order set represented the standard of care for this patient population at the study. The order set provided immediate access to commonly used diagnostic studies, intravenous fluid choices, vasopressor agents, and antibiotic options.

Activation of the sepsis order set also triggered an immediate page to a physician member of the study team, who responded to the ED and offered eligible patients enrollment in the study. Inclusion criteria were aged 18 years or older, ED management with the aforementioned sepsis bundle, and the ability to participate in the informed consent process and provide written informed consent. Potential subjects who were not able to provide consent because of their medical condition were considered for study enrollment provided that an appropriate decisionmaker was available to provide written informed consent. For subjects who were enrolled in this manner, follow-up was undertaken by an investigator in an attempt to assess the patients' desire to continue to participate in the study. After triage activation of the sepsis bundle, potential subjects who were determined not to have sepsis by a physician investigator were not enrolled in the study.

Interventions

After informed consent, study participants underwent 3 point-of-care ultrasonographic procedures performed by physician members of the study team: cardiac images to determine left ventricular ejection fraction and vascular images to measure inferior vena cava diameter and collapsibility.

Concurrent with the ultrasonographic examinations, the emergency physicians who were clinically managing the subjects and who were initially blinded to the point-of-care ultrasonographic findings were asked to complete data sheets outlining their treatment plans, presumed causes of observed vital sign abnormalities, and the degree of certainty or confidence in their plans and assessments. They were then provided with point-of-care ultrasonographic information and asked to complete a second data sheet, again reviewing their treatment plan, presumed causes of observed abnormalities, and certainty. In addition, they were asked to evaluate the clinical utility of the ultrasonographic data. Study physicians did not provide clinical care to study subjects, and, in each case, a separate emergency physician provided clinical care for the study subject.

To prepare for the study, all physician investigators participated in at least 2 hours of general cardiac ultrasonographic didactics, with 1 additional hour dedicated to estimating left ventricular ejection fraction and measuring inferior vena cava dimensions and central venous pressure estimates. After the training, physician investigators were expected to complete 25 additional cardiac ultrasonographic examinations to participate as an enroller for the study.

Sepsis severity was evaluated with the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference definitions for the systemic inflammatory response syndrome, sepsis, severe sepsis, and septic shock (Figure 1).[9] Mortality risk was assessed with the Mortality in Emergency Department Sepsis score.[3]

Methods of Measurement

Point-of-care ultrasonographic examinations were conducted with study subjects in the supine and left lateral recumbent position. Sonographic images were obtained with a Sonosite M-Turbo (SonoSite, Inc., Bothell, WA) with a P-21 2- to 4-MHz transducer.

Right atrial pressure was estimated with inferior vena cava volume and respiratory response. Images were obtained in the sagittal plane at the inferior vena cava/right atrial junction, and volume projections were based on inferior vena cava diameter and respiratory variability of either less than 50% (low intravascular volume) or greater than 50% (normal intravascular volume) inferior vena cava collapsibility.[10-15]

Cardiac contractility was categorized as being normal, moderately depressed, or severely depressed. The left ventricle was interrogated with all technically available windows, including subcostal, parasternal long and short axis, and apical 2- and 4-chamber views. Mitral valve annulus displacement was measured during M-mode imaging, using the apical 4-chamber window and with special emphasis on avoiding foreshortening of the left ventricle. Annulus displacement was categorized as follows: greater than 0.9 cm, ejection fraction greater than 50% (normal); 0.5 to 0.9 cm, ejection fraction 35% to 50% (moderately depressed); and less than 0.5 cm, ejection fraction less than 35% (severely depressed).[16,17]

Changes in emergency physician treatment plans were evaluated by asking treating physicians to document, using check boxes, their plans for the administration of intravenous fluids, resuscitative pharmacotherapy, and blood products. Physicians also documented plans for the insertion of central venous lines, tracheal intubation, central venous pressure monitoring, and continuous monitoring of mixed S_VO_2. These documented plans were dichotomized for analysis: yes (plan to use) or no (do not plan to use).

Certainty about the primary cause of vital sign abnormalities and treatment plans, confidence about anticipated disposition, and clinical utility of point-of-care ultrasonographic data were all evaluated with a 100-mm

visual analog scale. Our visual analog scale instruments consisted of a horizontal 100-mm line anchored by the descriptors "not certain/confident/useful at all" to the far left-hand side and "completely certain/confident/useful" at the far right-hand side. Treating physicians were asked to make a single, vertical line transecting the visual analog scale at the point best describing their certainty, confidence, and assessment of clinical utility. The categories of physician certainty investigated included (1) assessment of the primary cause of observed vital sign abnormalities; (2) the degree of certainty in intravenous fluid/pharmacologic/blood transfusion treatment plans; (3) the degree of certainty in central venous access/monitoring/tracheal intubation treatment plans; (4) the degree of certainty that the correct sequence of interventions had been chosen; and (5) the degree of certainty in expected patient disposition. Each of these areas was evaluated according to sepsis severity and by clinical characteristics. The clinical utility of point-of-care ultrasonographic information was assessed by asking treating physicians to rate the degree to which the availability of these data influenced their management plan decisions.

Data Collection and Processing

There were 3 components of data collection: point-of-care ultrasonographic data, treating emergency physician data, and clinical data. Point-of-care ultrasonographic data consisted of inferior vena cava measurements and cardiac function estimation for each of the participants. These data were recorded by the study physicians on a standardized data collection sheet immediately on completion of the examinations. Treating emergency physicians recorded data about their treatment plans, causes of observed abnormalities, certainty and confidence in their treatment plans, and opinions about the clinical utility of the ultrasonographic data. Clinical data, automatically collected electronically for all emergency patients treated with the sepsis bundle, included more than 50 markers of disease severity and physician management. All data were entered into a Microsoft Excel spreadsheet (Microsoft Excel 2002, Microsoft, Inc., Redmond, WA) before analysis.

Outcome Measures

Our primary outcome measure was change in clinical decisionmaking by treating emergency physicians after receipt of point-of-care ultrasonographic information. Our secondary outcome measures included changes in certainty or confidence in the causes of observed vital sign abnormalities and treatment plans after receipt of the same sonographic data, as well as treating physician assessments of the clinical utility of the data.

