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Paramedic-Initiated CMS Sepsis Core Measure Bundle Prior to Hospital Arrival: A Stepwise Approach

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Abstract

Background: To improve patient outcomes, the Center for Medicare and Medicaid Services (CMS) implemented core measures that outline the initial treatment of the septic patient. These measures include initial blood culture collection prior to antibiotics, adequate intravenous fluid resuscitation, and early administration of broad spectrum antibiotics. We sought to determine if Paramedics can initiate the CMS sepsis core measure bundle in the prehospital field reliably. **Methods**: This is a retrospective, case series from a 3rd service EMS system model in Greenville, South Carolina between November 17, 2014 and February 20, 2016. An adult Prehospital Sepsis Assessment Tool was created using the 2012 Surviving Sepsis guidelines: 2 of 3 signs of systemic inflammatory response (heart rate, respiratory rate, oral temperature) and a known or suspected source of infection. A "Sepsis Alert" was called by paramedics and upon IV access a set of blood cultures and blood for lactate analysis was collected prior to field antibiotic administration. The Sepsis Alert was compared to serum lactate levels and ICD 9 or 10 admitting diagnosis of Sepsis, Severe Sepsis, or Septic Shock. Blood culture contamination, serum lactate, and antibiotic match were determined by in-hospital laboratory analysis. **Results**: A total of 120 trained paramedics called 1,185 "Sepsis Alerts" on 56,643 patients (50.3% Male, mean age 70). Patients with missing discharge diagnosis were eliminated ($n = 31$). The admitting diagnosis of sepsis overall was 73.5% (848/1154): Sepsis 50% (578/1154), Severe Sepsis 14.6% (169/1154), Septic Shock 8.9% (101/1154). A total of 946 blood cultures were collected in the prehospital setting, with a 95.04% (899/946) no contamination rate. Contamination was found in 4.96% (47/946). A total of 179 (18.9%) of the uncontaminated blood cultures were found to have positive growth with 720 (76.1%) having no growth. EMS administered antibiotics matched blood culture positive growth in 72% of patients. The lactate level was greater than 2.2 in 46.9% of patients. No adverse effects were reported after prehospital administration of antibiotics. **Conclusion**: This study demonstrates the successful implementation of an EMS-driven CMS Sepsis Core Measure bundle in the prehospital setting. Paramedics can acquire uncontaminated blood cultures, and safely administer antibiotics prior to hospital arrival among patients who were recognized as sepsis alerts. **Key words:** sepsis; blood cultures; EMS sepsis; CMS sepsis core measures; antibiotics

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Introduction

Severe sepsis and septic shock continue to be the leading cause of death in non-cardiac ICU's in the United States.[1] To improve patient outcomes, the Center for Medicare and Medicaid Services (CMS) implemented core measures that outline the initial treatment of the septic patient.[2] These measures include initial blood culture collection prior to antibiotics, adequate intravenous fluid resuscitation and early administration of broad spectrum antibiotics. Traditionally, this treatment strategy has begun only after arrival to the hospital.

Over the past decade, Emergency Medical Services (EMS) systems have reduced morbidity and mortality of many life-threating conditions by providing early recognition, intervention, and activation of in-hospital resources. Most notably, EMS initiated ST elevation myocardial infarction (STEMI) and Stroke Alerts have decreased time from the patient's first health care contact to definitive treatment.[3,4] Prehospital providers encounter severe sepsis regularly and at a higher proportion than acute myocardial infarction or stroke.[5] EMS transports 34% of all patients diagnosed with sepsis, and 60% of all severe sepsis patients arriving to the ED.[6] Wang et al.,[6] Band et al.,[7] Studnek et al.,[8] among others have identified the key role EMS can play in the early identification and treatment of the septic patient. The use of a sepsis screening tool which incorporates vital signs and set criteria has been shown to have modest sensitivity in the prehospital setting.[9] This raised the question: can EMS personnel perform the initial CMS sepsis core measures in the prehospital setting?

This important inquiry raised a series of unanswered questions. First, could a Paramedic accurately

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identify the septic patient without a point of care lactate result using a Prehospital Sepsis Assessment Tool (PreSAT)? Second, could uncontaminated blood cultures be reliably obtained during a field IV start? Third, could Paramedics administer prehospital antibiotics without causing harm? Only after each question was positively answered and each step successfully maintained could one consider changing the EMS traditional standard of practice for the septic patient. Thus, the Greenville County Emergency Medical Service (GCEMS) Sepsis Alert stepwise prehospital treatment approach of the septic patient that met the CMS sepsis core bundle measures is described.

METHODS

This is a retrospective case series review of all adult 9-1-1 call patients that were identified as a "Sepsis Alert" in the prehospital setting from November 17, 2014 to February 20, 2016. All adult patients, age 18 years or older, who were evaluated by Greenville County EMS paramedics, who were identified as a "Sepsis Alert," and transported to either to a Greenville Health System or Bon Secours St. Francis Hospital Emergency Department were included in the study. This study was approved by the Greenville Health System's Institutional Review Board under the exempt category.

