INFECTIOUS DISEASE/BRIEF RESEARCH REPORT

Preliminary Performance on the New CMS Sepsis-1 National Quality Measure: Early Insights From the Emergency Quality Network (E-QUAL)

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Study objective: We describe current hospital-level performance for the Centers for Medicare & Medicaid Services' Severe Sepsis/Septic Shock Early Management Bundle (SEP-1) quality measure and qualitatively assess emergency department (ED) sepsis quality improvement best practice implementation.

Methods: Using a standardized Web-based submission portal, we surveyed quality improvement data from volunteer hospital-based EDs participating in the Emergency Quality Network Sepsis Initiative. Each hospital submitted preliminary SEP-1 local chart review data, using existing Centers for Medicare & Medicaid Services definitions. We report descriptive statistics of SEP-1 data availability and performance. The primary outcome for this study was SEP-1 bundle compliance, defined as the proportion of all severe sepsis and septic shock cases receiving all required bundle elements, and secondary outcomes included conditional compliance on reported SEP-1 numerator components and ED implementation of sepsis quality improvement best practices.

Results: A total of 50 EDs participated in the survey; 74% were nonteaching sites and 26% were affiliated with academic centers. Of all participating EDs, 80% were in regions with relatively high population density. The mean hospital SEP-1 bundle compliance was 54% (interquartile range 30% to 75%). Bundle compliance improved during fiscal year 2016 from 39% to 57%. Broad variation existed for each bundle component, with intravenous fluid resuscitation and repeated lactate bundle elements having the widest variation and largest gaps in quality. At least one consensus sepsis quality improvement best practice implementation occurred in 92% of participating sites.

Conclusion: Preliminary data on SEP-1 performance suggest wide hospital-level variation in performance, with modest improvement during the first year of data collection. [Ann Emerg Med. 2017; ■:1-6.]

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INTRODUCTION

Background and Importance

Sepsis affects more than 1.6 million hospitalized patients and results in more than 250,000 deaths every year in the United States. The emergency department (ED) serves as a primary site of initial identification and treatment of most sepsis patients and plays a central role in clinical trials and quality improvement efforts to improve sepsis outcomes. In October 2015, the Centers for Medicare & Medicaid Services (CMS) began collecting the first national quality measure of sepsis care for public reporting, the Severe Sepsis/ Septic Shock Early Management Bundle, commonly referred to as SEP-1. This measure triggered substantial debate during its first evaluation as part of the National Quality

Forum measure endorsement process and was ultimately approved after the publication of several large sepsis clinical trials prompted measure reevaluation and revision. 4-7 CMS later modified the measure specifications to operationalize its content for public reporting nationally, which again generated extensive discussion in regard to the validity and the burden of quality reporting. Since implementation, little has been discovered about achievement of SEP-1 benchmarks or variation in national performance to guide ED and hospital leaders or policymakers.

In October 2015, the American College of Emergency Physicians (ACEP) launched the Emergency Quality Network (E-QUAL) Sepsis Initiative as part of the CMS Transforming Clinical Practice Initiative, seeking to improve patient outcomes by enrolling EDs across the nation in a learning collaborative to improve the early

Editor's Capsule Summary

What is already known on this topic

The Centers for Medicare & Medicaid Services is collecting a new quality measure for public reporting, the Severe Sepsis/Septic Shock Early Management Bundle (SEP-1). Little is known about current performance to guide emergency departments (EDs) and policymakers.

What question this study addressed

Fifty EDs in an American College of Emergency Physicians–sponsored network reported performance for SEP-1 and assessed sepsis quality improvement practices.

What this study adds to our knowledge
Mean SEP-1 bundle compliance was 54% and
improved from 39% to 57% during 2016. Large
variation existed for each bundle component,
especially intravenous fluid resuscitation and repeated
lactate measurement.

How this is relevant to clinical practice EDs and policymakers now have baseline information to assess SEP-1 performance, demonstrating large variability among EDs.

identification, treatment, and reassessment of sepsis.⁸ As part of E-QUAL, the focused SEP-1 Benchmarking Challenge gathered sepsis quality data to provide early and real-time performance feedback at a national level.