Primary Data Analysis

Data were analyzed with SPSS for Windows (version 16.0; SPSS, Inc., Chicago, IL) to generate descriptive statistics and frequencies. Comparisons of the visual analog scale outcome measures for the pre– and post–point-of-care ultrasonographic periods are reported as mean differences and 95% confidence intervals (CIs). To assess the relative magnitude of the effect of the ultrasonographic intervention, we calculated Cohen's *d* as an estimate of effect size. Effect sizes were computed by dividing the mean difference between the groups by the pooled SD for the sample. Cohen's guidelines for effect size interpretation (0.20 is small, 0.50 is medium, 0.80 is large) were used.[18-20] To create our graphic data displays, Stata statistical software was used (version 11; StataCorp, College Station, TX). For the evaluations of changes in certainty, confidence, and utility, we considered at 20-mm change along the 100-mm visual analog scale to be of clinical importance. We are unaware of any validated 100-mm visual analog scale scoring systems that measure significant changes in clinician perception of certainty, confidence, and utility. Therefore, we chose a 20-mm threshold as being practically meaningful, assuming that a 20% change in clinician perception was likely to drive alterations in point-of-care decisionmaking. In addition, this 20-mm Δ is in concert with significant pre– and post–visual analog scale score changes that have been validated for other conditions. An a priori sample size calculation was not performed.

RESULTS

Characteristics of Study Subjects

A total of 75 patients were enrolled in the study. One was excluded because of a failure to fully satisfy the informed consent process, leaving data from 74 subjects for analysis. An approximately equal number of men and women were enrolled in the study. On enrollment, no subjects were receiving intravenous vasoactive medications or were tracheally intubated. Because of a delay in the availability of the enrolling study investigator, 1 subject had a central line in place at study entry. Demographic characteristics of the study subjects are presented in Table 1.

For each study subject, the number of systemic inflammatory response syndrome criteria present was evaluated. In addition, eligibility for early goal-directed therapy, as defined by Rivers et al,[2] was determined. Seventy-two of the 74 study subjects had at least 2 systemic inflammatory response syndrome criteria, and 15 subjects (20.3%) would have been eligible for early goal-directed therapy, according to the criteria of Rivers et al.[2] Clinical characteristics for the subjects are provided in Table 2, whereas Table 3 displays ED and hospital dispositions. Overall mortality for the cohort was 4.1% (n=3), with 1 death occurring in the severe sepsis/septic shock subgroup.

On average, study ultrasonography was performed 138 minutes (SD 83; 95% CI 118 to 158 minutes) into the subjects' visit. The mean time for the subjects' treating physician to view the ultrasonographic results was an additional 22 minutes (SD 14; 95% CI 18 to 26 minutes).

Main Results

When pre– and post–point-of-care ultrasonographic clinical plans were compared, alterations to the treatment plan were

Table 1. Demographic characteristics of the study subjects.

Characteristic	No. (%)
Age, mean (SD), y	62 (18.8)
Female sex	37 (50.0)
Sepsis severity*	
SIRS	1 (1.4)
Sepsis	27 (36.5)
Severe sepsis	30 (40.5)
Septic shock	16 (21.6)
MEDS score	
0–4	30 (40.5)
5–7	17 (23.0)
8–11	21 (28.4)
12–15	4 (5.4)
16–27	2 (2.7)
Lactate	
0–2.0	41 (56.2)
2.1–2.5	9 (12.3)
2.6–4.0	17 (23.3)
>4.0	6 (8.2)
GCS score category	
15	67 (90.5)
13–14	5 (6.8)
<13	2 (2.7)

SIRS, Systemic inflammatory response syndrome; MEDS, Mortality in Emergency Department Sepsis.
*Sepsis severity was evaluated with the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference definitions.

Table 2. Vital signs and systemic inflammatory response syndrome criteria.

Variable	Mean (SD)	95% CI
Temperature, °C	38.4 (1.1)	38.2–38.7
Pulse rate, beats/min	109.2 (20.6)	104.4–113.9
Respiratory rate, breaths/min	22.8 (6.1)	21.4–24.2
Systolic blood pressure, mm Hg	113.3 (22.1)	108.2–118.5
WBC count/mm^3	15,560 (11,232)	12,957–18,162
Lactate, mmol/L	2.2 (1.3)	1.9–2.5
SIRS criteria, No. (%)*	2.8 (0.8)	2.6–3.0
1	2 (2.7)	
2	28 (37.8)	
3	27 (36.5)	
4	17 (23.0)	
Qualify early goal-directed therapy, No. (%)†	15 (20.3)	
Central access, No. (%)‡	9 (13.0)	
Tracheal intubation, No. (%)‡	2 (2.9)	
Vasopressors, No. (%)‡	6 (8.7)	
Central venous pressure monitoring§	5 (7.4)	

*Evaluated with the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference criteria.
†Evaluated with the Rivers et al[2] early goal-directed therapy inclusion criteria.
‡Data available for 69 subjects.
§Data available for 68 subjects.

present in 39 (53% [95% CI 41% to 64%]) cases. More specifically, we identified 33 changes in intravenous fluid infusion plans (45% of cases [95% CI 33% to 56%]), 5 changes in vasoactive medication plans (7% of cases [95% CI 1% to 13%]), and 1 alteration in plans for blood product transfusion (1% of cases [95% CI −1% to 4%]). Intravenous fluid infusion changes were equally mixed between increases and decreases in the volume to be administered, whereas 4 of 5 pharmacologic intervention plans were altered to include vasoactive medications. The only alteration in transfusion plans involved a change from intending to administer blood to no longer planning for blood administration.

Table 3. Study subject ED and hospital disposition.

Disposition	No. (%)
ED	
Home	5 (6.8)
Medical/surgical admission	36 (48.6)
Telemetry admission	6 (8.1)
Intermediate care unit admission	10 (13.5)
ICU admission	17 (23.0)
Hospital	
Home*	46 (62.2)
Skilled nursing facility	13 (17.6)
Rehabilitation facility	7 (9.5)
Died	3 (4.1)
Transfer	2 (2.7)
Subject discharged against medical advice	1 (1.4)
Hospice	1 (1.4)
Correctional facility	1 (1.4)

*The home category includes subjects discharged to the home setting with home health care services.

Similarly, treating physicians' plans for procedural interventions were evaluated before and after point-of-care ultrasonographic intervention. In sum, 20 modifications to plans for procedural interventions were noted (27% of cases [95% CI 17% to 37%]). Of these alterations, 10 (14% of cases [95% CI 6% to 21%]) related to central venous access. In 6 instances, point-of-care ultrasonographic data resulted in the decision to establish central venous access (8% of cases [95% CI 2% to 14%]). Central venous pressure monitoring plans were altered in 4 cases (5% of cases [95% CI 0.3% to 11%]) and were equally split between adding and eliminating central venous pressure monitoring to the treatment plan. In 6 instances, changes in the need for continuous monitoring of mixed S_VO_2 were made (8% of cases [95% CI 2% to 14%]), with 4 of these changes eliminating the perceived need for this intervention. No modifications to plans for tracheal intubation were noted.

Table 4 presents mean visual analog scale scores for physician certainty pre- and postreceipt of point-of-care ultrasonographic data. As seen in the table, physician certainty increased across all sepsis severity categories after receipt of the ultrasonographic data. The largest gains in certainty occurred in the severe sepsis group, followed by subjects with septic shock and sepsis.

