Event Reporting & Analysis - Guidance

# Improving Recognition and Management of Sepsis and Septic Shock

## Executive Summary

Sepsis causes or contributes to the deaths of hundreds of thousands of patients each year. This issue of the *PSO Navigator* examines factors identified in reported events and offers strategies for improvement.

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## Leadership

### A Prime Target For Impactful Change

In lay terms, sepsis is "a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs" (Singer M et al.). The impact on mortality is massive; in fact, mortality rates for sepsis exceed those for heart attack, stroke, and trauma (Coopersmith). The condition causes or contributes to hundreds of thousands of hospital deaths each year (Elixhauser et al.).

Like many other life-threatening conditions, sepsis can strike suddenly and progress quickly. Prompt treatment is vital because for patients in septic shock, the chance of survival decreases by 7.6% every hour that antimicrobials for the underlying infection are delayed (Kumar et al.). Unfortunately, many healthcare providers have limited familiarity with sepsis and its signs and symptoms, which can mimic those of other conditions. Low awareness among the general public may be another factor; fewer than half of U.S. adults have even heard of the condition (Harris Interactive).

Because sepsis has profound effects on a vast number of patients, it is a prime target for healthcare organizations' patient safety and quality initiatives. This issue of the *PSO Navigator* provides an overview of the condition and challenges it poses, reviews events involving sepsis reported to ECRI PSO and its partner patient safety organizations (PSOs), and provides potential strategies for improvement. For a summary of ECRI's tips for improving sepsis care, refer to **Strategies to Improve Sepsis Recognition and Management** on page 2.

## Profound Effects on a Multitude of Patients

### Strategies to Improve Sepsis Recognition and Management

- Identify sepsis champions and specialists.
- Periodically review performance data and updates to guidelines, research, and tools.
- Undertake systems analysis of relevant work systems and processes.
- Analyze events involving sepsis, including transfers to a higher level of care.
- Design swift, coordinated processes for sepsis diagnosis and treatment.
- Educate all clinical staff on sepsis, and hone skills in its screening, diagnosis, and treatment.
- Promote vigilance for sepsis throughout the organization and for every patient.
- Use guidelines and tools, such as screening tools, bundles, and protocols, and measure how reliably they are implemented.
- Educate patients and the public about sepsis, and collaborate with care partners.

Sepsis is associated with high mortality and morbidity, and it affects vast numbers of patients. In-hospital mortality ranges from 15% to 30% (Gaieski et al. "Benchmarking"), and sepsis contributes to one of every two to three hospital deaths (Liu et al.). In fact, more than 258,000 in-hospital deaths with sepsis listed as a primary or secondary diagnosis occur each year (Elixhauser et al.). If this figure were represented in the list of top causes of death nationally, it would be the third leading cause of death after heart disease and cancer (CDC). But even these statistics may underestimate the impact of sepsis, because death certificates and coding may reflect the underlying infection or organ dysfunction without indicating sepsis as a factor (Popp; Saffer).

For survivors, postsepsis syndrome, amputations, and post-traumatic stress disorder are not uncommon. Up to half of sepsis survivors experience postsepsis syndrome, which may include effects such as worsening of cognitive function, hallucinations and panic attacks, severe muscle and joint pain, and fatigue (Sepsis Alliance).

Sepsis also has heavy financial implications for healthcare organizations. See **The Business Case** for more information.

Fortunately, sepsis outcomes are amenable to improvement. A recently published clinical review stated that despite increases in the incidence of sepsis, outcomes have "greatly improved overall" in the past 40 years—despite the failure of many proposed treatments in earlier clinical trials. According to the authors, likely reasons for the improved outcomes include the increased focus on the timeliness of diagnosis, fluid administration, and initiation of antibiotics and general improvements in the care of critically ill patients. However, many questions remain about optimal management of this complex condition. "Controversy continues to surround nearly every variable in the management of sepsis, with consensus around only a few key points," the authors write (Gotts and Matthay).

## New Definitions

### The Business Case

Sepsis is the most expensive condition treated in U.S. hospitals, accounting for 6.2% of hospital costs nationally, or $24 billion annually (Torio and Moore).

