

Optimize Your Hospital's Sepsis Performance

What Current Guidelines Don't Cover and How to Bridge the Gap



In recent years, several states have joined the federal government's efforts to reduce the devastating human and financial costs of sepsis to hospitals and health systems across the United States. In doing so, the states have significantly increased pressure on hospitals to step up their sepsis performance improvement efforts.

Numerous other states are and will continue joining these efforts because there is increasing evidence that regulation and incentives work. In July 2019, the Journal of the American Medical Association (JAMA) published an article that found, "Mandated protocolized sepsis care in New York State was associated with a significantly greater decline in risk-adjusted mortality in New York compared with a group of control states that did not implement mandated protocolized sepsis care.¹" A month earlier, Indiana passed a law creating a Sepsis Treatment Guideline Task Force to develop best practices and provide guideline recommendations to the Indiana State Department of Health, which in turn will ensure hospitals and health systems throughout the state will adopt and implement the guidelines².

Cumulatively, these efforts reflect a growing wave of attention to sepsis that began in the 1990s, but has dramatically accelerated in the past few years in response to a few disturbing facts: sepsis still accounts for nearly 270,000 deaths each year in the United States—about 1 in 3 of all hospital deaths. Corresponding financial costs are \$24 billion a year. What's more, the reimbursement rate for

each sepsis incident typically leaves hospitals holding the bag for somewhere between \$7,100 – \$12,000³. And according to The Lancet's 2020 Global Burden of Disease Study, sepsis accounts for almost 20 percent of all deaths in 2017 worldwide⁴.

Sepsis accounts for nearly **270,000** deaths each year in the US



1 in 3 of all hospital deaths

Cost per year **\$24 billion**



The good news is that deepening understanding of the condition and the development of new tools and processes to guide detection and treatment make now a good time to optimize your sepsis performance improvement program.

SIRS

- Body temperature
- Heart rate
- White blood cell count
- Respiratory rate
- Systolic blood pressure
- Mental status

qSOFA

- Respiratory rate
- Systolic blood pressure
- Mental status



and will identify nearly all cases of sepsis that appear in a hospital. But this definition is not very specific and, therefore, generates a lot of false positives; most patients in the hospital that have SIRS criteria do not have sepsis. If used for electronic alerting, these criteria lead to alert fatigue.

Dissatisfaction with the SIRS-based definition led to an alternative measure—a sequential organ failure assessment (SOFA) score. SOFA scores are based on six individual scores, one each for the respiratory, cardiovascular, hepatic, coagulation, renal and neurological systems. A modified version—qSOFA or quick SOFA—measures just blood pressure, respiratory rate and altered mentation. In 2016, a task force from the SCCM and the European Society of Intensive Care Medicine concluded that sepsis should be defined as life-threatening organ dysfunction caused by a dysregulated host response to infection as represented by an increase in a SOFA score of two points or more. That measure came to be known as Sepsis 3.

Sepsis 3 is considerably more specific than Sepsis 1, but it is not nearly as sensitive so can miss cases of sepsis. Moreover, Sepsis 3 criteria are often positive later in the course of the disease than Sepsis 1 criteria; by the time a patient is identified as having sepsis with Sepsis 3, the condition may have progressed to the point that the patient is at considerably greater risk of dying^{5,6,7}.

As medicine struggled with how to accurately detect sepsis in a timely fashion, it has also sought ways to properly treat it. In 2001, the New England Journal of Medicine published a randomized trial from Henry Ford Hospital in Detroit⁸, which concluded that early, goal-directed therapy (EGDT)—an approach involving

Roots of the Current Guidelines

Among the advances in recent years are refined detection and treatment guidelines from the Center for Medicare and Medicaid Services (CMS), the Society for Critical Care Medicine (SCCM), the Sepsis Alliance, the Rory Staunton Foundation and others—as well as CMS’s decision to publicly display sepsis scores on its Hospital Compare public portal. Transforming these guidelines into an effective tool for an individual hospital or health system begins with understanding how the efforts evolved.