The line plots displayed in Figure 2 provide information about the magnitude and direction of changes in physician certainty by sepsis severity. Across certainty categories, the most

Table 4. Mean visual analog scale scores for physician certainty pre- and postreceipt of point-of-care ultrasonographic data.

	Certainty About Cause of Vital Sign Abnormalities			
Sepsis Severity (n)	**Pre US Mean (SD)**	**Post US Mean (SD)**	**Mean Difference Change (95% CI)**	**Effect Size, Cohen's *d***
SIRS (1)	86	90	−4.0	n/a
Sepsis (27)	71.2 (18.2)	76.9 (28.5)	−5.6 (−18.7 to 7.4)	−0.24
Severe sepsis (30)	74.9 (21.4)	87.6 (17.3)	−12.7 (−22.8 to −2.6)	−0.65
Septic shock (16)	73.3 (22.5)	82.8 (30.7)	−9.5 (−28.9 to 9.9)	−0.35
Certainty about planned interventions (intravenous fluid resuscitation, use of vasopressive medications, blood transfusions)				
SIRS (1)	88	92	−4.0	n/a
Sepsis (27)	78.3 (17.1)	78.6 (26.8)	−0.3 (−12.6 to 12.0)	−0.01
Severe sepsis (30)	76.8 (22.9)	86.7 (22.7)	−9.9 (−21.6 to 1.9)	−0.43
Septic shock (16)	77.3 (25.8)	79.5 (32.8)	−2.2 (−23.5 to 19.1)	−0.07
Certainty about interventions foreseen (central venous access, central venous pressure monitoring, mixed venous saturation monitoring, tracheal intubation)				
SIRS (1)	83	90	−7.0	n/a
Sepsis (27)	70.4 (26.5)	82.8 (18.6)	−12.3 (−24.8 to 0.16)	−0.54
Severe sepsis (30)	72.0 (25.9)	73.5 (26.9)	−1.5 (−15.1 to 12.2)	−0.06
Septic shock (16)	65.8 (32.8)	72.2 (33.9)	−6.4 (−30.5 to 17.7)	−0.19
Certainty about choosing correct series of interventions				
SIRS (1)	85	93	−8.0	n/a
Sepsis (27)	74.0 (19.6)	83.9 (15.3)	−9.9 (−19.5 to −0.30)	−0.56
Severe sepsis (30)	81.3 (13.5)	86.4 (11.8)	−5.1 (−11.7 to 1.4)	−0.40
Septic shock (16)	74.2 (24.1)	81.9 (30.4)	−7.8 (−27.5 to 12.0)	−0.28
Certainty about disposition				
SIRS (1)	85	82	−7.0	n/a
Sepsis (27)	70.7 (20.3)	78.7 (23.7)	−8.1 (−20.1 to 4.0)	−0.36
Severe sepsis (30)	74.9 (14.7)	82.8 (14.2)	−7.8 (−15.3 to −0.38)	−0.55
Septic shock (16)	77.9 (19.0)	83.3 (29.6)	−5.4 (−23.4 to 12.5)	−0.22

US, Ultrasonography; *SD,* standard deviation.

increases occurred in the severe sepsis group, followed by the sepsis and septic shock groups. The largest gains in physician certainty were made in the sepsis group. Figure 2 demonstrates that there were some postultrasonographic decreases in certainty in the sepsis, severe sepsis, and septic shock groups.

Table 5 provides summary data for the point-of-care ultrasonographic measures obtained in the study by sepsis severity. For 3 subjects with severe sepsis, 2 subjects with septic shock, 2 subjects with sepsis, and 1 subject with systemic inflammatory response syndrome, physician investigators were unable to obtain an estimate of inferior vena cava size. Estimates of inferior vena cava collapse and central venous pressure were also not obtained for the systemic inflammatory response syndrome subject. Similarly, contractility was not obtained for 1 subject with septic shock. Complete ultrasonographic data were obtained for all other subjects.

Changes in physician certainty pre- and postreceipt of point-of-care ultrasonographic data were also evaluated by clinical characteristics of the study subjects. Large effect sizes were observed for subjects without tachycardia (>90 beats/min) in the areas of certainty about the cause of vital sign abnormalities (Cohen's d=1.01), planned interventions (about intravenous fluid resuscitation, use of vasopressive medications and or blood transfusions) (d=0.87), and choosing the correct series of interventions (d=1.02). Medium effect sizes were noted for normothermic subjects (temperature >36°C/<38°C) in the areas of certainty about the cause of vital sign abnormalities (d=0.72), interventions foreseen (about the need for central venous access, central venous pressure monitoring, mixed venous saturation monitoring, and tracheal intubation) (d=0.70), choosing the correct series of interventions (d=0.70), and disposition (d=0.70). Moderate effect sizes were also noted for normotensive subjects (d=0.53) and subjects who would not have met early goal-directed therapy criteria (d=0.54) when certainty about choosing the correct series of interventions was evaluated. In subjects without tachycardia, a moderate effect size (d=0.70) was observed when changes in physician certainty about disposition were examined. Finally, in subjects with tachypnea, changes in physician certainty about the cause of vital sign abnormalities also reached a moderate effect size (d=0.57). Increases in certainty for all other subject groups did not surpass a small effect size.

Figure 2. Changes in certainty about *A*, the cause of vital sign abnormalities, *B*, interventions foreseen, *C*, planned interventions, *D*, choosing the correct series of interventions, and *E*, disposition by sepsis severity and the magnitude of the change in visual analog scale score. Patient data are arranged by post–point-of-care ultrasonographic value on the *x* axis for each outcome. Patient "x" for one figure will not necessarily be patient "x" in the next. The gray line connects post–point-of-care ultrasonographic visual analog scale values. The black box plot represents pre–point-of-care ultrasonographic visual analog scale scores for the cohort, whereas the gray box plot represents post–point-of-care ultrasonographic visual analog scale scores. Box plots represent the median, 75th percentile, and 25th percentile visual analog scale scores, with the upper and lower adjacent values representing the most extreme data points within 1.5 times the interquartile range.

Table 5. Point-of-care ultrasonographic measures by sepsis severity.