Prior to protocol implementation, approval from the South Carolina Department of Health & Environmental Control Bureau of EMS (SCDHEC EMS) was received to allow paramedic administered intravenous antibiotics in cases of suspected sepsis. Prior to this study, antibiotics were not contained on the state medication formulary and could not be administered by paramedics. Approval was received in August 2014 by SCDHEC EMS to begin a pilot project allowing Greenville County EMS paramedics to administer broad spectrum antibiotics intravenous.

Setting

Greenville County EMS (GCEMS) covers an area of just over 785 square miles that is home to an estimated 482,752 citizens in 2014. Greenville County is located in the upstate of South Carolina which includes the foothills of the Blue Ridge Mountains in the northern most portion of the county. This is a mixed rural and suburban community with the largest city being the City of Greenville. Greenville County EMS serves this response area with 21 ALS transport units. In 2015 Greenville County responded to over 85,000 calls for service with an average transport time of approximately 16 minutes. GCEMS is the sole 9-1-1 service for Greenville County and utilizes Emergency Medical Dispatch (EMD) to prioritize calls based on current Medical Priority Dispatch System (MPDS) protocols. Each ambulance is staffed with at least one NREMT certified Paramedic and operate from Clinical Operating Guidelines that do not require online medical control. Paramedics complete all documentation of care on an internally secured electronic medical record that contains a searchable database.

All patients were transported to one of four Emergency Departments in the Greenville area. Greenville Memorial Medical Center and Greer Memorial Hospital are owned by Greenville Health System. St. Francis Downtown and St. Francis Eastside are owned and operated by Bon Secours Health System. Both systems are located in Greenville County. Transport times to these institutions range from 7 to 45 minutes with a mean transport time of 16 minutes.

Sepsis Alert Definition

An adult Prehospital Sepsis Assessment Tool (PreSAT) was created using the 2012 Surviving Sepsis guidelines[2] (Figure 1). Four Systemic Inflammatory Response Syndrome (SIRS) criteria were used, Tachycardia (heart rate greater than 90 bpm), Tachypnea (respiratory rate greater than 20) or mechanical ventilation, hyperthermia (> 101°F or 38°C) or hypothermia (< 96.8°F or 36°C), and/or signs of poor perfusion (systolic blood pressure less than 90 mmHg). Two signs of SIRS and a known or suspected source of infection required the paramedic to issue a "Sepsis Alert" to the receiving emergency department. These criteria were used after gaining consensus from the two receiving hospital systems EMS sepsis committees.

The sepsis alert criteria used in this study were designed to match the existing sepsis identification protocols in each hospital systems involved. Both hospital systems used the 2012 Surviving Sepsis guidelines which require two SIRS criteria and a known or suspected source of infection for initial identification.[2] During this study period, The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)[10] was published changing the definitions and screening for sepsis in-hospital. The new criteria suggest the use of quick Sequential Organ Failure Assessment (qSOFA) (respiratory rate of 22/min or greater; altered mentation; or systolic blood pressure of 100 mmHg or less)[10] in the emergency department and no longer recommend the use of SIRS for identification of sepsis and septic shock. Neither hospital system involved in this study made changes to their sepsis screening protocols after the publication of Sepsis-3 and continued to use two SIRS criteria and a known or suspected source of infection for the duration of this study. To maintain consistency, the PreSAT criteria was not changed.

Training

All paramedics received education and skill training, which included sepsis identification, sterile blood culture collection, and the use of the Prehospital Sepsis Assessment Tool (PreSAT). Training involved sched-

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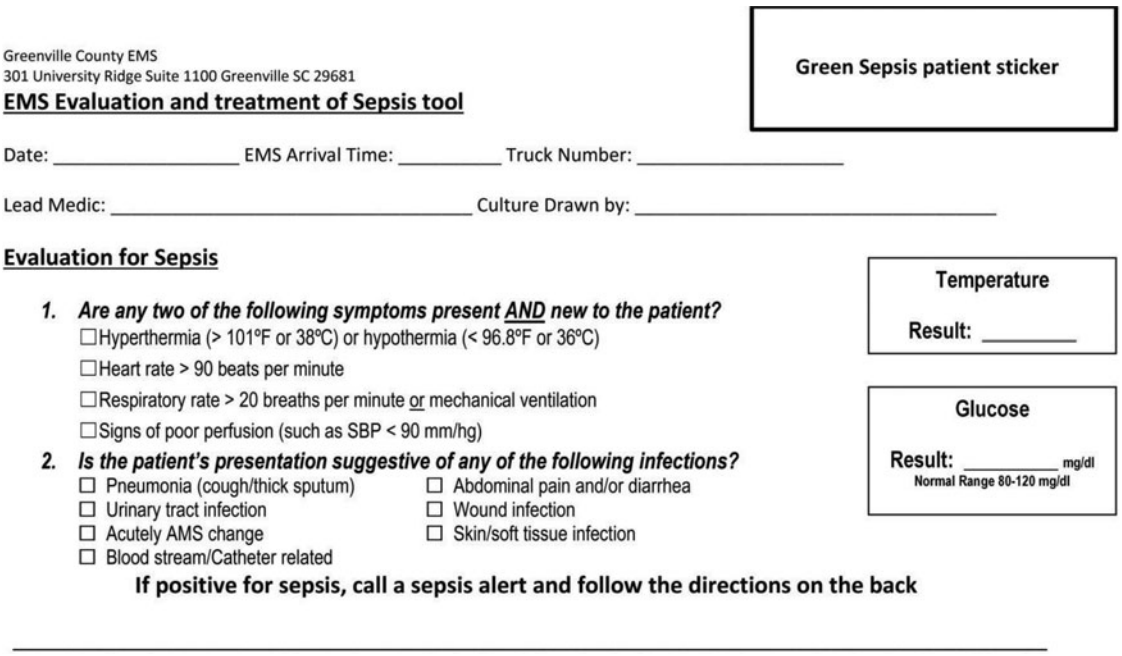

