

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

Jeremy S. Faust, MD, MS^{a,*}, Scott D. Weingart, MD^b

KEYWORDS

- Sepsis • Severe sepsis • Septic shock • CMS • Core measures • Quality
- Early goal-directed therapy • Shared decision-making

KEY POINTS

- The Centers for Medicare and Medicaid Services have enacted an executive branch rule (quality measure) known as SEP-1 that mandates the administration of a bundle that carefully prescribes precisely how patients with severe sepsis and septic shock must be treated in the early phases.
- CMS measures are meant to reflect best evidence and consensus practices. The provisions of SEP-1, however, are highly controversial among sepsis experts.
- CMS quality measures can fall under hospital-compare or value-based purchasing regimes. SEP-1 is currently hospital-compare, meaning that individual cases are not reimbursed differently depending on adherence. Rather a hospital's overall adherence is compared with others and rated publically.
- The definitions for severe sepsis and septic shock used in SEP-1 are not the same as those used in the four major prospective sepsis trials on which the measure was supposedly based.
- Some of the provisions of SEP-1 may be harmful to certain patients. The inclusion and exclusion criteria are not the same as the major prospective trials that were relied on.

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^a Department of Emergency Medicine, Brigham and Women's Hospital, Harvard Medical School, 10 Vining Street, Boston, MA 02115, USA; ^b Division of Emergency Critical Care, Department of Emergency Medicine, Stony Brook Hospital, 101 Nicolls Road, Stony Brook, NY 11704, USA

* Corresponding author.

E-mail address: jfaust@gmail.com

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- The administrative burden of SEP-1 is unprecedented. To our knowledge, SEP-1 is the largest quality measure ever introduced by CMS by virtue of the number of required actions to achieve adherence.
- There are several contraindications to administering the SEP-1 bundle. We describe those and other approaches to avoid administering the provisions of SEP-1 to those who may be harmed by it.

INTRODUCTION

In October of 2015, the Centers for Medicare and Medicaid Services (CMS) enacted a new national quality measure on sepsis called the Early Management Bundle for Severe Sepsis/Septic Shock (SEP-1). SEP-1 was the end result of a colossal undertaking to standardize care for severe sepsis and septic shock regardless of the size of the emergency department (ED) where the patient is being treated. The final product deviates substantially from the original measure (stewardarded by Henry Ford Hospital in Detroit, initially led by early goal directed therapy [EGDT] pioneer Dr Emmanuel Rivers) and does not necessarily follow the best current evidence available. Nevertheless, a thorough understanding of SEP-1 is crucial because all hospitals and emergency providers (EPs) will soon be accountable for meeting the requirements of this measure.

In brief, SEP-1 is the nation's first, and by law only, national quality measure on early management of sepsis care. It mandates that patients meeting criteria for SEP-1 must receive the bundle of care stipulated in the CMS Specifications Manual for National Hospital Inpatient Quality Measures. This measure applies to all US EDs.

This article provides a thorough review of the SEP-1 measure and all of the potential implications it may have on sepsis care provided in the United States. The measure has stirred up a great deal of controversy, which is not surprising given the complex nature of the sepsis disease process. The major concern is that hospitals may focus their attention on meeting compliance with the requirements of SEP-1 and consequently may stray from key patient-centered outcomes in sepsis. There is no question that the SEP-1 bundle is burdensome and much more complex than any previous core measure set forth by CMS. It remains to be seen if this will improve care of the patient with severe sepsis and septic shock in the ED.

A BRIEF HISTORY OF SEP-1

In 2003, the Surviving Sepsis Campaign (SSC) initiated work on guidelines on bundled sepsis care. The SSC group focused its efforts on ways to implement the tenets of the recently published EGDT trial, which focused on an aggressive, invasive, and protocol driven resuscitation of patients with severe sepsis and septic shock. The SSC was also cognizant of the recent Institute of Medicine report *To Err is Human*, which highlighted the impact of iatrogenic error in medicine. The best available evidence at the time suggested that EGDT and bundled care uniquely decreased mortality from severe sepsis and septic shock.

