

Sepsis' clinical evolution: Understand essential challenges to developing effective queries

ADVICE FROM THE ACDIS REGULATORY COMMITTEE

Summary: This paper provides a timeline of the various sepsis definitions and their implications for CDI and coding. Additionally, this paper includes a list of policy recommendations from the ACDIS Regulatory Committee.

FEATURES

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Sepsis is a common clinical finding in patients admitted to the hospital. Documenting the presence of sepsis is critical to best determine each individual patient's needs for care. However, clinicians often vary in their definitions of sepsis or fail to note the presence of sepsis in the medical record when the clinical indicators support such assessment.

These variances in how clinicians view sepsis have led to difficulties for CDI specialists, especially when third-party payers and quality programs adhere to different definition sets for sepsis as well. To demonstrate consistency in reporting, coding, and clinical care, healthcare facilities must develop a consistent approach to the definitions of sepsis as a reference for teaching, quality measurement, clinical care, and coding purposes.

Definitions: A literature review

To understand the current issues surrounding the definition of sepsis, some history is required. While sepsis has been a known clinical entity for many years, the story of sepsis in the modern era began in 1992 with the release of "Definitions for Sepsis and Organ Failure and Guidelines for the Use of Innovative Therapies in Sepsis" from the American College of Chest Physicians and the Society for Critical Care Medicine Consensus Conference Committee. (The document is now referred to as Sepsis-1.)

This seminal work was the first to apply a definition to the clinical syndrome of sepsis, based on the prior recognition of systemic inflammatory response syndrome (SIRS), a cascade of physiologic changes that follows insult to the body and includes elevated temperature, tachycardia, tachypnea, and white blood cell parameters. The Consensus Conference Committee established sepsis as "SIRS plus infection." The group also considered that sepsis existed along a continuum of severity, and established a conceptual model of sepsis, severe sepsis ("sepsis associated with organ dysfunction, hypoperfusion, or hypotension"), and septic shock ("sepsis-induced hypotension unresponsive to fluids with perfusion abnormalities") as points along the spectrum.

With the initial 1992 release of a consistent definition for sepsis, other groups began researching treatments for the disease progression. The seminal study in the modern era of sepsis management, "Early Goal-Directed Therapy [EGDT] in

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the Treatment of Severe Sepsis and Septic Shock,” emerged in 2001. This work, published in the *New England Journal of Medicine*, demonstrated decreased mortality rates for septic patients using a group of EGDTs under a patient care protocol. Together with subsequent works, it gave rise to the Surviving Sepsis Campaign.

The Campaign was formed by the Society of Critical Care Medicine, the European Society of Intensive Care Medicine, and the International Sepsis Forum in 2002 with the express goal of developing sepsis treatment guidelines and reducing sepsis mortality by 25%. It originated the use of the “sepsis bundle,” a term for a set of EGDTs designed to combat mortality from sepsis. Over time, the validity of the results of the early study has been questioned, and additional work has demonstrated that a less invasive approach to sepsis management focusing on early recognition, early antibiotics, fluid management, and use of vasopressors is also effective. The concept of the sepsis bundle persists today, albeit with modifications based on contemporary research.

In 2001, a second working group including the Society for Critical Care Medicine, the European Society of Intensive Medicine, the American College of Chest Physicians, the American Thoracic Society, and the Surgical Infection Society promulgated a revised definition for sepsis, which came to be known as Sepsis-2 (published in 2003). Recognizing that SIRS parameters were relatively nonspecific, and taking advantage of new work that better defined the physiologic and biochemical alterations in sepsis patients, Sepsis-2 expanded the list of findings that might be seen in such patients, and defined sepsis as the presence of infection and a wide list of general, inflammatory, perfusion, and hemodynamic parameters. The result of this was to “open up” the diagnosis of sepsis, reflecting the reality at the bedside rather than arbitrary criteria.

The diagnosis of severe sepsis defined by Sepsis-2 remains intact, as does that of septic shock; a key difference today is that in the discussion of severe sepsis, specific mention is made of measures of organ dysfunction, such as the Sequential Organ Failure Assessment (SOFA) score, to define the presence of dysfunction.

Years after the release of Sepsis-1, in 2015, the Centers for Medicare & Medicaid Services (CMS) initiated a sepsis-based National Hospital Inpatient Quality (NHIQ) measure, recognizing the high morbidity and mortality of sepsis and the efficacy of protocol-based therapy. This measure is often referred to as the SEP-1 bundle. It evaluates the care of patients who carry an ICD-10-CM code of severe sepsis or septic shock according to more than 60 diagnostic and treatment data points (the exact number of data points evaluated depends on the clinical status of the patient). The definitions of severe sepsis and septic shock for inclusion in the NHIQ measure were based on the Sepsis-2 definitions current at that time.

Both definitions and treatment recommendations for sepsis have matured over the ensuing years. The *spring of 2016 saw the release* of the latest definitions for sepsis. Known as Sepsis-3, these definitions abandon the concept of sepsis

as a continuum and posit that sepsis represents a distinct change in the body's response to infection manifested by organ system dysfunction (as measured by a SOFA score) rather than by the nonspecific inflammatory SIRS parameters. In this model, without gradual status changes, the idea of severe sepsis is abandoned, and patients are classified as either septic (based on SOFA criteria) or in septic shock with hypotension requiring vasopressor therapy and laboratory evidence of hypoperfusion with elevated lactate levels. The Sepsis-3 diagnostic criteria are much more restrictive, with increased specificity and decreased sensitivity compared to Sepsis-2 parameters.