	No. (%)			
POCUS Measure	**SIRS, n=1**	**Sepsis, n=27**	**Severe Sepsis, n=30**	**Septic Shock, n=16**
IVC size				
<1.5	0	9 (33.3)	9 (30.0)	5 (33.3)
1.5–2.5	0	13 (48.1)	15 (50.0)	6 (40.0)
>2.5	0	3 (11.1)	3 (10.0)	2 (13.3)
Unable	1 (100)	2 (7.4)	3 (10.0)	2 (13.3)
IVC collapse				
Total collapse	0	7 (28.0)	8 (30.8)	4 (33.3)
>50%	0	7 (28.0)	11 (42.3)	2 (16.7)
<50%	0	11 (44.0)	6 (23.1)	6 (50.0)
No change	0	0	1 (3.8)	0
Unable	1 (100)	0	0	0
CVP				
0–5	0	9 (36.0)	9 (34.6)	5 (38.5)
5–10	0	6 (24.0)	10 (38.5)	2 (15.4)
11–15	0	9 (36.0)	6 (23.1)	4 (30.8)
16–20	0	1 (4.0)	1 (3.8)	2 (15.4)
Unable	1 (100)	0	0	0
Contractility				
Normal	1 (100)	23 (85.2)	25 (83.3)	11 (68.8)
Depressed	0	3 (11.1)	1 (3.3)	3 (18.8)
Severely depressed	0	1 (3.7)	4 (13.3)	1 (6.3)
Unable	0	0	0	1 (6.3)

IVC, Inferior vena cava; *CVP*, central venous pressure.

Figure 3 displays changes in physician certainty about the cause of vital sign abnormalities (Figure 3*A*), interventions foreseen (central venous access, central venous pressure monitoring, mixed venous saturation monitoring, tracheal intubation) (Figure 3*B*), planned interventions (intravenous fluid resuscitation, use of vasopressive medications, blood transfusions) (Figure 3*C*), choosing the correct series of interventions (Figure 3*D*), and disposition (Figure 3*E*) by sepsis severity and point-of-care ultrasonographic findings (cardiac contractility and volume status findings). Examination of Figure 3*A* reveals several interesting findings, including that certainty increased for the majority of subjects who would have qualified for early goal-directed therapy and those with normal contractility and low volume status, whereas certainty tended to decrease for subjects with depressed contractility and low volume status, as well as for subjects with severely depressed contractility and low volume status. From this part of the figure, it appears that point-of-care ultrasonography was most helpful in increasing physician certainty in subjects with normal contractility and low or normal volume status.

The clinical utility of point-of-care ultrasonographic information was assessed by asking treating physicians to rate the degree to which the availability of these data influenced their management plan decisions. The mean visual analog scale rating evaluating the influence of point-of-care ultrasonographic data was 65 mm (95% CI 58 to 72 mm).

In only 10% of cases, treating physicians reported that they found point-of-care ultrasonographic measures (inferior vena cava size, inferior vena cava collapsibility, and left ventricular ejection fraction) to have "little to no" utility. Four physicians (6%) found inferior vena cava assessments not to be useful, whereas the physicians in 3 cases (4%) observed that the left ventricular ejection fraction information was not influential in modifying their management plan. However, in the majority of cases (n=52), physicians identified inferior vena cava assessments as having more robust utility, with estimations of left ventricular ejection fraction being of secondary importance.

LIMITATIONS

There are several limitations of this study deserving consideration. The investigation was conducted in a single tertiary care ED, potentially limiting the generalizability of our findings to other settings. In addition, subjects were enrolled on a convenience basis, depending on the availability of the physician sonographers who participated in the training portion of the study, and this may have introduced selection bias. Our sample was also relatively small and, given the fact that the majority of subjects did not require an ICU stay, those composing this sample may not have been as severely ill as sepsis patients reported in other studies. In addition, this intervention was not designed only for those patients with severe sepsis or septic shock. Our intention was to evaluate the intervention's utility across the diagnostic spectrum of sepsis; thus, all patients with evidence of systemic inflammatory response syndrome and a potential source were eligible for enrollment.

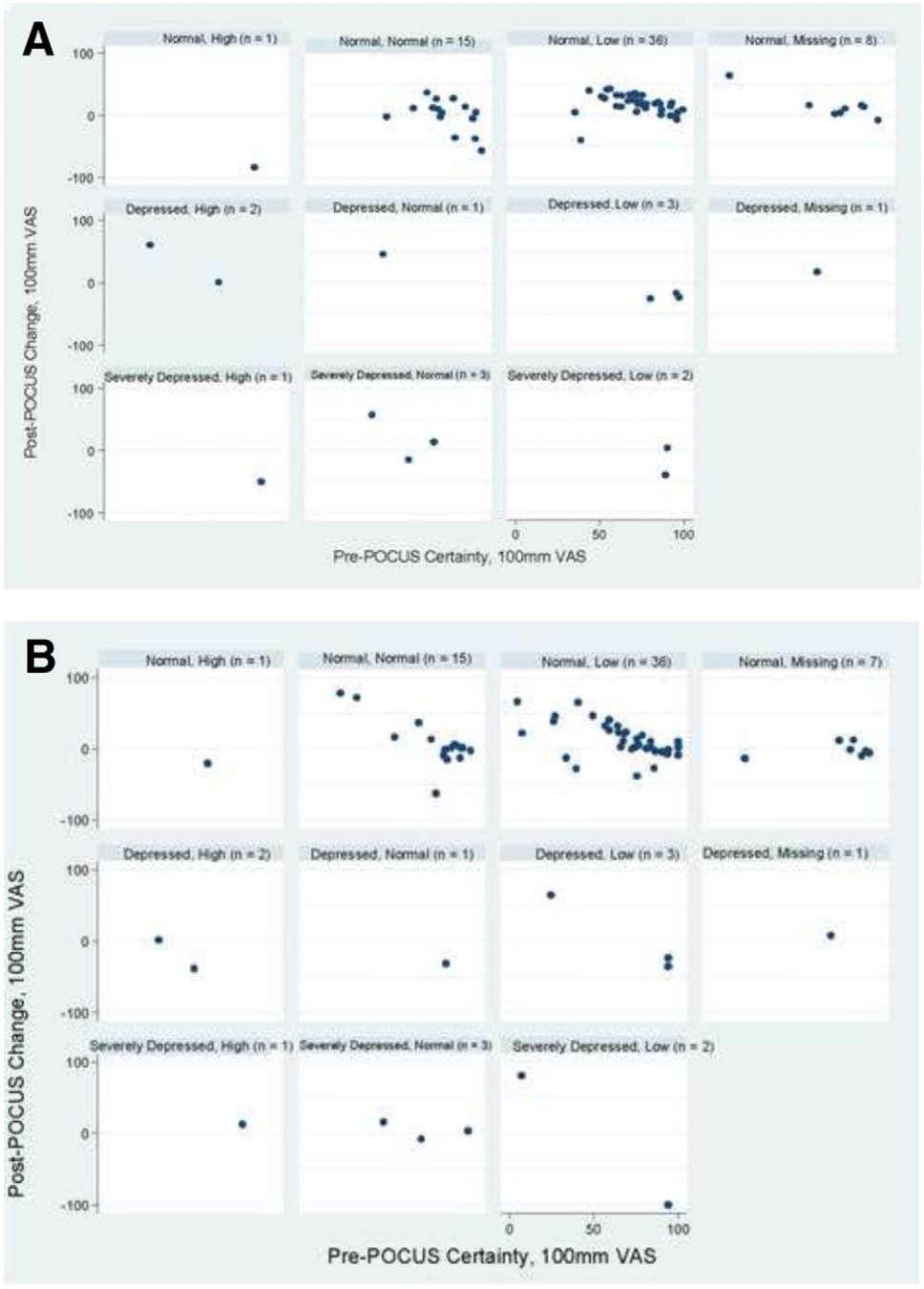

Figure 3. Pre-POCUS physician certainty against post-POCUS change in physician certainty about *A*, the cause of vital sign abnormalities, *B*, interventions foreseen, *C*, planned interventions, *D*, choosing the correct series of interventions, and *E*, disposition by cardiac contractility and volume status findings. Rows represent contractility, whereas columns represent volume status. *POCUS*, Point of care ultrasonography; *VAS*, visual analog scale.

