

Sepsis study comparing three treatment methods shows same survival rate

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Survival of patients with septic shock was the same regardless of whether they received treatment based on specific protocols or the usual high-level standard of care, according to a five-year clinical study. The large-scale randomized trial, named ProCESS for Protocolized Care for Early Septic Shock, was done in 31 academic hospital emergency departments across the country and was funded by the National Institute of General Medical Sciences (NIGMS), a component of the National Institutes of Health.

The results of the trial, led by Derek C. Angus, M.D., M.P.H., and Donald M. Yealy, M.D., of the University of Pittsburgh, appear online on March 18, 2014, in the *New England Journal of Medicine*.

"ProCESS set out to determine whether a specific protocol would increase the survival rates of people with [septic shock](#). What it showed is that regardless of the method used, patient survival was essentially the same in all three treatment groups, indicating that sepsis patients in these clinical settings were receiving effective care," said Sarah Dunsmore, Ph.D., who managed the ProCESS trial for NIGMS.

Sepsis is a body-wide inflammation, usually triggered by an infection. It can lead to a dangerous drop in blood pressure, called septic shock, that starves tissues of oxygen and chokes out major organs: lungs, kidneys, liver, intestines, heart. It remains frustratingly hard to identify, predict, diagnose and treat.

According to the Centers for Disease Control and Prevention, sepsis affects more than 800,000 Americans annually and is the ninth leading cause of disease-related deaths. The Agency for Healthcare Research and Quality lists sepsis as the most expensive condition treated in U.S. hospitals, costing more than \$20 billion in 2011.

The ProCESS trial set out to test three approaches to sepsis care. It enrolled 1,341 patients randomly divided into these groups:

Group 1: Early Goal-Directed Therapy

Doctors inserted a central venous catheter—a long, thin tube placed close to a patient's heart—to continuously monitor blood pressure and blood oxygen levels. For the first six hours of care, doctors kept these levels within tightly specified ranges using intravenous fluids, cardiovascular drugs and blood transfusions. This protocol was based on a 2001 study in an urban emergency department that noted a striking increase in sepsis survival using this approach.

Group 2: Protocolized Standard Care

This alternative tested a less invasive protocol that did not require central venous catheter insertion. Doctors used standard bedside measures like blood pressure (taken using an arm cuff), heart rate and clinical judgment to evaluate patient status and guide treatment decisions. Doctors kept patient [blood pressure](#) and fluid levels within specified ranges for the first six hours of care.

Group 3: Standard Care

Patients received the same high level of care they would typically get in an academic hospital emergency department. Their doctors did not

follow specific guidelines or protocols associated with the study.

After using an array of statistical analysis tools, the ProCESS investigators concluded that the three treatment arms produced results that were essentially indistinguishable for a range of patient outcomes. These outcomes included survival at 60 days, 90 days and one year; heart and lung function; length of hospital stay; and a standardized measurement of health status at discharge.

"ProCESS helps resolve a long-standing clinical debate about how best to manage sepsis patients, particularly during the critical first few hours of treatment," said Yealy.

"The good news from this study is that, as long as sepsis is recognized promptly and patients are adequately treated with fluid and antibiotics, there is not a mandated need for more invasive care in all patients," added Angus.

In addition to clarifying sepsis treatment options, ProCESS was a milestone for NIGMS.

"ProCESS was the first large-scale clinical trial to be supported by NIGMS, which primarily funds basic, non-disease-targeted research," said Dunsmore. "We hope that ProCESS and other NIGMS- and NIH-funded sepsis research efforts will help improve treatment, speed recovery and increase [survival rates](#) for [sepsis](#) patients."

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