

Fact Sheet

SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock

The Centers for Medicare & Medicaid Services (CMS) has introduced a new measure to assess the quality of sepsis care in hospitals. Consistent with the guidelines of the Surviving Sepsis Campaign, this composite measure evaluates the processes associated with high-quality care for patients with severe sepsis or septic shock. This fact sheet provides background information and details about the measure, with links to additional sources.

Why sepsis?

Sepsis was the sixth most common principal diagnosis for hospitalization in the United States in 2009, according to [national discharge data reported by the Agency for Healthcare Research and Quality \(AHRQ\)](#). The AHRQ data, reports that the sepsis mortality rate is more than eight times higher than mortality rates among patients admitted for other conditions. From 1993 to 2009, sepsis-related hospital stays increased by 153 percent, with an average annual increase of 6 percent. Reduced mortality rates have been achieved through the implementation of a bundle of interventions that address process of care for sepsis. In 2009, there were 1,665,400 patients in hospitals diagnosed with sepsis and 258,000 deaths from sepsis (a mortality rate of 16 percent). Sepsis is associated with mortality rates ranging from 16 to 49 percent for all ages, according to [the Surviving Sepsis Campaign International Guidelines \(2012\)](#).

Henry Ford Hospital, in collaboration with leadership and representatives from the Society of Critical Care Medicine, Infectious Diseases Society of America, and emergency physicians, developed a composite quality measure titled, “Severe Sepsis and Septic Shock: Management Bundle” to incorporate results of worldwide data collection and quality improvement initiatives in this area that have been shown to be successful. The National Quality Forum (NQF) originally endorsed this measure in 2008 (NQF #0500). Henry Ford Hospital has maintained endorsement of the measure since 2008, including most recent endorsement on June 20, 2013 after collaborations with the Surviving Sepsis Campaign to revise the specifications based on recently released studies. In the [FY 2015 IPPS/LTCH PPS final rule \(p. 50236\)](#), published on August 22, 2014, the Centers for Medicare & Medicaid Services (CMS) adopted this composite measure for the Hospital Inpatient Quality Reporting Program (IQR) for discharges occurring on or later than October 1, 2015.

Why this measure?

As stated in the [FY 2015 IPPS/LTCH PPS final rule \(p. 50236\)](#), the purpose of the Severe Sepsis and Septic Shock Early Management Bundle measure is to facilitate the “efficient, effective, and timely delivery of high quality sepsis care in support of the Institute of Medicine’s aims for quality improvement.” By providing timely, patient-centered care and making sepsis care more affordable through early intervention, this measure can result in reduced use of resources and lower rates of complications.

Why a Bundle or Composite Measure?

A bundle is a structured way of improving patient care processes and outcomes by grouping together a small set of evidence based interventions proven to improve patient outcomes. When performed collectively the elements of a bundle have a greater impact on outcomes than each element performed separately. Bundling interventions increases the likelihood they will all be performed collectively and reliably. The power of a bundle comes from the body of science supporting it and the method of execution. Elements of a bundle are not new. They are well established best practices that are often not performed uniformly making treatment unreliable. By grouping a small number of these proven interventions (usually 3 - 4) together in a bundle with clear parameters for implementation, the likelihood of them all being implemented appropriately increases significantly. Analysis of data from the Surviving Sepsis Campaign demonstrated that when all severe sepsis and septic shock bundle elements are performed consistently outcomes are better than when even one bundle element is not performed correctly. A composite measure is way of reporting the results of a patient care bundle.

Measure Information

Description

- This composite process of care measure focuses on adults ages 18 and older with a diagnosis of severe sepsis or septic shock. Consistent with the guidelines of the Surviving Sepsis Campaign, it assesses the (a) measurement of lactate levels, (b) obtaining of blood cultures, (c) administration of broad spectrum antibiotics, (d) fluid resuscitation, (e) vasopressor administration, (f) reassessment of volume status and tissue perfusion, and (g) repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions (measuring lactate, obtaining blood cultures, and administering broad spectrum antibiotics) should occur within three hours of presentation of severe sepsis. Fluid resuscitation should occur within three hours of septic shock presentation. The remaining interventions (vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement) are expected to occur within six hours of presentation of septic shock.

How is the measure calculated?