Goals of This Investigation

We sought to describe the current hospital-level performance for CMS SEP-1, and we sought to qualitatively assess perceived best practices deployed by participants.

MATERIALS AND METHODS

Study Design and Setting

We surveyed quality improvement data from hospital-based EDs participating in the E-QUAL Sepsis Initiative. We administered the survey during an 8-week period between October and December 2016 to collect hospital data in regard to SEP-1 during the previous, and first, year of national data collection (October 1, 2015, through September 30, 2016). This quality improvement study did not include patient-level information and was not considered human subjects research.

Selection of Participants

In October 2016, we invited leaders from hospital-based EDs that indicated an interest in sepsis quality improvement to participate in the SEP-1 Benchmarking Challenge as an optional, complementary data benchmarking exercise of the E-QUAL Sepsis Initiative. EDs self-select to participate in the E-QUAL Sepsis Initiative and represent primarily community EDs already engaged in or seeking to start a local sepsis quality improvement program. Although invitations were sent only to the limited number of EDs enrolled in E-QUAL, participation was permitted for any ED in the United States interested in sepsis quality improvement that was aware of the SEP-1 Benchmarking Challenge and requested an invitation for inclusion. A total of 81% of SEP-1 Benchmarking Challenge participating EDs were also enrolled in the E-QUAL Sepsis Initiative.

Methods of Measurement

We collected data with a standardized Web-based submission portal. Demographic data included annual ED visit volume, hospital zip code, and hospital type (choosing among academic/emergency medicine residency, academic/ no emergency medicine residency, community, or community—critical access/rural). We classified each ED as rural or urban according to zip code metropolitan statistical area. We requested each ED to submit all preliminary data available on SEP-1 generated by hospital quality departments. These data are commonly abstracted by employed or contracted hospital quality improvement staff and subsequently shared with ED leadership for data validation and feedback.

Each hospital submitted preliminary SEP-1 data obtained from local chart review consistent with existing CMS definitions. Hospital personnel did not resample, rereview, or recalculate results for this study. Data included the total number of cases reviewed, total number excluded, and counts of severe sepsis and septic shock cases during the data collection period (denominator) and the counts of cases in which sepsis bundle compliance was achieved (numerator). Consistent with the CMS SEP-1 measure specifications, all data elements were collected at the hospital level, whether the bundle element was delivered in the ED or not. Consistent with CMS guidance, hospitals without sufficient monthly sepsis case counts could submit data quarterly. There were no missing data for primary outcome assessment including total cases reviewed, total cases excluded, the bundle numerator, and bundle denominator. Following CMS skip logic, we also collected SEP-1 numerator components specific to emergency care, including initial and repeated blood lactate testing,

obtainment of blood cultures, antibiotic administration, intravenous fluid administration, and vasopressors use. A total of 7 EDs could not submit numerator component data based on hospital quality reports and were excluded from the secondary analysis.

We also surveyed respondents in regard to implementation of 8 best practices for quality improvement identified by the clinical content, quality improvement, administrative experts composing the E-QUAL Sepsis Initiative Steering Committee. This survey reflects a single cross-sectional assessment of sepsis quality improvement programs at participating EDs in October 2016.

Outcome Measures

The primary outcome for this study was SEP-1 bundle compliance, defined as the proportion of all severe sepsis and septic shock cases receiving all required bundle elements. Severe sepsis and septic shock were defined consistent with the SEP-1 consensus definition. Secondary outcomes included conditional compliance on reported SEP-1 numerator components and ED implementation of sepsis quality improvement best practices. Conditional compliance reflects the proportion of severe sepsis and septic shock cases in which a numerator component was completed, if assessed, or conditional on previous numerator components' being completed. This method replicates the skip logic used in SEP-1.

Primary Data Analysis

We report descriptive statistics of SEP-1 data availability and SEP-1 performance. For the few EDs submitting quarterly data, we evenly divided the data between each month of the quarter for analyses. Consistent with CMS, we calculated the SEP-1 bundle compliance score for each hospital as the mean of the SEP-1 score of each month or quarter, depending on the format of data submitted. We used the same method to calculate compliance for numerator components reported by each ED. We used R (version 3.3.3; R Core Team, Vienna, Austria) for all analyses.