For individual healthcare organizations, sepsis has financial implications for the following (Popp):

- The operational budget. Sepsis care can devour resources, sometimes requiring expensive drugs, specialists, and intensive care unit (ICU) care.
- Reimbursement. Postoperative sepsis is now a measure included in the hospital-acquired condition payment-reduction program. And beginning in fiscal year 2017, adherence to the National Quality Forum's bundle for managing severe sepsis (which is now termed "sepsis") and septic shock (measure number 0500) will be included in the hospital inpatient quality reporting program. (CMS)
- The medical malpractice budget. Medical malpractice costs for sepsis-related cases are high, with most verdicts and settlements ranging from $1.5 million to $20 million.

When sepsis and septic shock were redefined in early 2016, the article that presented the new definitions soon became one of the most viewed *JAMA* articles ever (SSC "New Recommendations"). As of this writing, it had surpassed 1 million views and counting.

The new definitions remove uncomplicated infection from the definition of sepsis and eliminate the term "severe sepsis." Members of the task force that developed the definitions have emphasized the following points (Singer M; Coopersmith):

- What was called sepsis is now called infection. The previous definition focused on inflammation, but some signs of inflammation, such as fever, can arise even with uncomplicated infection. In many studies, inflammatory criteria did poorly in identifying which patients would have bad outcomes.
- What was called severe sepsis is now called sepsis. By focusing on organ dysfunction rather than inflammation, the new definitions emphasize that "sepsis is life-threatening by definition" (Coopersmith).

The PSO data reflected in the discussion **What We Are Seeing** predates the new definitions. However, it is important for healthcare organizations to familiarize themselves with the new definitions and tools.

**Sepsis.** Sepsis is "life-threatening organ dysfunction caused by a dysregulated host response to infection." For clinical purposes, organ dysfunction refers to an increase in sequential organ failure assessment (SOFA) score of at least two points—which is linked to an in-hospital mortality rate greater than 10%. SOFA, which requires the use of laboratory values, is widely known among critical care clinicians (Singer M et al.).

General hospital ward, emergency department (ED), and out-of-hospital settings are unlikely to routinely calculate SOFA scores. For these settings, the task force created a new bedside index called the quick SOFA (qSOFA) to rapidly identify adult patients who are "more likely to have poor outcomes typical of sepsis." Per the qSOFA, patients are at risk if they have at least two of the following criteria (Singer M et al.):

- Respiratory rate of 22 breaths per minute or more
- Altered mentation
- Systolic blood pressure of 100 mm Hg or less

If the patient meets qSOFA criteria, providers should investigate for organ dysfunction, begin or escalate appropriate therapy, and consider referring the patient for critical care or increase the frequency of monitoring (Singer M et al.).

However, qSOFA is intended to stratify risk and is not a "management trigger" (Singer M). Providers should still diagnose and treat patients whom they are concerned about even in the absence of two or more qSOFA criteria. Increases in qSOFA may indicate a need for more aggressive management, as the patient may be sicker than providers realized or may be getting worse (Singer M). Further, current tools used to screen for sepsis and diagnose it need not be abandoned. For example, criteria previously used for identifying systemic inflammatory response syndrome (SIRS) may still be useful in diagnosing infection (Coopersmith).

**Septic shock.** Septic shock is "a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality." Clinically, septic shock is identified by a need for vasopressors to maintain mean arterial pressure of at least 65 mm Hg and a serum lactate level greater than 2 mmol/L despite adequate volume resuscitation—a combination that represents a hospital mortality rate exceeding 40% (Singer M et al.).

### Treatment

The Surviving Sepsis Campaign (SSC), which is an initiative of the Society for Critical Care Medicine (SCCM), offers guidelines for managing sepsis (formerly called "severe sepsis") and septic shock. The guidelines feature two evidence-based bundles for addressing sepsis and septic shock (SSC "Bundles"):

- Steps to take within three hours: Measure lactate level, obtain blood cultures (if they have not yet been obtained), administer broad-spectrum antibiotics, and give fluids for low blood pressure or a high lactate level
- Steps to take within six hours: Give vasopressors for hypotension that has not responded to initial fluid resuscitation, reassess volume and tissue perfusion if hypotension has not responded to initial fluid resuscitation or if the initial lactate level was high, and remeasure lactate level if the initial level was elevated

For details, see the bundles and clarification from the campaign regarding how the bundles fit in with the new definitions (see Online Resources).

