

Original Contributions



SEPSIS CORE MEASURES – ARE THEY WORTH THE COST?

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Abstract—Background: In 2015, the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission launched the sepsis core measures in an attempt to decrease sepsis morbidity and mortality. Recent studies call into question the multiple treatment measures in early goal-directed therapy on which these CMS measures are based. **Objectives:** The purpose of this study is to compare the utilization of resources due to the implementation of the sepsis core measures while examining whether complying with these treatment guidelines decreases patient mortality. **Methods:** Data were collected on patients suspected of sepsis in a suburban academic emergency department. These data were collected over the course of 3 consecutive years. The data collected included lactates, blood cultures, and antibiotics (vancomycin, piperacillin/tazobactam) ordered. The mortality rate of patients with a final diagnosis of sepsis present on arrival was calculated for a 3-month period of each year and compared. **Results:** There was no difference in the mortality rates of patients with sepsis across the 3 years. There was an increase in the amount of piperacillin/tazobactam and vancomycin administered. There was a significant increase in the number of lactates and blood cultures ordered per patient across all 3 years. **Conclusions:** There was no difference in the mortality rate of patients with a final diagnosis of sepsis. However, there was a significant increase in the utilization of resources to care for these patients. As a result of the overutilization of these resources, the cost for both patients and hospitals has increased without improvement in mortality. © 2018 Elsevier Inc. All rights reserved.

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INTRODUCTION

One of the highest causes of morbidity and mortality in hospitalized patients across the world is sepsis, a multifactorial manifestation of an infection that can progress to severe sepsis or septic shock (1,2). The incidence of sepsis has been approximated to be 6.1% to 7.3%, with a mortality rate ranging from 17.8% to 35%. Sepsis is costly as well, with treatment of sepsis accounting for approximately 5.2% (\$23.7 billion) of total hospital costs (2–6).

The standard treatment of severe sepsis and septic shock was called into question in the emergency department (ED) when early goal-directed therapy (EGDT) was found to decrease sepsis-related mortality, leading to new guidelines for the treatment of sepsis (7–10). The American College of Emergency Physicians updated treatment guidelines based on this single study in 2008 (9,10). The updated guidelines stressed the importance of EGDT during the first 6 h after the recognition of sepsis using vital sign abnormalities and laboratory values that are defined by the SIRS (systemic inflammatory response syndrome) criteria (11). The revised guidelines included specific interventions, or bundles, which were widely incorporated as a way to standardize EGDT across the country (12).

However, during 2014 and 2015 three large multi-center studies (ARISE, ProCESS, ProMISe) demonstrated that there was no statistical difference in morbidity and mortality between EGDT bundles and standard care of patients with sepsis (13–15). Despite this, in 2015 the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission launched the sepsis core measures, which mandated the ordering of specific laboratory tests (lactates and blood cultures) and treatment of patients with presumed sepsis with broad-spectrum antibiotics under a time constraint (16).

To be compliant with the guidelines, we hypothesized that physicians are ordering more tests and treatments when the improvement in patient mortality is in doubt. The purpose of this study was to compare whether there has been an increase in tests (lactates and blood cultures) ordered and antibiotic treatment administered for patients with presumed sepsis secondary to the CMS measures with no concurrent decrease in mortality. We hypothesized that an upsurge in antibiotics administered and laboratory utilization would coincide with the implementation of CMS core measures without significant improvement in mortality.

METHODS

Study Design

This was a retrospective cohort study of patients suspected of sepsis present on admission (POA) at an academic ED of a 646-bed suburban hospital with a census of > 91,000 visits per year. All physicians were educated extensively on the CMS sepsis core measures. Means of education included lectures at weekly conference, signs prominently displayed throughout the department, and monthly sepsis chart audits. Data were collected on ED patients for a corresponding 3-month period over the course of 3 consecutive years. This study was submitted for institutional review board approval, and was marked exempt by the committee at our institution. Our primary outcome measure was to determine if there has been an increase in antibiotics, lactates, and blood cultures ordered for patients with presumed sepsis. Our secondary outcome was to determine if there was an overall increase in costs for patients treated with presumed sepsis.

