New Definitions of Sepsis and Septic Shock: Response from the ACDIS Advisory Board

POSITION PAPER

Summary

On February 23, 2016, the Journal of the American Medical Association (JAMA) published definition updates for sepsis and septic shock.1 The following is a response from members of the ACDIS Advisory Board. Its purpose is to summarize the importance of these published articles, render analysis and preliminary opinion on their documentation and coding implications, and offer advice on how CDI departments may wish to respond within their facilities.

Background

Systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis, and septic shock were initially defined in 1991 by a consensus panel convened by the AmericanCollege of Chest Physicians (ACCP) and the Society of Critical Care Medicine (SCCM).2 The definitions were revisited in 2001 during the International Sepsis Definitions Conference, which included members from the ACCP, the SCCM, the American Thoracic Society (ATS), the European Society of Intensive Care Medicine (ESICM), and the Surgical Infection Society (SIS).3

The task force published that sepsis should be defined as a "life-threatening organ dysfunction caused by a dysregulated host response to infection."

The February 23, 2016, issue of JAMA included three articles from the "Sepsis Definitions Task Force" to update the definition of sepsis and offer the validation studies done to support the updates. In their definition article, Singer and colleagues described the relevance, process followed, and findings from the available evidence to develop the third iteration of consensus conference definitions for sepsis and septic shock.1 A major support for the new change was the use of analyses in large cohorts of patients from electronic health records (EHR) and database from the "Surviving Sepsis" campaign to provide quantitative evidence.4,5

The updated definitions publications (Sepsis-3)

A 19-member joint task force of the SCCM and the ESICM developed the guidelines through expert consensus and literature review, as well as by studying data from EHR-recorded encounters of patients with suspected infections. The task force published that sepsis should be defined as a "life-threatening organ dysfunction caused by a dysregulated host response to infection." Septic shock was defined in Singer et al.'s article as "[s]epsis with circulatory and cellular/metabolic abnormalities profound enough to substantially increase mortality." Thirty-one medical societies listed in the acknowledgment section of the article endorsed the proposed definition.1

The task force analyzed the SIRS criteria, Sequential (Sepsis-related) Organ Failure Assessment (SOFA) score, and Logistic Organ Dysfunction System (LODS) for validity in predicting mortality for patients with suspected hospital- or community-acquired infections. Of note, the SOFA score has been used clinically in critical care settings

and in research to evaluate organ dysfunction among patients in the intensive care unit (ICU) based on clinical and laboratory measurements of several physiological parameters.6 LODS is another type of clinical scoring tool used to determine severity levels and projection of a probability of mortality.7

The task force's analysis showed that among adult patients with suspected infections in the ICU, the predictive validity of SOFA and LODS for patient mortality were statistically similar to each other, and both were higher than the validity of the SIRS criteria. According to the article, a patient with a diagnosed or suspected infection with an increase of two points or more from the baseline SOFA score meets the criteria for sepsis.

Because SOFA requires laboratory tests, the task force also recommended that clinicians use another scoring tool called quick SOFA (qSOFA) to evaluate patients for possible sepsis outside of the ICU—but only as a screening tool. The task force reported that the qSOFA score, which includes altered mental state, systolic blood pressure of 100 mm Hg or less, and respiration rate of 22 breaths/minute or greater, is a trigger that the patient be more closely monitored, given more intensive treatment, and possibly referred to critical care.

As a result of the proposed definition update, the task force considered the terminology "severe sepsis" to be superfluous. The authors wanted to move away from the concept of spectrum of disease.

Based on results from a systematic literature review and meta-analysis of observational studies, and the "Surviving Sepsis" campaign's registry of 28,150 patients, the article also updated the definition of septic shock to sepsis with "underlying circulatory and cellular/metabolic abnormalities" that can result in substantially greater mortality. The clinical identification criteria are: sepsis with hypotension needing vasopressor therapy to maintain a mean arterial pressure of 65 mm Hg or greater, and serum lactate level greater than 2 mmol/L (>18 mg/dL) despite adequate volume resuscitation.

As a result of the proposed definition update, the task force considered the terminology "severe sepsis" to be superfluous. The authors wanted to move away from the concept of spectrum of disease.

