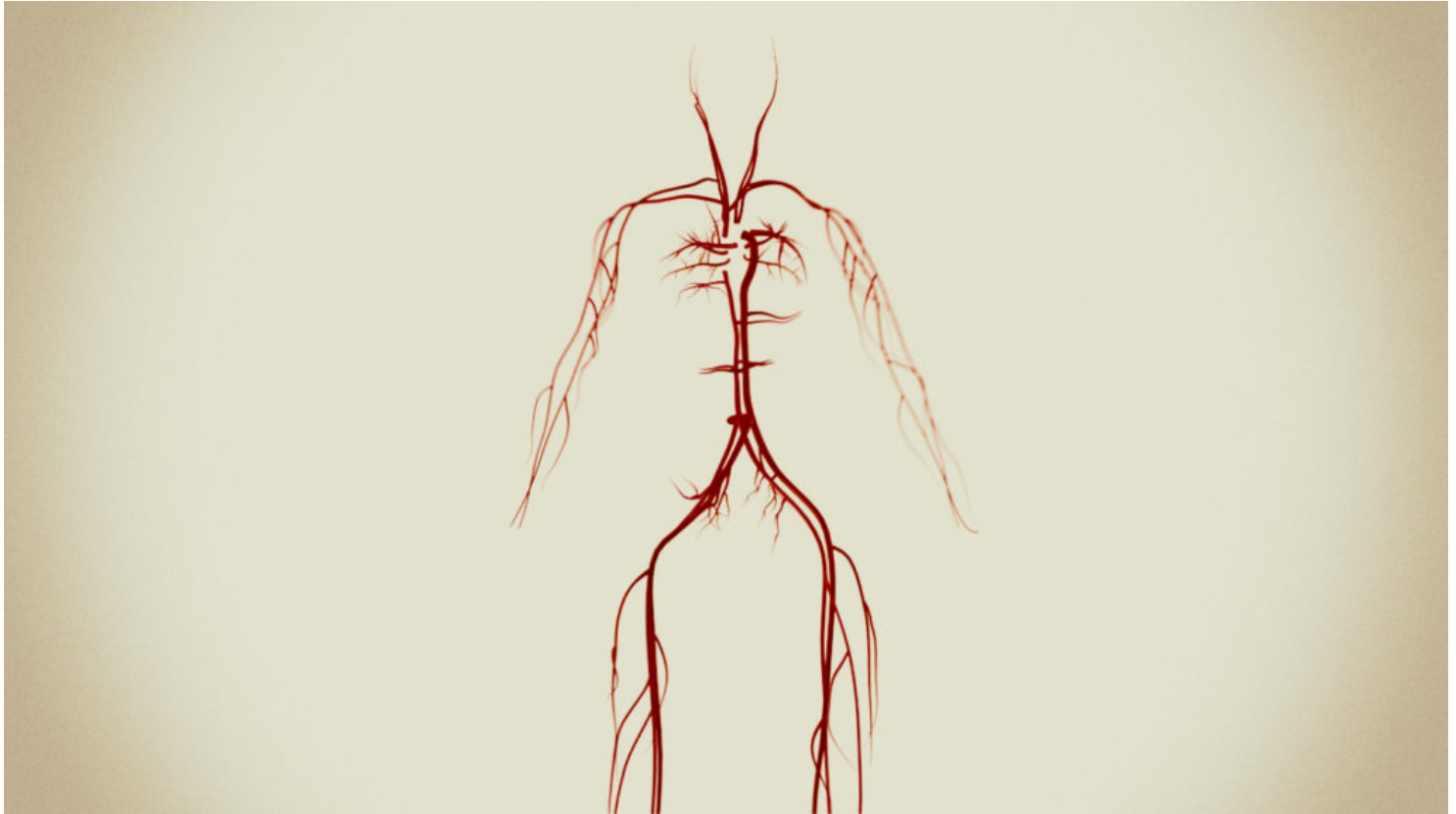


# STAT

## Doctors have resisted guidelines to treat sepsis. New study suggests those guidelines save lives

By Bob Tedeschi

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Dom Smith/STAT

Even in the face of increased pressure from regulators, many doctors have failed to fully embrace early screening and treatment protocols for [sepsis](#)<sup>1</sup>, an infection-related complication that afflicts tens of thousands of Americans every year and that can be life-threatening.

Skeptics have argued that there haven't been any comprehensive studies to support the notion that the protocols can actually save lives.