RESULTS

A total of 50 EDs, which care for an estimated 2 million patients annually, participated in the survey. Of all participating EDs, 74% were community nonteaching sites and 26% were affiliated with academic centers. Eighty percent of EDs were located in metropolitan statistical area regions with relatively high population density. Characteristics of EDs are shown in Table E1, available online at http://www.annemergmed.com.

The availability of preliminary SEP-1 performance data made available to EDs and subsequently submitted for the SEP-1 Benchmarking Challenge increased during the first year of public reporting from 695 to 1,530 cases per quarter (Figure E1, available online at http://www.annemergmed.com). Thirty-two (64%) EDs received data monthly and 18 (36%) received quarterly data from hospital quality departments.

The overall SEP-1 bundle compliance was 54%, with performance variation between hospitals ranging from 10% to 100% (interquartile range 30% to 75%) (Figure 1). The mean SEP-1 bundle compliance in community hospitals was 51% (interquartile range 31% to 75%), whereas the mean bundle compliance in teaching hospitals was 59% (interquartile range 29% to 85%). The overall reported SEP-1 bundle compliance improved during fiscal year 2016 from 39% to 57% (Figure E2, available online at http://www.annemergmed.com). Hospitals participating the ACEP E-QUAL network demonstrated an 18% increase in compliance during the study period.

Conditional performance on numerator components declined at each step of the SEP-1 measure. Broad variation existed for each bundle component, with intravenous fluid resuscitation and repeated lactate bundle elements having the widest variation and largest gaps in quality (Figure 2).

The survey of participating EDs revealed that almost all (92%) have implemented some form of nursing-initiated sepsis screening in the ED, whereas implementation of a dedicated sepsis or ED critical care team was least used (14% of participating EDs) (Table).

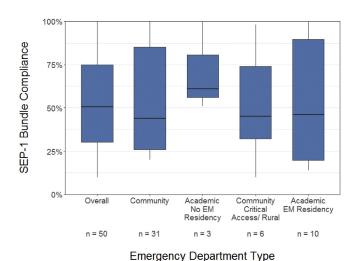
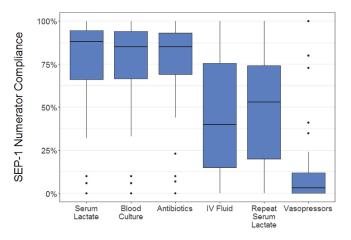


Figure 1. Hospital-level variation in SEP-1 bundle compliance by ED type.



Numerator Component

Figure 2. Hospital-level conditional performance on SEP-1 numerator components.

LIMITATIONS

Our observations have limitations with implications for sepsis quality improvement. First, the lack of patient-level data collection for this work may result in estimates that do not reflect actual sepsis care, but rather reflect performance on a national quality measure intended for public reporting. Our findings on SEP-1 performance are likely to carry more significance to policymakers and hospital executives seeking to interpret individual hospital scores in comparison to the national experience. Second, the skip logic of SEP-1 necessitates terminating evaluation of SEP-1 numerator components once a single numerator component is not met. This CMS requirement results in measure of conditional, as opposed to actual, compliance with each numerator component. Despite this limitation, we collected numerator components to mirror hospital feedback to EDs, and these results should be interpreted relative to one another as opposed to as accurate numeric estimates of hospital-level compliance with each sepsis bundle numerator element. EDs should locally develop quality dashboards that measure each bundle component

Table. Implementation of sepsis quality improvement best practices.

Proportion of EDs Implementing Each Intervention	Percentage	
Nursing sepsis screen	92	
Sepsis metrics data dashboard	73	
Electronic health record sepsis screen/alert	71	
Multidisciplinary sepsis team	67	
Reflex or automatic repeated lactate testing	67	
Code sepsis protocol and alert (similar to	38	
ST-segment elevation myocardial infarction)		
Use of point-of-care lactate testing in the ED	34	
Dedicated sepsis or ED critical care team	14	

on all patients with severe sepsis and septic shock or participate in new data registries such as the ACEP Clinical Emergency Data Registry that includes 5 electronic health record-based metrics of component compliance. Third, observed improvement in performance may have resulted from improvement in hospital or ED understanding and documentation to optimize measure performance as opposed to changes in care performance, otherwise commonly described as "gaming." Furthermore, CMS could improve the value of this quality measure for local quality improvement by both requiring data collection on each bundle element and removing data elements such as blood culture collection or specific reassessment measure (eg, skin examination, passive leg raise, vascular ultrasonographic measures) with limited evidence to support practice. Finally, our sample of 50 EDs reflects "early adopters" of the E-QUAL Sepsis Initiative, which is likely to reflect SEP-1 performance at hospitals most engaged in sepsis quality improvement. Whether these hospitals reflect higher or poorer performers is unknown.

