

Study results validate a rapid diagnostic test for sepsis in the emergency department

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Critical care physician Hollis O'Neal, MD, MSc, Associate Professor of Medicine at LSU Health New Orleans School of Medicine's Baton Rouge campus, presented data that validate a rapid diagnostic test for

sepsis at the American Thoracic Society 2023 International Conference.

Dr. O'Neal is the national principal investigator of the CV-SQulSH-ED trial, a multi-site prospective study to evaluate the diagnostic performance of the investigational Cytovale System & IntelliSep Test for patients presenting to the Emergency Department with signs or suspicion of infection. The IntelliSep Test is a microfluidic test that measures the biophysical properties of white blood cells (leukocytes) in conjunction with other laboratory findings and clinical assessments to aid in the early detection of sepsis.

Dr. O'Neal led the prospective, multicenter study of adults presenting to the ED with signs or suspicion of infection to assess the IntelliSep Test. It provides a test result, called the IntelliSep Index (ISI), in less than 10 minutes in three interpretative bands from a low (Band 1) to high (Band 3) probability of sepsis.

IntelliSep results were compared to retrospective judgment of Sepsis-3 by an independent panel of critical care, infectious disease, and emergency medicine physicians. Research and clinical personnel were blinded to the ISI results. Clinical outcomes were extracted from the [medical record](#).

A total of 572 patients were enrolled in EDs from medical centers in four states. Sepsis was the final diagnosis in 152 patients (26.6%). The prevalence of sepsis in Band 3 was 79 of 160 (49.4%); Band 2, 45 of 160 (28.12%); and Band 1, 28 of 252 (11.1%). Emergency Department physicians diagnosed sepsis in 52 of 152 patients with sepsis and 24 of 420 (5.7%) of patients without sepsis.

The study showed that ISI provided a rapid, reliable diagnostic aid for sepsis in a population of patients with signs or suspicion of infection. Based on these data, the United States Food & Drug Administration

granted the system 510k clearance in December 2022.

"Every minute counts when it comes to sepsis diagnosis, and EDs operate under major time and resource constraints that could impact patient outcomes," said Dr. O'Neal, who also serves as Medical Director of Research at Our Lady of the Lake Regional Medical Center, LSU Health's major teaching hospital in Baton Rouge.

"These results validate the efficacy and efficiency of IntelliSep as a diagnostic aid that may improve sepsis triage when incorporated into existing clinical protocols."

According to the National Institutes of Health, sepsis is a person's overwhelming or impaired whole-body [immune response](#) to an insult—bacterial infections, viral infections, such as COVID-19 or influenza; or fungal infections. It is unpredictable and can progress rapidly. Without prompt treatment, sepsis can lead to tissue damage, organ failure and death.

It's a serious condition and a leading cause of death in hospitals. It's also a main reason why people are readmitted to the hospital. Each year, according to the Centers for Disease Control and Prevention (CDC), at least 1.7 million adults in the U.S. develop sepsis, and nearly 270,000 die as a result. The number of sepsis cases per year in the U.S. has been on the rise. Many patients who survive severe sepsis recover completely, but some people can have permanent organ damage.

The researchers conclude that, if integrated into a process of clinical decision making, the ISI has the potential to improve the efficiency and efficacy of [sepsis](#) care delivery in the Emergency Department.

More information: Conference: conference.thoracic.org/

Provided by Louisiana State University

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