

Sepsis Risk Management

Tactics to Help Hospitals and Healthcare Providers Reduce Sepsis-Related Malpractice Risk

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SEPSIS is a serious medical condition

that affects more than 1 million Americans each year. Although healthcare professionals are making strides in reducing sepsis-related mortality, individuals who survive sepsis often experience long-term complications including physical, psychological, and/or cognitive impairment. These possible devastating consequences of sepsis and the general lack of understanding about the condition among patients and families have led to healthcare providers becoming targets of sepsis-related lawsuits. Ironically, our ability to save the lives of sepsis patients has resulted in increased professional liability exposure due to sepsis complications, which may be anticipated consequences of the disease rather than negligent care delivery.

This white paper discusses the risks associated with sepsis and outlines steps that hospitals and physicians can take to reduce their sepsis-related malpractice risks.

BACKGROUND

The Centers for Disease Control and Prevention has defined sepsis as “the body’s overwhelming and life-threatening response to an infection, which can lead to tissue damage, organ failure, and death.” Sepsis can arise from a variety of infections—even minor ones—such as skin infections, pneumonia, or urinary tract infections. When caught early, sepsis is treatable with fluids and antibiotics. Unfortunately, its symptoms such as elevated or lowered body temperature, increased heart rate, increased breathing rate, and low blood pressure can mimic symptoms of other conditions. However, sepsis can progress quickly and lead to organ failure and death when left untreated.

Annually, more than 1 million Americans are diagnosed with sepsis and more than 258,000 people die from the condition.¹ Between 2000 and 2008, the number and rate of hospitalizations for sepsis at U.S. hospitals more than doubled,² and it continues to rise.

As sepsis has become more prevalent, efforts such as the “Surviving Sepsis Campaign” have helped

improve clinical processes around sepsis with the goal to reduce the mortality rate.³ A study from Australia and New Zealand found a steady decline in the mortality rate for sepsis patients between 2000 and 2012.⁴ In the U.S., a Boston University study showed in-hospital mortality rates for patients with sepsis decreased from 47 percent for 1991 through 1995 to 29 percent for the period of 2006 and 2009.⁵

CHALLENGE

While reduced mortality is inarguably positive news for patients and the entire medical community, it also means an increase in the number of patients who may be living with the long-term and often devastating aftereffects of sepsis, such as cognitive impairment, organ dysfunction, and limb amputations. In addition, sepsis survivors have an increased risk of death even several years following their admission for sepsis.^{6,7,8} Specifically, the five-year mortality rate of sepsis survivors is double that of other hospitalized patients.⁹

Because few patients and families are aware of the possible consequences of sepsis and surviving sepsis, they may assume that medical misadventure has caused those consequences. That assumption prompts many to pursue sepsis-related malpractice litigation, which is increasingly associated with a disproportionate number of excess limits on judgments and settlements.

Generally, medical malpractice trial outcomes favor defendants 9:1, but sepsis creates substantial challenges that narrow the gap between plaintiffs and defense outcomes. The medicine is complex and subject to retrospective bias, and with their associated disabilities and disfigurements, plaintiffs are often very sympathetic to juries of laypeople charged with the task of sorting through the testimony of medical experts. Sepsis is very complicated even for healthcare providers. How can we expect jurors to fully understand this disease process when the medical community has not reached consensus on many issues—the greatest being how to diagnose it?

DIAGNOSING SEPSIS

In 1498 in his book, *The Prince Book III*, Niccolò Machiavelli wrote, “Hectic fever [sepsis] at its

inception is difficult to recognize, but easy to treat. Left untended, it becomes easy to recognize but difficult to treat.”

More than five centuries later, this statement still applies with respect to diagnosing sepsis.

