

New Sepsis Criteria A Change We Should Not Make

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The Society of Critical Care Medicine and the European Society of Intensive Care Medicine recently released a consensus statement redefining the clinical syndrome of sepsis. The new diagnostic criteria eliminate the concept of the Systemic Inflammatory Response Syndrome (SIRS) and rely on known or suspected infection with a change in Sequential Organ Failure Assessment (SOFA) score ≥ 2 , or a modified “quick SOFA” for simpler use.^{1,2} Physicians of multiple specialties have expressed concern that widespread application of this new definition could cost patient lives, and we cannot support its adoption.

It is a daunting undertaking to assign clinical definitions to “a condition,” sepsis, which is associated with a high mortality rate, has variable clinical presentations, and has few unifying pathophysiological features. Since the time of the original sepsis definitions conference in 1991, it has become clear that the initial definitions of sepsis, severe sepsis, and septic shock, though imprecise, provide a useful framework for clinical intervention.^{3,4} Two aspects of this older framework remain true today: first, the syndromes predict associated mortality and, second, their application and interventions associated with their use have reduced global sepsis mortality.⁵⁻⁷ Given that use of the current definitions results in saving lives, it seems unwise to change course in midstream by shifting the definition. This is especially true because

there is still no known precise pathophysiological feature that defines sepsis.

The end point of the proposed criteria is increased specificity for predicting mortality or ICU stay of ≥ 3 days. Because ideal outcomes for patients result from early recognition and intervention in potentially life-threatening infection, the revised criteria may lead to failure to recognize the signs of potentially lethal infection until the combination is significantly more likely to be deadly. The supporting paper by Seymour et al⁸ is somewhat of a non sequitur, having used a sophisticated retrospective analysis to demonstrate that the presence of organ dysfunction, as detected by SOFA score, optimizes the combined sensitivity and specificity for life-threatening organ dysfunction. The logic of this approach, in terms of saving lives, is not evident. In fact, the lethality of severe sepsis demands a screening mechanism that exhibits high sensitivity, even at the expense of specificity.

The consensus statement argues that the SIRS concept is not helpful. The supporting evidence cited is a recent study demonstrating that SIRS is absent in one of eight patients with infection and organ dysfunction.⁹ This could be restated that seven of eight patients (87.9%) with life-threatening organ dysfunction have SIRS, making SIRS a highly sensitive indicator for organ dysfunction. Sepsis experts have never believed that SIRS alone is a “criterion” for sepsis, but recognize that when infection is present or suspected, SIRS is a harbinger of the possibility of life-threatening organ dysfunction. The presence of such organ dysfunction is the key clinical feature that shifts patients into the higher mortality risk category. However, abandoning the use of SIRS to focus on findings that are more highly predictive of death could encourage waiting, rather than early, aggressive intervention. This is a mistake that we cannot make.

Infection + SIRS is, itself, associated with a substantial mortality (5% to 16%).^{4,10} Compare that with acute myocardial infarction, which has an in-hospital mortality of 5% after revascularization, down from 14% in the prethrombolytic era.¹¹ It is not conceivable that we would change the definition of acute coronary syndrome because it is no longer as specific for mortality as it once was. It is also not clear to us that readjusting

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the sepsis criteria to be more specific for mortality is an exercise that benefits patients.

The consensus statement **assumes that the SOFA score is commonly used in practice.** In discussion of this issue with both critical care specialists and non-critical care specialists throughout the United States, it is apparent that SOFA score is used in some academic intensive care units and is **essentially unheard of in smaller hospitals,** whereas larger community hospitals may recognize its presence, but do not routinely use it. **To abandon one system of recognizing sepsis** because it is **imperfect** and not yet in universal **use for another system** that is **used even less** seems **unwise** without prospective validation of the new system's utility.

The steady application of a consistent and easy to use set of sepsis definitions has resulted in a declining mortality rate across the world in centers that use them.^{7,12}

However, it often takes multiple training sessions in a given facility before the definitions are adopted and sepsis practices begin to improve. Additionally, we must remember that the vast majority of septic patients live or die in hospitals that are not academic centers, where the presence of a trained sepsis expert or intensivist may be lacking. A change in definition and diagnostic criteria could set back decades of work persuading providers at all levels to recognize sepsis early and to intervene aggressively. **It seems unlikely that simply changing the clinical definition of sepsis will lead to additional substantial reductions in mortality.** What patients need is that we continue to build on the momentum of the last two decades and that we not disrupt it by conflating change with progress.

As sepsis and quality improvement educators, my team and I have spent over a decade training providers in small and medium sized hospitals across our own state and others to recognize and aggressively treat sepsis in all its forms. What we have learned may translate well to rural and suburban hospitals across the world. We suggest that the ubiquity and the lethal nature of sepsis demand that we approach **any change in its clinical definition and diagnostic criteria with prospective studies that demonstrate improved outcomes before attempting a wholesale change.** We also suggest a

reconvening of a conference with a **broader base of constituents,** especially including **physicians** on the **frontlines** of recognizing sepsis, such as hospitalists and emergency medicine physicians, to seek a **broader consensus.** Our **principal concern** is that the **new definition de-emphasizes** intervention at **earlier stages** of **sepsis** when the syndrome is actually at its **most treatable.** We believe that adopting a **more restrictive definition** that requires further progression along the sepsis pathway **may delay intervention** in this highly time-dependent condition, with additional risk to patients.

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