In 2008, Henry Ford Hospital and Dr Rivers succeeded in getting the National Quality Forum (NQF) to endorse their proposed sepsis bundle and embrace EGDT (NQF #0500).¹ Although the NQF is a feeder for CMS measures, a CMS measure did not materialize after initial NQF endorsement. In 2013, in accordance with new provisions of the Affordable Care Act, the Department of Health and Human Services identified sepsis as a priority for the following measure cycle. Simultaneously, NQF #0500

came up for its scheduled maintenance review. The new iteration of NQF #0500 now required the invasive components (eg, central venous catheter, arterial line) of EGDT and measurement of central venous pressure and central venous oxygen saturation. However, because the three largest sepsis trials ever were underway (ProCESS, ProMiSe, and ARISE), it was decided that an ad hoc committee would reconvene when new data emerged.

When the landmark ProCESS trial demonstrated that EGDT performed no better than both a less-invasive protocol and usual care (ie, physician discretion determines care), the committee was forced to reconsider the portions of NQF that involved the most invasive portions of EGDT. Because CMS would likely now adopt the re-endorsed NQF #0500, many members of the NQF committee believed that it might be untenable to assess quality of sepsis care by provider compliance with EGDT. The NQF patient safety committee voted 11 to 7 to remove the invasive requirements of EGDT from the measure. Ultimately, the expensive and invasive aspects of the protocol (eg, central venous catheter, central venous pressure monitoring, and central venous oxygen saturation monitoring) were now optional. EPs were also given the option of documenting certain physical examination features or cardiac ultrasound in place of these modalities. This compromise was approved and thus NQF #0500 was finally re-endorsed in September of 2014 (20 days before the ARISE trial confirmed the ProCESS findings).

NQF #0500 was thus cleared for final approval by CMS. However, to turn NQF #0500 into a measure that could be implemented, CMS subcontracted Mathematica Policy Research group and Tellegen to turn the measure into the specification manual and the data dictionary needed for future chart reviewers to assess adherence. The result was a 51-page specification manual accompanied by a 393-page guide. Within these documents lie the keys to understanding and implementing SEP-1 (version 5.1, which we use for this article, is the latest version available, for use July–December, 2016).

WHERE ARE THE TEETH?

CMS quality measures are federal regulations, enacted under the Department of Health and Human Services. The teeth of quality measure enforcement may be tied to either hospital-compare or value-based purchasing regimes. In hospital-compare, a hospital's overall adherence to CMS measures is reported and compared with other hospitals. However, it is the Joint Commission that carries the genuine threat to hospitals not complying with CMS measures at stipulated thresholds. If a Joint Commission survey of a hospital exposes poor compliance to CMS measures, that hospital risks losing its accreditation. Therefore, adherence to CMS measures is compulsory under threat of loss of accreditation, under a hospital-compare regime.

After a CMS measure has been in use for some time, it may also be used for value-based purchasing. In value-based purchasing, Medicare and/or Medicaid reimbursement for sepsis cases is directly tied to rates of measure adherence, even on a case-by-case basis. Therefore, if a patient's case qualifies for that measure, the hospital's adherence would determine whether or not the hospital would be reimbursed for that care. Currently, SEP-1 is a hospital-compare measure. It may become a part of value-based purchasing in fiscal year 2017 to 2018.

The metric of interest to CMS for SEP-1 is adherence to the measure, not mortality or other patient-centered outcomes. That is because it is an a priori assumption that adherence to the quality measure improves mortality. This assumption is derived from the lengthy process before measure approval, which includes a rigorous testing regime during NQF measure development.

If the measure development process is flawed, there is no immediate recourse after a measure has been endorsed by the NQF or adopted by CMS and the Department of Health and Human Services. However, in a process somewhat analogous to a phase IV clinical trial, CMS measures, like all federal regulations, are also eventually subject to retrospective review. These reviews often lead to changes in, and in some cases the repealing of, CMS measures. SEP-1 has not yet come up for such review.

WHAT IS SEP-1 AND WHICH PATIENTS MUST RECEIVE ITS PROVISIONS?

The language that CMS uses for inclusion and exclusion criteria for measure applications is worth reviewing. Because such measures are designed to assess overall hospital performance by way of adherence, CMS thinks in terms of statistics. Thus, “numerators” are the patients to whom providers/hospitals have “correctly” applied a measure, whereas “denominators” are the patients that CMS deems should have had the measure applied to them. The definitions of these populations are termed numerator statements and denominator statements. For SEP-1, the denominator statement therefore identifies the pool of patients who should have received the CMS sepsis bundle, whereas the numerator represents those who actually received it and had it properly documented.