Study Protocol

Patient sepsis data were extracted from ED electronic medical records and from the hospital sepsis data registry, which is based on a positive SIRS criteria screen and possible infection. Both International Classification of Diseases (ICD)-9 and ICD-10 billing codes were utilized, as data collection occurred during the transition period to

ICD-10. Data analysis occurred from January through March over 3 consecutive years starting in 2015. These data collection dates were randomly selected prior to any collected data being analyzed to prevent selection bias in the results. Volumetric trends were analyzed for possible contributory impact on results. Data collected for 2015 were considered pre-CMS measures (baseline), and the years 2016 and 2017 were considered post-CMS measures. Patient mortality data were obtained from the University Health System Consortium, a national quality assurance review for sepsis measures data based on ICD-10 coding. Study variables analyzed included all ED iSTAT (Abbott, Princeton, NJ) lactates and blood cultures collected, as well as antibiotics administered. These study variables were selected due to the CMS mandates for sepsis identification and treatment.

Our study limited antibiotics administered to vancomycin and piperacillin/tazobactam, as this combination is the most common regimen for the treatment of sepsis of unknown etiology. The total doses of all intravenous antibiotics administered during the study time frame was obtained from Vizient (Irving, TX). The cost of acquisition for vancomycin and piperacillin/tazobactam was obtained from the hospital pharmacy. The cost of blood cultures and lactates was obtained from the hospital chargemaster. The mortality rates for patients with a diagnosis of sepsis POA was calculated for each study period and compared.

Data Analysis

Data were entered into a Microsoft Excel 10 (Microsoft Corporation, Redmond, WA) database and analyzed using STATGRAPHICS Centurion XVI Version 16.1.11 (Statpoint Technologies, Inc., The Plains, VA) and Analyze-It Software Version 2.24 Excel 12+ (Analyze-IT Software Ltd, Leeds, UK). Data were analyzed comparing parameters between control (pre-CMS, baseline) and study (post-CMS) groups. Chi-squared was used for nominal variable. Data are expressed with 95% confidence intervals (CI), with a significant p value being < 0.05.

RESULTS

The number of sepsis cases POA and the mortality rates for these patients can be seen in [Table 1](#). There was no significant difference in the mortality rates of patients with sepsis POA pre-CMS measures and post-CMS measures (2015: 13.98%, 95% CI 11.5–16.9, to 2016: 14.72%, 95% CI 12.1–17.8, $p = 0.72$; 2015 to 2017: 15.27%, 95% CI 12.6–18.4, $p = 0.53$). The change to ICD-10 billing codes occurred during data collection, however, the number of sepsis patients remained consistent with the change from ICD-9 to ICD-10.

Table 1. Sepsis POA Mortality Across a 3-Month Period Over 3 Consecutive Years

	2015 (Pre-CMS Baseline)	2016	2017
Sepsis cases POA	615	591	596
Deaths from sepsis (POA)	86	87	91
Mortality rate	13.98 (11.5–16.9)	14.72 (12.1–17.8) <i>p</i> = 0.72	15.27 (12.6–18.4) <i>p</i> = 0.53

Mortality rate data are expressed with 95% CI and *p* value.

POA = present on admission; CMS = Centers for Medicare and Medicaid Services.

The total ED patient volume during each 3-month period evaluated in this study is as follows: 21,615 in 2015, 23,402 in 2016, and 23,371 in 2017. There was noted to be an 8.27% increase in patient volume from 2015 to 2016, and 8.13% increase between 2015 and 2017. There was a 0.13% decrease in patient volume between 2016 and 2017.

There was a significant increase in the amount of piperacillin/tazobactam administered to patients with sepsis POA (2015: 660 total doses administered to ED patients, 1.07 administered per patient with final diagnosis of sepsis POA, 95% CI 1–1.2, and 2017: 823 total doses administered to ED patients, 1.38 doses administered per patient with final diagnosis of sepsis POA, 95% CI 1.3–1.5; *p* = 0.001); this correlates to a 24.7% increase in the amount of piperacillin/tazobactam administered from 2015 to 2017 (Figures 1A and 1B).

There was an increase in the amount of vancomycin administered (2015: 773 total doses administered to ED pa-

tients, 1.25 administered per patient with final diagnosis of sepsis POA, 95% CI 1.2–1.3; and 2017: 962 total doses administered, 1.61 administered per patient with final diagnosis of sepsis POA, 95% CI 1.5–1.7, *p* = 0.001); this correlates to a 24.5% increase in the amount of vancomycin administered from 2015 to 2017 (Figures 1A and 1B).

