VANTAGEPOINT®

CNA
We can show you more.®

VP 2018 ISSUE 2

Sepsis Management: Five Strategies to Save Lives and Reduce Risk

Sepsis and septic shock are serious secondary consequences of infection, in which a toxic response by the body affects tissue integrity and organ function (and blood pressure, in the case of septic shock). Over the last two decades, considerable advances have been made in the diagnosis and treatment of sepsis. (See "Sepsis Care Initiatives," page 2). Nevertheless, it remains among the most serious of medical conditions. Sepsis is a major cause of death for hospital patients, and survivors may experience such sequelae as limb amputation, chronic post-traumatic stress disorder and post-sepsis syndrome, a condition marked by impaired cognition, hallucinations, panic attacks, fatigue, and severe muscle and joint pain. (See "Sepsis by the Numbers," at right.)

From a financial perspective, sepsis is associated with both high treatment costs – amounting to approximately $24 billion in annual healthcare expenditures – and significant liability exposure. Patients who suffer sepsis-related disabilities requiring ongoing medical care may seek legal recourse, with malpractice claims often alleging delayed or missed diagnosis and treatment. Due to the severity of patient injury and the extent of future treatment needs, indemnity payments or settlements in sepsis-related lawsuits may range as high as $1.5 million to $20 million.

Did someone forward this newsletter to you? If you would like to receive future issues of *Vantage Point*® by email, please register for a complimentary subscription at **go.cna.com/HCsubscribe**.

SEPSIS BY THE NUMBERS

It is difficult to overestimate the extent of mortality and morbidity associated with sepsis and septic shock. Studies show that sepsis …

- Strikes more than 1 million Americans every year.
- Is the nation's third leading cause of death.
- Is fatal in one in 10 cases.
- Is the principal cause of death for one third of patients who die in hospital settings.
- Represents 11 percent of the diagnoses of patients discharged from an acute care hospital.
- Has a readmission rate two to eight times higher than such serious conditions as heart failure, heart attack, pneumonia and chronic obstructive pulmonary disease.

SEPSIS CARE INITIATIVES

In recent years, a number of quality improvement initiatives have been introduced at the national level. These efforts, which include the following, promote an integrative and collaborative approach to sepsis detection and management, as well as reporting and performance measurement:

- Centers for Medicare and Medicaid Services (CMS) Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1), which consists of a prescriptive list of reporting measures designed to evaluate the quality and appropriateness of care provided to patients with sepsis or septic shock, including the timely administration of antibiotics.
- Institute for Healthcare Improvement Severe Sepsis Bundles, which comprise a three-hour resuscitation bundle and six-hour septic shock bundle.
- National Quality Forum (NQF) Severe Sepsis and Septic Shock: Management Bundle, which contains various guidelines and checklists, and is the basis of the CMS hospital inpatient quality reporting program listed above. (It is also known as NQF #0500.)
- Surviving Sepsis Campaign (SSC): International Guidelines for Management of Sepsis and Septic Shock, which emphasize the need for early goal-directed therapy when treating sepsis and shock. (SSC also has issued other evidence-based practice guidelines and resources designed to improve sepsis-related care. See the Surviving Sepsis Campaign Bundle: 2018 Update for a revised hour-1 bundle.)

(Note that *bundle* in the above descriptions refers to a structured set of evidence-based interventions designed to coordinate procedures and improve patient outcomes.)

To help providers in hospitals and ambulatory care settings combat the deadly and costly risks associated with sepsis, this edition of *Vantage Point*® focuses on five defense-minded strategies:

1. **Develop a single, consensual definition of sepsis** and apply it in all clinical settings.
2. **Raise awareness among providers of populations at heightened risk of sepsis,** as well as common predisposing conditions.
3. **Expand screening interventions** in clinical settings where most septic patients are initially seen, including emergency departments (EDs), urgent care centers and primary practice sites.
4. **Strengthen antibiotic stewardship programs** and align them with sepsis recognition efforts.
5. **Audit patient healthcare information records** to measure compliance with sepsis-related documentation protocols.

(For a discussion of sepsis care safeguards designed for pediatric patients, see *CNA Vantage Point*®, 2018–Issue 1, "Pediatric Acute Care: A Systemic Approach to Error Reduction," page 3.)

