

New study aims to stop sepsis in its tracks

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If you've had a heart attack or stroke, paramedics, doctors, and nurses follow standardized protocols for what to do right away, and their efforts improve your odds for a full recovery. That's not the case if you have a body-wide infection known as sepsis, which can be fatal within a few hours and is often not diagnosed until it is too late.

Now, a new, multicenter research consortium, called Protocolized Care for Early Septic Shock (ProCESS), is beginning a large-scale study to determine whether specific interventions can halt the progression to severe sepsis and septic shock. Key to the project is determining whether there are "golden hours" during which prompt, rigorous, standardized care can save patients' lives.

The project may establish the first set of standard procedures to diagnose and treat sepsis in emergency departments.

The National Institute of General Medical Sciences (NIGMS), part of the National Institutes of Health, launched the project this month with a grant totaling more than \$8.4 million over five years. Derek C. Angus, M.D., M.P.H., of the University of Pittsburgh School of Medicine, leads the consortium, which is a partnership between physicians in emergency medicine and those in critical care medicine.

"By improving the treatment of those critically ill with sepsis, the consortium's work will have enormous implications for the thousands of patients who suffer from this infection," said NIH Director Elias A. Zerhouni, M.D.

Every year, sepsis affects more than 700,000 Americans. About 30 percent of them die. Sepsis occurs when the body's normal reaction to an infection goes into overdrive, causing widespread inflammation and dramatic changes in body temperature, blood pressure, breathing, and heart rate. It can lead to the malfunction or failure of several major organs.

"The goal of this project is to speed recovery, increase survival rates, and improve the long-term quality of life for those who have had sepsis," said NIGMS Director Jeremy M. Berg, Ph.D.

One of the major challenges is to recognize sepsis when it starts. That's because in its early stages, it is often mistaken for a milder infection or other problems, said Angus. "A person may arrive with what looks like a simple case of pneumonia, and the emergency department team starts antibiotics and believes things will go well. Only when the blood pressure drops or is no longer responsive to intravenous fluids does the team realize it is suddenly behind the eight ball. By then, the patient is quickly spiraling into multisystem organ failure. Starting resuscitation at this point may already be too late."

To test ways of managing the disease during the first six hours after diagnosis, the consortium will train teams of doctors, nurses, and other emergency department workers at more than a dozen institutions. Like dedicated trauma teams, the sepsis teams will focus all their attention on one patient at a time and will follow a scripted protocol to stabilize, diagnose, and treat sepsis.

The protocol includes a sequence of resuscitation methods to deliver fluids, restore blood pressure, and monitor cardiovascular function and other organ activity. It was developed several years ago by Emanuel Rivers, M.D., M.P.H., a researcher and physician at Henry Ford Hospital in Detroit, where it dramatically increased survival rates.

To implement this approach across the entire country is a daunting task. As a first step, the consortium aims to find out whether the protocol will have similar success at multiple hospitals across the nation.

Following a year-long period of establishing and training sepsis teams, the consortium plans to treat early severe sepsis in nearly 2,000 patients, enrolling patients over a two- to three-year period. It will randomly assign patients to Rivers' protocol or to the existing "usual care" approach, which does not include such aggressive resuscitation. It will then follow all the patients for a full year after their recovery to detect any long-term differences in health and mortality rates.

The scientists will also measure blood levels of certain factors that are thought to cause severe sepsis. By examining how these levels change over time and with the different interventions, the scientists will discover whether the factors can serve as molecular markers to help track organ function and recovery progress in patients. This molecular approach may also shed light on new ways to understand and treat sepsis.

And consortium researchers will study the cost-effectiveness and logistics of establishing such protocols in emergency departments around the country. The scientists aim to develop a blueprint, complete with lists of tips and traps, to help hospitals adopt standardized methods for evaluating and treating early sepsis patients.

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