Similarly, treatment protocols for sepsis released through the Surviving Sepsis Campaign have evolved. The newest revisions do away with most invasive monitoring, blood transfusions, and other complex care by emphasizing the need for early recognition, early antibiotics, and fluids and vasopressors to treat hypotension. The most recent revision to the Surviving Sepsis Campaign guidelines also *takes its cues from the Sepsis-3 definitions* of sepsis and septic shock.

Despite these new guidelines, as of the writing of this paper, CMS SEP-1 has not changed the SEP-1 bundle's definitions of severe sepsis and septic shock to meet the Sepsis-3 definitions. This conflict gives rise to a significant challenge: On the surface, it seems like we need to use one definition for sepsis to meet SEP-1 criteria and a second definition (Sepsis-3) to stay current within the clinical literature and defend ourselves against the inevitable third-party (payer) audits and claim denials. To complicate matters, coding rules continue to stress that coding professionals must enter the diagnosis as written by the physician, irrespective of adherence to or consistency with clinical definitions.

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Pediatric considerations

The diagnosis of sepsis in pediatric patients was codified in 2005 by the International Pediatric Sepsis Consensus Conference. The Conference modified the adult-based SIRS criteria to be congruent with physiologic measures in newborns, neonates, infants, children, and adolescents. In addition, the diagnosis of sepsis was modified to state that either fever or white blood cell count criteria must be one of the applicable SIRS criteria supporting the diagnosis. In the pediatric setting, severe sepsis is characterized by organ dysfunction, and septic shock by evidence of tissue hypoperfusion, similar to its Sepsis-2 analogs.

The Sepsis-2 workgroup did attempt to introduce pediatric criteria within its framework, but the workgroup's effort was superseded by the 2005 publication. It has been suggested that Sepsis-3's focus on organ failure as the hallmark of sepsis might be adapted to the pediatric population, and some recent efforts have begun to evaluate this approach. As of yet, however, there is no consensus document that has contested the 2005 pediatric definitions.

Issues in coding and clinical documentation for pediatric sepsis are not as acute, as there is a single leading document establishing diagnostic criteria. However,

the clinical assessment of the attending pediatric physician always remains the cornerstone of diagnosis in atypical cases.

Implications for coding and CDI

Medical coding aims to report all clinical conditions in play during an inpatient admission in order to best reflect the patient's severity of illness and need for care. Clinical diagnoses are reported as ICD-10-CM codes, which are reviewed by outside organizations focused on epidemiology, quality, and reimbursement.

Coding and CDI challenges in the documentation of sepsis are complex. In addition, the Sepsis-3 criteria are not universally accepted within the medical community, and in some cases they have been rejected as clinical standards. Most notably, CMS itself continues to use definitions of sepsis within its SEP-1 measure as consistent with the Sepsis-2 definitions published in 2003. CMS describes concerns that "the proposed task force definitions [Sepsis-3] may delay the diagnosis of sepsis" and that changes "to the existing definition[s] [Sepsis-2] could disrupt a 15-year trend toward further reduction in sepsis mortality." CMS has directed its contractors to continue to use Sepsis-2 definitions for review and payment; the agency has also issued public statements supporting the use of Sepsis-2 definitions and the SEP-1 measure criteria in preference over Sepsis-3.

Some professional groups have also declined to endorse the Sepsis-3 standards. The American College of Emergency Physicians, which represents those physicians tasked with identifying the majority of sepsis cases, does not endorse Sepsis-3, calling it a risk to patient safety from delayed diagnosis; the Infectious Diseases Society of America also does not back Sepsis-3. International groups such as the Latin American Sepsis Institute have similarly declined to endorse Sepsis-3, stating that the focus on measures only available in developed countries deprives clinicians of the opportunity to identify sepsis early on clinical grounds alone.

While the literature reflects significant disagreement with the validity and clinical utility of the Sepsis-3 definition, Sepsis-3 is given weight by third-party auditors looking for opportunities to deny payment. This poses a challenge to CDI specialists in balancing the need for documentation supportive of revenue claims against the need to respect the physician's clinical judgment.

Policy statements

In view of the current controversy regarding the definition of sepsis for clinical diagnosis, coding, and claims-based billing, the ACDIS Regulatory Committee proposes that:

- The determination of the diagnosis of sepsis is the province of the physician. Whether the physician chooses to use Sepsis-2, Sepsis-3, the International Pediatric Sepsis Consensus Conference definition, or some other criteria, we believe that the physician alone can establish the diagnosis.

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- All parties involved in coding, billing, and payment processes should be encouraged to support the principle that the physician at the bedside has the most information, experience, and knowledge to establish the diagnosis.
- Facilities, CDI program directors, and/or physician advisors should appeal to the Cooperating Parties responsible for updates to the ICD-10-CM/PCS code set to clarify that not only are coding professionals ethically bound to the physician's real-time assessment and documentation, but that all parties involved in claims, billing, and payment processes should be similarly ethically bound.
- Hospitals and healthcare systems should develop institutional definitions for sepsis. Such definitions, when adopted by the medical staff, provide consistency and clarity for clinicians and CDI staff in documentation, education, clinical validation, and the query process. Institutional definitions can also be used as a bulwark against claim denials.
- Hospitals and healthcare systems should carefully examine their payer contracts, as well as their CMS national and local coverage determinations, to ensure that all payers are acting in a manner consistent with regulatory, legal, and contractual obligations.

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