DISCUSSION

Preliminary data on SEP-1 performance suggests wide hospital-level variation in performance, with modest improvements during the first year of data collection. This parallels similar improvements in quality observed for acute hospital care at the inception of public reporting for acute myocardial infarction. 11 Not surprisingly, our data confirm that septic shock bundle management elements known to face the strongest clinician skepticism or uncertainty, notably, mandated intravenous fluid resuscitation at 30 mL/kg and repeated lactate assessment, demonstrate the lowest performance and broadest hospital-level variation in conditional numerator component compliance. Furthermore, although our sample was limited to 50 EDs that self-selected to participate in a national sepsis quality improvement campaign, we still found consistent variation between different ED types, suggesting broad opportunities for future sepsis quality improvement and continued dissemination of the E-QUAL Sepsis Initiative resources.

Active local quality improvement programs can advance performance for acutely ill and injured patients, including those with sepsis. ¹² For successful SEP-1 compliance, quality improvement programs require multidisciplinary collaboration between intensivists, hospitalists, and emergency physicians, as well as cross-organizational collaboration between hospitals and EDs. Our data suggest that ED engagement in hospital sepsis quality improvement improved during the first year of SEP-1 data collection.

Although the results of audit and feedback on ED practice have been mixed, previous work shows that the

collection and review of data can drive improvement in quality measure performance both in the ED and as part of previous national quality campaigns for other time-sensitive illnesses such as acute myocardial infarction and stroke. ¹³⁻¹⁵ To optimize the effect of audit and feedback, the E-QUAL Sepsis Initiative sought to combine data already being collected locally in a manner that would provide EDs with the benchmarks necessary to contextualize their performance for both hospital administrators and clinicians. Our hope is that the value of collective benchmarking demonstrated by the SEP-1 Benchmarking Challenge will encourage EDs across the nation to join the E-QUAL for quality benchmarking purposes in addition to the financial incentives for joining and participating in the new CMS Quality Payment Program.

Our results reveal that although several best practices are widely used, such as nursing-driven sepsis screening, other consensus best practices identified by the E-QUAL Sepsis Steering Committee remain to be implemented, even among highly motivated EDs participating in the SEP-1 Benchmarking Challenge. For example, despite investments in electronic health records and national regulatory requirements for clinical decision support, we observed modest use of electronic health record alerts. This may reflect the lack of hospital support for ED information technology resources required to target high-yield areas of opportunity. In addition, best practices such as the creation of a "sepsis alert" protocol or sepsis or critical care ED team can be precluded by strained staffing or ED crowding. These barriers to best practice implementation transcend hospital type. Most EDs participating in E-QUAL are community based, and nearly one fifth are rurally located or based in critical-access hospitals. As leaders seek to continue improvements in sepsis care, garnering additional resources from hospitals and learning from the experience of other resource-constrained EDs are essential to improving care.

We conclude that early indicators of national performance on the CMS SEP-1 quality measure show wide variation, with less than half of patients receiving the entire sepsis bundle. Opportunity exists to improve collaboration between EDs and hospitals in sepsis quality improvement, including the implementation of best practices such as data benchmarking available through national initiatives.

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REFERENCES

- Elixhauser A, Friedman B, Stranges E. Statistical Brief #122—Septicemia in US Hospitals, 2009. Rockville, MD: Agency for Healthcare Research and Quality; 2011.
- Wang HE, Shapiro NI, Angus DC, et al. National estimates of severe sepsis in United States emergency departments. Crit Care Med. 2007;35:1928-1936.