In the late 1980s and early 1990s, hospitals became increasingly aware of the burden that sepsis exacts on patients. Initial responses focused on better defining the condition and on creating proper criteria for detection. In 1991, the American College of Chest Physicians and the SCCM introduced definitions for systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis, septic shock and multiple organ dysfunction syndrome.

SIRS—a combination of abnormal body temperature, rapid heart rate, tachypnea, and a low white blood cell count—became the basis for a definition during a 1991 consensus conference, commonly referred to as Sepsis 1. It requires two or more SIRS elements, plus infection. Sepsis 1 has been and remains the most widely used measure for detection, since it is highly sensitive





While current guidelines have considerable overlap, the differences reflect how experts continue to wrestle with the best ways to detect and treat this devastating condition [sepsis].

adjustment of cardiac preload, afterload and contractility to balance oxygen delivery with oxygen demand by measuring utilizing objective data to decide treatment options—was superior to standard therapy. EGDT became best practice until 15 years later when the PRISM trials⁹ (ProCESS, ARISE, and ProMiSe^{10,11,12}) led to a change in best practices. Today, EGDT is not better than usual care, probably because over the ensuing decade or so, medical staff have advanced their understanding and treatment of sepsis. Individual physician decision-making, rooted in an understanding of the basic principles of sepsis treatment, has become the standard approach.

This evolving understanding has given way to two prominent sepsis initiatives: CMS “bundles” and reporting requirements and the SCCM’s Surviving Sepsis Campaign. While these guidelines have considerable overlap, their differences reflect how experts continue to wrestle with the best ways to detect and treat this devastating condition.

Pros and Cons of Today’s Leading Initiatives

Centers for Medicare and Medicaid Services (CMS)

CMS first required hospital reporting on the SEP-1 measure beginning in October 2015. Since then, the agency has continued to modify the measure, requiring hospitals to make corresponding changes to the way

they document and report their adherence to the measure and the recommended CMS three- and six-hour treatment bundles, which have proscribed elements for items such as fluid administration and lactate testing. In addition, in July 2018, CMS announced that it would publicly display sepsis scores on its Hospital Compare public portal.

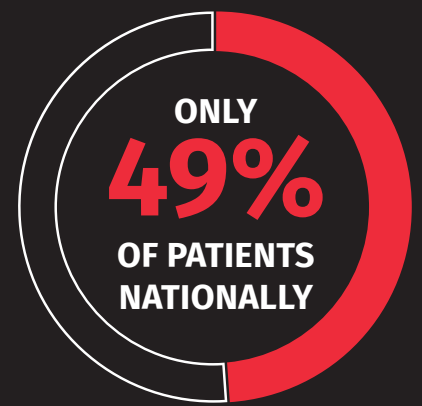
Sepsis reporting to CMS is based on ICD-10 coding for sepsis; patients coded for sepsis are eligible for the measure. Yet ICD coding has changed in recent years, because the publication of the Sepsis 3 definition has resulted in only recognizing sepsis in patients that have organ dysfunction as a result of the disease. Consequently, CMS sepsis reporting is limited to cases with organ dysfunction or shock.

How do the CMS regulations and incentives affect sepsis treatment and detection? If history is any guide, they should contribute to improvements in reducing mortality, long-term disability from sepsis and length of stay. These are no small things.

However, some have raised concerns that the requirement that hospitals only report those cases that also involve organ dysfunction could incent sepsis improvement programs to focus on that measure, rather than on the need for early care—a critical success component for reducing mortality rates. Another concern is that CMS regulations may require excessive testing, such as a second lactate test. For an experienced physician who can evaluate patient progress without such a test, the requirement can seem an unnecessary burden. Finally, some argue that reporting mandates of any kind steal time and attention from addressing the most important outcomes, like sepsis-related mortality and disability—and even other life-threatening conditions in a hospital.

Surviving Sepsis Campaign

As noted above, the SCCM has long been a leader in defining how to address sepsis. Its Surviving Sepsis Campaign devises and refines detection and treatment guidelines in collaboration with the Institute for Healthcare Improvement. While there is considerable overlap with CMS guidelines, distinctions emerge because the Surviving Sepsis Campaign updates its guidelines more frequently than CMS, based on the latest evidence.



receive appropriate care for severe sepsis or septic shock, according to CMS's Hospital Compare.

