

Complex government-mandated hospital performance measure not supported by evidence

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Evidence supporting the use of a complex government-mandated hospital performance measure does not hold up to scientific rigor. Findings from a systematic evidence review are published in *Annals of Internal Medicine*.

The Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) is a hospital performance measure introduced by the Centers for Medicare & Medicaid Services (CMS). It requires clinicians perform up to 7 interventions, and as many as 141 tasks and 3 hours to document for a single patient. Hospitals will be forced to fully adopt this complex performance measure or jeopardize reimbursement and accreditation. CMS uses published criteria to grade the [evidence](#) supporting its performance measures. To be considered high- or moderate-level evidence, studies must be free of confounders and have low risk of bias.

Researchers from the National Institutes of Health searched databases for all available scientific evidence and examined whether moderate- or high-level evidence shows that SEP-1 or five of its hemodynamic interventions improve survival in adults with sepsis. They found 20 published studies addressing this question. These were mostly observational studies (n=15) subject to selection bias and not [randomized controlled trials](#). Only one single-center, observational study reported lower in-hospital mortality after implementation of the SEP-1 bundle. Sixteen studies, again mostly observational (n=14), reported

increased survival with serial lactate measurements or 30-mL/kg fluid infusions, which are part of the mandate. None of these 17 studies were free of confounders or at low risk of bias. No studies showed that other investigated hemodynamic interventions improved survival.

According to the researchers, these findings suggest that CMS should examine its [performance](#) measure approval process to determine how it adopted interventions lacking evidence meeting the agency's own criteria and how it can improve this process in the future.

More information: Study:

<http://annals.org/aim/article/doi/10.7326/M17-2947>

Editorial: <http://annals.org/aim/article/doi/10.7326/M18-0290>

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