Our primary method for determining severity of illness in this trial was the use of previously agreed-on classifications of sepsis severity (systemic inflammatory response syndrome, sepsis, severe sepsis, and septic shock), as well as the Mortality in Emergency Department Sepsis Score.[3,9] However, an additional retrospective analysis of our data with the Rivers et al[2] inclusion criteria for early goal-directed therapy was conducted to try to identify subjects who would have been included in the initial early goal-directed therapy trial. The judgment about eligibility for early goal-directed therapy was not made during the conduct of the trial by investigators who were observing subjects in real time. As a result, the eligibility for early goal-directed therapy characteristics used in the study may not be completely representative of this categorization had it been made at the

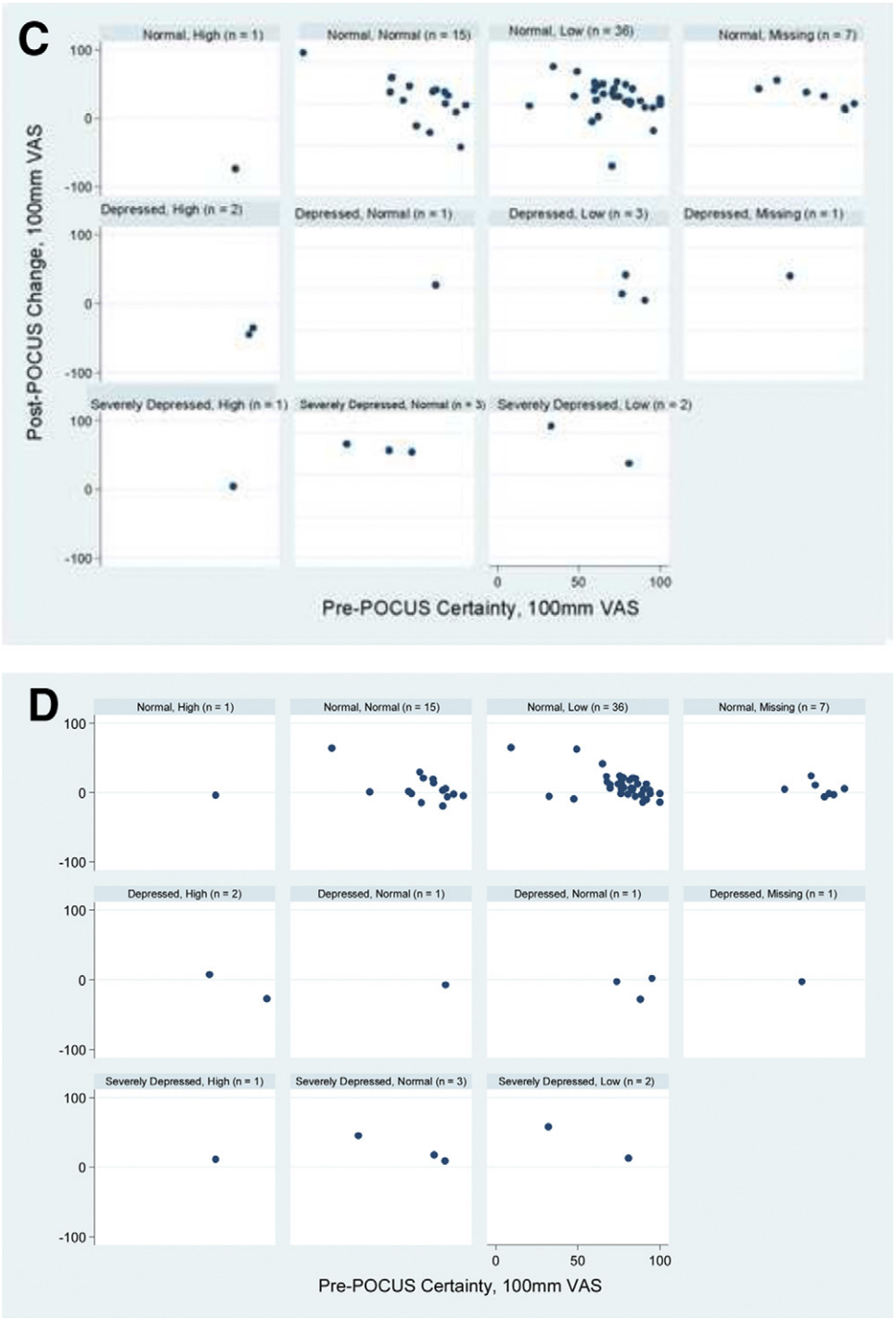

Figure 3 Continued.

bedside. We followed the early goal-directed therapy criteria strictly in our analysis. If necessary data were missing, subjects were considered not to have been eligible; therefore, we suspect the true number to be a bit higher. The classification was included in the article to help the reader better appreciate the spectrum of patients included in the study.

As with most ultrasonographic techniques, the acquisition of mitral valve annulus displacement and inferior vena cava diameter and collapsibility is influenced by sonographer experience and patient characteristics, such as body habitus. Additionally, there were inherent differences in treating physicians' previous experience with point-of-care ultrasonography that may have affected the