The debate over which patients should be in the denominator group and what actions must be taken for the patient to be counted in the numerator, is the crucial focus for debate on sepsis care, and in any CMS measure (**Boxes 1 and 2**).

The SEP-1 numerator statement is the number of patients from the denominator population who had all of the actions in **Box 2** completed and documented properly. Because there are provisions for both severe sepsis and septic shock, there are two separate “clocks” in this measure. This means that there are interventions for patients that must be completed within 3 hours of presentation of severe sepsis. However, if septic shock is noted later, a separate “shock clock” is started. For interventions that must be completed within 3 hours of presentation of septic shock, it is the shock clock that must be used. This means that if severe sepsis was detected at 1 PM, the 3-hour bundle for severe sepsis would be due at 4 PM. If septic shock was detected

Box 1

CMS SEP-1 inclusion and exclusion criteria

Inclusion criteria (denominator statement)

Discharge age >17 and any of the following diagnoses:

- International Classification of Diseases-10-CM principal or other diagnosis code of sepsis
- Severe sepsis (CMS version only, see **Box 3**)
- Septic shock (CMS version only, see **Box 3**)

Exclusion criteria

- Comfort care within 3 hours of presentation for severe sepsis or 6 hours for septic shock
- Administrative contraindication to care (eg, patient refusals)
- Length of stay >120 days
- Transfer in from another acute care facility (see **Box 2**)
- Patients with severe sepsis who expire within 3 hours of presentation
- Patients with septic shock who expire within 6 hours of presentation
- Patients receiving intravenous antibiotics >24 hours before presentation of severe sepsis

Box 2**CMS SEP-1 required actions for included patients (numerator statements)***CMS Sep-1 Severe Sepsis Requirements*

Must meet all of within 3 hours of presentation:

- Initial lactate level measurement
- Broad-spectrum or other antibiotics administered
- Blood cultures drawn BEFORE antibiotics

And within 6 hours of presentation of severe sepsis:

- Repeat lactate level measurement (if initial elevated)

CMS Sep-1 Septic Shock Requirements

All must receive within 3 hours if septic shock present:

- Resuscitation with 30 mL/kg crystalloid fluids

If hypotension persists after fluid administration must receive within 6 hours of presentation:
Vasopressors

If hypotension persists after fluids or initial lactate ≥ 4 mmol/L must receive within 6 hours of presentation:

Repeat volume status and tissue perfusion assessment via:

- A focused examination including vital signs, cardiopulmonary examination, capillary refill, peripheral pulse evaluation, and skin examination
- OR

Any two of the following four:

- Central venous pressure measurement
- Central venous oxygen measurement
- Bedside cardiovascular ultrasound
- Passive leg raise or fluid challenge

at 2:30 PM, the 3-hour bundle for septic shock would be due at 5:30 PM, and the 6-hour bundle at 8:30 PM (for an excellent graphic representation, see Ref.²).

Certain patients may be excluded from the denominator. When a permitted reason has been documented as to why a patient with a chart coded to have severe sepsis or septic shock diagnoses did not receive the appropriated SEP-1 bundle interventions, the case is not scored (ie, does not count in the hospital's statistics). That said, a permitted reason that is not properly documented does in fact count in the aggregate metrics. Thus, the case counts against a hospital's statistics for adherence if the exclusion criteria are not properly documented. Patients who may be excluded are outlined in **Box 1**.

Receiving credit for adherence to SEP-1 depends on four things: (1) performance of all the required actions, (2) correct documentation of these actions, (3) proper documentation of patients with permissible exclusion from the denominator, and (4) chart abstractors being able to find and interpret all of this documentation. Because SEP-1 is a composite measure, all of the intervention outlines must completed for a case to pass the measure and count favorably on hospital compare metrics. It is then up to chart abstractors and their hospitals to report the aggregate rate of adherence to CMS. This must all be done manually, because there are no software applications available for this bundle.

THE TROUBLE WITH COMPOSITE MEASURES AND POTENTIAL LEGAL IMPLICATIONS

Composite measures require perfect adherence for hospitals to be scored as compliant in each case. SEP-1 requires documentation of adherence to an astounding

141 specific actions or variables. These variables are represented by 20 separate flow-charts with multiple decision points within each tree. If an EP fails to perform or correctly document adherence to a single variable, the entire case is considered to be noncompliant (ie, “Rejected.”) Proponents of protocolized care see this as vital, because strictly obeying such checklists is precisely what they believe reduces error and improves outcomes. Looking at this from a different perspective, if there is failure to document or perform even the smallest required variable, the EP no longer has any incentive to continue to adhere to or document adherence to the remainder of the measure, because the EP has already “failed” to comply. Alternatively, if measure adherence were to be changed and defined as, for example, greater than 90% adherence to the defined variables, one deviation from the protocol would not be akin to the falling house of cards.

