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SEP-1: Easing Antibiotic Selection

Introduction

Since it was first introduced in October 2015, the Centers for Medicare and Medicaid Services (CMS) sepsis core measure (SEP-1) raised concerns that the required bundle elements regarding antibiotic therapy would drive inappropriate antibiotic use.[1] Initial nationwide estimates of bundle compliance were less than 50% in 2016, and compliance has risen only slightly to 60% as of the most recent reporting period.[2,3] Data presented by CMS shortly after implementation of SEP-1 suggested that clinical outcomes were worse among patients without bundle compliance.[4] However, this difference did not persist once there was adjustment for underlying risk factors.[4, 5]

As predicted, increased antibiotic use has been documented in the SEP-1 patient population.[6] This finding was highlighted in the publication by Pakyz et al from early 2021.[6] These investigators examined antibiotic use in the Vizient database between October 2014 and September 2015 (pre) and October 2015 to June 2017 (post). There was an immediate increase of overall antibiotic use of 1.4% (p=0.0293) at the time of SEP-1 implementation. This increase was largely driven by an immediate 2.3% (p=0.0375) rise in use of broad-spectrum agents predominantly used for hospital-onset infections/multi-drug resistant organisms.* This trend persisted with a monthly increase of 0.4% (p=0.0273). No statistically significant changes were observed in the other agent categories (surgical prophylaxis, broad spectrum agents for community-acquired infections and anti-MRSA agents). Interestingly, *Clostridiodes difficile* rates decreased at the time of SEP-1 implementation.

SEP-1 Changes Coming July 2021

The recently released Hospital Inpatient Specifications Manual (available at this link) includes some important updates to the overall measure. The most substantial change is the complete removal of the broad-spectrum or other antibiotic administration selection element. This change begins with discharges after 7/1/2021.

> ***The Broad-spectrum or Other Antibiotic Administration Selection*** data element was removed entirely - CMS is no longer abstracting or reporting on the agent selected to treat patients for sepsis.

What does this mean for stewardship programs?

Prompt treatment for patients with severe sepsis remains essential for optimal outcomes. Additionally, CMS will continue to abstract and report on antibiotic administration date and time with the same target window of 24 hours prior to and 3 hours after severe sepsis presentation date and time. This means that many of the processes already in place to ensure rapid access to antibiotic therapy for patients presenting with severe sepsis will not change.

Antibiotic selection, and importantly, the order in which antibiotics are administered, will no longer raise the same level of concern. Empiric sepsis treatment guidelines can also be revised to reflect local disease epidemiology. Although it is likely that piperacillin/tazobactam will continue to be a mainstay of empiric therapy, this change does allow use of more narrow spectrum agents like cefazolin in appropriate settings (e.g., nonpurulent cellulitis).

*Agents included: amikacin, aztreonam, cefepime, ceftazidime, ceftazidime-avibactam, ceftolozane-tazobactam, doripenem, gentamicin, imipenem-cilastatin, meropenem, piperacillin, piperacillin-tazobactam, ticarcillin-clavulanate, tigecycline, tobramycin

Were there other substantial changes?

Many of the changes in the core measure relate to adopting plain language throughout all CMS documents. Additional changes include:

- Timing of blood culture collection abstraction was previously stopped 3 hours after the onset of severe sepsis, the guidance has been removed
- A section providing clarifying guidance for determining the total required volume of crystalloid fluids was added. This includes modifications if the patient has contraindications to the 30mL/kg volume requirement such as advanced for end-stage heart failure or chronic kidney disease (please note, there are very specific documentation requirements for this modification)

Are other changes anticipated?

Other potential changes to future specification manuals for the SEP-1 core measure are not known. In February 2021, the Infectious Diseases Society of America (IDSA) Sepsis Task Force published a position statement recommending revisions to the SEP-1 measure.[7] The main concerns of the task force are summarized in the Table.

Table 1. IDSA's Major Concerns with the Severe Sepsis and Septic Shock Early Management Bundle[7]

Antibiotic Administration Concerns
- Requirement to immediately administer antibiotics to all patients within 3 hours - Conflating urgency of antibiotic administration for sepsis and septic shock
Other Concerns
- Complex and subjective definition of time zero - Mandating lactate measurements for all patients with possible sepsis - Bundle studies used to justify the implementation of SEP-1 are prone to bias

The authors of this position statement also propose solutions to address these main concerns:

- Removing sepsis from the quality measure and focusing solely on septic shock
- Change the interval for antibiotic administration to 1 hour or less for the septic shock only population
- Clarified definition for septic shock
- Hospitals should report time intervals for antibiotic administration
- Remove lactate measurements from SEP-1

It is not known if CMS will adopt any of these proposed changes, but based on the changes for discharges beginning July 1st, 2021, it is clear the agency is receptive to changes based on real-world data on patient outcomes. We believe this initial change to remove the broad-spectrum or other antibiotic administration selection element of the SEP-1 measure will allow hospitals to revise sepsis order sets to reflect local disease epidemiology and permit use of narrower spectrum agents when appropriate.

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