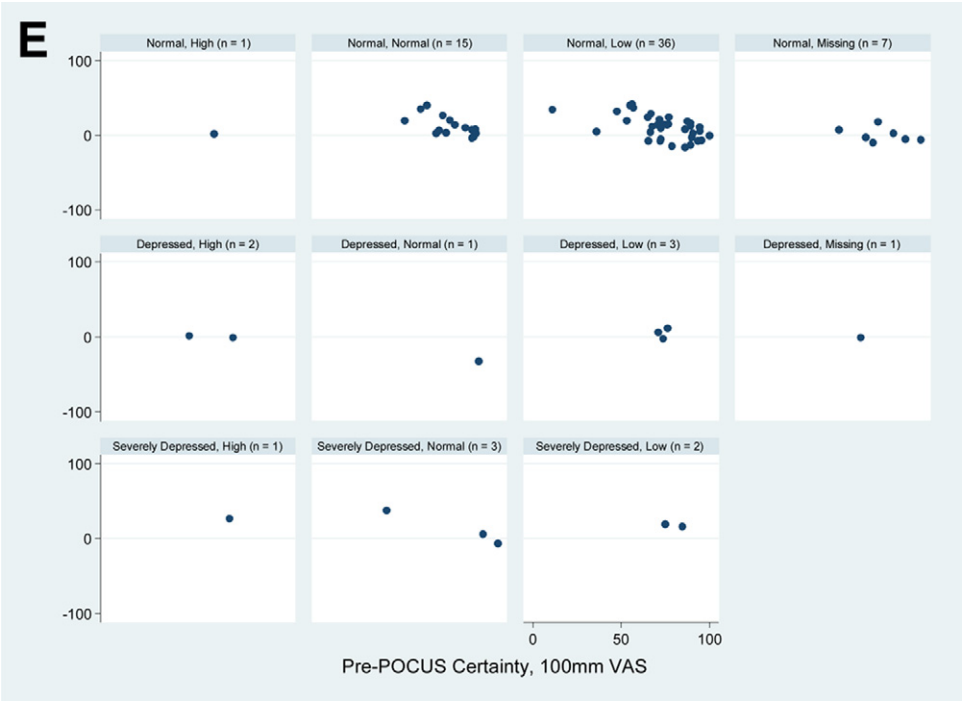

Figure 3 Continued.

secondary outcome of change in treatment plans after receipt of the sonographic data, as well as their assessments of the clinical utility of the data. We suspect, however, that in the absence of 24-hour coverage by fellowship-trained ultrasonographers or cardiologists, our scenario likely mirrors the reality of many ultrasonographically related interventions conducted in the ED setting.

Finally, we did not correlate point-of-care ultrasonographic data availability with ultimate patient outcomes. Further study will be required to determine whether noninvasive bedside sonography can effectively replace more invasive measures in the management of the septic patient.

DISCUSSION

Point-of-care ultrasonography has rapidly emerged as a vital and commonly used component of the emergency physician's physical examination.[21] In the hands of trained clinicians, bedside ultrasonography has been used to efficiently and accurately diagnose such conditions as pneumothorax, cardiac tamponade, hydronephrosis, acute cholecystitis, deep venous thrombosis, abdominal aortic aneurysm, and intraperitoneal hemorrhage, thus facilitating expedited decisionmaking processes and transforming the quality of care provided in the emergency setting.[22,23] Point-of-care ultrasonography is now also routinely used by emergency physicians in the evaluation of intravascular volume status and overall cardiac function in critically ill patients.[10-12,16] We chose to focus on a subgroup of this critically ill patient population, those with suspected sepsis, and the core procedural and diagnostic elements disseminated in early goal-directed therapy protocols.[2,24-27]

Many emergency physicians have become understandably reluctant to implement all of the bundled components of early goal-directed therapy protocols routinely.[8,28,29] Critics of these protocols point to recent evidence suggesting that nonadherence to all or portions of the bundled components associated with early goal-directed therapy is more common than previously thought.[5,30] In addition, some authors have implied that early goal-directed therapy–associated mortality benefit estimates may be inflated because of higher-than-typical mortality rates in the control group.[30]

Although not completely understood or agreed on, data seem to imply that there are several reasons for nonadherence to early goal-directed therapy.[8] Compliance rates appear to be lower for the more invasive components of the initial early goal-directed therapy interventions. Ward et al[31] recently reported on a single-institution experience quantifying the noncompletion rates for several of these components, including blood transfusion (85%), central venous pressure monitoring (76%), mixed tissue oxygenation monitoring (74%), vasopressor administration (73%), and central line insertion (49%). Only 18% of the study subjects received care that was in full compliance with the recommended early goal-directed therapy protocol. These findings suggest that treating physicians may currently find that the risks associated with the invasive components of early goal-directed therapy (central line insertion, blood transfusion) outweigh the potential benefits.

In addition, physicians have expressed particular concern about the use of central venous pressure to guide fluid resuscitation.[5,30] Some researchers suggest that central venous pressure is not a strong predictor

of intravascular volume or fluid responsiveness and that use of central venous pressure to titrate volume resuscitation can result in either underresuscitation or pulmonary edema.[5,32-35] Dynamic methods of determining preload responsiveness, such as inferior vena cava diameter and collapsibility, pulse pressure variation, brachial artery peak flow velocity variation, and passive leg raising have been suggested as more accurate methods of determining fluid status.[5,30,33] For these reasons, demonstrating that the availability of point-of-care ultrasonographic data can appropriately decrease the requirement for invasive procedures while promoting intravascular volume repletion or effective pharmacologic therapy in the septic patient has significant clinical implications.

We believe that this study provides an important foundation for future work toward this end. Our findings demonstrate that real-time point-of-care ultrasonographic assessments can influence early management decisionmaking and physician certainty in their decisions when caring for adult sepsis patients. As a result, we believe that point-of-care ultrasonography offers an alternative, noninvasive approach to obtain much of the diagnostic information currently being provided by central venous catheterization.

To provide a realistic and transferable bedside experience, we used point-of-care ultrasonographic techniques familiar to most emergency physicians, whether they practice in a community, urban, or academic setting. These included subcostal, parasternal long-axis, parasternal short-axis, apical 2-chamber, and apical 4-chamber views. In addition, we attempted to acquire mitral valve annulus displacement measurements in our study subjects. Although emergency physicians are less familiar with this ultrasonographic method, it is an easily reproducible objective measure of cardiac contractility that is commonly used by cardiologists.[17]

Before performing sonographic evaluation, treating clinicians were asked to identify the most likely cause of the patient's vital sign abnormalities, commit to a specific management plan (including volume resuscitation decisions, as well as anticipated pharmacologic and procedural interventions), and indicate their degree of certainty with their approach.

In this study, the availability of point-of-care ultrasonographic data clearly influenced the bedside decisionmaking process. After receipt of the point-of-care ultrasonographic information provided in this study, 17% of physicians altered the presumed cause of recorded vital sign abnormality (typically, insufficient volume versus cardiac contractility), 45% altered their intravenous fluid resuscitation plans, 7% altered their plan to administer vasoactive medications, and 14% altered plans to obtain central venous access. Overall, more than half of physicians in this study altered their initial management plan after the receipt of the point-of-care ultrasonographic data.

Availability of point-of-care ultrasonographic data also increased clinician confidence and certainty in establishing a cause for the patient's vital sign abnormalities and determining that a correct series of interventions had been chosen. In addition, 90% of participating clinicians found point-of-care ultrasonographic data to have overall positive clinical utility. Although the availability of point-of-care ultrasonographic data was found to increase clinical certainty across many of the variables examined, of equal importance were the instances of decreased clinical certainty (decreasing pre– to post–point-of-care ultrasonographic visual analog scale scores) depicted in Figures 2 and 3. In either situation, treating clinicians were compelled to revisit and potentially modify their management plans. It is likely that at these times, this added point-of-care information was discordant with their clinical gestalt, thus motivating clinicians to consider an alternate perspective testing their initial assumptions. This appears to be among one of the fundamental values of point-of-care ultrasonography in the management of the septic patient in the emergency setting.