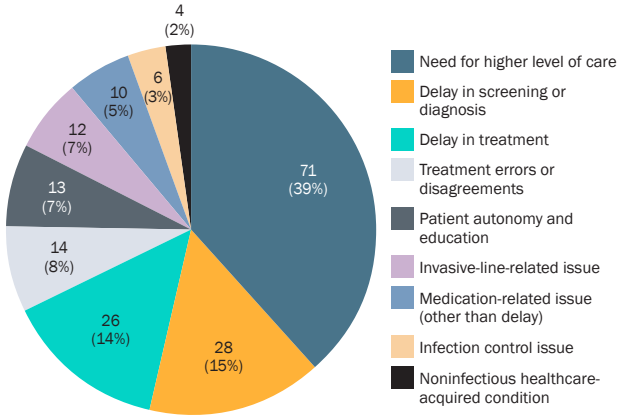
## What We Are Seeing

### Examples From the Database

ECRI PSO's database was queried for reports submitted between January 1, 2014, and December 31, 2015. The search terms used were sepsis, septic, SIRS, septicemia, and organ failure. A total of 446 relevant reports were identified.

For a sample of 184 reports (41%), the primary patient safety issue identified in each report was noted. A large sample was chosen to allow analysis of a range of patient safety concerns. These granular primary issues were grouped into overarching categories. Figure. Categories of Primary Patient Safety Issues Identified in a Sample of Sepsis-Related Reports from ECRI PSO Database (n = 184) illustrates the categories most commonly identified in reported events from the sample.

**Figure. Categories of Primary Patient Safety Issues Identified in a Sample of Sepsis-Related Reports from ECRI Institute PSO Database (n = 184)**




**Source:** ECRI Institute PSO Database. Component of ECRI Institute, Plymouth Meeting, Pennsylvania.

## Need for Higher Level of Care

Overall, 71 reports included in the sample fell under the category of need for a higher level of care. In 38 of the reports in this category, transfer to a higher level of care was the event being reported. In many of these cases, the underlying cause of the infection was not noted, and no other patient safety issues or concerns were raised.

It may be that in these cases, the care was appropriate and there was no opportunity for earlier recognition of sepsis or earlier intervention. However, healthcare organizations may consider analyzing a sample of reports involving transfer of sepsis patients to evaluate whether sepsis or the underlying infection might have been identified sooner or managed more aggressively. Factors to investigate may include how quickly the patient's condition and the seriousness of the condition were recognized and diagnosed, whether appropriate orders were entered and carried out in the transferring setting, and what systems factors may have contributed to any observed gaps.

Many reports in this category involved neonates. Of the 46 reports involving need for a higher level of care for which the patient age could be calculated or inferred (e.g., based on neonatal intensive care unit [NICU] or nursery location), 22 (48%) involved neonates. Similarly, need for a higher level of care accounted for about half of the 43 cases in the overall sample that involved neonates. Most of these reports noted no medical errors or other patient safety concerns. However, investigation may reveal opportunities to prevent or improve management of maternal infection or to prevent or improve management of early- or late-onset neonatal sepsis (**Early- versus Late-Onset Neonatal Sepsis** describes these terms and how the underlying infection of each is transmitted).

### Early- versus Late-Onset Neonatal Sepsis

Neonatal sepsis is classified as either early- or late- onset. In early-onset neonatal sepsis, the infant acquires the microorganism "vertically" from the mother before or during delivery. Definitions vary, but early-onset neonatal sepsis is often characterized as occurring within the first three days of life for infants in the NICU and less than seven days of life for term infants. Although maternal prophylaxis has reduced the incidence of earlyonset group B streptococcus (GBS) disease in the United States, GBS remains a leading cause of early-onset neonatal sepsis.

In late-onset neonatal sepsis, the infant acquires the organism vertically from the mother or horizontally from other sources. Late-onset neonatal sepsis has been characterized as occurring after the early-onset period, up to 90 or 120 days (Simonsen et al.).

Return to the operating room (OR) was the primary issue identified in 14 cases. In several of these cases, sepsis was potentially precipitated by surgical-site infections or surgical complications, as in the following report:

*After undergoing placement of a feeding tube, the patient had abdominal pain. Computed tomography imaging the day after the procedure identified a small space in the abdominal cavity, but the feeding tube was in the stomach. The next day, the patient went into septic shock and cardiac arrest. The patient underwent emergency surgery, which found that the feeding tube was in place but the stomach had partly fallen away from the abdominal wall and was leaking. The leak was repaired.*

Activation or other involvement of the rapid response team was the primary issue identified in 11 cases. As with reports involving transfer to a higher level of care, several reports involving the rapid response team noted few, if any, potential errors.

