

Sepsis and CMS

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Sepsis is the physiologic response to a systemic infection. Since the concept of Early Goal Directed Therapy (EGDT) was introduced by Rivers in 2001, sepsis has gained considerable notoriety. There have been many attempts to optimize care for patients with a systemic response to infection. While some studies have looked at optimizing therapies, the “Sepsis – 3:

The Third International Consensus Definitions for Sepsis and Septic Shock,” which was presented at the 45th Annual SCCM Critical Care Congress in 2016 attempted to redefine sepsis and its categories.¹

Sepsis holds a high mortality when not properly treated. This mortality can be reduced with early intervention. In the U.S. in the early 1990s, sepsis, severe sepsis, and septic shock cases exceeded 750,000 per year with mortality averaging 28%, 50%, and 80% respectively.² In 1997, Rivers felt that this set of patients were either identified too late, or did not receive aggressive care. In 2001, Rivers et al., introduced EGDT, an algorithmic approach for the treatment of severe sepsis and septic shock. Results were significant with absolute mortality reductions of 15.9% and 12.6% at 28 and 60 days respectively.³ From that moment, sepsis began to be recognized as a time sensitive disease. In 2002, the Surviving Sepsis Campaign (SSC) was initiated with goals of building awareness and improving diagnosis to define appropriate treatment bundles. Subsequently, hospitals created rapid detection initiatives and early sepsis screening, which led to increased incidence, namely due to increased recognition.

Prompt identification of patients who warrant early intervention is a difficult task. Since the EGDT paper was published, early antibiotics have become a crucial step in the algorithm. Kumar et al. showed that for every hour without antibiotics, sepsis related mortality increased by 7.6%.⁴ Aggressive fluid resuscitation is now another mainstay of treatment. Recent new evidence including the most recent sepsis trilogy, the ProCESS, ARISE, ProMISE trials, compared the new standard care to EGDT and showed no difference and declared EGDT ineffective.^{5,6,7} They reported an unadjusted mortality between 19-30%. The sepsis trilogy standard group is an example of how medical knowledge penetrates among physicians. It takes an average of 13-19 years for 90% of physicians to adopt pivotal clinical evidence.⁸ Now, 14 years after Rivers first described EGDT and after multiple SSC guidelines, it can be stated that the current standard care is not the same as it was prior to 2001. With greater recognition, a new concern is proper resource allocation. Now the difficulty is determining which patients need these early interventions.

Rivers et al. and the SSC used systemic inflammatory response syndrome (SIRS) criteria with suspected or known infection as the inclusion criteria. The sensitivity of SIRS ranges from 69-93% with a specificity nearing 35%.^{9,10,11,12} Despite a low specificity, the positive predictive value (PPV) of SIRS is close to 90.⁹ Comparatively, the Sequential Organ



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Failure Assessment (SOFA) score, which was originally defined as a predictor of mortality for ICU patients, has a significantly higher specificity, 67% but the sensitivity is only 54%.¹³ The Sepsis-3 guidelines have taken the SOFA score to represent triage methodology.

The main goal of the EP is to rule out severe processes, as opposed to necessarily ruling in an exact diagnosis. Using SIRS criteria allows the triage process to cast a wide net. SIRS criteria may not be particularly specific, but it does have a higher sensitivity, thereby including more people into the criterion standard. The Sepsis-3 consensus definition is more specific and helps to identify patients for whom resources should be allocated for early intervention. However, identification using SOFA or qSOFA promotes delayed diagnosis as end organ dysfunction is needed.

The Sepsis-3 consensus statement noted that this scoring system was studied in ICU patients, not ED patients, which impacts the application of the scoring system in the ED. It is most useful for patients that have already been in the hospital. Generally, 50 to 60% of sepsis cases are identified in the emergency department. Therefore, it would seem prudent to establish triage guidelines that are better suited for ED identification and risk stratification.

Recognizing the potential lives at risk with lack of systematic early screening and sepsis protocols the CMS launched the Sepsis Core Measures in late 2015 as a value based purchase (VBP), creating a frenzy for fear of lost revenue. Hospitals across the nation are trying to meet these requirements given the VBP's all or nothing nature. While these measures are simple and rooted in evidence, they are resource intensive (see table 1). The core measure are broken down into two bundles for severe sepsis and septic shock to accomplish at 3 and 6 hours (see table 2). Given the time sensitive nature of the core measure, defining time zero, while challenging, is the most crucial step in initiating aggressive lifesaving therapies. CMS continues to use SIRS criteria as inclusion criteria for this VBP measure.

Critical to the CMS measure is checking serum lactate. In its current state, the CMS bundle advocates early serum lactate measurements to stratify patients with organ dysfunction. However, the Sepsis-3 criteria uses lactate in the septic shock category, not as a definer for early or occult organ dysfunction. In this setting, SOFA score promotes delayed diagnosis of organ dysfunction.

While the consensus unanimously agreed that the SIRS criteria is fraught with poor specificity, the SOFA and qSOFA scores do not provide a

Continued on next page

superior alternative for non-ICU patients. There is still more work to be done to better identify ill patients in a timely matter to optimize interventions and resources.

	Established Definition (used by CMS)	Sepsis-3 Definition	SSC Guidelines
Sepsis	Suspected/ known infection + >2 SIRS	>2 SOFA criteria (present/ increased) Includes: hypotension + normal lactate	Sepsis = Severe Sepsis
Severe Sepsis	Sepsis + End Organ Dysfunction, lactate >2 mmol/L	Not a category	The new Sepsis category
Septic Shock	Sepsis + Refractory hypotension (+/- lactate)	Vasopressors AND lactate >2 mmol/L	Sepsis + Refractory hypotension (+/- lactate)
Mortality Ratio=Observed mortality/Expected mortality	Sepsis=low acuity Observed mortality low/ expected mortality low	Sepsis=higher acuity Observed mortality higher/ expected mortality low	NA

Table 1, Comparisons of established definition, SEPSIS-3 definitions, and SSC guidelines adopted from Tiffany Osborn, MD MPH FAEM.

SEP-1: Completing the Bundles

Required Action	Severe Sepsis		Septic Shock	
	Three Hour Bundle	Six Hour Bundle	Three Hour Bundle	Six Hour Bundle
Initial Antibiotic Started	Yes	Must be completed within three hours of severe sepsis presentation	Yes	Must be completed within three hours of hypotension
Blood Culture Collection	Yes			
Initial Lactate Collection	Yes			
Repeat Lactate Collection (if initial lactate is greater than two)	Yes		Must be completed within six hours of severe sepsis presentation	
30mL/kg Crystalloid Fluids Started	N/A	N/A	Yes	Must be completed within three hours of hypotension
Vasopressor Given (if decreased BP persists)	N/A	N/A	Must be completed within six hours of septic shock	
Repeat Volume Status / Tissue Perfusion Assessment	N/A	N/A	Yes	

Table 2: CMS core measure bundle this need to be redone

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