To give a sense of how complex and potentially confusing this process is, consider the decision tree on only the *very first* of the 141 variable items of SEP-1. The abstractor judging measure adherence must first evaluate whether the patient was received from another hospital or an ambulatory surgical center. If the patient was received by an outside hospital or ambulatory surgical center, SEP-1 does not apply and the case is scored as “not in measure population.” Such a case is not processed and the EP and that hospital need not have adhered to SEP-1. However, if documentation of a transfer was not properly completed, the case not only counts but is immediately scored as nonadherent. But it is not that simple, because some types of transfers exclude patients from SEP-1, whereas others do not (**Box 3**).

Thus, if a patient was not a transfer (or if it was either unclear if the patient was a transfer), the abstractor must progress from variable #1 to variable #2 of SEP-1. This process occurs for each of the 141 variables. Because SEP-1 has never actually been tested from an administrative standpoint, it is unclear what average rates of adherence to this measure will turn out to be nationally. We suspect the rates will be low. Although we do not believe that the measure is intentionally abstruse, the

Box 3

Inclusion and exclusion criteria of transfers for CMS SEP-1

Transfers included (CMS SEP-1 measure applies)

- Urgent care center
- Psychiatric or rehabilitation units (only if part of your hospital)
- Dialysis centers (with some exceptions)
- Same-day surgery centers within your hospital
- Any clinic
- Any skilled nursing facility

Transfers excluded (CMS SEP-1 measure does not apply)

- Patients coming from long-term acute care (not nursing homes)
- Any acute rehabilitation
- Any outside psychiatric hospital
- Cardiac catheterization laboratory (from an outside hospital)
- Same-day surgery (from an outside hospital)
- Patients brought to the ED as part of a mass casualty

process of turning a complicated algorithm on sepsis management into discrete data points that are adjudicated by nonphysician abstractors makes this sort of complexity inevitable.

In fact, the administrative burden that we have already alluded to may now pose a threat to the legality of SEP-1. Under Executive Order 13,563 (section 6), signed by President Obama in 2011, such agencies as CMS are required to create and implement an ongoing Retrospective Analyses of Existing Rules, with a particular eye toward rules that are determined to be “excessively burdensome.” When such rules are identified, CMS is legally obligated to “modify, streamline, expand, or repeal them in accordance with what has been learned.” Simply complying with the chart abstraction aspects of SEP-1 alone may be a practical impossibility and thus render this measure unworkable. This is especially true given how broad the inclusion population for SEP-1 is (ie, the expanded definition of severe sepsis that the NQF used for this measure, discussed later). For context, we must note that not all CMS measures are quite so burdensome, including even some controversial ones. For example, the newly adapted CMS measure on thrombolytic therapy administration for acute stroke (CMS measure STK-4), contains only 18 variables for abstraction, in comparison with the 141 variables required in SEP-1. Moreover, the burden of having to perform the SEP-1 measure on patients whom an EP believes may be hurt by its provisions (eg, the requirement of giving broad-spectrum intravenous antibiotics to a patient whose suspected source of severe sepsis is *Clostridium difficile*) is not a typical posture in other CMS measures. The STK-4 measure maintenance is guided by the Joint Commission’s Stroke Measure Maintenance Technical Advisory Panel and this measure allows EPs to invoke clinical judgment to exclude patients from the measure. All that is required is an EP to document a reason for not initiating intravenous thrombolytics. Currently, no such provision exists for SEP-1 where an EP may determine a patient should be excluded from the measure.

CRITICISMS OF SEP-1

Because CMS is the single largest payer for health care in the United States, assessing and encouraging quality care seems like a logical endeavor.³ CMS quality measures are the prime mechanism for this. Thus, it would seem reasonable that a CMS measure should be the result of settled science. In the case of SEP-1, however, numerous aspects of the measure do not logically follow what the literature suggests is best practice for care in severe sepsis and septic shock.