From a financial perspective, sepsis is associated with both high treatment costs – amounting to $24 billion in annual healthcare expenditures – and significant liability exposure.

ADOPTING A UNIFORM DEFINITION OF SEPSIS

In 2016, a global task force published the Third International Consensus Definitions for Sepsis and Septic Shock, known as "Sepsis-3." The document includes definitions of sepsis and septic shock, as well as clinical criteria for diagnosing these conditions. The Sepsis-3 definitions represent a significant departure from the previous clinical guidelines, last revised in 2001, and also from the more recent Surviving Sepsis Campaign (SSC) guidelines and practice bundles. Whereas sepsis was once defined around the presence of systemic inflammatory response syndrome (SIRS), the threshold finding is now life-threatening organ dysfunction, which distinguishes an uncomplicated infection from sepsis. (The essential changes introduced under the Sepsis-3 framework are summarized in Figure 1, below.)

Figure 1: Sepsis-3 Changes to Previous Clinical Guidelines

WHAT SEPSIS-3 REMOVES:	WHAT SEPSIS-3 ADDS:
The concept that sepsis is defined by systemic inflammatory response syndrome (SIRS) due to an underlying infection.	The definition of sepsis as a life-threatening organ dysfunction, which occurs when the body's reponse to infection injures its own tissues.
SIRS criteria – i.e., elevated heart and respiratory rates, as well as an altered body temperature and white blood cell count – as a basis for diagnosis.	Inclusion of the quick Sequential Organ Failure Assessment (qSOFA) as a means of identifying sepsis, utilizing three clinical criteria: altered mental status, increased respiratory rate and low systolic blood pressure.
The category of "severe sepsis."	Clarification that severe sepsis – i.e., acute organ dysfunction – is not a separate category or condition, but rather an advanced form of sepsis.
Outdated terminology, such as "septicemia" and "sepsis syndrome."	Adoption of a strict definition of septic shock, i.e., persistent hypotension requiring vasopressors to maintain a mean arterial blood pressure ≥ 65 mmHg and a serum lactate level > 2 mmol/L (18 mg/dL), despite adequate volume resuscitation.

Whereas sepsis was once defined around the presence of systemic inflammatory response syndrome (SIRS), the threshold finding is now life-threatening organ dysfunction, which distinguishes an uncomplicated infection from sepsis.

While Sepsis-3 offers healthcare providers a framework for identifying at-risk patients earlier and more efficiently, some critics assert that the new criteria are less concrete. In their view, the qSOFA scoring system focuses on *suspected* infection without confirmation based upon laboratory blood work, thus countering Sepsis-3's announced goal of helping providers make more definitive diagnoses.

The lingering concerns among some physicians over the validity of the Sepsis-3 framework may create the appearance that more than one diagnostic standard is in use. Such a lack of consensus regarding the nature and treatment of sepsis has both clinical and legal implications, considering that sepsis-related malpractice claims often focus on timeliness and accuracy of diagnosis. The following organizational initiatives can enhance provider understanding, acceptance and application of Sepsis-3 principles:

- **Appoint a physician champion to drive necessary changes** in clinical practice and written policy, and to help educate all providers.
- **Prepare a written handout or online resource delineating the differences between SIRS and qSOFA criteria** for members of the medical staff, and solicit their questions and concerns. (For guidance, see Rodriguez, R. et al. "Comparison of qSOFA with Current Emergency Department Tools for Screening of Patients with Sepsis for Critical Illness." *Emergency Medicine Journal*, May 2, 2018.)
- **Arrange an open forum with providers to discuss barriers to the adoption of Sepsis-3,** comparing the diagnostic nuances of the new definitions with the criteria found in existing practice bundles and evidence-based guidelines. Emphasize the similarities between Sepsis-3 and the older SSC guidelines, e.g., that both advocate screening patients for early identification and timely treatment of sepsis.* The aim is to encourage dialogue regarding the revised diagnostic criteria, thus gently guiding providers toward consensus.
- **Request provider feedback when developing guidelines for sepsis diagnosis,** and present the new or revised guidelines to the medical staff and quality improvement committee for discussion and approval prior to formal adoption.
- **Educate providers in all settings about the approved definitions and diagnostic criteria,** thus fostering a facility-wide shared approach to sepsis management, including documentation practices as well as diagnostic and treatment protocols.

