# Modify Centers for Medicare & Medicaid Services' Sepsis Core Measure (SEP-1) Now to Optimize Care for COVID-19

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The Infectious Diseases Society of America and 5 other endorsing societies have officially recommended that lactate measurement be removed from the national Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) (1). Considering the current coronavirus disease 2019 (COVID-19) crisis, we urge the Centers for Medicare & Medicaid Services (CMS) to immediately make this change or at least consider a 1-year moratorium. At a time of limited resources, the second lactate measurement consumes limited phlebotomy and laboratory capacity and also exposes phlebotomists to COVID-19 without a compelling medical indication.

The SEP-1 mandates lactate measurement on admission for sepsis and a remeasurement within 6 hours if lactate level is significantly elevated. The CMS also requires hospitals to publicly report this number as a CMS-endorsed measure of hospital quality. We argue that, particularly during the COVID-19 pandemic, high performance on this metric is not associated with high-quality care because repeating the measurement occurs at a time when normally no other bloodwork would be drawn. Because many patients with sepsis are suspected to have COVID-19, the phlebotomist must don scarce personal protective equipment and potentially face exposure to infection; moreover, the patient has to undergo the pain and discomfort of a blood draw when medical societies recommend against such a mandate. This in no way should detract from the need for a physical examination within this 3- to 6-hour window, and repeating a lactate measurement may be indicated for select patients if there is clinical question regarding hypoperfusion on repeated physical exami-nation. Clinical laboratories are already strained during the COVID-19 pandemic, and the lactate blood tube must be handled separately. Extra work steps that are not clearly beneficial may contribute to caregiver burnout; requiring a second lactate while local facilities scramble to revise workflows to minimize the need to enter COVID-19 rooms is one prime example. Removing the second lactate requirement is a simple modification that reduces waste, enhances staff safety, and improves patient experience without compromising quality of sepsis care. This can be easily implemented immediately.

There is no question that higher lactate levels correlate with higher mortality rates. Nonetheless, the evidence that lactate-based therapy improves outcomes is scanty at best. One study merely shows that lactate-guided therapy gives results equivalent to measuring continuous mixed venous saturation (2). However, 3 large randomized controlled trials showed that measuring mixed venous oxygen produced no benefit but did cause longer intensive care unit stays and a trend toward higher cost as originally advocated in the SEP-1 bundle (3). Another randomized, open-label study showed improved outcomes with lactate-guided therapy. However, there was no difference between the groups in lactate level at 8 hours. Furthermore, the primary intervention in the lactate group was intravenous nitroglycerin and ketanserin for hypothesized microvascular dysfunction (4). Ketanserin is not approved for use in the United States, and nitroglycerin is certainly not routinely used for this purpose. A randomized study demonstrated that lactate measurement was no better than a physical examination (5). It should be noted there has been controversy regarding the significance of nondisclosure of conflicts of interest of those involved in clinical studies of lactate and the approval of the lactate measurement as a mandated element (6).

It is imperative that CMS quality measures focus on areas where there is clear-cut evidence for benefit. According to Pronovost and Wachter, leaders in the quality field, "We agree that we need to proceed cautiously and err on the side of parsimony in choosing practices that are suitable for an accountability approach. Candidate practices should be relatively easy to follow, have a strong and enduring evidence base . . ." (7). It is also important to mention that many recommended elements for sepsis have been modified over the years after undergoing more scrutiny. We support the concept of patient-centered process measures, and placing a hold on lactate measurement (rather than just putting a moratorium on all SEP-1 2020 reporting) could lead to further dialogue on improving other aspects of SEP-1. The CMS quotes studies in defense of SEP-1 that describe an association between bundle compliance and outcomes (8). However, correcting for confounding factors shows that bundle compliance per se does not lead to better outcomes (9).

There is no high-level evidence supporting improved outcomes with lactate measurement. The CMS can improve the quality of care and engage clinicians in ongoing quality refinement by removing this measurement. This adjustment in no way precludes institutions who feel that this is important from continuing. The COVID-19 crisis has fortunately propelled the speed with which government working in partnership with clinicians makes beneficial changes happen. We hope that CMS will make this change and consider other Infectious Diseases Society of America–recommended changes so providers and the public can focus on what is most important in 2021.

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