However, others provided more detail, as in the following case:

*Information in the electronic health record (EHR) suggested that an ED patient had possible sepsis. The charge nurse called the nursing supervisor, who went to the ED to investigate. The physician felt that the patient was stable for the floor. The patient a high heart rate, fever, and white blood cell count, and his blood pressure had dropped substantially. The patient arrived on the floor clammy and sweaty; his blood pressure had dropped further. One hour after fluids were administered, his blood pressure was very low. The physician and rapid response nurse were called. The physician ordered the patient's transfer to the ICU.*

Healthcare organizations may wish to investigate whether such cases reveal opportunities for improvement, such as timelier recognition of sepsis or escalation of management.

## Delay in Screening, Diagnosis, or Treatment

Together, cases involving delay in screening or diagnosis and those involving delay in treatment accounted for 54 cases in the sample, or 29%. Table. Issues Involving Delay in Sepsis Diagnosis or Treatment in a Sample of Reports from ECRI PSO Database illustrates patient safety issues identified in the reports.

## Table. Issues Involving Delay in Sepsis Diagnosis or Treatment in a Sample of Reports from ECRI PSO Database

| Patient Safety Issue | No. of Reports |
|---|---|
| **Delay in Screening or Diagnosis** | |
| Problems with specimens | 8 |
| Sepsis screening or evaluation delayed or not done | 7 |
| Test result communication problems | 5 |
| Laboratory delays | 4 |
| Radiology delays | 2 |
| Physician response or consultation delays | 2 |
| **Delay in Treatment** | |
| Medication administration delays | 10 |
| Pharmacy-related delays | 5 |
| Medical equipment not available | 4 |
| Phlebotomy-related treatment delay | 3 |
| Orders delayed or not entered | 2 |
| Inability to stabilize patient for transfer | 1 |
| Multiple delays | 1 |

Source: ECRI PSO Database. Component of ECRI, Plymouth Meeting, Pennsylvania.

As the table shows, delays were not limited to one area of the organization. Rather, they spanned many areas, including patient care locations (e.g., ED, ICU), the laboratory, the pharmacy, radiology, and communication with physicians. Additionally, many reports indicated that a result or response was delayed but did not indicate underlying reasons for the delay or factors contributing to it.

These two categories—delay in screening or diagnosis and delay in treatment—were also the most varied in terms of the types of patient safety issues identified; each comprised several distinct types of patient safety issues. These findings underscore the need for organizational strategies and systems and human factors analysis of work systems and processes for sepsis screening, diagnosis, and treatment.

Although many cases identified only one point of delay, the following case illustrates some of the many ways in which sepsis diagnosis and treatment can be delayed:

*The patient was in the ED for several hours. During this time, one antibiotic ordered to be given as soon as possible was never given. Stat labs were never drawn. No sepsis alert was called on admission. The patient was admitted to the ICU with sepsis. On calling the ED to clarify orders, the ICU physician was put on hold for more than five minutes with no response.*

Because sepsis and septic shock can progress quickly, delays can have serious consequences for patients. The following case provides one example, which also involved a medication dosage error:

*An intravenous (IV) antibiotic was ordered for an ED patient but was not available in the ED. When the patient arrived in the medical ICU, a sedative and two drugs to raise blood pressure, norepinephrine and vasopressin, were infusing via a peripheral IV line. The vasopressin was infusing at only 0.03 units per hour, instead of the recommended 0.03 units per minute. Fluids were infusing via a double-lumen peripherally inserted central catheter (PICC). The IV antibiotic ordered in the ED had never been administered. The patient was in profound septic shock and was severely hypotensive.*

### Treatment Errors or Disagreements

Among the 14 cases in the category of treatment errors or disagreements, common patient safety issues included inadequate discharge instructions or discharge plan, disagreement over the treatment plan, and missed diagnosis. In the following case, a missed diagnosis had serious consequences for a pediatric patient:

*The patient presented with abdominal pain and was admitted but then discharged home. Several days later, she presented to the ED. She had a ruptured appendix with a large abscess. She was brought to the pediatric ICU, where her many serious diagnoses included septic shock, respiratory failure, and fluid in the lungs.*

### Patient Autonomy and Education

In 10 of the 13 cases in the category of patient autonomy and education, the patient left against medical advice (AMA) or left the ED without being seen, as in the following case:

*A homeless patient was admitted at 23 weeks' gestation after her water had broken. She left AMA, then returned during the next day shift. A moderate amount of bloody amniotic fluid and foul odor was noted. IV fluids and antibiotics were ordered and started. The patient became agitated when her significant other prepared to leave with the patient's two other young children. The patient refused further treatment and insisted on leaving, despite a lengthy explanation regarding risks to the fetus and patient. The patient signed the AMA form and was brought to the reception area to await transportation.*

In other cases, patients left because they did not feel very sick and did not want to continue waiting for evaluation or treatment, had concerns about taking care of their children or missing work, or wanted to visit seriously ill loved ones, for example.