Greenville County EMS
301 University Ridge Suite 1100 Greenville SC 29681

EMS Evaluation and treatment of Sepsis tool

Green Sepsis patient sticker

Date: _____ EMS Arrival Time: _____ Truck Number: _____

Lead Medic: _____ Culture Drawn by: _____

Evaluation for Sepsis

1. ***Are any two of the following symptoms present AND new to the patient?***
   - ☐Hyperthermia (> 101°F or 38°C) or hypothermia (< 96.8°F or 36°C)
   - ☐Heart rate > 90 beats per minute
   - ☐Respiratory rate > 20 breaths per minute or mechanical ventilation
   - ☐Signs of poor perfusion (such as SBP < 90 mm/hg)
2. ***Is the patient's presentation suggestive of any of the following infections?***
   - ☐ Pneumonia (cough/thick sputum)
   - ☐ Urinary tract infection
   - ☐ Acutely AMS change
   - ☐ Blood stream/Catheter related
   - ☐ Abdominal pain and/or diarrhea
   - ☐ Wound infection
   - ☐ Skin/soft tissue infection

Temperature
Result: _____

Glucose
Result: _____ mg/dl
Normal Range 80-120 mg/dl

If positive for sepsis, call a sepsis alert and follow the directions on the back

FIGURE 1. Greenville County EMS prehospital sepsis assessment tool (PreSAT).

uled in-service training sessions for a total of 12 hours, which was divided equally into 4 hour sessions on didactic, simulation, and skills stations. Competency was evaluated by a passing score of 90% on written exam. Critical blood culture collection competency was evaluated by use of high fidelity simulation mannequin models. Remediation occurred for those individuals that failed initial competency evaluations until all providers achieved minimum passing requirements. All providers were found to be competent in the clinical protocol and aseptic blood culture collection prior to leaving their assigned training session.

Patient Care Protocol

A prehospital sepsis care protocol was developed in collaboration with an established EMS sepsis committee consisting of representatives from both hospital systems included in the study. Input was sought from specialists such as critical care, emergency medicine, pharmacy, and laboratory, who would have direct involvement in the care of sepsis patients after arrival at the receiving facility. The protocol and alert criteria created was aligned with the current in-hospital initial treatment protocols at both health systems. Criteria were focused narrowly to identify patients with a high likelihood of requiring the CMS Sepsis Core Measure bundle being acquired by the receiving hospital staff, thus a seamless transition of care after arrival in the ED. The goal was to determine if paramedics could safely and in reduced time begin the CMS Sepsis Core Measure bundle on "true positive" septic patients.

All adult patients evaluated by Paramedics that met two SIRS criteria, were evaluated using the Prehospital Sepsis Assessment Tool. Paramedics would initiate a Sepsis Alert if the above criteria were positive with a known or suspected source of infection. Paramedics would then gain intravenous access, obtain 1 set of anaerobic and aerobic blood cultures, and collect a venous blood sample for lactate analysis upon arrival to the hospital. Blood samples for lactate analysis were collected in blood collections tubes containing sodium fluoride and kept at room temperature during transport. No point of care blood testing by EMS was performed. Fluid resuscitation was then begun at 30 mL/kg for a total of 1000 mL of normal saline or arrival at the receiving hospital, which ever occurred first.

All patients were screened for allergy to Penicillin by self-reporting, healthcare records if from a skilled nursing facility or by internal EMS health records at time of care. Any patient with a reported or identified allergy to penicillin did not receive intravenous antibiotics. Penicillin allergy excluded a patient from receiving antibiotics only as all other sepsis care was provided.

All Sepsis Alert patients were transported to one of 4 receiving emergency departments operated by the 2 separate health systems. A sepsis kit was created which included chloroprep, blood culture bottles, and blood tubes for lactate collection. Intravenous Ceftriaxone 1 gram was administered for suspected pneumonia while Piperacillin/Tazobactam 3.375 Grams for all other potential sources of infection. Both antibiotics (ABX) were stored in the ambulance sepsis kit in

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powder form that was reconstituted at the time of administration by use of a point-of-care active minibag system. Antibiotics were administered intravenously via gravity by use of a 10 drop set over 20 minutes. The antibiotics were chosen for their broad spectrum activity, compliance with CMS core measures, and receiving hospital pharmacy predetermined community bacteria sensitivities. These antibiotics also represented the standard of care at both receiving hospital systems and were consistent with the in-hospital continuum of care.

In Hospital Care

Emergency Department and in hospital care was determined by the receiving clinician and was the current standard of care within each health system. Each transport destination had an in-hospital sepsis coordinator that performed daily reviews of all Sepsis Alert patients transported by EMS. This review also analyzed for adverse events from all prehospital treatments, signs of allergic reaction, and variance from final hospital diagnosis.