For more than 20 years after the initial introduction of the definition of Systemic Inflammatory Response syndrome (SIRS) in 1992, SIRS was the rule of the land for identifying those who are at risk for sepsis, and healthcare providers followed it faithfully.^{2,3} Once adopted, SIRS was rarely questioned. Despite its limitations in specificity (i.e., producing many false positives), we found comfort in its reported nearly perfect sensitivity; no case of sepsis would be missed if a patient exhibited two or more SIRS criteria and a suspected or confirmed infection. That was, of course, until 2015 when Kirsi Maija, et al., published an article in the *New England Journal of Medicine*⁴ that looked at more than 1.1 million patients, of which 109,663 had infection and organ failure. Their conclusion is below.

“The need for two or more SIRS criteria to define severe sepsis excluded one in eight otherwise similar patients with infection, organ failure, and substantial mortality and failed to define a transition point in the risk of death.” This undermined the primary clinical decision instrument that had been in use for more than 20 years. Previously, SIRS received criticism for perhaps being oversensitive, identifying patients without sepsis along with those with sepsis. This revelation noted that SIRS lacked the sensitivity once assumed. This illustrates the complexity of identifying early sepsis, which is when treatment is most effective.

In February 2016, Singer, et al., published the new consensus definitions for sepsis and septic shock.⁵ Although a well-defined mechanism was used to come to consensus, consensus still means agreement and should not affirm anything more. But there is value in the new definitions as they attempt to simplify prior definitions and the approach to diagnosing sepsis.

As noted in boxes 2 and 3, the terminology and references related to sepsis have changed and reflect the above concepts. The consensus definitions recognize sepsis as a “syndrome,” that is

defined as life-threatening organ dysfunction caused by a dysregulated host response to infection,” and “Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality.”

These statements are a move forward in illustrating and communicating to others what sepsis really means. However, they may not get us any closer to diagnosing it. The SOFA and qSOFA (quick Sequential Organ Failure Assessment) scores are used in this outlined diagnostic strategy. However, skeptics have been quick to note that these tools may not perform any better than SIRS and have not been validated for use in this way and with populations outside of the intensive care unit.

New concepts and publications should not be construed as providing new evidence, effectiveness, or clarity. The Third International Consensus Definitions for Sepsis are new; however, they may not have solved the age-old question of how to identify sepsis. This new set of definitions should confirm how complex and difficult to define sepsis really is and continues to be.

SOLUTION

Although providing high-quality sepsis care and optimizing our ability to identify patients at risk for sepsis is always of critical importance, fully relying on diagnostic accuracy is a flawed strategy in light of our recognition that diagnosing sepsis has serious limitations.

Going forward, there are steps that healthcare providers can take to improve the quality of care delivery to patients while reducing their risk of sepsis-related professional liability exposure. Specifically, these would include:

- Clearly communicating information about sepsis and its potential complications to patients and their families
- Consistently utilizing an informed discussion/consent process for vasopressor use.

COMMUNICATION

Despite the prevalence of sepsis, a large portion of the population has never heard of it. Results of an

international survey¹⁰ published in 2009 showed a mean of 88 percent of interviewees in Italy, Spain, the United Kingdom, and the United States had never heard of the term. Furthermore, for those who had heard of it, 58 percent did not recognize that it is a leading cause of death. More recently, a 2014 survey by the Sepsis Alliance found that fewer than half of all Americans had ever heard of sepsis.¹¹

With such little general knowledge about sepsis, communication is even more critical. Physicians must be good bedside educators for patients with sepsis and their families, sharing information about the condition, answering questions, and appropriately conveying that sepsis is not a short-term affliction that will be “cured” when discharged from the hospital, but is instead a long-term disease process that increases the risk of health complications and death years after the event.

Physicians should also communicate about sepsis with patients who are at increased risk of developing sepsis, such as patients with infection, fever, increased heart or respiratory rate. Because of the diagnostic difficulties, some patients may have early sepsis before it is readily apparent, and some patients may develop the condition later. If there is no communication with the patient about the condition, the logical assumption is that the clinician never considered it. A simple conversation that explains sepsis and its associated risks and advises the patient about what signs and symptoms to watch for, along with specific “watch out for sepsis” after-care instructions for discharged patients and their families, would be valuable communication tools.