- The measure calculates the percentage of patients with severe sepsis or septic shock for whom all of the process of care measures are completed as a single composite measure. All of the appropriate interventions must be completed for a case to pass the measure. Data should be reported as an aggregate rate generated from count data reported as a proportion.

Denominator

- Inpatients ages 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock.

Numerator

- The numerator for this measure is patients from the denominator who had their lactate levels measured, had blood cultures obtained prior to receiving antibiotics, and who received broad spectrum antibiotics within three hours of presentation of severe sepsis, and who had a repeat lactate level drawn within six hours of presentation of severe sepsis if the initial lactate was elevated. If septic shock is present, the patients also must receive 30 ml/kg of crystalloid fluids for hypotension or lactate ≥ 4 mmol/L within three hours of septic shock presentation. Within six hours of presentation of septic shock vasopressors should be given (for hypotension that does not respond to initial fluid resuscitation or lactate is ≥ 4 mmol/L) and reassessment of volume status and tissue perfusion performed.

Updates to the Measure Specification

Since publication of the FY 2015 IPPS/LTCH PPS final rule, changes to the specifications have been undertaken by the steward and endorsed by NQF in response to newly published evidence. Changes have centered on one of the composite elements, referred to as “Element F.” These changes do not reflect variations to the measurement strategy. In September, the measure had seven elements. Today, the measure has seven elements. “Element F” has maintained the same purpose—to reassess the patient for volume status (that is, does the patient have enough fluid in circulation?) and perfusion status (that is, is that fluid circulated appropriately?).

The September 2014 version of the measure reassessed volume and perfusion (Element F) using a complicated and invasive approach to patient care. It called for assessment of central venous pressure (CVP) and percent of oxygen saturation in blood returning to the heart (ScVO₂). This assessment required providers to place a long catheter in the patient’s neck or chest in a position that approximated the location of the heart. Blood and pressure readings were obtained from this catheter.

The present version of the measure reassesses volume and perfusion (Element F) giving providers the opportunity to simply re-examine their patients with a physical exam. Rather than placing an invasive catheter into a patient, requiring consent to do so, and risking complications to patients and hospitals, providers may now simply return to the bedside to manually re-examine their patient. The simple focused physical exam replaces what was an onerous requirement, and one of the most cited objections to the measure by commenters. Element F now allows a provider choice and does not mandate the use of invasive strategies.

These changes to the requirement to reassess volume and perfusion (Element F) were made after three clinical research studies were published. In March 2014, the Protocolized Care for Early Septic Shock (ProCESS²) trial demonstrated that an invasive approach was not required. This trial was followed in October 2014 by the Australian Resuscitation in Sepsis Evaluation Randomized Controlled Trial (ARISE³), which arrived at the same conclusion. In March 2015, the Protocolised Management in Sepsis Trial (ProMiSe⁴) also reached the same conclusion. NQF and the measure developers acted on the basis of the first trial, ProCESS² and liberalized the requirement to reassess volume and perfusion (Element F). The revised Element F, only makes compliance with the previously posted measure easier. The revision retains the same strategy but makes it easier for hospitals and clinicians to be deemed compliant.

Additional Resources

- For more information on the Early Management Bundle, Severe Sepsis/Septic Shock, visit [QualityNet](#) to review the [measure specifications](#) and [data elements](#).
- For questions about this measure, please use the [Hospitals—Inpatient Questions & Answers tool](#).
- More information about the implementation of severe sepsis/septic shock care bundles and tools is available on the [Surviving Sepsis Campaign website](#).

References

1. Rivers E, Nguyen B, Havstad S, Ressler J, Muzzin A, Knoblich B et al. Early goal-directed therapy in the treatment of severe sepsis and septic shock. *N Engl J Med*. 2001; 345:1368-77.
2. ProCESS Investigators, Yealy DM, Kellum JA, Juang DT, et al. A randomized trial of protocol-based care for early septic shock. *N Engl J Med* 2014; 370(18):1683-1693.
3. The ARISE Investigators and the ANZICS Clinical Trials Group. Goal-directed resuscitation for patients with early septic shock. *N Engl J Med* 2014; 371:1496-1506.
4. Mouncey PR, Osborn TM, Power GS, et al. for the ProMISe trial investigators. Trial of early, goal-directed resuscitation for septic shock. *N Engl J Med* 2015: DOI: 10.1056/NEJMoa1500896.