Perhaps the most prominent example is the Campaign's recommendation to begin antibiotics within one hour, rather than three. The recommendation is controversial. Some evidence supports earlier administration of broad-spectrum antibiotics^{13,14,15}. Nevertheless, without any randomized, controlled studies to look at the advantages and potential drawbacks of the one-hour window, some argue that an hour to recognize symptoms, properly diagnose, and then order, deliver, and administer antibiotics is inappropriate. It may seem reasonable, but a recent randomized controlled trial of pre-hospital administration of antibiotics did not demonstrate an improvement in patient outcomes with the earlier administration of antibiotics¹⁶. More important, perhaps, one hour may not be enough to properly determine if a patient truly has sepsis and hospitals could wind up administering broad spectrum antibiotics to people that don't need them. This could do more harm than good and come directly into conflict with antimicrobial stewardship programs—another element of enhanced patient safety.

The Sepsis Alliance/Rory Staunton Foundation

Two other major players guiding sepsis detection and treatment are the Sepsis Alliance and the Rory Staunton Foundation. The Sepsis Alliance primarily emphasizes the need to educate and train providers. Its educational materials include webinars, fact sheets, posters and checklists that are based on other guidelines and best practices. Similarly, the Rory Staunton Foundation has

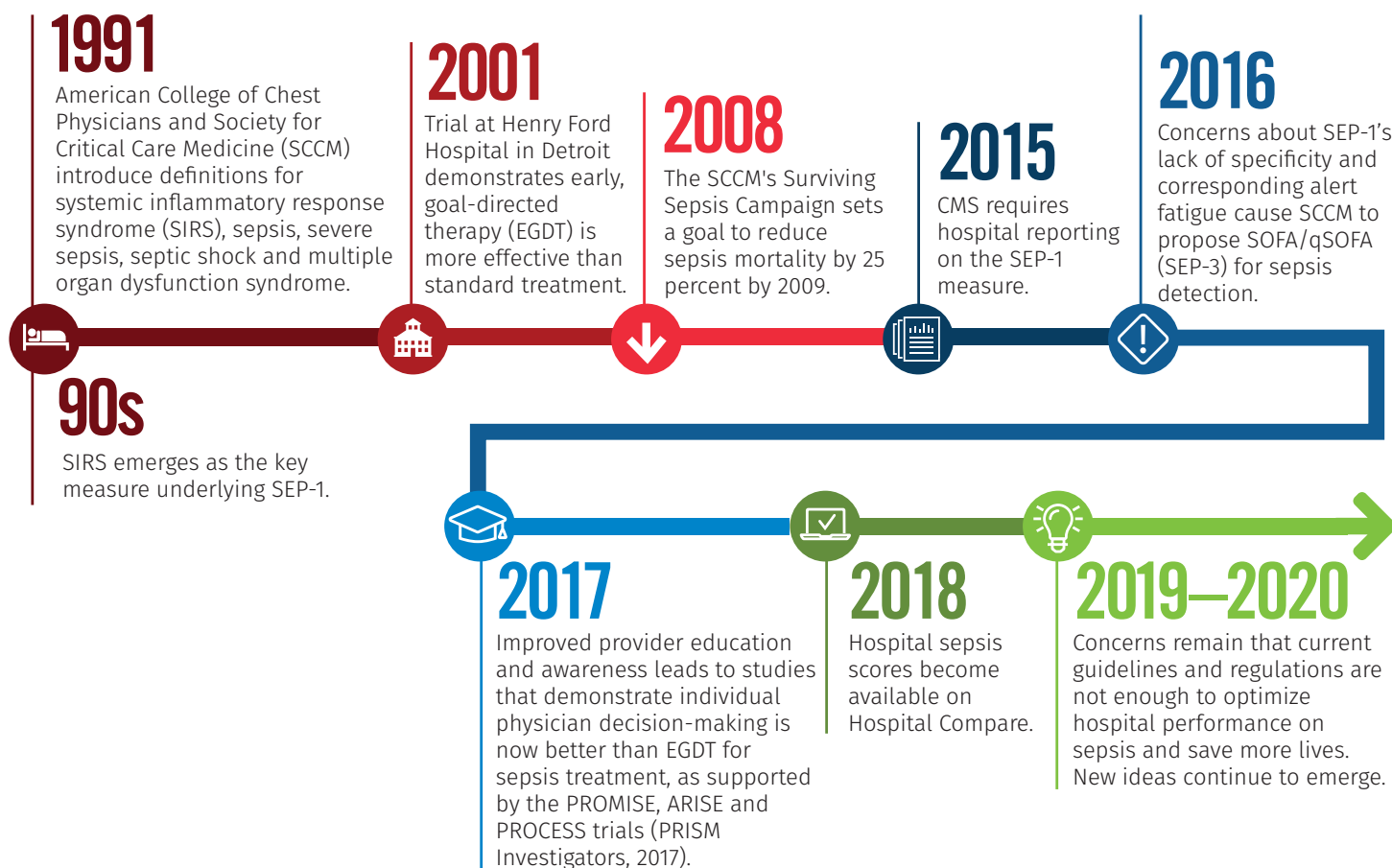
been an important player in raising sepsis awareness. While hospitals and health systems should not look to either of these groups to change practice patterns based on new research, both play a critical role in effectively disseminating best practices throughout the clinical environment.