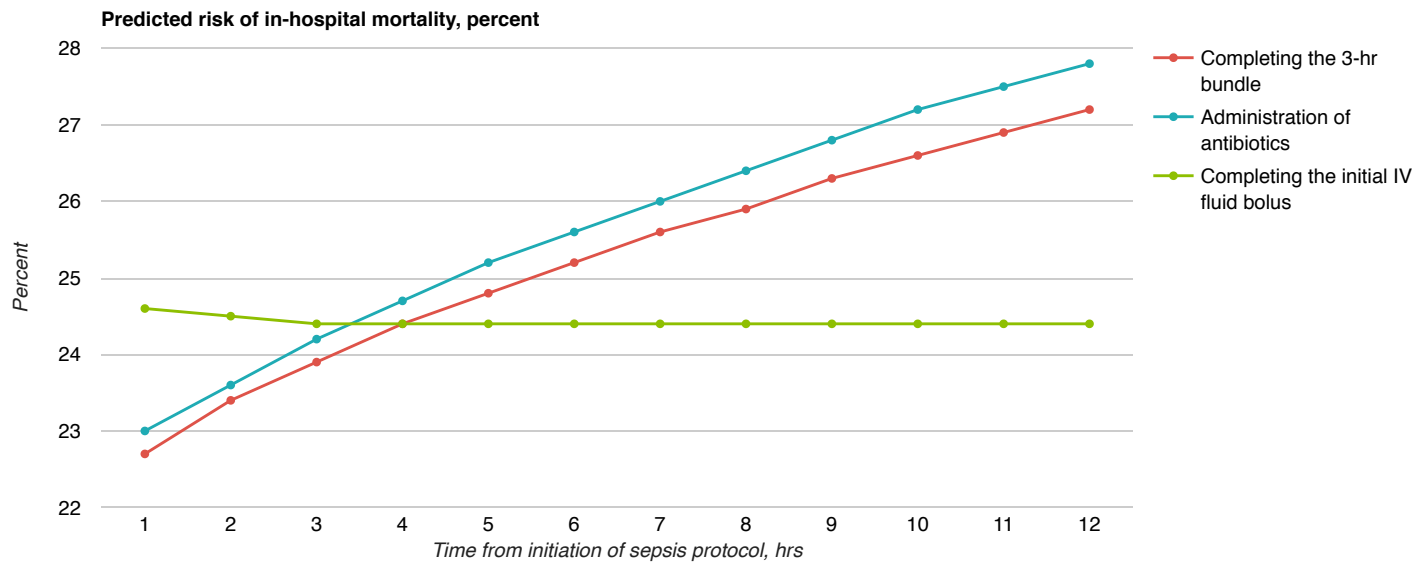
On Sunday, however, the New England Journal of Medicine published a large study that could make doctors reconsider — and help hospitals address head-on one of the most common dangers their patients face.

The study, involving more than 49,000 patients at 149 hospitals in New York state, suggests that for every hour that clinicians failed to complete the anti-sepsis protocols, known as the “three-hour bundle,” mortality rates climbed by between 3 percent and 4 percent.

[Related:](#)<sup>2</sup>

[How one hospital is beating sepsis and saving lives](#)<sup>2</sup>

“Our data shows that hospitals really need to do this at the outset, especially at the emergency department when they suspect sepsis,” said Dr. Christopher Seymour, a critical-care specialist at the University of Pittsburgh Medical Center, who led the study. “It can be lifesaving.”



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Talia Bronshtein/STAT Source: [The New England Journal of Medicine](#)<sup>3</sup>

Dr. Steven Q. Simpson, who leads critical care medicine at the University of Kansas Medical Center, and who was not involved in the study, said the analysis is “especially important” because it looks at one of only two states that have essentially mandated sepsis-prevention practices.

“This was every hospital in the state of New York, and they got in line with the regulations,” he said. “That is amazing.”

“I hope this helps convince people to follow suit.”

The protocols call on clinicians to first obtain a blood culture and measure the serum lactate level — often an indicator of septic shock, when the body’s immune system attacks vital organs — and to administer broad-spectrum antibiotics, usually by IV.

For a typical 40-year-old with septic shock, failure to follow these protocols increased the risk of death from 11 percent to 15 percent, according to the new study. For a 70-year-old with more than one serious illness, the risk of death increases from 29 percent to 38 percent.

Doctors who have already adopted the protocols and avoided treatment delays, according to proponents, have likely saved thousands of lives annually in New York alone, and could save tens of thousands nationally if the protocols are more widely adopted.

For now, though, the adoption rates remain spotty, according to Dr. Sean Townsend, an intensive-care doctor and researcher at Sutter Health in Northern California. Even the best-performing hospitals in the country, he said, comply with sepsis measures between 60 percent and 70 percent of the time.

Doctors and administrators who resist the protocols generally cite a few concerns: They fear that strict adherence to any protocol prevents doctors from exercising their best judgment with patients; others feel the protocols further deepens an emerging medical crisis around the overprescribing of antibiotics.

Some, like Dr. Mervyn Singer, professor of intensive care medicine at University College London, said that given the increase in antibiotic resistance, clinicians need more precise data about when such treatments are needed.

This study, he said, fails to provide that data.

He pointed out that while 23.6 percent of patients who did not complete the treatment protocols within three hours ultimately died, the proportion of patients who completed the protocols in the allotted time and also died was only marginally lower: 22.6 percent.

The study did not explain why some patients did not receive timely treatments, he said. But since most of the patients were elderly and possibly suffering from more than one chronic illness, he said, some may have had prolonged discussions with doctors about whether to aggressively treat a possible infection.

