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

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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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- 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 (stewarded 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