* See "Surviving Sepsis Campaign Responds to Sepsis-3", March 1, 2016.

RAISING AWARENESS OF SEPSIS RISKS

All healthcare organizations should take steps to increase awareness among staff, providers, patients and their families of the populations most in danger of sepsis, as well as common predisposing conditions. The necessary and most obvious risk factor is an underlying infection, as described in "Common Types of Sepsis-related Infections" on page 5.

To ensure organization-wide consistency of knowledge and treatment approach, sepsis awareness initiatives should be directed at *all* healthcare professionals, including physicians, hospitalists, nurse practitioners, physician assistants and nurses, as well as triage specialists, emergency medical technicians, appointment schedulers and other support personnel. The following resource list is designed to support organizational training efforts, as well as awareness campaigns aimed at both healthcare professionals and patients:

- From the **Centers for Disease Control and Prevention (CDC):** Get Ahead of Sepsis, Sepsis, Clinical Resources and Sepsis, General Index.
- From the **Safe Care Campaign:** Sepsis-related fact sheets, posters and other resources.
- From the **Sepsis Alliance:** Frequently Asked Questions About Sepsis and Sepsis Alliance, Nurses' Station, "Sepsis and …" (information on prevention, risk factors and related topics), Sepsis Awareness Month Toolkits and Webinars for Healthcare Professionals.
- From the CDC's **Surviving Sepsis Campaign:** Educational Videos and Other Resources.

QUICK LINKS

- "Early Recognition of Sepsis in the Outpatient Setting: The Role of Practitioner, Patient and Family in the Earliest Phase of Sepsis." Atlantic Quality Innovation Network (AQIN), AQIN Community Based Sepsis Initiative, June 16, 2016.
- Get Ahead of Sepsis, a suite of educational materials from the CDC.
- Sepsis Information Guides from Sepsis Alliance.
- "Sepsis Mortality Reduction," from the Health Research & Educational Trust (HRET), 2017 Update.

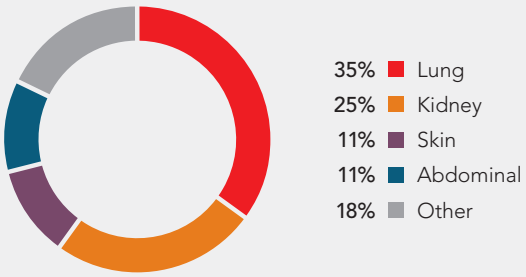
EXPANDING OUTPATIENT SCREENING

Nearly two-thirds of all admitted septic patients present initially to EDs. In order to detect symptoms sooner, caregivers throughout the ambulatory continuum should incorporate infection screening into their daily routine, whether in the context of an office encounter, admissions screening, urgent care visit or triage assessment. This clinical expectation should be addressed in job descriptions and included among performance review criteria.

Develop diagnostic aids. In cases of septic shock, the likelihood of survival decreases by 7.6 percent for every hour that antimicrobial treatment is delayed. Organizations can help providers recognize sepsis more quickly by incorporating diagnostic aids into primary, urgent/immediate, home, skilled and dialysis care settings, as well as hospital EDs, grand rounds and rapid response teams. In addition to adopting a standard screening tool, administrators should consider incorporating the following diagnostic aids into their formal sepsis protocol:

- Clinical decision bundle cards, infographics and pathways.
- Documentation templates adapted for electronic or hard copy records.
- Physician order sets.

Figure 2: Common Types of Sepsis-related Infections



Almost any type or severity of infection can trigger sepsis, ranging from infected insect bites and skin abrasions to more lethal conditions, such as meningitis and acute respiratory distress syndrome. Infections can be bacterial, viral, fungal or parasitic in origin, with the most common microbes being *Staphylococcus aureus* (*staph*), *Escherichia coli* (E. *coli*) and some types of *Streptococcus*. The very young and old are at a higher risk of developing sepsis, as are individuals who have an impaired immune system or suffer from a chronic or debilitating illness, such as diabetes, alcoholism or cancer.