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- Silverman M, Sverha JJ. Understanding the new SEP-1 sepsis rollout. Available at: http://epmonthly.com/article/understanding-the-new-sep-1-sepsis-rollout/. Accessed July 24, 2017.
- Aaronson EL, Filbin MR, Brown DF, et al. New mandated Centers for Medicare and Medicaid Services requirements for sepsis reporting: caution from the field. J Emerg Med. 2017;52:109-116.
- National Quality Forum. NQF revises sepsis measure. Available at: http://www.qualityforum.org/NQF_Revises_Sepsis_Measure. aspx. Accessed July 24, 2017.
- Faust JS, Weingart SD. The past, present, and future of the Centers for Medicare and Medicaid Services quality measure SEP-1: the early management bundle for severe sepsis/septic shock. *Emerg Med Clin North Am.* 2017;35:219-231.
- Mack R. Sepsis: the new core measure in 2016. Is your hospital ready? Available at: http://www.vbpmonitor.com/news/item/48-sepsis-the-new-core-measure-in-2016-is-your-hospital-ready. Accessed July 24, 2017.
- American College of Emergency Physicians. E-QUAL Network sepsis initiative. Available at: https://www.acep.org/Advocacy/E-QUAL-Network-Sepsis-Initiative/.
- Centers for Medicare & Medicaid Services; Joint Commission. Specifications manual for national hospital inpatient quality measures. Available at: https://www.jointcommission.org/

- specifications_manual_for_national_hospital_inpatient_quality_measures.aspx. Accessed July 24, 2017.
- American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Crit Care Med. 1992;20:864-874.
- Werner RM, Bradlow ET. Public reporting on hospital process improvements is linked to better patient outcomes. Health Aff (Millwood). 2010;29:1319-1324.
- Damiani E, Donati A, Serafini G, et al. Effect of performance improvement programs on compliance with sepsis bundles and mortality: a systematic review and meta-analysis of observational studies. PLoS One. 2015;10:e0125827.
- Bradley EH, Nallamothu BK, Herrin J, et al. National efforts to improve door-to-balloon time results from the Door-to-Balloon Alliance. J Am Coll Cardiol. 2009;54:2423-2429.
- Heidenreich PA, Zhao X, Hernandez AF, et al. Impact of an expanded hospital recognition program for stroke quality of care. J Am Heart Assoc. 2017;3:e000950.
- **15.** Le Grand Rogers R, Narvaez Y, Venkatesh AK, et al. Improving emergency physician performance using audit and feedback: a systematic review. *Am J Emerg Med*. 2015;33:1505-1514.

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Table E1. Hospital characteristics of SEP-1 Benchmarking Challenge EDs.

Characteristic	No.	%
Annual ED visit volume		
<20,000	8	16
20,000-39,999	9	18
40,000-59,999	14	28
60,000-79,999	10	20
>80,000	9	18
Hospital type		
Academic, emergency medicine residency	10	20
Academic, no emergency medicine residency	3	6
Community	31	62
Community, critical access/rural	6	12
Hospital location		
Northeast	20	40
Midwest	11	22
South	13	26
West	6	12
MSA status		
MSA	40	80
Non-MSA	10	20
MSA, Metropolitan statistical area.		

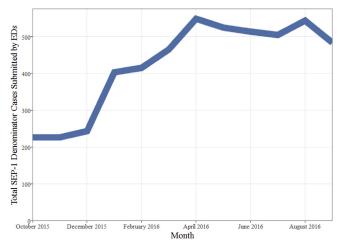


Figure E1. SEP-1 data availability for ED quality improvement over fiscal year 2016.

Table E2. CMS SEP-1 denominator cases reported per hospital for local quality improvement purposes by quarter.

	25th			75th		
Quarter	Mean	Min	Percentile	Median	Percentile	Max
October-December 2015	33	1	16	32	40	128
January-March 2016	43	2	19	32	47	236
April-June 2016	42	4	18	27	47	212
July-September 2016	43	6	18	30	52	139

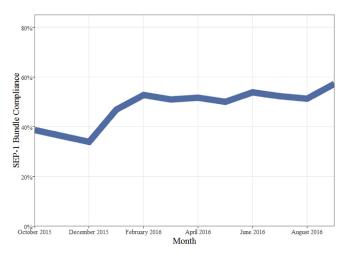


Figure E2. Mean SEP-1 bundle compliance over fiscal year 2016.