Analysis of our findings underscores the value of a number of already appreciated attributes of point-of-care ultrasonography and suggests that its routine use in the septic patient can result in improved clinician confidence, evidence-based changes in management decisions, and a better understanding of the perceived primary cause of vital sign abnormalities. Therefore, point-of-care ultrasonography appears to be a useful modality in evaluating and treating victims of this life-threatening condition. Adoption of point-of-care ultrasonography could result in fewer invasive procedures without compromising patient safety and therapeutic efficacy. As with any new diagnostic tool, point-of-care ultrasonographic evaluations of individual septic patients should be applied and interpreted carefully within the unique parameters of each clinical setting.

In conclusion, we found that emergency physicians caring for adult patients with sepsis in this study considered point-of-care ultrasonographic data about cardiac contractility, inferior vena cava diameter, and collapsibility to be clinically useful. In addition, physicians reported changes to their treatment plans after receipt of point-of-care ultrasonographic data in more than half of cases studied. Finally, physicians reported increased certainty and confidence in their treatment plans and clinical decisionmaking after receipt of the ultrasonographic data. Additional research is recommended to evaluate the relationships between point-of-care ultrasonography performed by emergency physicians and patient outcomes, complications, and sepsis-associated costs.

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Author contributions: SAH conceived the study. SAH, ETM, and TDS designed the trial, prepared the study proposal, supervised the conduct of the trial and data collection, and managed the data, including quality control. SAH, ETM, GLH, CBI, and WBO undertook recruitment of patients. TDS provided statistical advice on study design, analyzed the data, and interpreted the results. All authors helped to draft the article and contributed substantially to its revision. SAH takes responsibility for the paper as a whole.

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Patient Sticker

ADULT SEPSIS ALERT

CRITERIA FOR RAPID TRIAGE AND TREATMENT

Age ≥18 y/o

TRIAGE ALERT (two or more of the following plus a clinical suspicion for infection)

☐Temp > 38 or < 36 [____]

☐HR > 90 [____]

☐SBP <90 or SBP 40 below baseline or MAP <65 [_____]

☐RR > 20 [____]

AND

☐Clinical Suspicion for infection (ie. pneumonia, cellulitis, UTI, meningitis)

EXCLUSION CRITERIA

(Any of the following)

☐Sore Throat

☐Suspected Ear infection

☐Suspected dental abscess

☐Suspected AMI

☐Suspected CVA

IF 2 or more triage criteria are present and there is a suspected source of infection:

- Transfer to monitored bed (Trauma room or Critical Care Area if HYPOTENSIVE)

  [HYPOTENSION = SBP <90 or SBP 40 below baseline or MAP <65]
- Logicare alert message
- Physician reviews and orders sepsis bundle as indicated

ED COMMENTS:

Appendix E1. Adult sepsis alert protocol.

TREATMENT ALERT CRITERIA *(Clinical evaluation of the severity of SEPSIS)*

*******DOCS*******

ILLNESS SEVERITY (highest)

- ☐ SIRS
- ☐ SEPSIS
- ☐ **SEVERE SEPSIS**
- ☐ **SEPTIC SHOCK**
- ☐ Other NON SEPSIS

SUSPECTED SOURCE

- ☐ Pulmonary
- ☐ Urinary/GU
- ☐ CNS
- ☐ Dermatologic
- ☐ GI/intrabdominal
- ☐ Viral
- ☐ Unknown
- ☐ Other _____

DISPO FROM ED

- ☐ Med/Surge
- ☐ Home
- ☐ Tele
- ☐ IMC
- ☐ SCU
- ☐ Expired in ED

*******Nursing*******

ED INTERVENTIONS

- ☐ **Total IVF Given in ED**
  - ○ _____
- ☐ **Urine Output in ED**
  - ○ _____
- ☐ **Central line** ☐ USg
  - ○ IJ ○Fem ○SCL
  - Time/date(mm/dd/yy)
  - [___/___/___|___:___:___]
- ☐ **Initial Pressors**
  - Time/date(mm/dd/yy)
  - [___/___/___|___:___:___]
  - ○ Levo
  - ○ DOPA
  - ○ Vaso
  - ○ EPI
  - ○ NEO
  - ○ Dobutamine
- ☐ **CVP (worst)** [____]
  - Time/date(mm/dd/yy)
  - [___/___/___|___:___:___]
- ☐ Intubation
  - Time/date(mm/dd/yy
  - [___/___/___|___:___:___]

*******Anyone*******

MEDS SCORE

☐ Prior Terminal Illness (<30days)	6
☐ Tachypnea or Hypoxia	3
☐ Septic Shock	3
☐ Platelets <150	3
☐ Bands >5%	3
☐ Age >65	3
☐ Lower Respiratory Infection	2
☐ Nursing Home Resident	2
☐ Altered Mental Status	2
☐ Total	[_____]