At the time of transfer from EMS to the Emergency Department, a written report was provided to the receiving nurse that included time of blood culture collection, total amount of Normal Saline administered and time and name of antibiotic administered. Blood work collected by Paramedics in the prehospital setting was sent to the in-hospital laboratory for analysis of blood cultures and serum lactate level. Antibiotics and normal saline boluses that were not completed prior to the arrival at the receiving facility were completed in the emergency department based on the in-hospital clinician's clinical judgement. Hospital care continued was individualized based upon further testing results and each hospital's standard of care.

Outcome Measures

Primary outcomes included agreement of paramedic identification with ICD 9 or 10 discharge diagnoses of sepsis, severe sepsis, and septic shock. Primary source of infection was retrieved from discharge diagnosis, and if not available was labeled as other. Standard hospital laboratory and infectious disease protocols determined the presence of blood culture growth, contamination, and match to EMS administered antibiotic. Blood culture contamination determination included gram staining and review of all other cultures obtained during the patient's hospital stay. This process was blinded to the location of the initial blood culture draw, EMS vs hospital, and was used to direct on going patient care. Venous serum lactate level, from blood drawn in the field or the emergency department, was used as the patient's initial serum lactate level.

The retrospective case series method of this study was not designed to capture data necessary for a sensitivity or specificity analysis of the Sepsis Alert Protocol. However, sepsis cases that were transported by EMS but not properly identified as such were monitored by each institution's Sepsis Coordinator and feedback given to the EMS crew.

Stepwise Implementation

A stepwise approach was used to incorporate the components of the CMS Sepsis core measure bundle into the prehospital setting. Each area of the bundle was evaluated consecutively in a way that would provide evidence for the next step. Step 1 included evidence of knowledge and skill competency of the PreSAT and treatment protocol. Step 2 evaluated paramedic accuracy of identifying a Sepsis Alert patient correctly and blood culture contamination rate for a period of four months. Step 3 added the prehospital administration of intravenous antibiotics, with continued evaluation of the step 2 outcome measures. Administration of ABX in the field occurred approximately 6 months after the initiation of the prehospital sepsis education program.

Statistical Analysis

Patient demographic data were gathered for descriptive statistical analysis with Excel spreadsheet (Microsoft, 2013). Outcomes are reported as frequency distributions.

RESULTS

During the 14 months of this study, 120 trained paramedics called 1,185 "Sepsis Alerts" on 57,828 of patients (Figure 2) (50.3% male, mean age 70) (Table 1). 762 (62.1%) patients were transported from a residence, 340 (28.7%) from a nursing facility, and 50 (4.2%) from a medical facility. Of these "Sepsis Alert" patients, 1,154 had complete ICD 9/10 discharge diagnosis data. The admitting diagnosis of sepsis overall was 73.5% (848/1154): Sepsis 50% (578/1154), Severe Sepsis 14.6% (169/1154), Septic Shock 8.9% (101/1154) (Figure 3). Emergency department standard of care for sepsis was continued in 94.1% (1115/1185) of EMS sepsis alert patients. Blood for lactate analysis was successfully collected and recorded in 702/848 patients with a sepsis diagnosis. The lactate level was greater than 4.0 mmol in 13% and greater than 2.2 in 46.1%. Non-Sepsis diagnoses included: other (140/1154), UTI (29/1154), and COPD (24/1154). The most common sources of infection were pulmonary (47.4%) and urinary (28.2%) (Table 2). 946 blood cultures were collected from 1,185 patients in the prehospital setting with a 95.04% (899/946) no contamination rate. Contamination was found in 4.96% (47/946) (Figure 4). 179 (18.9%) uncontaminated blood cultures were found to have positive growth with 720 (76.1%) having no