Consider a comparison with another CMS measure, AMI-1. AMI-1 is instructive for the quality of underlying research and the lower administrative and safety burden it places on EPs and hospitals. AMI-1 measures the percentage of patients presenting with acute myocardial infarction who received aspirin within 24 hours of presenting to the hospital. The only data element that must be reached for a patient to be successfully counted in the CMS numerator is “Was aspirin received within 24 hours before or 24 hours after hospital arrival?” The allowable answers are yes or no. The SEP-1 numerator, by contrast, contains 59 such elements (from which the previously mentioned 141 variables are derived). AMI-1 contains several permitted exclusion criteria and assesses adherence to a treatment with a well-established number needed to treat for mortality that comes from a study that will likely never be repeated.⁴

Conversely, SEP-1 does not reflect the best evidence in management of early severe sepsis and septic shock. This fact led the SEP-1 measure stewards to publicly consider withdrawing the entire measure after the ProCESS trial came out. At that

time, Dr Sean Townsend (writing for the stewards) suggested waiting for the results of ProMISe and ARISE. He and others believed that ProMISe and ARISE might contradict ProCESS and thus EGDT would be retained in SEP-1.^{5,6} If those trials confirmed ProCESS, the NQF committee would then need to determine whether to reject the entire measure. Despite this, the committee decided against waiting, and a compromise was made. This was fortuitous for the stewards because, ultimately, the two remaining trials showed no mortality benefit for bundled sepsis care. By confirming the findings of the ProCESS trial, a contradiction now existed for the data brought to the NQF at the time of re-endorsement of NQF #0500.⁷ In sum, SEP-1 is the antithesis of CMS core measure AMI-1. AMI-1 has a foundation in high-quality literature demonstrating significant patient benefit and the measure is exceptionally straightforward and it is reasonable to expect hospitals of any size to comply with this measure. SEP-1, conversely, is exceptionally complex and as it is currently written, does not follow the best available evidence and it may not result in the overall CMS goal of improved patient outcomes.

One of the major criticisms for SEP-1 involves the definition of severe sepsis they opted to endorse and enforce. There are, to our knowledge, at least five definitions of severe sepsis that one might have selected from the past 25 years. First, there is the Society of Critical Care Medicine (SCCM)/1992 guideline, which defined severe sepsis as “sepsis associated with organ dysfunction, hypoperfusion abnormality, or sepsis-induced hypotension. Hypoperfusion abnormalities include lactic acidosis, oliguria, and acute alteration of mental status.”⁸ At that time, no other specific laboratory abnormalities were required, although the use of multiple organ disease scoring was seen as a prognostic tool.^{8,9} For all intents and purposes, Rivers and colleagues¹⁰ proposed the second definition of severe sepsis in their landmark EGDT trial as follows: two of four systemic inflammatory response syndrome criteria, suspicion of infectious etiology, and an initial blood lactate concentration greater than or equal to 4 mmol/L. The third option for a severe sepsis definition is the SCCM definition from 2001 to 2003.¹¹⁻¹³ In this definition, several upper-limit-of-normal parameters for organ dysfunction were proposed, to our knowledge, for the first time. For example, a sepsis-attributed rise in creatinine of 0.5 mg/dL was considered a sign of organ dysfunction. By 2012, the fourth severe sepsis definition was offered by the SSC and they stated that severe sepsis was met if a patient had sepsis plus one of nine qualifiers of end-organ damage (eg, elevated creatinine, thrombocytopenia, hypoxia, hypotension).^{13,14} The authors of the 2012 SSC guideline cite the 2001 to 2003 definitions of severe sepsis as a source for their nine qualifiers of end-organ damage. However, it is not clear that there was a solid literature basis for these specific criteria or the cutoffs (eg, platelets <100,000 μ L, creatinine >2.0 mg/dL). Nevertheless, these qualifiers were adopted by NQF #0500 and ultimately the SEP-1 measure (**Box 4**). Finally, there is the 2016 SCCM/European Society of Intensive Care Medicine consensus definitions, which have removed the term “severe sepsis” entirely.¹⁵

Unfortunately the NQF #0500 and now CMS SEP-1 definition of severe sepsis was never studied as part of River’s EGDT trial or the ARISE, ProMISe, or ProCESS trials. These trials used a lactate greater than 4 mmol/L as the inclusion criteria for patients enrolled with severe sepsis. Conversely, the SEP-1 inclusion of a lactate greater than 2 mmol/L in the severe sepsis cohort is not consistent with the best prospective evidence available today.