Research has shown that improved communication between patients and providers is associated with both improved outcomes¹² and a reduction in malpractice lawsuits.¹³

INFORMED CONSENT

In some cases of sepsis, physicians must administer a type of medication called a “vasopressor.” Vasopressors (e.g., norepinephrine) constrict peripheral blood vessels, increasing blood pressure and diverting blood flow to the vital organs (i.e., brain, heart lungs, kidneys). Sepsis results in vascular complications that could result in loss of digits and/or limbs, and the use of vasopressors may likely exacerbate this phenomenon.

When possible, prior to administering vasopressors, patients and their families should receive information about the dangers of vasopressors and be asked to consent to vasopressor use.

Hospitals and physicians can reduce their risk of alleged negligence by instituting an “informed consent” process when using vasopressors for patients with sepsis. That means conducting an informed discussion about the benefits and risks of vasopressors with the patient and/or the patient’s family prior to administering these drugs and documenting that discussion in the patient’s medical record. Some physicians and hospitals use a consent form that the patient or patient’s representative signs that they will accept treatment. However, the

form is not the most important action; the discussion is the critical piece to ensure the patient is truly “informed” about the proposed treatment.

CONCLUSION

Sepsis is a serious medical condition that affects a large and growing number of Americans each year. The condition carries long-term and frequently devastating health consequences, including an increased risk of death years after the event. To reduce the likelihood of medical malpractice allegations and to improve defensibility of the care provided, hospitals and healthcare providers should enhance patient communication and institute a discussion and informed consent process related to the use of vasopressors.

- ¹ Centers for Disease Control and Prevention. Sepsis Questions and Answers. 5 October 2015.
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- ³ Levy, Mitchell M. MD, FCCM, et al. “Surviving Sepsis Campaign: Association Between Performance Metrics and Outcomes in a 7.5-Year Study.” *Critical Care Medicine*. 2015;43(1):3-12. doi: 10.1097/CCM.0000000000000723.
- ⁴ Kaukonen K, et al. “Mortality Related to Severe Sepsis and Septic Shock Among Critically Ill Patients in Australia and New Zealand, 2000-2012.” *JAMA*. 2014;311(13):1308-1316. doi:10.1001/jama.2014.2637.
- ⁵ Boston University Medical Center. “Study shows decrease in sepsis mortality rates.” *ScienceDaily*, 13 November 2013. <www.sciencedaily.com/releases/2013/11/131113143558.htm>.
- ⁶ Centers for Disease Control and Prevention. Life After Sepsis Fact Sheet.
- ⁷ National Institute of General Medical Sciences. Sepsis Fact Sheet. August 2014.
- ⁸ Iwashyna TJ, Ely E, Smith DM, Langa KM. “Long-term Cognitive Impairment and Functional Disability Among Survivors of Severe Sepsis.” *JAMA*. 2010;304(16):1787-1794. doi:10.1001/jama.2010.1553.
- ⁹ Angus DC. “The Lingering Consequences of Sepsis: A Hidden Public Health Disaster?” *JAMA*. 2010;304(16):1833-1834. doi:10.1001/jama.2010.1546.
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- ¹¹ Centers for Disease Control and Prevention. Sepsis Awareness Month: Fewer than Half of Americans Have Heard of this Devastating Illness. 3 September 2014.
- ¹² Stewart, M A. “Effective Physician-Patient Communication and Health Outcomes: A Review.” *CMAJ: Canadian Medical Association Journal* 152.9 (1995): 1423–1433. Print.
- ¹³ Carroll, Aaron E. “To Be Sued Less, Doctors Should Consider Talking to Patients More.” *The New York Times*. 1 June 2015.