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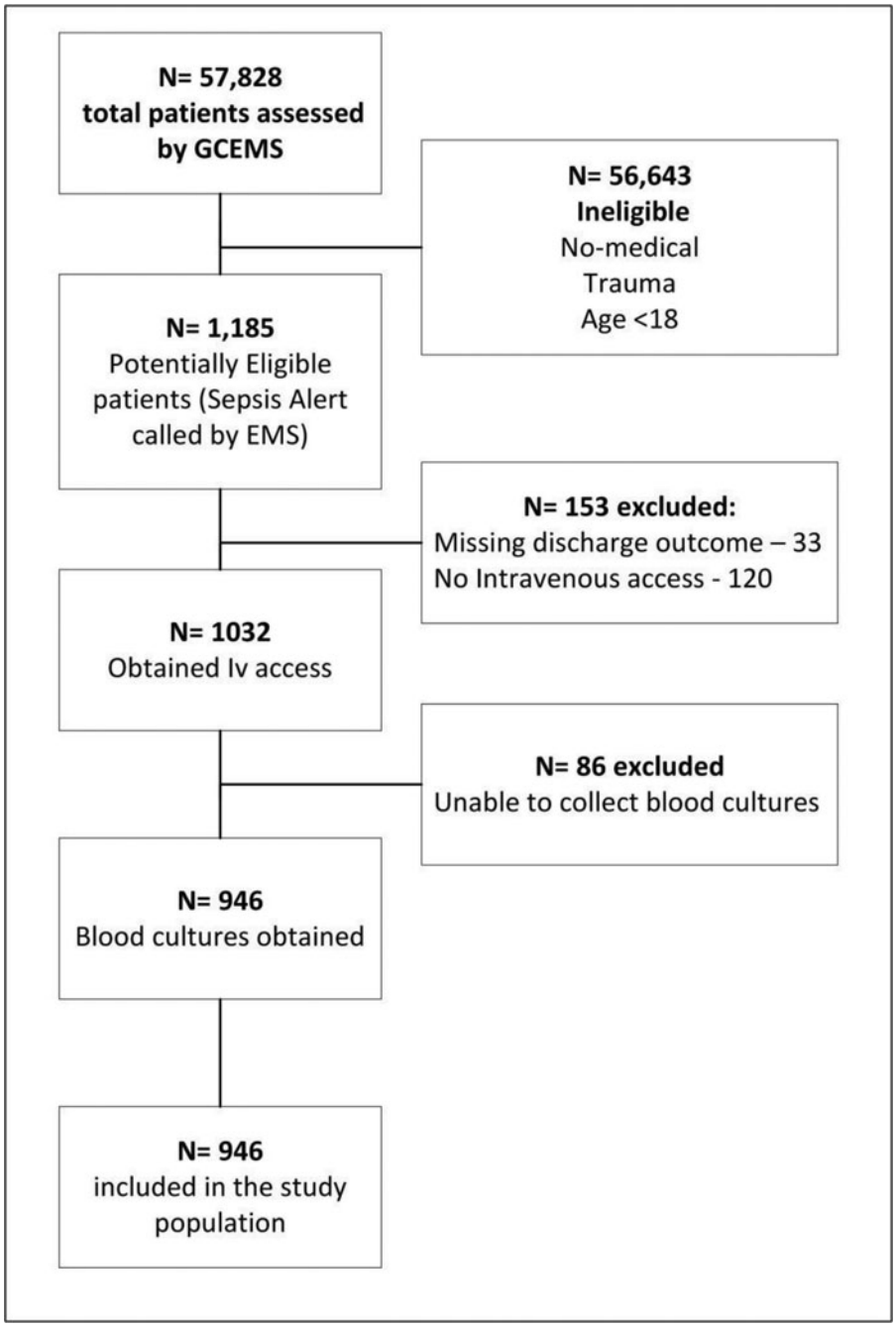

FIGURE 2. Study population.

growth. 571 patients received intravenous antibiotics once authorized on 16 February 2015. Antibiotics were administered in the presence of positive blood cultures in 72% (72/100) of patients (Figure 5). No adverse effects were reported after prehospital administration of antibiotics.

DISCUSSION

This retrospective case review demonstrates the implementation of the CMS sepsis core measure bundle in a single EMS system in the upstate of South Carolina. The patient demographics of this study population are similar to other prehospital sepsis research in regards to age, sex,[5,10] and dispatch location.[10] It appears that after demonstrated competency using the GCEMS Pre-SAT, Paramedics were able to accurately identify the septic patient. The GCEMS results vary from the recent work published by Barrett et al. and Van der Wekken et al., which showed that severe sepsis and septic shock was only identified 13.7% to 30% of the time by EMS providers who only received minimal or no initial sepsis education.[11,12] Guerra et al. also examined the ability of paramedics to accurately identify severe septic