### Invasive-Line-Related Issues

In 4 of the 12 cases in the category of invasive-line-related issues, a central line was deemed necessary but was not placed or was delayed, as in the following example:

*The patient presented to the ED with very low blood pressure. Sepsis was diagnosed and antibiotics ordered. No central line was attempted in the ED. Interventional radiology received an order for a central line due to no IV access nearly seven hours after the patient's arrival in the ED. The patient was not a candidate for a PICC line due to kidney failure. The patient arrived with a small-gauge IV line in his hand; the site was red and very tender. A piggyback system had been set up; the bag of antibiotic medication was empty. The patient said he had been stuck by at least five people and had lost count of how many times he had been stuck. His skin had multiple bloody spots from IV attempts.*

Other common issues included contamination or infiltration of invasive lines.

### Medication-Related Issues

The category of medication-related issues, which included 10 reports, involved issues that are commonly seen with medications generally, such as wrong-dose errors, incorrect timing of doses, and problems with medication reconciliation. (Reports involving delays in the initiation of medications were included in the "delay in treatment" category.) Following is an example of a wrong-dose event:

*An older adult patient was started on an IV antibiotic at a dose of 2.25 g every eight hours for sepsis due to possible necrotizing infection. However, the recommended dose for a patient with his estimated creatinine clearance level was 4.5 g every eight hours. The next day, the patient went to the OR for incision and drainage. He arrived at the surgical ICU in septic shock.*

### Infection Control Issues

Of the six cases in the category of infection control issues, four involved failure to follow infection prevention and control practices, as hospital staff suspected in the following case:

*A patient presented to the clinic and received a chemotherapy drug via a chest wall port. In the following days, she felt unwell and reported fatigue. Four days after her visit to the clinic, her son found her unresponsive. She was taken to the hospital. On admission to the ICU, her port was draining pus. She was diagnosed with bacterial meningitis and sepsis and died the same day. Blood cultures were positive for Staphylococcus aureus; hospital staff believed the infection stemmed from her port access at the clinic.*

Other reports involved possible healthcare-associated infections in NICUs.

### Noninfectious Healthcare-Acquired Condition

As previously discussed, potentially healthcare-associated infections were observed in the sample. Additionally, four reports identified other hospital-acquired conditions, as defined by the Centers for Medicare and Medicaid Services (CMS), that are not inherently infectious (e.g., fall, pressure ulcer) in patients with sepsis. The following is one such case:

*The patient, who had been weak and confused due to sepsis, was found on the floor with stool around him. The patient was noncompliant with calling for help when out of bed. No injury was noted.*

Patients with sepsis often have risk factors for falls, such as low blood pressure and altered mental status. Effective falls prevention plans account for factors such as patient confusion, which may hamper patients' ability to remember to call for help whenever they need to get out of bed. Although this fall resulted in no injury and likely would have been exempt from CMS's policy regarding hospital-acquired conditions, other falls in the sample did result in patient injury.

## Lessons Learned

### Need for a Well-Coordinated Response

Many of the issues identified in reports from ECRI PSO's database relate to the larger work system in which sepsis is recognized and treated. Improving individual care processes is important, but attention must also be paid to the work system. As a result, many of the lessons learned underscore the need for organizational strategies.

### Teams, Champions, and Specialists

A sepsis initiative requires leadership support. To allocate sufficient resources, staff time, and commitment, leaders must understand the scope of the condition's impact on the organization's patient population. Sepsis Alliance and ECRI offer tools that can be used to inform leaders about sepsis (see **ECRI Resources** and Online Resources).

#### ECRI Resources*

- Sepsis: Combating the Hidden Colossus
- Sepsis at a Glance
- What is Sepsis?

* For information on obtaining ECRI resources, contact ECRI PSO at psohelpdesk@ecri.org.

Sepsis requires a well-coordinated interdisciplinary team to lead the effort. Potential members include physicians, nurses, laboratory, pharmacists, patient safety professionals, quality improvement staff, and risk managers.