The overall intravenous antibiotic use at our institution was obtained from the pharmacy database and can be seen in Table 2. These values include all intravenous antibiotics administered throughout the hospital during the selected study periods. There was a 0.06% increase in total antibiotics administered (demonstrated as days of therapy per 1000 patient days) between 2015 and 2016. There was a 2.09% increase in antibiotic usage between 2015 and 2017.

There was a significant increase in the number of lactates ordered per patient (2015: 340 ordered, 0.55 ordered per patient with final diagnosis of sepsis POA, 95% CI 0.5–0.6, to 2016: 1950 ordered, 3.29 ordered per patient with final diagnosis of sepsis POA, 95% CI 3.2–3.4, *p* < 0.001; 2015 to 2017: 2969 ordered, 4.98 ordered per patient with final diagnosis of sepsis POA, 95% CI 4.8–5.2, *p* < 0.001); this correlates to a 773% increase in the number of lactates ordered pre- and post-CMS measures (Figures 2A and 2B).

There was a significant increase in the number of blood cultures ordered per patient (2015: 3032 ordered in the ED, 4.93 ordered per patient with sepsis POA, 95% CI 4.8–5.1, to 2017: 4287 ordered in the ED, 7.91 ordered per patient with sepsis POA, 95% CI 7–7.4, *p* < 0.001); this correlates to a 41.4% increase (Figures 3A and 3B).

The cost for each of the resources can be seen in Table 3.

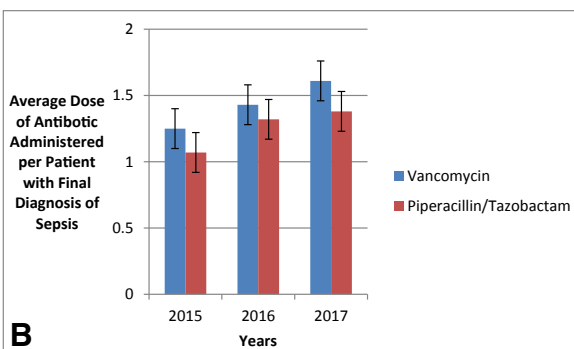
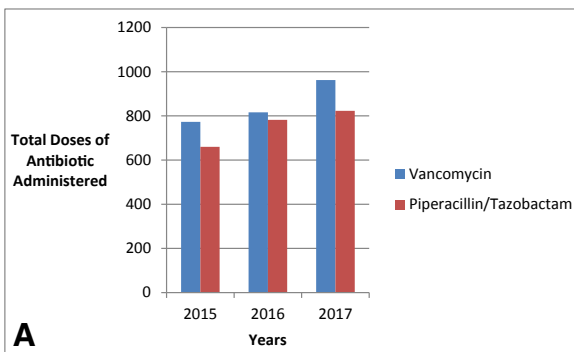


Figure 1. Antibiotics administered during the study period.

Table 2. Overall Institutional Antibiotic Use During Study Period

	DOT per 1000 Patient Days	% Increase from Pre-CMS Baseline
2015 (Pre-CMS baseline)	816.75	
2016	817.25	0.06%
2017	833.83	2.09%

Antibiotic use expressed as days of treatment (DOT) per 1000 patient days.

CMS = Centers for Medicare and Medicaid Services.

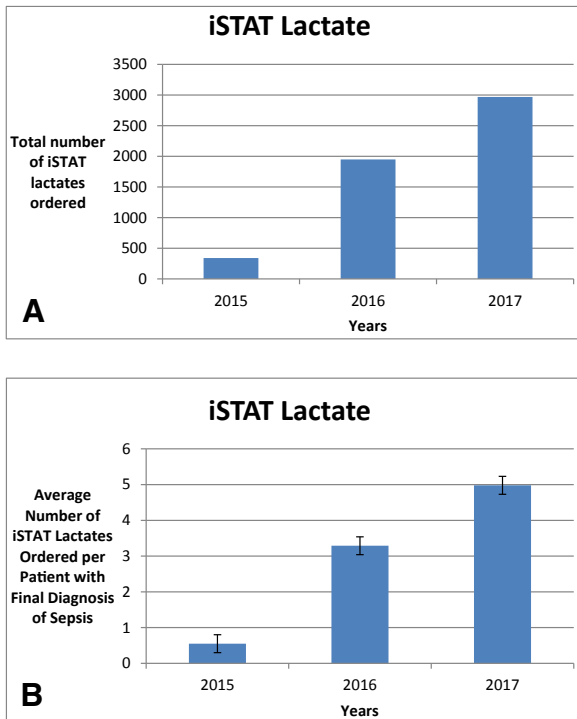


Figure 2. iSTAT lactates ordered during the study period.

