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COMMENTARY - INVITED

CMS is only happy when it rains

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When the Centers for Medicare & Medicaid Services (CMS) mandated reporting of a bundle of sepsis-related performance metrics (SEP-1)[1] in 2015, it created a storm of controversy and resistance. In the 6 years since, the SEP-1 metrics have been simplified to remove compulsory but unproven volume status assessments yet expanded to include severe sepsis in the mandated 30 ml/kg fluid bolus. Many subsequent articles arguing both in favor and against have been written and observational studies of the effect of SEP-1 have been largely underwhelming.[2] Yet, the slow march of compliance continues as hospitals around the country continue to expend limited resources bending administrative and electronic health record data to both report and improve compliance with the complex requirements of SEP-1. This has been further compounded by the perpetual threat of linking payments to SEP-1 leading to the question, "Is CMS only happy when it rains?"

In the current issue of *Academic Emergency Medicine*, Litell and colleagues[3] report the results of their retrospective study evaluating final diagnoses in a cohort of patients presenting to an urban, academic ED and meeting Sepsis-3 criteria. Using directly queried EHR data, the authors identified a cohort of more than 3000 patients during an 8-year period who met Sepsis-3 criteria and compared these patients to billing codes for sepsis associated with their hospitalization. The authors defined both explicit and implicit criteria for sepsis where the explicit definition included those patient encounters with ICD-9 codes for septicemia, sepsis, severe sepsis, and septic shock. The implicit definition included encounters with a code for infection and at least one code for organ dysfunction. Using both of these definitions, the authors found that only a minority of patients presenting to the ED and meeting Sepsis-3 criteria were eventually diagnosed with sepsis (25.1% for explicit and 47.8% for implicit criteria). While the proportion of patients was higher in those with Sepsis-3 criteria and shock (47.9% and 61.7%), the results illustrate the difficulty in differentiating sepsis from other conditions that may cause organ dysfunction using administrative data. The authors of this study also identified a significant subpopulation of patients that could plausibly be harmed by indiscriminate crystalloid boluses using billing codes that encompassed patients with CHF, ESRD, cirrhosis, and morbid obesity. Given the relatively nonspecific nature of the Sepsis-3 criteria, it is not surprising that more patients met this administrative definition of potential harm than for sepsis itself.

The results of this study suggest that, despite the efforts to improve specificity from the prior, SIRS-based definition of sepsis,[4] there is much work yet to be done. This is particularly true for the ED population where providers often operate with a higher level of diagnostic uncertainty and, as Litell et al. have also demonstrated, the potential for real harm exists. As emergency providers, we are often forced to act on presumed diagnoses which, in most patients, may end up being wrong. CMS has had a complex relationship with emergency care performance metrics. Unlike stroke and myocardial infarction, the case definition of sepsis remains nonspecific leading to a heterogenous population of sick patients both at risk of under- and overtreatment.

Prior efforts to mandate emergency care in the face of this diagnostic uncertainty, such as the 4-h antibiotic rule for pneumonia, led to failure.[5] In the case of the 4-h rule, which was based on large but retrospective studies suggesting that earlier antibiotics improved mortality in community-acquired pneumonia, the CMS mandate prompted other payers to follow suit. While this phenomenon has thus far been limited in sepsis, the risk of a pay-for-performance metric that does not ensure better outcomes remains. In the years following its implementation, subsequent studies demonstrated that

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the 4-h rule led to an increase in misdiagnosis and unnecessary exposure to antibiotics.[6] Moreover, the strict time window forced some EDs to administer antibiotics prior to complete evaluations including patients in the waiting room.[7] Anecdotally, there were even reports of hospitals gaming the metric by administering topical antibiotics as a stopgap measure. Presumably, any CMS inspectors who witnessed this practice would not have been amused by meeting the letter of the regulation and ignoring the spirit (and biological plausibility).

While the existing body of evidence for early antibiotics and adequate fluid resuscitation in sepsis is far stronger than the evidence that led to the 4-h rule, the SEP-1 mandate is also more complex and sepsis as a disease is even more confounded. Whereas Littell et al. focused on the risks of over resuscitation from diagnostic uncertainty in the ED, others including the Infectious Diseases Society of America (IDSA) have focused on the risk of antibiotic overuse. Indeed, a recent study by Shappell and colleagues[8] showed that up to one-third of ED patients treated with IV antibiotics after the implementation of SEP-1 reporting ultimately ended up without an infection-related diagnosis. As a compromise, the IDSA has advocated for narrowing the SEP-1 requirement to those with septic shock to improve specificity of the mandate.[9] A similar approach for the crystalloid bolus may be warranted.

To further pour misery down on the SEP-1, recent evidence suggests that from a patient-centered perspective, the mandated bundles of care may have little to no effect on outcomes. In the largest study to date, Barbash and colleagues[10] performed a before-and-after 2015 implementation of the SEP-1 time-series analysis of more than 50,000 encounters in their health system. While they found that the core measures of SEP-1 compliance increased, there was no impact on mortality or hospital disposition. These results are congruent with other studies all demonstrating little patient-centered benefit from the implementation of SEP-1.[2] Furthermore, concurrent sepsis recognition campaigns have likely led to overdiagnosis of milder sepsis during this time and the fact that no differences in outcomes have been detected may in fact mask an increase in negative outcomes.

Additionally, Littell and colleagues' data alludes to another question regarding the evaluation of potentially septic patients. If only a minority of patients identified by Sepsis-3 criteria in the ED end up with sepsis, but providers are incentivized by SEP-1 to initiate mandated bundles of care, does this cause the early closure of differential diagnoses? While the answer remains unknown, we emergency providers run the risk of yielding to the diagnostic momentum produced by a "sepsis pathway" that may result in failure to diagnose other potentially life-threatening conditions. The concept of early biasing is not new[11] and it is often a cautionary tale of a missed sepsis diagnosis. However, should we now consider the reverse scenario where mandated care drives the misdiagnosis of sepsis? The case where the sepsis button has been clicked, antibiotics have been given, lactate has been obtained, and 30 ml/kg infused is a hard one to fight with a clear disposition looming. The nature of the ED makes us especially susceptible to the biasing inherent in "fast," pattern recognition–based information processing. As a pattern that is both easy to fit and one that we are administratively pressured to fulfill, the SEP-1 bundle may require that cognitive debiasing strategies be employed not to ask "Could it be sepsis?" but rather "Is this really sepsis?"[12]

A common refrain in the discussion of sepsis management in the ED is the notion that prior to 2001,[13] typical sepsis management consisted primarily of ignoring septic patients in a far off corner of the ED. In the two decades since, tremendous gains have been made in reducing sepsis mortality but are those gains attributable to the processes advocated by SEP-1? We know that care and attention paid to septic patients by clinicians is of benefit but rigidly mandating specific therapies has not been shown to be of benefit.[14] Performance metrics may have the effect of altering care, but not always in a way that benefits patients, especially the patients who do not end up with the disease of interest. As with the 4-h rule a generation ago, mandating specific care in the ED via a mechanism that is retroactively applied to a subset of initially eligible patients will likely produce off-target effects. These effects, given the exclusion of patients who are not ultimately deemed to have had sepsis, may also go unnoticed as quality assurance departments across the country laud improvements in compliance with SEP-1. As Litell and colleagues have demonstrated, attempting to meet the requirements of the retrospectoscope in the ED may lead to unintended harm in those patients who ultimately do not have sepsis. Iterative changes to SEP-1 are thus likely to continue and we may be left wondering if the framers of these complex and potentially misapplied rules will "only be happy when it's [even more] complicated?"[15]

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