Sepsis champions and specialists can lead and promote clinical efforts and offer expertise. Anecdotally, the STOP Sepsis Collaborative found that hospitals that identified, funded, and empowered sepsis champions in the ICU and the ED were the hospitals that excelled (Weingart). Some hospitals identify specialists in sepsis care, especially for pediatric populations (Popp; Saffer).

Sepsis is a high-risk condition, and understanding of its pathobiology is improving but "still uncertain" (Singer M et al.). Therefore, organizations may wish to periodically monitor data and new developments not just during implementation of a sepsis initiative but also on an ongoing basis thereafter. For example, a steering committee may meet periodically to review process and outcome data, changes to applicable guidelines, new research, screening tools, order sets, and other relevant information (Messineo). The recently published clinical review ("Clinical Review of Sepsis and its Management") provides an interactive overview of the current evidence regarding sepsis treatments (see **Online Resources**).

## Clinician Familiarity

Many clinicians have a limited understanding of sepsis and its signs and symptoms. Until recently, sepsis was the domain of EDs and ICUs and was not discussed or taught in educational programs in general hospital wards (Weingart). SSC's sepsis management guidelines first came out in 2004 (Dellinger et al.), after many clinicians in practice today underwent their initial training.

All clinical staff throughout the organization must be educated about sepsis, its recognition, and organizational processes to support diagnosis and treatment. In particular, nurses throughout the organization need to know the early warning signs of sepsis, be proficient in using screening tools, and take appropriate action if sepsis is suspected.

Potential strategies to improve clinician familiarity with sepsis include periodic education and training, opportunity to practice sepsis-related skills such as screening and diagnosis, and inclusion of these skills in competencies. Organizations may wish to share with clinicians information on the impact of sepsis and feedback on organizational and location-based performance to help spread awareness and garner commitment.

Many reports from the PSO database involved transfer to the ICU or calls to the rapid response team. On reviewing such events, healthcare organizations may find that signs of sepsis or the underlying infection, or the need to escalate management due to worsening condition, were missed in some cases. The organization can then identify strategies to facilitate timelier recognition and management.

## Vigilance Throughout the Organization

Although the ED and ICU are prime locations where sepsis is diagnosed and treated, sepsis can develop in patients throughout the organization. It is also a condition that can easily be missed or mistaken for something else. Therefore, healthcare organizations should promote vigilance for sepsis throughout the organization and for every patient.

Healthcare organizations can consider using sepsis screening tools in all care delivery settings (Messineo). However, the specific tools and criteria used may vary from one setting to another. Pediatric units, for example, typically have screening criteria that differ from criteria used in adult units. Some organizations have incorporated electronic screening tools that analyze data in the EHR, alerting clinicians to consider screening or evaluation for sepsis (Messineo). Additionally, a team of researchers created an algorithm that pores over EHR data in real time and "learns" which factors predict septic shock, rather than relying on existing screening criteria. It identified at-risk patients more than a day before septic shock occurred and, in the majority of cases, before they experienced any organ dysfunction (Henry et al.).

Clinicians should maintain a high index of suspicion for sepsis. The underlying infection may be unrecognized, or organ dysfunction may be occult. Therefore, the task force that created the new definitions stresses that clinicians should consider infection in patients with organ dysfunction and watch for organ dysfunction in patients with infection (Singer M et al.).

## Guidelines and Tools

### Online Resources

- AAP's commentary harmonizing neonatal sepsis guidelines with the CDC algorithm
- AAP's guidelines on managing early-onset neonatal sepsis
- ACCM's practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock
- American Heart Association's PALS guidelines
- CDC's GBS guidelines
- Clinical review of sepsis and its management
- EMCrit's lessons from the STOP Sepsis Collaborative
- EMCrit's list of resources, including links to STOP Sepsis protocols
- New definitions for sepsis and septic shock (Sepsis-3)
- SCCM's collection of resources on the new sepsis definitions
- Sepsis Alliance
- SSC's bundles
- SSC's clarifications regarding Sepsis-3
- SSC's implementation and improvement guide
- SSC's guidelines for managing sepsis and septic shock

Compared with many other medical emergencies, such as stroke, sepsis is complex to treat (Weingart; Saffer). The sepsis team should review available guidelines and tools for diagnosing and managing sepsis, such as the new definitions, the SSC guidelines and bundles, and protocols from clinical trials. Even after implementation, ongoing review of the evolving literature can help the organization ensure that its care processes stay up to date. In fact, the SSC guidelines and the American College of Critical Care Medicine (ACCM) practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock are undergoing revision (SCCM).