“I think a three-hour window is reasonable for treating most cases of sepsis, and some may benefit from more aggressive antibiotic treatment, he said. “But the idea that every hour makes a difference forces doctors to think they’re racing against time. And I’d argue that that three-hour window for some patients makes no difference whatsoever.”

## **A child’s case draws attention**

The issue of sepsis was long ignored by many in the medical community, including in New York state.

In 2012, however, a 12-year-old New York boy, Rory Staunton, died from a sepsis infection that resulted from a scrape on his arm and that was poorly managed by hospital staff.

His case was [later written about](#)<sup>4</sup> by New York Times columnist Jim Dwyer, and buoyed by that coverage and the attention it generated, New York state adopted “[Rory’s Regulations](#)”<sup>5</sup> the following year. The regulations made New York the first state to require that all hospitals provide early screening and documentation for sepsis, and adopt sepsis-response protocols to guide treatment — most notably, by administering antibiotics within the first hour of diagnosis.

Then, in 2015, the Centers for Medicare and Medicaid Services, which oversees the nation’s government-run insurance programs, adopted new guidelines that compel all hospitals that accept federal funds — nearly all hospitals, that is — to track their adherence to the sepsis-management protocols. (The protocols are known as the “Severe Sepsis/Septic Shock Early Management Bundle,” or SEP-1, for short, and it largely mirrors the “three-hour bundle” protocols adopted by New York.)

Some critics point out that the protocols were instituted before a deep analysis of costs and benefits. One element of the protocols calls for rapid administration of IV fluids, for instance, and the new research shows no association between that step and lower mortality rates.

There can be significant burdens, in terms of staff responsibilities and hospital finances. Some hospitals have had to add staff to process antibiotic prescriptions more quickly, and the protocols require physicians to circle back to any patients with symptoms of sepsis.

And sepsis is trickier to diagnose than other conditions.

“Humans just like a yes or no answer, like with heart attacks: you have a test for it. Yes or no,” said Simpson, of the University of Kansas. “It’s not, ‘Well, first you have to look for abnormal vital signs, then organ dysfunction and if they’re hypotensive I’ll pay attention.’”

“If it’s a little complex to diagnose, like sepsis, you can have trouble getting people to do it.”

In some environments, hospital administrators may be unwilling to devote resources to something they don’t necessarily see as a problem.

Morris Miller, CEO, Xenex Disinfection Services, a San Antonio-based maker of disinfection robots, said that in recent years, hospitals have begun to respond to the issue of sepsis when faced with CMS penalties for high infection rates. But some retain attitudes similar to a hospital CEO he encountered in 2011.

“I was describing the cost savings that a hospital could achieve by avoiding infections. He laughed and said ‘It’s not very flattering but we still make money even when we make people sick.’”

### **‘Hospitals are finally starting to listen’**

Many family members of those who have died of sepsis say their loved ones were doomed by clinicians who were overworked or negligent, or whose judgment was simply clouded with hubris.

Lisa Bartlett Davis lost her husband Jeff in 2012, roughly 24 hours after he checked himself into an Illinois hospital with a temperature of 104.6. He was told he had the flu and that he’d be discharged, despite his nurse’s verbal insistence that there was something else wrong.

“The doctor just blew her off,” Davis said.

After a shift change the next morning, her husband was in agony from the spreading infection. His blood pressure skyrocketed and a new doctor ordered tests of his spinal fluid. But Davis entered septic shock and died shortly after being transported to another hospital.

“We never found out the cause of the infection,” she said. “I still don’t know.”

Debbie Shearer’s son, George, faced even more troubling issues with his medical staff in Florida in early 2006 when he was recovering from surgeries following a car accident.

Hospital staff insisted that the 20-year-old shower, despite recovering from a craniotomy he had undergone to relieve pressure in his brain. Another staff person insisted on changing bandages on his legs as he sat on a toilet. When he started showing major signs of infection the next day – his legs turned black, among other symptoms – staff ignored the symptoms.

He languished for days in that hospital and in a subsequent rehabilitation facility before EMTs urged his mother to transport him to an acute care facility and an ICU. By the time he got there, his organs were failing. He later died.

“When I tried to explain to my dearest friends what happened, they said ‘Are you sure?’ There’s no way this could happen in our country,” she said.

“Now I feel like hospitals are finally starting to listen, and realizing that not only does it help to save lives if you have protocols — because every minute counts, as we know —but it also saves on health care costs,” she said.

If researchers quibble with the timing threshold at which sepsis-prevention protocols should be mandated, Simpson said, patient stories like these reveal the wisdom of at least attempting quick responses.

“There’s nothing wrong with shooting for shorter, but it’s clearly a mistake to shoot for longer,” he said. “Because whatever goal you set, you’re going to miss sometimes. Look at this as if you’re a patient. Or it’s your mom and dad.”

## Tags

## Links

1. <https://www.statnews.com/2017/04/27/sepsis-hospitals-coalition/>
2. <https://www.statnews.com/2016/02/22/sepsis-hospitals/>
3. <http://www.nejm.org/>
4. <http://www.nytimes.com/2012/10/26/nyregion/tale-of-rory-stauntons-death-prompts-new-medical-efforts-nationwide.html>
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