The task force recognized the following facts in its publication:

- Sepsis is not a specific illness but rather a syndrome encompassing a still-uncertain pathobiology.
- Sepsis is a syndrome without a validated criterion standard diagnostic test.
- Nonspecific SIRS criteria will continue to aid in the general diagnosis of infection.
- The SIRS criteria do not necessarily indicate a dysregulated, life-threatening response. SIRS criteria are present in many hospitalized patients, including those who never develop infection and never incur adverse outcomes.
- No current clinical measures reflect the concept of a dysregulated host response.

ACDIS Advisory Board preliminary opinion

The ACDIS Advisory Board met on February 26, 2016, following the release of the JAMA publications, to discuss the impact of the proposed definition updates on clinical documentation specialists and their day-to-day efforts, as well as the implications for documentation, coding, and CMS quality measures.

The board reviewed the published articles and has also consulted with documentation and coding experts. Below are a few notes from the review process. This process is still in its preliminary stage and will continue as Advisory Board members gather facts, listen to members, and engage other clinical leaders, regulatory leaders, and stakeholders involved with coding and ICD-10.

1. The work presented by the Sepsis-3 task force ("Assessment of Clinical Criteria for Sepsis," "Assessment of Clinical Criteria for Septic Shock," and "Consensus Definitions for Sepsis and Septic Shock") was well researched and employed scientific rigor to study clinical criteria beyond the expert opinion of the task force itself. This raises the level of confidence in the evidence that was presented.
2. The data was based on large databases of patients, allowing analysis based on clinical findings and not administrative claims; this further strengthens the findings.
3. The updated definitions were endorsed by 31 scientific societies. Some of these societies are U.S. based, while others are non-U.S. based or international.
4. The updated definitions are for adults only and exclude pediatric populations.
5. The SOFA score is not intended to be used as a tool for patient management, but as a means to clinically characterize a septic patient.
6. Depending on a patient's baseline level of risk, a SOFA score of 2 or greater identified a two- to 25-fold increased risk of mortality compared with patients with a SOFA score less than 2, when the baseline is 0. The application of SOFA must be from the patient's baseline when there are other comorbidities.
7. There is a distinction drawn between the new definition of sepsis (or septic shock) and clinical criteria used to identify sepsis (or septic shock), based on the absence of a gold-standard diagnostic test and the importance of recognition from a clinical perspective.

The publications gave explicit coding recommendations, listing two specific ICD-10 codes to be used. The ACDIS Advisory Board is concerned about these recommendations

The Advisory Board also identified several significant concerns regarding the publications:

1. The publications gave explicit coding recommendations, listing two specific ICD-10 codes to be used. The ACDIS Advisory Board is concerned about these recommendations. For hospitals in the United States, coding of diseases must follow the ICD-10-CM Official Guidelines for Coding and Reporting, as published by the Cooperating Parties (the American Health Information Management Association, the American Hospital Association, the Centers for Medicare and Medicaid Services [CMS], and the National Center for Health

Statistics). Coding of specific conditions is dependent on documentation within the medical record and follows rules established to determine selection and sequencing, amongst other coding conventions.

2. The authors acknowledge that neither qSOFA nor SOFA are intended to be a stand-alone definition of sepsis. This leads us to believe that the clinical judgment of a physician examining these clinical findings, in combination with potential other factors, should be the ultimate basis for diagnosis of sepsis and septic shock. The 2001 definition consensus emphasized the role of the clinician at the bedside, but this was not elaborated on in the updated definitions.

3. It is not entirely clear why only the stated outcomes (hospital mortality, ICU stay of three days or longer, or both) were used to assess predictive validity both overall and across deciles of baseline risk. Although the ability to predict mortality and ICU stays is important from a clinical perspective, it may not always fit the need to define a disease or syndrome. Other morbidity outcomes were not used.

4. The articles emphasize that early recognition is particularly important because prompt management of septic patients may improve outcomes. This has been proven in the literature. However, the recommended scoring tool (SOFA) is complex and potentially not accessible. This is particularly true for PaO2, which would require an arterial blood gas measurement. The board also noted the uncertainty of how to deal with baseline mental status changes and/or baseline abnormal SOFA. Although the qSOFA is intended to provide simple bedside criteria to identify adult patients with suspected infection, it would only serve as a screening tool to prompt clinicians to further investigate for organ dysfunction, to initiate or escalate therapy as appropriate, and to consider referral to critical care or increase the frequency of monitoring.

5. While the guidelines rely more on concrete physiological criteria for diagnosing sepsis, it remains uncertain whether there will be gains in clinical precision or standardization.