DISCUSSION

In this study of ED patients with sepsis, there was no statistically significant difference in the mortality rate of patients with sepsis present on admission to the hospital

during a similar 3-month period of time over 3 consecutive years. Despite there being no difference in mortality for patients with sepsis, we noted a marked increase in the utilization of resources to be compliant with the CMS sepsis core measures in the ED. Of the measures we reviewed, the most pronounced increase in resource utilization was the ordering of iSTAT lactates, which increased 773% from 2015 to 2017. Treatment with vancomycin and piperacillin/tazobactam both increased approximately 25%. Although this study focused on only these two antibiotics, we did also demonstrate an overall increase in hospital antibiotic use by 2.09%. The increase in resource usage identified in this study far exceeds the increase in overall ED patients treated during this same time period. As a result, the cost of treating patients identified as possibly being septic has substantially increased despite the fact that these CMS measures do not improve patient mortality.

In addition to not improving patient mortality, the CMS measures may cause harm to those patients who are not septic, but are treated as such due to these measures and the overutilization of resources. Patients with certain vital sign abnormalities, such as a patient with a chronic obstructive pulmonary disease exacerbation that is tachycardic, tachypneic, and has an elevated lactate, would fall under the definition of SIRS and thus, physicians may feel pressure to treat them as having sepsis to comply with the CMS measures. The broad-spectrum antibiotics used to treat these patients may leave them open to developing pathology or infections secondary to these aggressive measures. One very prominent example of this is the development of *Clostridium difficile* infections after the administration of broad-spectrum antibiotics. The estimated cost to the health care system of *C. difficile* infections from 2005–2015 was found to be approximately \$6.3 billion dollars, with the mean cost per case approximately \$21,448 (17).

The cost of complying with sepsis core measures puts an unneeded pressure on the health care system. When a patient is admitted to the hospital with sepsis, the cost of their care is bundled—every intervention related to sepsis is billed at the same price regardless of the amount of diagnostic testing and antibiotics ordered. However, when a patient meets the designated SIRS criteria and is treated to comply with the CMS measures, but only requires outpatient observation, these patients are billed for each individual intervention. Although the approximate cost per intervention is identified in Table 2, hospitals may charge up to 10 to 20 times more than the noted prices when the interventions are not bundled. These prices also do not include what is charged for the administration of the antibiotics, i.v. access, or blood draws. This means that when patients present to the ED with two or more SIRS criteria and are treated according to the measures,

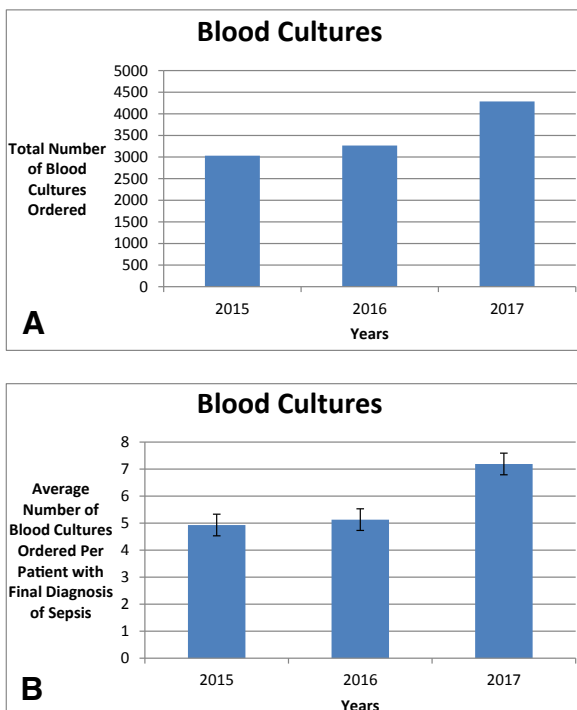


Figure 3. Blood cultures ordered during the study period.