(Source: "It's Time to Talk About Sepsis," a fact sheet from the Centers for Disease Control and Prevention.)

Adopt a "critical next step" protocol based upon qSOFA scores. The qSOFA scoring system is a mortality predictor, rather than a stand-alone diagnostic test. For patients with an infection, a "positive" qSOFA score (see box below) indicates heightened risk of a poor outcome. It should prompt clinicians to take swift and decisive steps to identify the nature and assess the severity of the infection, including but not limited to the following:

- **Transfer outpatients or residents of aging services settings** to a higher level of care.
- **Increase the frequency of inpatient monitoring,** and communicate the rationale to staff.
- **Request diagnostic laboratory work,** e.g., blood counts and cultures, lactate level, arterial blood gas analysis.
- **Initiate a physician order set,** including the administration of intravenous fluids and broad-spectrum antibiotics.
- **Calculate the Sequential Organ Failure Assessment (SOFA) score of hospitalized patients** and otherwise check for early signs of organ dysfunction. (Note that SOFA, designed for patients in intensive care, is the parent scoring system of the qSOFA.)
- **Transfer inpatients to an intensive care setting,** if clinically appropriate.

POSITIVE qSOFA CRITERIA

In non-intensive care settings, a qSOFA score is considered positive if the patient has two or more of the following clinical criteria:

- Respiratory rate ≥ 22/min.
- Altered mental state (i.e., a Glasgow Coma Scale score of 15 or less).
- Systolic blood pressure < 100 mmHG.

Utilize templates to document findings. Suspected sepsis must be documented in an objective and consistent manner. Key information includes the clinical observations and findings that prompt the call to the physician, as well as the name of the responder, the time of the response and the interventions rendered. The following sample "SBAR" (i.e., Situation, Background, Assessment, Recommendations) format for septic patients can help enhance documentation in a variety of healthcare settings:

Sample SBAR Format: Reporting Suspected Sepsis

SITUATION

1. (Patient name) has screened positive for sepsis at (time).

2. The patient has met two or more of the following qSOFA criteria *(check those that apply)*: ☐ Respiratory rate ≥ 22/min ☐ Altered mental state (i.e., a Glascow Coma Scale score of 15 or less) ☐ Systolic blood pressure < 100 mmHG

BACKGROUND

1. The patient is being seen/was admitted *(circle one)* for (insert diagnosis).

2. The suspected source of infection is: *(check all that apply)* ☐ Recent surgery, trauma or open wound(s) ☐ Respiratory illness ☐ Urinary tract infection ☐ Gastrointestinal symptoms ☐ Central line or dialysis catheter ☐ Other: _____

ASSESSMENT

1. Vital statistics are as follows. BP: _____ Respiratory rate: _____ Pulse: _____ Temperature: _____

2. Fever during last week. Yes/No *(circle one)*

3. Mental status is now (alert/verbal/lethargic). *(circle one)*

4. Lung sounds are _____.

5. Saturated O_2 is now _____, compared with _____ at (time).

6. Urine output is _____ cc per hour.

RECOMMENDATIONS

1. Based on positive screening criteria, the following actions should be taken:
   - Evaluate the patient to confirm clinical findings.
   - Consider transfer to an acute care facility (if outpatient) or intensive care unit (if inpatient).

2. Orders needed: ☐ Lactic acid level ☐ ABG analysis ☐ Blood culture ☐ Complete blood count

3. Should broad-spectrum antibiotics be ordered? Yes/No *(circle one)*

4. Should an intravenous line be started and fluids administered? Yes/No *(circle one)*

5. What other lab or diagnostic studies must be obtained? *(check all that apply)* ☐ Chest X-ray ☐ Urine culture ☐ Other: _____

6. If there is no improvement, when should the physician be called again? _____.

Date: _____ Caller's name: _____

Time of call: _____ Responder's name: _____

This sample form is for illustrative purposes only. As each organization experiences unique situations and statutes may vary by state, it is recommended that you consult with legal counsel prior to use of this or similar forms in your organization.