True Performance Improvement Moves Beyond Guidelines

In formulating a sepsis improvement performance program, each hospital will determine which guidelines to follow and to what degree, based on their particular situation and understanding of the pros and cons of each. That said, understanding and using the guidelines is simply the essential starting point for full-blown sepsis performance improvement. Truly effective programs have a number of additional elements. We list some of the most important ones here.

Team with senior leadership to inspire change and bring the entire organization on board to optimize sepsis detection and treatment.

While some sepsis program coordinators can drive change simply by force of personality, that is the exception rather than the rule, because it can be such a heavy lift. It's no secret, of course, that significant organizational change is hard. Therefore, wherever possible, it's important to have the support of senior leadership. Equally important, sepsis program coordinators should find ways to garner buy-in from



clinical leaders such as the chief medical officer, chief nursing officer and key administrative nurses, as well as the informatics, IT and quality departments. Data can play an important role to communicate why change is important and the impact that can be made with strategic changes to a sepsis program.

Use data to identify problems and drive change.

Many hospitals and health systems don't recognize they are underperforming with sepsis and, so, can't begin to understand where the concerns are and how to address them. Gaps in care can occur everywhere, from failing to recognize sepsis in a timely way through ordering delays, failures to use order sets, intentional noncompliance with orders and protocols, delays in getting or acting on orders, delays in getting lab results and delays with phlebotomy or pharmacy.

Why do these problems occur? There are multiple reasons, including:

The failure to create multiple order sets. Most hospitals have a standard sepsis order set that is used upon admission, but many fail to create different versions of the order set that focus on additional treatments

for sepsis as it progresses during a hospital stay, such as a rule-out sepsis protocol, or the patient that develops nosocomial sepsis with hypotension or shock. Furthermore, many hospitals do not delineate screening order sets for nursing staff or rapid response team members as opposed to provider order sets.

Inadequate protocols. Protocols must meticulously detail roles and responsibilities, such as when a bedside nurse should call rapid response teams or the provider. Many don't.

Inadequate provider education. There should be clear educational requirements for all nurses and providers, as well as training requirements for any new personnel—a piece of the puzzle that is often overlooked.

Gaps in data analysis and reporting. Hospitals should be collecting data on everything from CMS bundle compliance through alert response times, use of order sets, compliance with protocols, length of stay and mortality. They can use the ensuing reports for regulatory compliance and to help drive provider change.

Establishing the proper metrics for your hospital's needs and putting in place data collection around those

metrics enable hospitals to analyze all components of sepsis care, and determine how to institute life- and money-saving changes. If the solution doesn't become clear from initial reports, hospitals can diagram workflow to unearth the root cause of failure.

Often, once a hospital identifies a problem, the solution can be quite simple. For example, some hospitals choose to move antibiotics from pharmacy to an emergency department refrigerator to save time in getting antibiotics to the point of care. Others do lactate testing at the point of care without waiting for phlebotomy and lab testing.