The literature illustrates the impact on outcomes. A study of 165 sites adopting SSC bundles—including hospital ICUs, EDs, and wards in the United States, Europe, and South America—found that unadjusted hospital mortality decreased from 37% to 31% over two years. This finding was observed despite only 31% compliance with the resuscitation bundle and 36% compliance with the management bundle at the end of the two-year period (Levy et al.). In one study of treatment for sepsis and septic shock in the ED, patients who received early, goal-directed therapy in the ED had an in-hospital mortality rate of 30%, while those who received standard therapy had a mortality rate of 46% (Rivers et al.). And as of June 2013, hospitals in the STOP Sepsis Collaborative had seen a 23% drop in mortality from sepsis (McKinney).

Management of pediatric and neonatal patients in septic shock is addressed in ACCM practice parameters for hemodynamic support of these patients and pediatric advanced life support (PALS) guidelines. The SSC guidelines also address pediatric patients, recommending use of the ACCM and PALS guidelines for initial resuscitation. Additionally, the Centers for Disease Control and Prevention (CDC) offers an algorithm for evaluating neonates with early-onset sepsis in its guidelines on preventing GBS disease. The American Academy of Pediatrics (AAP) has issued guidelines on managing early-onset neonatal sepsis, as well as commentary harmonizing the guidelines with the CDC algorithm. See Online Resources for information on accessing these materials.

Organizations should also measure how reliably guidelines and tools are implemented. If adherence is low, systems and human factors analysis may be used to identify ways to adjust the work system and processes to facilitate better adherence.

## A Swift, Coordinated Response

Delays in diagnosis and treatment of sepsis were frequently identified in sampled reports. Because patients with sepsis or septic shock can deteriorate quickly, healthcare organizations should design swift, coordinated processes for diagnosis and treatment—much like they have for other life-threatening conditions, such as heart attack and stroke. Systems and human factors analysis may be used to identify factors contributing to delays and strategies to facilitate more timely response.

The laboratory and pharmacy, in particular, may need to quickly provide test results and drugs. Because high lactate levels are often a key marker of sepsis, one lesson learned from the STOP Sepsis Collaborative is the importance of guaranteeing a 30-minute turnaround for lactate testing or investing in point-of-care lactate testing (Weingart). Studies conducted in the ED and delivery room have found that point-of-care lactate testing compares favorably with laboratory-based testing for normal to moderate lactate levels (Gaieski et al. “Accuracy”; van Horssen et al.). In a study of 160 patients in the ED with lactate levels of 2 mmol/L or greater, patients who underwent point-of-care lactate testing had lower time to test results (34 versus 122 minutes), time to IV fluids (55 versus 71 minutes), ICU admission rate (33% versus 51%), and mortality (6% versus 19%) than patients who underwent laboratory testing (Singer AJ et al.).

ECRI PSO’s analysis showed that many reports involve delays in screening or diagnosis, particularly test ordering, result reporting, and follow-up. Following are steps that healthcare organizations can take to improve test result reporting and response that apply to sepsis diagnosis:

- Analyze the entire test reporting and follow-up process, identify risk areas, and look for improvement and standardization opportunities.
- Identify critical tests, critical results, and fluid-refractory shock, as well as consider-critical values that require timely communication, and establish time frames for reporting results based on urgency.
- Establish a process for reporting critical results to the ordering provider. Include escalation steps to take if the provider does not respond or acknowledge the report. Consider using a call center to centralize this function, and ensure all results are reviewed each day.
- Use technology to flag critical and abnormal results in the EHR (e.g., by using a different color or font).
- Educate and engage patients about what tests are being ordered, why they are important, and when results will be ready.

## Invasive Lines and Antimicrobials

The SSC guidelines state that “establishing vascular access and initiating aggressive fluid resuscitation are the first priorities when managing patients with severe sepsis [since redefined as sepsis] or septic shock” (Dellinger et al.). Noninvasive protocols are available; the STOP Sepsis Collaborative created both an invasive and a noninvasive protocol, which are applied

depending on the patient's criticality and how he or she responds to hemodynamic support. The noninvasive protocol eschews the insertion of central lines for monitoring central venous pressure and oxygen during initial resuscitation, instead emphasizing empiric doses of fluids. Patients are switched to the invasive protocol if certain indications arise (Weingart).