A major concern regarding the severe sepsis definition of SEP-1 is the potential for excessive use of broad-spectrum antibiotics. As the measure stands, broad-spectrum antibiotics must be given within 3 hours of patient presentation if a patient has a lactate greater than 2 mmol/L (or any one of the other severe sepsis qualifiers). Although there is evidence to show benefit of early antibiotics in patients with septic shock, there is

Box 4**CMS SEP-1 definitions of severe sepsis (and upper limits of normal for organ failure) and septic shock***Severe Sepsis*

Documentation of suspected or "possible" source of infection

AND

≥2 systemic inflammatory response syndrome manifestations

AND

Organ dysfunction evidenced by any one of the following:

Systolic blood pressure <90 OR mean arterial pressure <65, OR a systolic blood pressure decrease of more than 40 mm Hg

Acute respiratory failure as evidenced by a new need for invasive or noninvasive mechanical ventilation

Creatinine >2.0 OR urine output <0.5 mL/kg/hour for 2 hours

Bilirubin >2 mg/dL

Platelet count <100,000

International normalized ratio >1.5 or activated partial thromboplastin time >60 seconds (nonanticoagulated patient)

Lactate >2 mmol/L

Septic Shock

Documentation of severe sepsis present

AND

Hypotension persists in hour after the fluid bolus as evidenced by:

Systolic blood pressure <90 OR mean arterial pressure <65, OR a systolic blood pressure decrease of more than 40 mm Hg.

OR

Tissue hypoperfusion present by initial lactate level ≥4 mmol/L

only one lower quality study to demonstrate benefit of early administration of antibiotics for severe sepsis.^{14–18} This is the crux of the major complaint about SEP-1 from the Infectious Diseases Society of America (IDSA). They, along with other organizations, believe that the current SEP-1 inclusion criteria will lead to antibiotic shortages and increased drug-resistant organisms. Furthermore, the IDSA and other organizations have registered on-record dissents that there are no exclusion criteria for suspected *C difficile* as the source of severe sepsis or septic shock. Treating undifferentiated severe sepsis with broad-spectrum intravenous antibiotics is a known cause and exacerbating factor for *C difficile*. Although the latest version of SEP-1 addresses this concern, the new requirement demands laboratory-confirmed proof of *C difficile*, which is often impossible in the ED and SEP-1-imposed timeframe. The IDSA further noted an objection because the chart of approved broad-spectrum antibiotics was developed after NQF endorsement (ie, During CMS development of the specification manual) and thus there was never a comment period for the antibiotic specifications in the measure (the required CMS comment period came after NQF endorsement but before CMS released its manual containing the list of approved antibiotics). In sum, the IDSA believes that SEP-1 represents a large threat to antibiotic stewardship.

As we have alluded, septic shock has also been redefined in NQF #0500 and thus in CMS SEP-1. Our main concern is that an initial lactate of greater than 4 mmol/L has, since EGDT, defined severe sepsis, not septic shock. This matters because patients with septic shock are subjected to a more aggressive bundle in SEP-1. We are

unaware of any randomized controlled trials that used these definitions. Thus, this bundle seems to widen the denominator without evidence of benefit.

Box 5 outlines some suggested changes (author recommendations) to improve SEP-1. These suggestions would help bring SEP-1 more in line with the 2016 SCCM/European Society of Intensive Care Medicine consensus definitions of sepsis and septic shock. Furthermore, these changes would bring SEP-1 closer in line with current best evidence by limiting the interventions to only evidence-based ones and by excluding patients excluded in the previous high-quality studies on which the measure relies.

APPLYING SEP-1 TO PATIENTS WHO MIGHT BE HARMED BY IT

Some patients are excluded from the measure and thus their sepsis cases are not to be scored. Such cases do not count against EPs and hospitals, if a permitted exclusion criterion is properly documented. However, the permissible exclusion criteria for SEP-1 are narrow (see **Box 1**). It seems logical to permit an EP to document that their clinical judgment suggests that a patient should not be included in the SEP-1 protocol. However, the current measure does not afford EPs this autonomy, a point of significant contention for many. For many EPs, this alone renders the current measure untenable given the complexity of sepsis.

