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qSOFA: Illness Severity Indicator, Clinical Decision Support Tool, or Both?

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While the devastating consequences of sepsis are well-known [1], the diagnosis of this clinical syndrome has proven to be highly challenging [2]. Until recently, sepsis was defined by two or more systemic inflammatory response syndrome (SIRS) criteria in the presence of infection [3]. However, after countless editorials and studies decrying the weaknesses of this definition [4, 5], a Task Force was convened to update the definition [6].

Sepsis-3 declared sepsis to be "life-threatening acute organ dysfunction due to a dysregulated host response to infection," removing systemic inflammation from the definition. However, there is not yet a diagnostic test to confirm sepsis, or even a "dysregulated host response." To identify the syndrome in clinical practice, Sepsis-3 recommends a threshold of 2 or more new SOFA points in a patient with clinically suspected or confirmed infection.

Along with the new definition and clinical operationalization, Sepsis-3 also introduced a new clinical tool—the qSOFA score. This 3-point measure is based on physical exam alone: respiratory rate 22/min or greater; altered mentation; and SBP of 100mg or less [6]. The score can be used to rapidly identify non-ICU patients at the highest risk for poor outcomes, defined as a prolonged ICU stay or in-hospital death. The parsimonious qSOFA tool was validated in multiple datasets and out-performs SIRS criteria at identifying patients at risk for poor outcomes [7]. In the Sepsis-3 validation study, only 24% of infected patients had a qSOFA ≥2, but these patients accounted for 70% of the poor outcomes [7]. As such, qSOFA is not a screening tool, but rather a grave alarm bell of potential impending decompensation in patients with infection.

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Over the past year and a half, clinicians and researchers have responded to the new qSOFA tool. Several studies have validated the measure in additional patient populations, and qSOFA has consistently out-performed SIRS criteria at predicting risk of in-hospital mortality in these external validation studies [8, 9]. Nonetheless, clinicians have expressed reservations regarding the utility of qSOFA for clinical practice [10–12]. Some question whether qSOFA adds value beyond physician judgment [10]. Others lament the lower sensitivity by qSOFA compared to SIRS [11]. More recently, Churpek et al. [9] compared qSOFA to two general Early Warning Scores and found that both general scores out-performed qSOFA at predicting poor outcomes in infected patients.

In this issue of *Critical Care Medicine*, Moskowitz and colleagues [13] address a different concern about qSOFA—the decision to use mortality and prolonged ICU stay as the outcome. They argue that this end-point makes qSOFA purely a severity-of-illness score and, therefore, inappropriate for clinician decision-support [13, 14]. A patient's risk for death may be low, but only because he or she received critical care intervention. Thus, they argue that a model for poor outcome, which does not account for the treatment received, should not be used to guide treatment allocation or ICU triage.

To determine the utility of qSOFA as a clinical support tool, the authors evaluate qSOFA against an alternative outcome: critical care intervention (CCI) within 48 hours of emergency department triage. They define CCI as any of six treatments: vasopressors; invasive or non-invasive ventilation; continuous insulin infusion; ≥4 liters of fluid resuscitation within 12 hours of ICU admission; placement of an invasive catheter; or continuous renal replacement therapy.

In a single-center cohort of over 24,000 patients presenting to the ED with suspected infection, the authors tested the ability of both qSOFA and SIRS to predict (1) receipt of CCI, and (2) in-hospital mortality. Overall, 18% of the cohort received CCI—most commonly a central venous catheter, invasive mechanical ventilation, or vasopressor therapy —and 5% died.

Two main findings come from the paper. First, qSOFA was better than SIRS at predicting both receipt of CCI and mortality. Second, qSOFA had a low sensitivity for both receipt of CCI and mortality, at 38% and 39%, respectively. (Meaning, of all patients receiving CCI, only 38% had qSOFA ≥2). The sensitivity was even lower when using the qSOFA at ED presentation.

For patients with a qSOFA<2, 13% received any CCI, and 4% died. The most common CCIs were a central line or mechanical ventilation, each used in about 7% of patients. By contrast, among patients with a qSOFA≥2, 48% received a CCI, and 13% died. But, given the low sensitivity of qSOFA for CCI, the authors recommend caution in using qSOFA as an early identifier of impending clinical deterioration.

Moskowitz et al. have shown us yet again that we have no silver bullet when it comes to identifying sepsis, predicting which infected patients will fare poorly, or guiding clinical management in real-time. Indeed, these results only strengthen the call for additional basic and translational research to inform sepsis diagnosis and treatment decisions.

The authors have also shown that qSOFA—while designed to predict poor clinical outcomes—also outperforms SIRS at predicting receipt of CCI.

Lastly, this study demonstrates that the sensitivity of qSOFA for CCI and mortality is low. The majority of patients who received CCI had a qSOFA <2. And thus, qSOFA cannot and should not be used to rule out a diagnosis of sepsis, the risk for clinical deterioration, or the need for ICU admission.

Given that sepsis contributes to as many as half of all inpatient deaths [15], it is important to optimize sepsis care now. qSOFA is imperfect—just as our understanding of sepsis is imperfect. However, qSOFA can be measured rapidly in virtually any healthcare setting, and is available to deploy today. Unlike many clinical tools based on expert opinion or small studies, qSOFA was developed and validated using data from hundreds of thousands of patients. And, as Moskovitz and colleagues nicely show, qSOFA is associated with a 3-fold increased risk for both receipt of CCI and in-hospital mortality.

A negative qSOFA does not mean patients are low-risk. However, a positive qSOFA score should raise alarm bells. And in a busy ED, it should move patients to the front of the queue.

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