For all patients receiving vasopressors, the SSC guidelines recommend placing an arterial catheter as soon as practical, if resources allow, to allow reproducible and continuous measurement of blood pressure (Dellinger et al.). For pediatric patients, the ACCM, PALS, and SSC guidelines address options for vascular access for various purposes, such as fluid resuscitation, infusion of vasopressors and inotropes, and cardiovascular monitoring in children with fluid-refractory shock, as well as considerations for fluid management.

Prompt initiation of antimicrobials is another time-sensitive priority. The SSC guidelines state that "the administration of effective intravenous antimicrobials within the first hour of recognition of septic shock…and severe sepsis without septic shock [since redefined as sepsis]…should be the goal of therapy." Whenever possible, blood cultures should be obtained before antibiotics are started, but antibiotic administration should not be delayed. Children may be given antimicrobials intramuscularly or orally until IV access is available. The guidelines cite several studies finding increases in mortality with delays in administering effective antimicrobials (Dellinger et al.), and delays of antimicrobial therapy were noted in the sample of reports from the PSO database.

But it is also essential to prevent antibiotic resistance so that when antibiotics are needed for a patient with sepsis they will be effective. The SSC guidelines state that initially, the antimicrobials chosen "should be broad enough to cover all likely pathogens," based on local prevalence and susceptibility patterns and patient exposure to antimicrobials within the past three months. However, therapy should be adjusted to target the causative pathogen as soon as it has been identified. The guidelines encourage collaboration with antimicrobial stewardship programs (Dellinger et al.).

## Infection Prevention and Control

Some of the sampled reports may indicate opportunities for improvement in infection prevention and control and related issues, either within the reporting organization or in prehospital settings. For example, in several cases, a healthcare-associated infection or infection resulting from a surgical complication was believed to be the underlying infection. Cases involving early-onset neonatal sepsis may indicate a need for better recognition, screening, and management of maternal infection before labor or a need to address challenges patients may face in accessing prenatal care.

Healthcare-associated infections are a concern in and of themselves, but cases leading to sepsis or septic shock—life-threatening conditions that are challenging to diagnose and treat—should give organizations even more impetus for preventing these infections. Organizations may wish to evaluate their infection prevention and control practices and to share concerns and collaborate with physicians and prehospital settings to improve infection prevention and control processes.

## Patient and Community Education

To optimize the timeliness of treatment, patients and the general public should know the signs and symptoms of sepsis, appreciate the need to seek immediate medical attention, and say to clinicians, "I am concerned about sepsis," as advocated by CDC and Sepsis Alliance. Healthcare organizations should ensure that patients understand sepsis and what they need to do if they experience its signs and symptoms, and they may wish to engage in community outreach to promote sepsis awareness.

### Education Teaser*

1. Conducting a failure mode and effects analysis is one way facilities can identify impediments to improving the timeliness of reporting test results. True
2. False

To improve the timeliness of reporting test results, facilities should work with physicians to:

1. Determine which tests and results are considered critical.
2. Establish appropriate turnaround times.
3. Establish target times for critical test reporting.
4. All of the above
5. None of the above

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Providers can proactively educate patients who have undergone procedures or are being treated for an infection on the signs and symptoms of sepsis and the need to seek immediate medical attention if they arise. Patients who are suspected of having or have been diagnosed with sepsis and/or their families likewise need to understand the condition and its treatment. The sample of events from the PSO database included cases of patients leaving AMA or leaving the ED without being seen. CDC and Sepsis Alliance offer information and tools for patients and the general public. Organizations should consider creating user-friendly patient education

materials and adopting universal precautions for health literacy— presenting information in a way that all patients can understand.

Because several patients in sampled reports left AMA because they were concerned about missing work or taking care of their children or they abused IV drugs, healthcare organizations, perhaps with the help of internal social services and external community organizations, may wish to investigate ways to ensure that patients who need care can stay to receive it. Others left because they did not want to keep waiting for evaluation or treatment. Factors contributing to long wait times may be analyzed and addressed.

Some sampled reports may indicate gaps throughout the continuum of care, such as accessibility and use of prenatal care and infection prevention practices in clinics. Healthcare organizations may work with care partners, such as physician practices, skilled nursing facilities, home care agencies, urgent care, freestanding EDs, and emergency medical services, to address identified gaps, improve sepsis recognition, and facilitate better care transitions.

Finally, healthcare organizations may consider undertaking activities to promote sepsis awareness among the general public. Sepsis Alliance offers resources that can be used for outreach and education, including patient stories, videos, resources for community events, and information for patients, the general public, and healthcare providers.

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