Table 3. Cost of Resources Utilized for Treatment of Sepsis

Resource	Cost (Dollars)	Total Ordered in 2015	Total Ordered in 2017	Percent Increase from Pre-CMS to Post-CMS Measures	Approximate Additional Cost
Lactate (iSTAT)	\$9.00	340	2969	773%	\$23,661.00
Blood culture	\$8.00	3032	4287	41.40%	\$10,040.00
Piperacillin/tazobactam	\$13.75	660	823	24.70%	\$2241.25
Vancomycin	\$5.75	773	962	24.50%	\$1086.75

CMS = Centers for Medicare and Medicaid Services.

but then do not meet the inpatient admission criteria, they are responsible for paying a percentage of the cost of tests and treatments that may have been unnecessary.

Measures imposed on the health care system do not account for cost, and any measure put in place should be both cost effective and show a clinically significant difference in patient outcome (18). Despite there being no clear benefit in patient mortality when the sepsis core measures are followed, physicians and providers in the ED are expected to comply with these measures. As a result, the monetary cost of caring for these patients has substantially increased with no improvement in patient mortality. Instead of being beneficial and cost effective, these sepsis core measures may be doing more harm than good.

Limitations

There are limitations to this study. The exact cause of death for all the patients with sepsis POA was not identified, and it is possible some may have died from pathology not related to sepsis. In addition, iSTAT lactates and blood cultures are ordered for other patients in the ED, not just those identified as having sepsis. However, routine uses of lactates and blood cultures have not necessarily changed for other groups of patients that are presenting to the ED without sepsis pathology. We do acknowledge that there was an 8% increase in ED visits for this given time period from 2015 to 2016 and 2015 to 2017; however, given the dramatic increase in the utilization of these two resources after the implementation of the CMS measures, it is less likely that this increase was solely coincidental based on the increase in overall ED visits. For example, it is unlikely that an 8% increase in ED visits would result in a 773% increase in ED iSTAT lactates ordered.

Treatment of sepsis is not limited to only vancomycin and piperacillin/tazobactam, however, our study focused solely on the administration of these two antibiotics. Although this combination is the primary choice for treatment of patients with presumed sepsis with no definitive source, there are other antibiotic combinations that can be used in the treatment of these patients. Although we were able to demonstrate that there was an overall increase in antibiotics administered in our institution

during the identified study periods, we did not further delineate what percentage of the total antibiotics administered was solely in the ED. Further research could look more closely at all the possible intravenous antibiotics that could be utilized to treat sepsis, and to identify trends in certain antibiotic usage.

Although we were able to obtain the cost for each intervention explored in this study, the price provided is a gross underestimation of the charges and costs for the patient. When put in this perspective, the actual cost of sepsis is much greater than this research demonstrates.

Additional research should be performed to determine the true utility of these CMS sepsis core measures, and whether they are truly beneficial to patients with sepsis.

CONCLUSION

It was the hope that the implementation of the CMS sepsis core measures would decrease the mortality rate due to sepsis for patients in the United States. However, despite these new measures and an increased utilization of resources to diagnose and treat these patients, our study demonstrates that there is no statistically significant difference in sepsis-related mortality with a concurrent rise in health care costs.

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ARTICLE SUMMARY

1. Why is this topic important?

The identification and treatment of sepsis is extremely important for emergency physicians, given its high rate of morbidity and mortality for our patient population. The sepsis core measures currently dictate how we should be treating these patients, and it is important to determine if these measures are beneficial to patients and the health care system.

2. What does this study attempt to show?

This study attempts to show that the sepsis core measures that we are expected to follow may not improve patient mortality while concurrently increasing the utilization of resources required to stay compliant with these measures.

3. What are the key findings?

There was no significant improvement in patient mortality after the implementation of the sepsis core measures, but there was an increase in resource utilization (the amount of blood cultures, lactates, and broad-spectrum antibiotics ordered).

4. How is patient care impacted?

The current sepsis treatment guidelines we are expected to follow as emergency physicians may not be improving patient mortality and may, at the same time, be increasing resource utilization and overall health care costs.