
Severe Sepsis and Septic Shock Management Bundle Compliance and Mortality



Sepsis is a major cause of death and disability. The Centers for Medicare & Medicaid Services (CMS) aims to improve sepsis outcomes through the Severe Sepsis and Septic Shock Management Bundle (SEP-1), which hospitals must report compliance with. SEP-1, based on the Surviving Sepsis Campaign bundle, is linked to lower mortality rates.

CMS is shifting SEP-1 from a "pay for reporting" to a "pay for performance" model. However, there is significant controversy over the true impact of SEP-1. Critics argue that observational studies comparing outcomes between compliant and non-compliant groups are prone to confounding, as certain patients, such as those with septic shock, older patients, or those with serious comorbidities, are less likely to receive SEP-1-compliant care, which skews results.

Previous studies mostly rely on administrative or electronic health records, which miss complex clinical factors like clinicians' initial suspicion of infection or difficult intravenous access. To address this, the authors reviewed medical records to examine patient characteristics influencing SEP-1 compliance, focusing on clinical factors not captured in typical data. They then analysed how adjusting for these confounders affected the association between SEP-1 compliance and mortality.

The study included 590 adults with sepsis who were treated in the emergency departments of four academic hospitals from January 1, 2019, to December 31, 2022. The review of patients' medical records took place between September 2022 and December 2023.

The study focused on two outcomes: (1) comparing the characteristics of patients who received SEP-1-compliant care versus those who did not, and (2) assessing the relationship between SEP-1 compliance and hospital mortality. To evaluate this, multivariable models were used, adjusting for potential confounders in stages—first demographics and comorbidities, then infection source, followed by severity of illness and clinical markers of complexity.

Out of 590 patients with sepsis, 335 (56.8%) received SEP-1-compliant care, and 225 (43.2%) received non-compliant care. Patients in the non-compliant group were more likely to be older (65+ years), have multiple comorbidities, and present with conditions like septic shock, kidney dysfunction, and thrombocytopenia. They also had more nonfebrile presentations, impaired mental status, a need for bedside procedures, acute non-infectious illnesses, and non-infectious illnesses as the primary factor in their presentation.

While SEP-1 compliance was initially associated with lower crude mortality rates (11.9% vs. 16.1%), after adjusting for demographics, comorbidities, infection source, severity of illness, and clinical markers of complexity, there was no significant difference in mortality between the compliant and non-compliant groups. After adjusting for these confounding factors, the association between SEP-1 compliance and mortality shifted from protective to null, particularly for patients with severe sepsis, although the effect remained for those with septic shock.

The study highlights that noncompliance with SEP-1 can reflect the complexity of sepsis presentations rather than poor care, as some patients require more time to diagnose or have urgent nonsepsis-related issues needing immediate attention.

The findings suggest that while there is room for improvement in SEP-1 compliance, the CMS plan to shift SEP-1 from pay-for-reporting to pay-for-performance may not significantly improve sepsis survival. This study, along with others, raises concerns about the effectiveness of SEP-1 in reducing mortality, recommending a shift toward risk-adjusted [outcome metrics](#) instead of rigid early resuscitation bundles. The findings highlight the need for careful consideration in using national quality measures to improve sepsis outcomes.

Source: [JAMA](#)
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