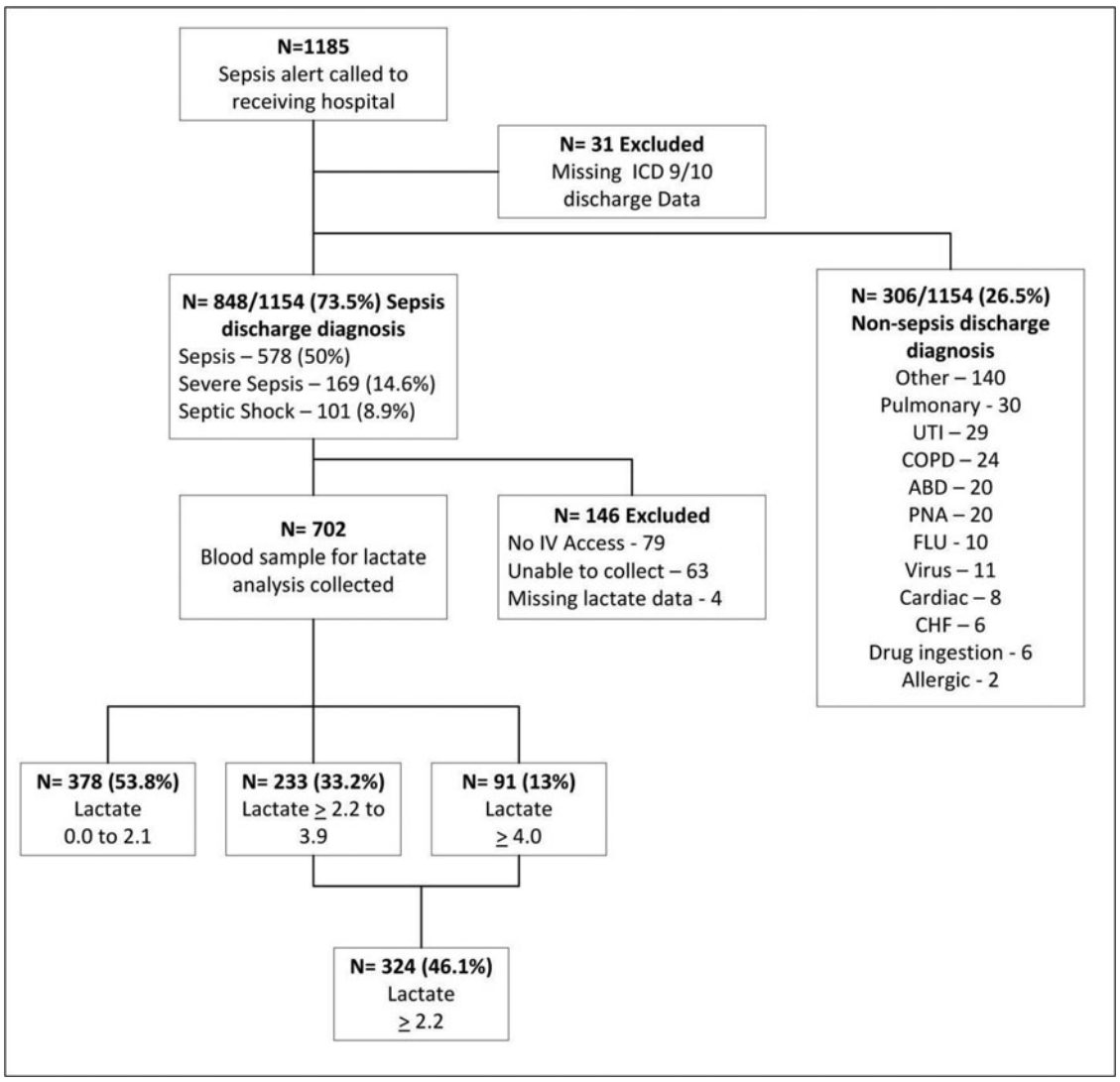

FIGURE 3. Discharge diagnosis/serum lactate.

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patients by use of a venous point-of-care lactate monitor.[13] They reported only 47.8% accuracy of prehospital point-of-care lactate to identify severe sepsis patients in the prehospital setting.[13] The EMS providers in our study were educated on serum lactate but a level was not incorporated into the PreSAT criteria, and was not used to guide treatment in the field. Additionally, the method used in our study for collection and transport of blood for lactate measurement has known stability concerns.[14] In recognition of this limitation blood collection tubes containing sodium fluoride/potassium oxalate were used in place of blood tubes containing heparin. Sodium fluoride/potassium oxalate has been shown to decrease glycolysis and provide better stability for serum lactate measurements (+1.5 mmol/L in 24 hours).[15] However, no attempt was made to confirm or validate the measured lactate level of the sample collected in our study. Yet, implementation of CMS core measures without concurrent knowledge of blood lactate level in the prehospital environment appears possible.

Initial blood culture acquisition is part of the CMS sepsis core measure bundle. This study focused on the initial set of field acquired blood cultures and the growth found in those cultures alone. It is understood that even in critically ill septic patients, positive blood culture growth is only found in 60% of patients.[16] Thus, the lack of positive blood cultures in septic patients does not necessarily infer improper acquisition technique. The rate of no growth in this study is 36.1% higher than commonly reported in the critical care literature.[16] The difference in our sample may be explained by the earlier acquisition of the blood cultures. More importantly, the Paramedic acquired blood culture contamination rate was 4.96%, which is comparable to established thresholds of hospital obtained blood cultures by non-phlebotomists.[17] It is understood that contaminated blood cultures can have a significant impact