6. The updated definitions create a direct conflict with the current CMS clinical quality measure for process, SEP-1, which is part of the Inpatient Quality Reporting Program (IQR). Hospitals participating in IQR are required to submit abstracted data according to the specifications manual of each quality measure. The SEP-1 specification manual has not yet included any updates in relation to the updated definitions (Sepsis-3) as of February 26, 2016. The manual instructs abstractors to follow a specific path to collect data about compliance with the three-hour and six-hour bundle. For example, recent release notes for version 5.0b of SEP-1 state: “Documentation of sepsis is not an acceptable alternative for documentation of severe sepsis.” The authors of

the JAMA articles did not comment on the quality measure; this may be due to the fact that it is a CMS measure limited to the United States.

7. It was not clear from the publications if the authors intend on submitting requests for changes in ICD-10 coding guidelines for sepsis and septic shock at the upcoming ICD-10 coordination and maintenance committee meeting. This would obviously be in relation to U.S.-based coding.

Conclusion

We recognize that most clinical documentation specialists have "felt the rug being pulled from underneath them" with the newly published definition updates for sepsis and septic shock. They represent a significant change from the 2001 definitions. The publications set forth compelling evidence that cannot be dismissed; however, it remains to be seen how the clinical community will be able to operationalize or change its understanding of sepsis and septic shock. This situation is somewhat analogous to what happened when the SCIP measure for beta blockers was at odds with Society of Thoracic Surgeons recommendations. As was the cast then, it takes time for evidence to be promulgated and incorporated into clinical practice or quality measures.

In the meantime, the ACDIS Advisory Board recommends the following:

- **Obtain a full understanding of the updated definitions.** CDI specialists should read the three published JAMA articles listed in the reference section below. It is also recommended that physician advisors who work with clinical documentation specialist read the articles in depth.
- **Go directly to the source articles, not to second-hand analysis.** Avoid using interpretations of the definitions that may be published in a variety of other sources. Because the updated definitions are complex, there is a high likelihood that lay media will misrepresent them. In the short period of time since their publication, the Advisory Board has already noticed erroneous information being disseminated.
- **Work closely with your physician advisors, the members of the medical staff, and your quality department to decide how to clinically validate sepsis and provide supporting documentation while acknowledging the possible shift that may occur within the physician community.** Each hospital or health system should establish its own standard at this point in time, while keeping in mind that further information might emerge.
- **Avoid blindly following the coding recommendations in the articles.** Discuss them with leadership first.
- **Stay tuned for additional guidance from ACDIS.** The ACDIS Advisory Board is already reaching out to other stakeholders in the realms of clinical practice, coding, and documentation to obtain further clarification about the implications of these new definitions for physician documentation.

References

1. Singer, M., Deutschman, C. S., Seymour, C. W., Shankar-Hari, M., Annane, D., Bauer, M., … Angus, D. C. (2016). The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA, 315(8), 757–759. Retrieved from http://jama.jamanetwork.com/article.aspx?articleid=2492881

2. American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. (1992). Crit Care Med, 20(6), 864.

3. Levy, M. M., Fink, M. P., Marshall, J. C., Abraham, E., Angus, D., Cook, D. … SCCM/ESICM/ACCP/ATS/SIS. (2003). 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. Crit Care Med, 31(4), 1250.

4. +Seymour, C. W., Liu, V. X., Iwashyna, T. J., Brunkhorst, F. M., Rea, T. D., Scherag, A., … Angus, D. C. (2016). Assessment of clinical criteria for sepsis: For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA, 315(8), 762–774.

5. Shankar-Hari, M., Phillips, G. S., Levy, M. L., Seymour, C. W., Liu, V. X., Deutschman, C. S., … Singer, M. (2016). Developing a new definition and assessing new clinical criteria for septic shock: For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA, 315(8), 775–787.

6. Ferreira, F. L., Bota, D. P., Bross, A., Mélot, C., & Vincent, J. (2001). Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA, 286(14), 1754–1758.

7. Le Gall, J. R., Klar, J., Lemeshow, S., Saulnier, F., Alberti, C., Artigas, A., & Teres, D. (1996). The Logistic Organ Dysfunction system. A new way to assess organ dysfunction in the intensive care unit. ICU Scoring Group. JAMA, 276(10), 802–810.

What is an ACDIS Position Paper?

An ACDIS Position Paper sets a recommended standard for the CDI industry to follow. It advocates on behalf of a certain position or offers concrete solutions for a particular problem. All current members of the ACDIS advisory Board must review/approve a Position Paper and are encouraged to materially contribute to its creation.