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**Citation:**

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(1):219-231.

**Question:**

What are the origin, the specifics, the implications and the future of the recently enacted CMS quality measure for early sepsis care?

**Introduction:**

EM Clinics of North America publishes quarterly review articles on a central topic. This issue reviews current concepts and controversies in early sepsis management. This specific article reviews the origin, requirements and controversies of the relatively recently enacted CMS quality measure for early sepsis care.

“SEP-1” was released in October 2015 as the new and only quality measure on sepsis from the Centers for Medicare and Medicaid Services (CMS). It was largely based on the concept of the “sepsis resuscitation bundle” that originated from the 2001 Rivers study on “Early Goal Directed Therapy” (EGDT) and was further championed by the Surviving Sepsis Campaign (SSC). SSC guidelines were first published in 2004 and have been renewed every four years since then. The most recent SSC guidelines from 2016 are pending publication in March 2017 and are therefore not yet part of the SEP-1 standards. Similarly, the newer definitions of sepsis described in the Feb 2016 JAMA article by the “Sepsis 3” task force, which include items such as the use of “SOFA” and “qSOFA”, are not a significant part of the SEP-1 framework.

Of note, quality measures are updated every six months, and the original SEP-1 framework has been adjusted based on the three recent landmark sepsis trials published in 2014 and 2015. The ProCESS, ProMISe and ARISE trials all demonstrated non-inferiority of “usual care” compared with the EGDT pathway, specifically excluding invasive measures such as central line placement and use of the EGDT derived protocol driven resuscitation. As a result, the final SEP-1 measure made these EGDT provisions optional while focusing its requirements on the other more established concepts of modern sepsis care, such as early antibiotics and fluids.

As with other CMS quality measures, a hospital’s adherence to SEP-1 standards is reported and compared to other hospitals. Moreover, a hospital risks loss of accreditation from the Joint Commission for poor compliance. Eventually, CMS compensation for individual patients can be directly tied to adherence on a case-by-case basis.

**Key SEP-1 Definitions, Criteria and Requirements:**

“Severe sepsis”	Suspected infection + SIRS (x2) + organ dysfunction (defined by one of the following): -SBP <90, MAP <65, SBP down 40 -Acute resp failure requiring NIPPV or mechanical ventilation -Creat 2.0, UOP <0.5 cc/kg/hr for 2 hours -Bilirubin >2 -Platelets <100k
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	-INR >1.5, PTT>60s - <b>Lactate &gt;2</b>
“Septic shock”	Hypotension or tissue hypoperfusion 1 hour after fluid bolus: - <b>Lactate &gt;4</b> OR -SBP <90, MAP <65, SBP down 40
Inclusion criteria	- Adults with severe sepsis or septic shock
Exclusion criteria	- Patient refusal - Transfer from another “acute care facility” - Mass casualty - IV ABx >24 hours before presentation (severe sepsis) - Death, comfort care or discussion about comfort care within 3 hours (severe sepsis) or 6 hours (septic shock)
Requirements within 3 hours	- Initial lactate - Antibiotics - Fluid bolus 30 cc/kg (septic shock)
Requirements within 6 hours	- Repeat lactate (if initially elevated) - Vasopressors (septic shock, refractory to fluids) - “Repeat volume assessment” (septic shock, see below)
General requirements:	- Blood cultures before antibiotics
“Repeat volume assessment”	-Physical exam (including VS, heart, lungs, CR, pulses, skin) OR -Fluid responsiveness indices (CVP, SCVO <sub>2</sub> , bedside ultrasound, passive leg raise or fluid challenge)

### **Discussion:**

The purpose of SEP-1 has been to standardize early sepsis care, a colossal undertaking given the complexity of sepsis management. This fact is highlighted by the 393 page guide which details the 141 variables that must all be documented for a case to be considered compliant. This can be contrasted with 18 variables for thrombolytics in CVA, or with a single variable for “AMI-1”, which simply looks at whether or not aspirin was given within 24 hours of an AMI. In fact, when CMS performs its required “Retrospective Analysis” of SEP-1 in the coming years, it may be determined that SEP-1 is not legal if it is deemed “excessively burdensome”.

While the origins of SEP-1 are evidence based, the final product deviates substantially from the original measure and does not necessarily follow best current evidence. For example, SEP-1 uses a lactate cutoff of 2 for the “severe sepsis” requirements, while the major sepsis studies (e.g. EGDT, ProCESS) used a Lactate cutoff of 4. And while there is quality evidence of mortality benefit for early use of broad spectrum antibiotics in septic shock, there is only one lower quality study demonstrating benefit of early antibiotics in severe sepsis. In fact, IDSA is one of several organizations who have publically dissented to the SEP-1 requirements as they believe SEP-1 represents a large threat to antibiotic stewardship. Similarly, the requirement to always obtain blood cultures prior to initiation of antibiotics, even if it delays treatment, is not based on sound evidence.

Most importantly, SEP-1 does not allow the emergency physician to exclude patients based on clinical judgment, such as in cases of acute pulmonary edema. The absence of appropriate exclusion criteria is another way that SEP-1 deviates from the evidence. The only ways around this issue would be for the physician to document patient refusal based on shared decision making or in cases where the physician is able to document a discussion about comfort care.

**Conclusion:**

Every hospital and EP will be held accountable for adherence to SEP-1 when it comes to CMS patients. Given the difficulty and heterogeneity of sepsis management, it is not surprising that a quality measure could be excessively complex and even counterproductive to the physician's efforts to optimally care for the sickest patients with sepsis. Fortunately, it is possible that future updates to SEP-1 and the required retrospective review may alleviate some of the key controversies and administrative burden. In the meantime, each provider and hospital should be careful that adherence to the SEP-1 requirements do not adversely affect individual patient care.

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