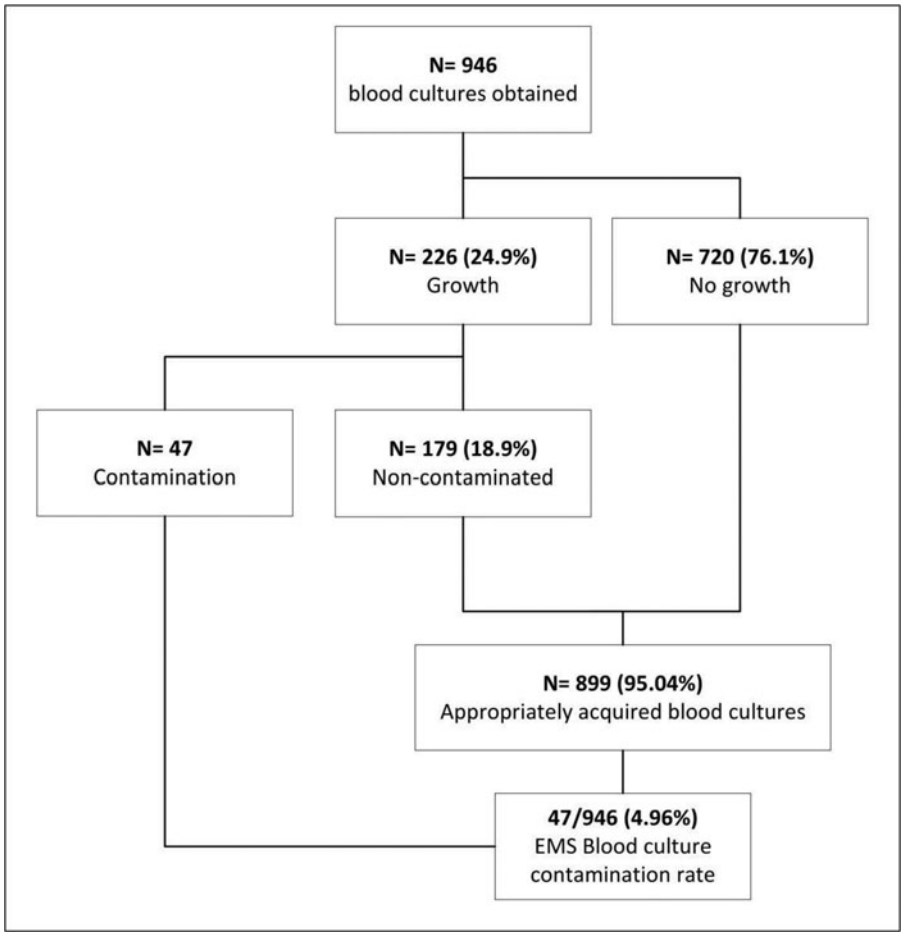

FIGURE 4. Blood culture collection and growth.

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on patient healthcare cost and unnecessary treatment[17]; therefore, it is for the EMS physician to decide if a 4.96% contamination rate is acceptable and equally important sustained. Ongoing monitoring of blood culture results was paramount for successful continuation of the GCEMS Sepsis Alert protocol.

Initiation of early empiric broad spectrum antibiotics is considered the standard of care according to surviving sepsis guidelines.[2] A total of 12.1% (Table 1) of patients had an alternative discharge diagnosis other than sepsis. Yet, hospital coordinators did not identify any adverse events from prehospital treatment such as fluid overload or allergic reaction. This may be related to the protocols exclusion of "allergy declared" patients. Of interest, blood culture growth was present in 22.2% of patients in which prehospital antibiotics were administered, with a drug match sensitivity of 72%. By design the prehospital administered antibiotics were chosen to begin treatment based on current guidelines in the receiving emergency department. The goal of this study was to begin the initial administration of a broad spectrum antibiotic as outlined by CMS. It was beyond the scope of this study to evaluate the change of antibiotic therapy or in-hospital care.

This evidence demonstrates that an EMS-driven CMS Sepsis Core Measure bundle in the prehospital setting is possible. Paramedics can acquire uncontaminated blood cultures, and safely administer antibiotics prior to hospital arrival among patients who were recognized as sepsis alerts. As hospitals systems search for ways to improve population health and adjust to CMS funding methods, EMS should be considered a vital partner in meeting CMS sepsis core bundle measures.

LIMITATIONS

This study's findings are not without limitations. First, this study was performed in a single EMS system with third service Paramedics who completed an extensive sepsis continuing education curriculum that included both didactic and skill competency testing. Second, as with all retrospective case series, missing data may have affected the findings. Missing data was minimized by the presence of dedicated hospital sepsis coordinators and EMS agency quality managers who reviewed all EMS runs and ED patient admissions on a daily basis. Since the number of missed cases of