INTEGRATING SEPSIS RECOGNITION EFFORTS WITH ANTIBIOTIC STEWARDSHIP GOALS

In many cases, patients with suspected sepsis are treated with a swift application of broad-spectrum antibiotics, administered intravenously. However, prolonged administration of empirical antibiotics can be counterproductive, potentially weakening the patient's immune system and rendering the current pipeline of medications ineffective. To minimize side effects, specific pathogens should be identified as quickly as possible.

In an age of increasing antibiotic resistance and a proliferation of nosocomial "superbugs," healthcare organizations, government agencies and professional associations have developed a range of antibiotic stewardship goals, standards and processes. The various protocols should be aligned with sepsis recognition programs to ensure appropriate drug utilization. The following strategies can aid providers in swiftly determining the particular pathogen causing the infection and selecting the most suitable, least toxic antimicrobial agent:

- **Explore options for expedited pathogen-drug matches,** using rapid pathogen identification technology and antibiotic susceptibility testing, in contrast to slower blood culture growth-based systems.
- **Align physician order sets with national recommendations for appropriate antibiotic therapy** in the treatment of sepsis. (See the sample Adult Sepsis Order Set from Kaleida Health, which includes options for antibiotic therapy based upon probable sources of infection.)
- **Require physicians to assess the effectiveness of broad-spectrum antibiotic therapy within 48 to 72 hours,** utilizing available blood cultures and susceptibility profiles, as well as other available diagnostic data.

Providers should carefully document administration of antibiotics, including medication, dosage, route, time and patient response. In addition, all clinical findings, changes in antibiotic therapy and underlying rationale should be noted in the patient healthcare information record.

AUDITING SEPSIS-RELATED DOCUMENTATION

Of the 10 diagnoses most frequently associated with inadequate documentation, sepsis ranks second, according to the American Healthcare Information Management Association. (Scroll down to the section titled "Explain Why If Questioned.") In addition to enhancing quality and continuity of care, comprehensive documentation helps clarify providers' decision-making process in the event of later scrutiny.

Organizations can significantly enhance providers' compliance with sepsis documentation parameters by incorporating built-in checklists and alerts into electronic healthcare record systems. In addition, vigorous auditing of patient healthcare information records can shed light on problematic practices. (See "Ten Common Sepsis-related Documentation Pitfalls" on page 8 for guidance in monitoring patient records.)

Once sepsis strikes, every second counts. By ensuring that providers and staff respond to sepsis in a timely, compliant and well-coordinated manner, hospitals and healthcare systems can lessen the threat to patients' lives and well-being, while minimizing their own costs and exposure to liability, sanctions and negative publicity. And by emphasizing the need to thoroughly document all decisions made and actions taken, especially in such critical areas as screening and diagnosis, organizations can significantly strengthen their defense posture in a claim situation.

Providers should carefully document administration of antibiotics, including medication, dosage, route, time and patient response.

Ten Common Sepsis-related Documentation Pitfalls

1. **Slow response to outpatient symptoms.** Documentation suggesting a failure to appreciate signs and symptoms of a worsening bacterial infection in an outpatient may reflect negatively on the provider. Consider the case of a patient who comes to the office with a cough, low-grade fever and sore throat. She is treated with over-the-counter remedies and sent home, but returns two days later with an elevated fever, mild tachycardia and complaints of body ache. She is again discharged home, but later presents to an emergency department (ED) in septic condition. In hindsight, documentation of the two visits creates the appearance of a serious delay in diagnosing a patient with a suspected infection, especially when the second visit signaled potential systemic inflammatory changes. Utilization of an established diagnostic pathway can help ensure consistency and thoroughness in documenting the work-up of outpatients who may have early-onset sepsis.

2. **Delayed assessment in the ED.** ED records often note mild initial symptoms – such as a sinus cold or flu-like signs – in septic patients. A benign initial presentation may suggest that the patient was not fully evaluated. If a patient shows signs and symptoms of an active infection, exercise caution and promptly document a basic physical examination, including the patient's respiratory rate, oxygen saturation level and, if clinically indicated, a complete blood count and chest X-ray. Claims alleging delayed inpatient admission are more readily contested when the ED work-up includes sepsis as a differential diagnosis.

