Insight and Perspectives

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We are pleased to offer our latest installment of *Insight and Perspectives*. This newsletter is dedicated to sharing healthcare news, trends and developments impacting our broker and insured customers.

In this particular installment you will find Scott Crockett's article on *Sepsis and Amputation: A High Priority Loss Trend.*

As always, we appreciate your continued support and thank you for allowing Endurance to be a part of your risk and insurance programs.

About Us

Our U.S. and Bermuda teams provide healthcare professional liability coverage to non-profit and for-profit hospitals and other healthcare organizations.

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Sepsis and Amputation: A High Priority Loss Trend

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Experience across multiple hospital systems, health-care providers and insurers offers a somewhat unique view of high severity medical malpractice cases and highlights distinct claims patterns. With a half dozen cases pending now and an equal number resolved in the last 12 months, the trend is unmistakable: sepsis cases involving amputation have been on the rise. Three or so years ago these sorts of claims were seen only occasionally.

While the causes leading to the increased frequency of these claims are not clearly evident, there is anecdotal consensus across the vast majority of Chief Medical Officers, infectious disease specialists and risk managers that the following three factors appear to be contributing to this trend:

- patients with sepsis who would have died as recently as five years ago are being saved, but with significant cost in terms of loss of limbs and organs, particularly kidneys;
- antibiotic resistance is making treatment more difficult; and
- there may be more septic patients.

The annual number of deaths in the U.S. caused by sepsis is estimated to be about 250,000. According to a study published in 2011 by the Agency for Healthcare Research and Quality, hospital stays for sepsis in the U.S. have at least doubled in the last few years and account for 1.6 million hospitalizations a year.

Sepsis: "The Catch 22"

Sepsis begins as an overly aggressive immune system response to a fungal, bacterial or viral infection. It is not well understood why this reaction occurs, but the result is blood clotting in smaller vessels, inflammation, low blood pressure and, in some cases, organ failure. When clotting prevents blood flow to tissues such as fingers, hands, arms, toes, feet, and legs, the tissues die and develop gangrene. Dead tissue must be removed (amputated) to prevent spread of the infection.

Diagnosing sepsis is difficult because its clinical presentation is consistent with many routine illnesses, such as cold viruses and flu. Sepsis victims often complain that they should have

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been given antibiotics at the initial time of presentation to the healthcare provider. The "Catch 22" is that over-prescription of antibiotics has contributed to bacteria becoming increasingly antibiotic resistant.

Practitioners worried about the possibility of a patient developing sepsis are inclined to administer broad spectrum antibiotics, which are thought to only increase the organisms' resistance to the antibiotics. Some researchers have suggested that in certain locales as much as 30% of organisms causing sepsis are "pan-resistant", meaning they are highly difficult (and expensive) to treat.

Defense and Cost of Sepsis

Medical malpractice cases involving sepsis are burdening more than our tort system. Infectious disease specialists have opined that infection and sepsis combined are generally one of the largest sources of operating losses for their hospital systems. Why is this?

Cases involving sepsis with amputation are challenging to defend simply due to the overwhelmingly sympathetic nature of the injury—although alive, the patient has lost body parts. The burden of proof invariably falls on the defendants to demonstrate the standard of care was met. Jurors need a coherent and convincing explanation of the events of the case to overcome their natural sympathy for the plaintiff. For this reason, while our office is aware of two defense outcomes in cases involving multiple amputations, the majority are settled prior to trial.

There are multiple variables that affect the value of an amputation case including the defensibility of the care provided, whether there are any applicable damage caps, and venue. One constant in these cases is future care costs which can range from $5 million to $30 million (according to plaintiffs' experts) depending on the age of the plaintiff, whether there is organ damage, and other factors. In states without pain and suffering caps, the exposure is significantly higher.

Because many cases settle with confidentiality agreements, it is difficult to know the entire range of claim outcomes. There are published settlements ranging from $1 million to more than $30 million, and settlements in the eight figure range are numerous. On the higher end of the spectrum, there have been recently reported sepsis/amputation cases with verdicts and settlements of $17.9 million, $21 million, $25 million, and $32 million.

Innovative Treatment Techniques

The costs of infection (sepsis in particular), both in human and monetary terms, have not gone unnoticed by healthcare providers, insurers and researchers. Dr. Patrick Conway, CMS Chief Medical Officer, has suggested that recently piloted techniques for reducing sepsis have resulted in mortality reductions as high as 50%. He expects those practices to become national standards with the implication that failure to adopt them will reduce reimbursements.

Some promising and even revolutionary approaches are also in development. A new FDA approved test, the Verigene Gram-positive Blood Culture Nucleic Acid test, can identify in approximately three hours a dozen or so specific bacteria that can lead to sepsis, while conventional blood cultures can take a day or more. Knowing up front what the pathogen is, doctors can more effectively and quickly identify an appropriate treatment regimen. However, cost is a limiting factor given that the equipment for the new test can cost as much as $100,000, versus about $75 for a blood culture.

More recently, The Wyss Institute for Biologically Inspired Engineering in Boston developed an artificial 'biospleen' to filter blood. They ran human blood containing a mixture of bacteria and fungi through the filter and reported most pathogens were removed in five hours. If equally effective in human trials (which could begin in two years), the filters could reduce the degree of infection to levels that the body could fight off on its own. The biospleen is now set for trial with pigs.

Mitigation Approaches Available Today

In the meantime, risk managers and insurers will need to be vigilant in identifying sepsis with amputation cases as high severity claims that merit their most capable lawyers and experts. Cases with standard of care weaknesses should be considered candidates for early resolution where possible. As for the disease itself, in the absence of these new treatments, early identification and aggressive diagnostic workup are key to better outcomes. Sepsis protocols should outline patient treatment interventions to be administered at the same time as confirming the diagnosis. The Society of Critical Care Medicine's Surviving Sepsis Campaign Website provides sample protocols for early identification and treatment guidelines, available at: http://www.survivingsepsis.org/Resources/Pages/Protocols-and-Checklists.aspx. ◄