Predicted Mortality

0-4	→	**1.0%**
5-7	→	**4.4%**
8-12	→	**9.3%**
13-15	→	**16.1%**
>15	→	**39%**

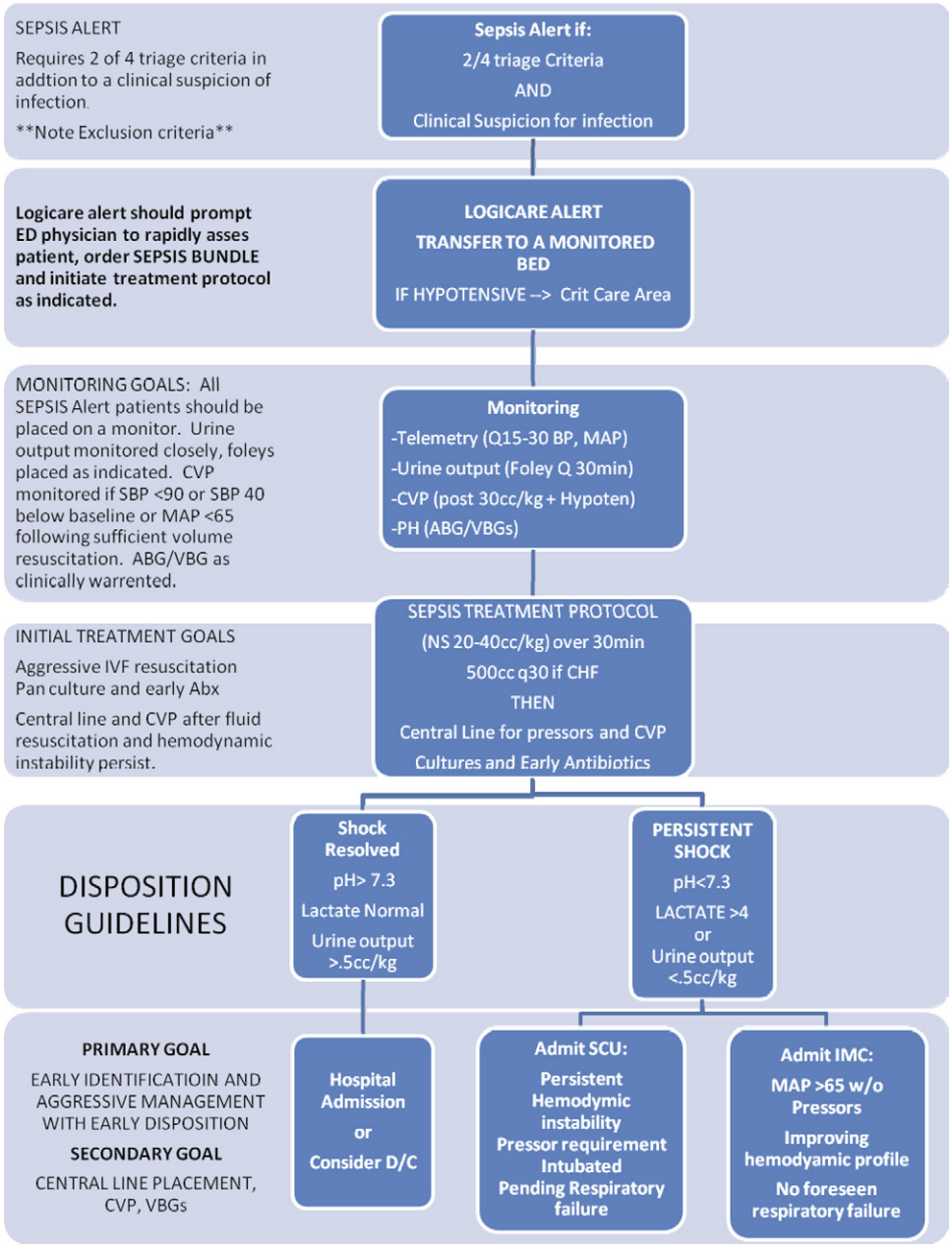
Past Medical:

- ☐ CAD
- ☐ CHF
- ☐ IDDM
- ☐ NIDDM
- ☐ COPD
- ☐ CA
- ☐ RA
- ☐ IMMUNSUP
- ☐ ESRD
- ☐ Hep A/B/C

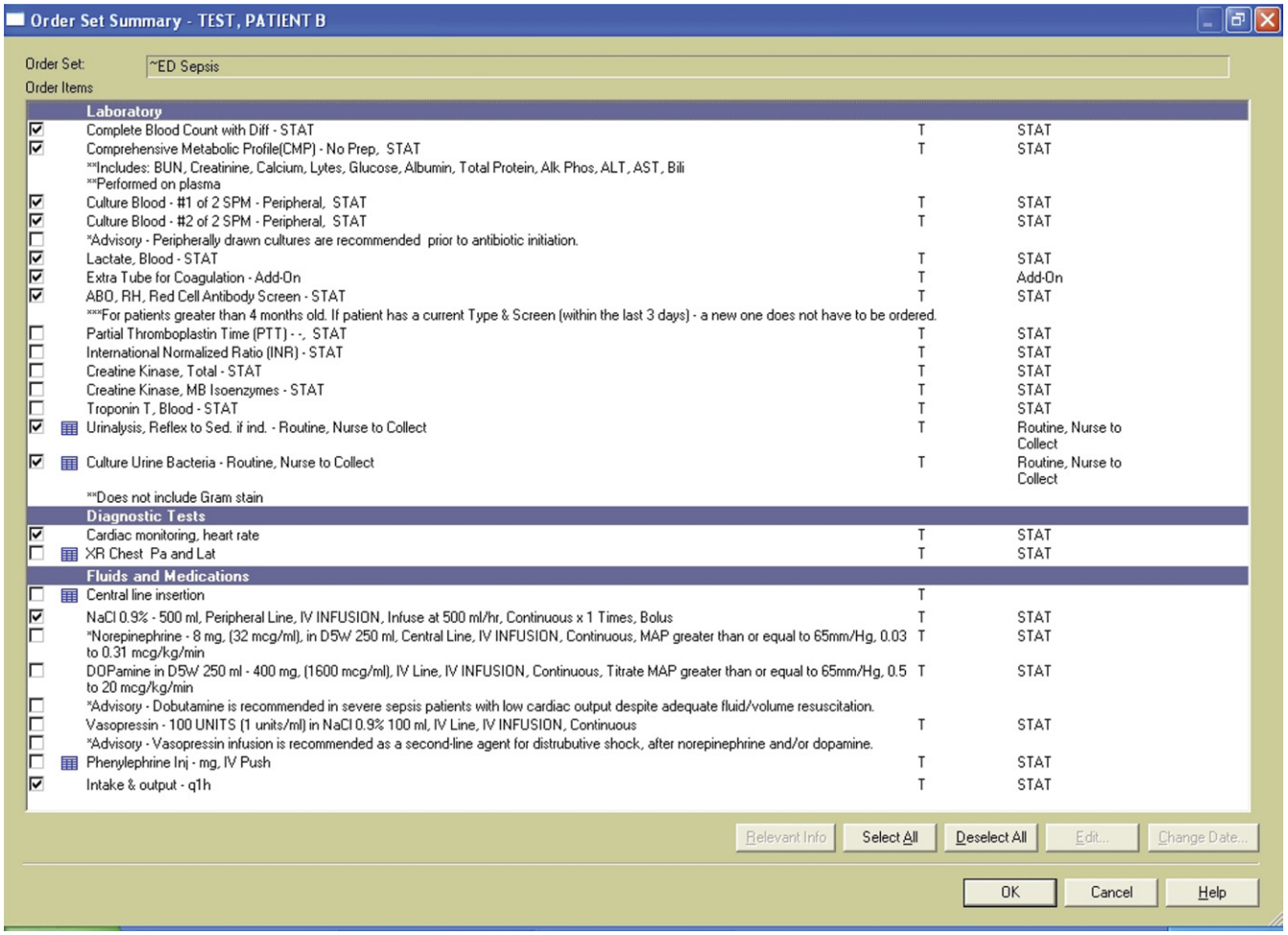
Reviewer Comments:

Attn_____ Res_____ Triage Alert Y/N/NA

Appendix E1 *(Cont'd)*



Appendix E2. Adult sepsis bundle.



Appendix E3. ED sepsis order set.