One potential opportunity for improvement is to involve the patient in a shared decision-making model especially in situations where harm may be done by the SEP-1 measure. Shared decision-making is one of modernity's most ethical responses to the paternalism that plagued medicine of the past. For example, a patient's refusal to receive any portion of the protocol qualifies as a permissible administrative contraindication to the protocol (although the most recent iteration of the measure has some exceptions to this). Does a patient with severe systolic dysfunction or end-stage renal disease realize that 30 mL/kg may not be appropriate when considering these comorbid conditions if they would otherwise qualify for the SEP-1 measure? Why not engage the patient in a shared-decision making model so the patient may be educated on the risk of fluid overload with the aggressive fluid resuscitation regime of SEP-1. Although physicians should not use the patient "opt-out" as a means to avoid the SEP-1 measure uniformly, there are circumstances where the potential for harm mandates that the physician consider the benefits and risks to protocolized care for the individual patient.

Box 5

Recommendations for bringing CMS SEP-1 consistent with best evidence

Limit inclusion criteria to severe sepsis and septic shock studied in EGDT, ProCESS, ProMISE, and ARISE

Exclude patients who were excluded in EGDT and subsequent trials

Eliminate the requirement to draw blood cultures

Limit the antibiotic requirement within 3 hours to the new definition of septic shock

Keep the 20–30 mL/kg of fluid for the CMS patients with septic shock

Allow clinicians to document why particular patients should be permitted to be excluded from fluid intervention (eg, presence of ventricular assist device, exceedingly low cardiac ejection fraction)

Keep the vasopressors for patients with persistent hypotension after fluid resuscitation

Eliminate the focused re-examination

Furthermore, we also notice that among the permitted exclusion criteria for severe sepsis and septic shock is the “directive for comfort care.” A note that the EP has “discussed comfort care with family on arrival prior to onset of septic shock” is a permitted exclusion. Thus, the patient or family need not have decided on comfort care. Rather, a documentation of a discussion of comfort care suffices for exclusion. This is, of course, in addition to other allowable documentation, such as noting that the family or patient requests comfort measures only, an order exists for hospice evaluation or consultation, or wording that states “comfort measures only recommendation” in the provider documentation.

SUMMARY

Every EP and hospital throughout the country will be held accountable for SEP-1 and as such, a thorough knowledge of this measure is imperative. Each CMS core measure is designed to improve patient care and allow patients some reassurance that common disease processes, such as sepsis, will be treated within parameters of accepted standard care at any size hospital in this country. However, sepsis is perhaps the most difficult disease process encountered in emergency medicine and thus it is not surprising that a core measure on sepsis is extraordinarily complex and potentially counterproductive to providers’ efforts to optimally care for the sickest patients with sepsis. That said, according to CMS, new versions of SEP-1 are released every 6 months and it is possible that future changes to the measure may be significant. In the meantime, each provider and hospital has to be careful that their efforts to satisfy SEP-1 do not adversely impact patient outcomes in sepsis.

Those interested in checking on revisions to SEP-1 and future directions of this measure can check: <https://www.qualitynet.org/dcs/ContentServer?c=Page&page name=QnetPublic%2FPAGE%2FQnetTier2&cid=1141662756099>.

WHERE TO GET FURTHER INFORMATION

Because transparency in government regulations is required, CMS must provide a public forum for answers to questions in addition to the required comment periods during measure development at the NQF. Several administrative and clinical questions are answered at <https://cms-ip.custhelp.com/> (found under the “Hospital Inpatient Measures and Data Element Abstraction” tab). Additionally, anyone can posit a question and expect an answer. Other helpful resources include the following:

- SEP-1 Fact Sheet (CMS publication): http://www.mhanet.com/mhaimages/Sepsis_FactSheet.pdf (or Google “Fact Sheet SEP-1: Early Management Bundle).
- SEP-1 Frequently Asked Questions (CMS publication): http://www.mhanet.com/mhaimages/Sepsis_FAQ.pdf (or Google “Frequently Asked Questions SEP-1: Early Management Bundle).
- CMS SEP-1 Specifications Manual: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPAGE%2FQnetTier2&cid=1141662756099>
- Department of Health and Human Services Regulations Toolkit: <http://www.hhs.gov/regulations/regulations-toolkit/index.html#additional>
- CMS Pre-Rule Making Process (as required under the Affordable Care Act): <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html>
- Executive Order 13,563 (President Barack Obama): <https://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>

- Press with Two Clocks Scheme: <https://prezi.com/1qp7kbctjnqi/sep-1-cms-sepsis-core-measure/>

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