As hospitals devise change plans, they should carefully and thoroughly lay out roles and responsibilities for the various hospital settings.

As noted above, one of the most common mistakes in sepsis improvement plans is the failure to develop detailed protocols for the most common settings and situations. This must go beyond an order set and a high-level plan. All members of the team need to understand what they need to do and when and who to call for each of the key points in the plan. Depending on each hospital's individual situation, the team members will typically include bedside nurses and/or charge nurses at the point of care, providers, providers-in-training and members of the rapid response team. All should be represented when devising the plans.

Empower clinical staff, particularly nurses, to practice to the top of their license.

Empowering nurses to become more involved in sepsis screening—and, if patients meet sepsis criteria, ordering appropriate tests—can expedite both sepsis detection and treatment. This can be more of a challenge in some hospitals than others, but it is a proven model for improving sepsis care. For nurses and sepsis coordinators, overcoming cultural barriers to empowering nursing staff likely involves nursing leadership approaching provider colleagues and hospital governance with a concrete plan that: a) draws on studies showing how having trained nurses deeply involved in sepsis education and detection can improve surveillance, and b) outlines a nurse-driven, provider-approved protocol for nurses to initiate testing under specific circumstances as part of an effort to speed detection and treatment.

Incorporate electronic surveillance into any sepsis performance improvement program.

Well-selected electronic surveillance can use advanced techniques like artificial intelligence and natural language processing to free data that is often buried in EHRs. The benefits of doing so include the ability to:

- Identify crashing patients faster and message appropriate administrative personnel in a variety of ways for rapid transfer to the ICU.
- Track therapeutic implementation while integrating hospital assignment systems into its algorithms so it can send targeted reminders to clinical staff to perform those elements of care that haven't been completed.
- Document cases where comorbidities may warrant appropriate deviation from sepsis protocols, as reduced IV fluid administration.

Stay Focused on What Truly Matters

Over the last 25 years, there is no question that sepsis detection and treatment have improved, with clear reductions in patient deaths. Of late, however, the improvements have leveled off, but the cost in human lives remains unacceptable, as does the cost to hospital bottom lines. The latter compromises hospitals' ability to implement improvement efforts, whether it is for sepsis or any of the other important challenges in health care.

With this in mind, clinicians certainly must understand and address the increased regulatory pressures they are facing at both the state and federal levels, because most have emerged for good reasons.

Yet if clinicians only see or respond to the requirements, they are likely missing out on the most promising elements for improving sepsis care. Those elements will do more than meet minimum standards set by regulators; they will save more dollars for the health system and, most importantly, save more lives.

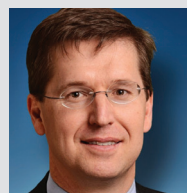


A Better Way: Senti7® Sepsis Monitor

The only sepsis surveillance solution with scientifically calculated and published results, Sepsis Monitor has achieved outcomes unmatched in the industry. A 2016 study in the journal of the American Medical Informatics Association (JAMIA)⁶ found:



Sepsis Monitor delivers proven improvements in key sepsis performance metrics by detecting the condition six to eight hours before patients develop organ dysfunction, a commonly used sepsis definition for EHR-based surveillance. Every hour sepsis goes undetected means an increase in mortality and cost. Real-time identification of patients with sepsis and providing clinicians with evidence-based guidance is crucial to reduce variation in care and to improve financial and clinical outcomes.



Author

Steve Claypool, M.D.

*Former Medical Director,
Clinical Surveillance & Compliance,
Wolters Kluwer, Health*

Stephen Claypool, MD, is Medical Director of the Surveillance business for Wolters Kluwer Health, an organization that delivers expert solutions that empower healthcare professionals to make the best decisions using clinical decision support technology, evidence-based medicine and predictive analytics to improve patient outcomes. Dr. Claypool has more than 20 years of experience in informatics research and product development, as well as 10 years of experience as a practicing physician in Minnesota. He received an undergraduate degree from Colorado College, Colorado Springs, and a medical degree from the University of Minnesota School of Medicine in Minneapolis. Dr. Claypool also obtained board certification in clinical informatics in 2014.

SoleSource_info@wolterskluwer.com | 800.654.8395

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