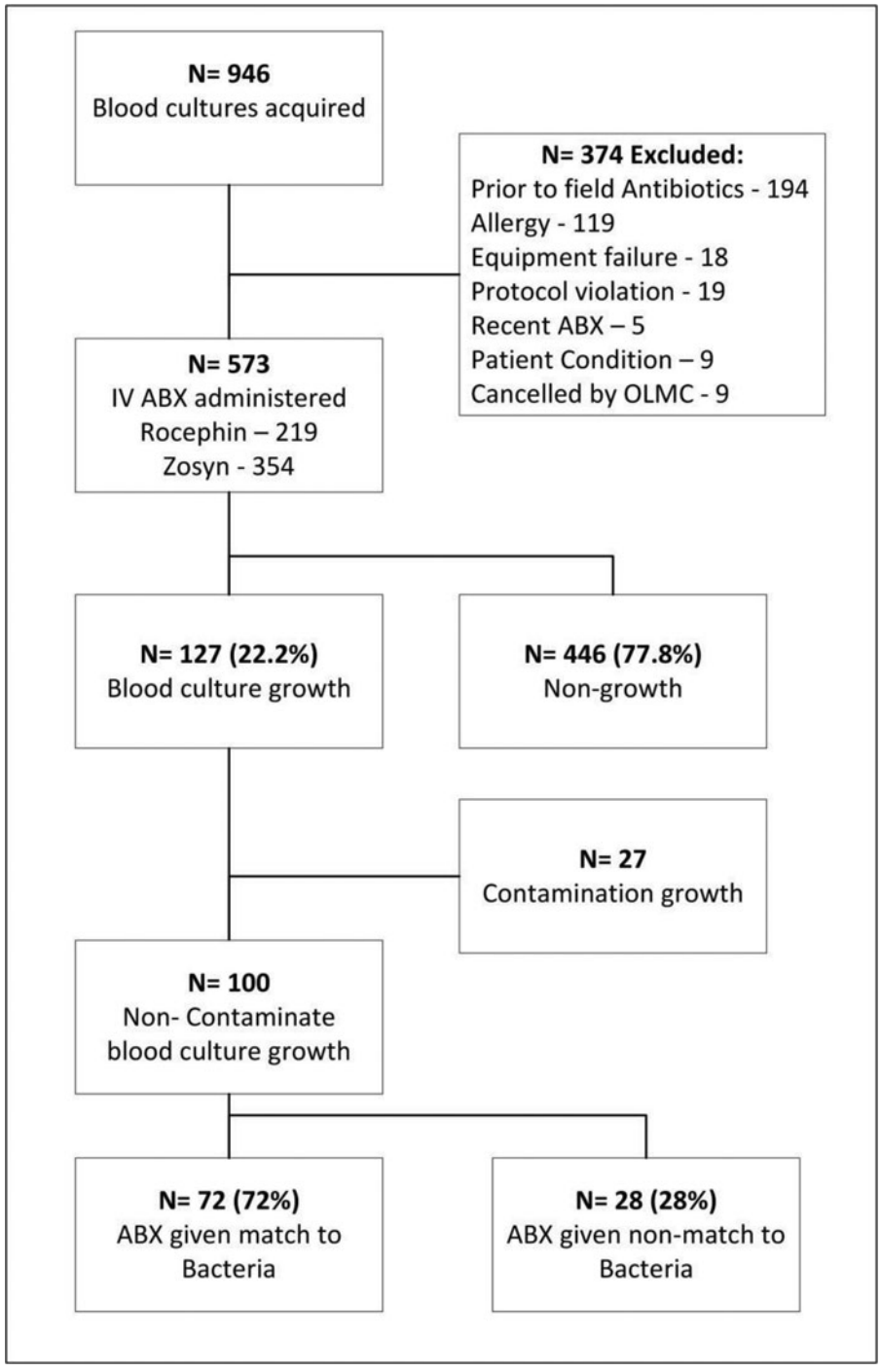

FIGURE 5. Protocol/antibiotic administration.

this retrospective study was not captured no sensitivity or specificity analyses were performed. Third, in-hospital care was not specified in this study. ED and hospital clinicians continued their respective institution's standard of care which may or may not have included changing antibiotic selection. Fourth, hospital laboratory analyses to determine lactate levels relied upon each receiving hospital's standards of practice and were not validated independently. Similarly, hospital laboratory labeling of blood culture contamination was determined by standard of practice at each receiving facility. This may influence reproducibility of our results in different geographical areas. Fifth, only cases with a hospital discharge diagnosis of sepsis, severe or septic shock were included in this analysis. The limitation of the use of ICD codes used to identify cases is well described.[18] Unrecognized cases of septic patients may have occurred, yet these are not believed

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TABLE 1. Demographics/sepsis alert

	n= 1185	
Age: range 18–101 years		mean 70.19
Sex:	Number	Percent
Male	596	50.3
Female	589	49.7
Receiving Location:		
Residence	763	62.1
Nursing Facility	340	28.7
Medical Office	50	4.2
Public	12	1
Shelter	8	< 1
Hotel/Motel	6	< 1
Business	5	< 1
Wilderness	1	< 1
SIRS Criteria:		
Heart Rate[a]	1090	91.9
Respiratory Rate[b]	1030	86.9
Temperature[c]	474	40
Hypotension[d]	133	11.2
Prehospital treatment:		
IV access	1032	87
Blood cultures	946	79.8
ABX admin.[e]	573	76.1
ED agreement with Sepsis Alert:[f]		
Yes	1115	94.1
No	54	4.6
Missing data	16	1.3
ICD 9/10 Discharge Diagnosis:		
Sepsis	578	50
Severe Sepsis	169	14.6
Septic Shock	101	8.9
Other	140	12.1
Pulmonary	30	2.6
UTI	29	2.5
COPD	24	2.1
GI	20	1.7
PNA	20	1.7
Flu	10	1
Virus	11	1
Cardiac	8	1
CHF	6	<1
Drug ingestion	6	<1
Allergic reaction	2	<1
Missing data	31	excluded

[a]Heart rate greater than 90
[b]Respiratory rate greater than 20 or mechanical ventilation
[c]Temperature greater than 101°F (38°C) or less than 96°F (36°C)
[d]Systolic blood pressure less than 90mmHg
[e]ABX administration began 4 months after the start of this study, 573/752 patients (IV access & blood cultures) during this time period.
[f]Two SIRS criteria and source of infection confirmed and sepsis treatement continued in the ED.

TABLE 2. Primary Source

Pulmonary	215
Urinary	128
Unknown	40
Skin	34
GI	23
Device	13
Other*	732

*Includes patients when source of infection was unavailable.

to more or less likely to influence blood culture contamination rates. Finally, this study was designed to determine if EMS personnel could initiate the CMS sepsis core bundle successfully, not patient outcomes. Although early antibiotic administration has demonstrated improved patient outcomes[19] and it appears that Paramedics can reliably identify septic patients and draw uncontaminated blood cultures, no inference on patient mortality can be made from this study. Other ongoing prospective randomized sepsis trials should be able to be better to measure patient centered outcomes.[20]

CONCLUSION

This study demonstrates the successful implementation of an EMS-driven CMS Sepsis Core Measure bundle in the prehospital setting. Paramedics can acquire uncontaminated blood cultures, and safely administer antibiotics prior to hospital arrival among patients who were recognized as sepsis alerts.

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