3. **Belated documentation of suspected sepsis.** As soon as possible after inpatient admission, providers should link signs and symptoms present on admission (POA) to the condition likely causing the problem. This practice has multiple benefits in terms of quality and continuity of care, patient outcome, reimbursement and legal defensibility. While additional work-up may be needed to confirm a diagnosis of sepsis, including as many descriptors as possible in POA documentation – such as "Fever, hypertension and tachycardia; differential diagnosis: sepsis" – strengthens the clinical record.

4. **Skimpy or unclear record of diagnostic work-up.** Once sepsis is suspected in a patient, providers may order additional diagnostic and laboratory tests in rapid succession. The record must include all test results and recommended follow-up, such as ultrasounds, scans and other radiological studies ordered to assess the nature and extent of the infection, as well as the time these interventions were ordered and performed.

5. **Confusion as to "time zero" for the purpose of starting the sepsis treatment clock. The** importance of timely intervention in treating sepsis patients cannot be overstated, which is why both the three- and six-hour bundles from the Surviving Sepsis Campaign impose time requirements. Although occasionally there may be some variance due to late onset of symptoms or elapsed time in the ED, most institutions use the time of triage as the zero point for patients presenting to the ED.

6. **Omission of definite sepsis diagnosis.** If sepsis is confirmed in a patient, an unequivocal statement of the diagnosis should appear on the patient healthcare information record. Notations such as "qSOFA 2+" or "increased RR and low BP" may later raise questions about when the condition was officially diagnosed and treatment begun.

7. **Untimely administration of antibiotics.** According to evidence-based treatment guidelines, intravenous antimicrobials should be started within an hour of recognition of septic shock. If the time lapse between the physician's order, pharmacy processing and administration of medications routinely exceeds this one-hour target, then the hospital should launch a performance improvement initiative, documenting the steps taken to achieve compliance.

8. **Ambiguous linkage of sepsis with organ dysfunction.** In view of the revised Sepsis-3 definition, documentation must expressly link organ dysfunction to the infectious process. Examples of such clear documentation would be "Sepsis with acute respiratory failure" or "Acute kidney injury due to sepsis."

9. **Inadequate documentation of specialty consultations**. Specialty providers in areas such as infectious disease, critical care and nephrology may be consulted early on during sepsis therapy, especially in cases of septic shock. Consultations should be thoroughly documented in the record, including the purpose of the consultation, name of the consulting provider, time of the assessment, clinical findings and any orders received.

10. **Failure to clearly indicate septic shock.** If a patient is in septic shock, document it directly. Do not assume that an implicit diagnosis will be understood by others. References to "hypotension," "lethargic" and "non-responsive to fluid" are not equivalent to a written notation indicating that a patient meets the clinical criteria for septic shock.

CNA Risk Control Services

ONGOING SUPPORT FOR YOUR RISK MANAGEMENT PROGRAM

CNA provides a broad array of resources to help hospitals and healthcare organizations remain current on the latest risk management insights and trends. Bulletins, worksheets and archived webinars, as well as past issues of this newsletter, are available at www.cna.com/riskcontrol.

Your SORCE® for Education

CNA's School of Risk Control Excellence (SORCE®) offers complimentary educational programs that feature industry-leading loss prevention, loss reduction and risk transfer techniques. Classes are led by experienced CNA Risk Control consultants.

SORCE® *On Demand* offers instant access to our library of risk control courses whenever the need arises. These online courses utilize proven adult-learning principles, providing an interactive learning experience that addresses current regulatory requirements and liability exposures.

Allied Vendor Program

CNA has identified companies offering services that may strengthen a hospital's or healthcare organization's risk management program and help it effectively manage the unexpected. Our allied vendors assist our policyholders in developing critical programs and procedures that will help create a safer, more secure environment.

When it comes to understanding the risks faced by hospitals and healthcare organizations… **we can show you more.®**

Publisher
Coleen K. Flynn, RN, BSN, JD, CPHRM

Editor
Hugh Iglarsh, MA

CNA

For more information, please call us at 866-262-0540 or visit www.cna.com/healthcare.