Hospital Inpatient Quality Reporting (IQR) Program

Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Contractor

SEP-1 and the 2021 Sepsis Guidelines Update: New Evidence, New Recommendations Question and Answer Summary Document

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The following document provides actual questions from audience participants. Webinar attendees submitted the following questions and subject-matter experts provided the responses during the live webinar. The questions and answers have been edited for grammar.

Question 1: **Can you explain why this is a 2021, not 2023, sepsis guidelines update and how this update relates to the specifications manual?**

This is a 2021 sepsis guidelines update because the new international guidelines for managing severe sepsis and septic shock were released in 2021. When talking about the sepsis guidelines, we are referring to the Surviving Sepsis Campaign (SSC) guidelines. The intent of this presentation is to illustrate the relationship between the updated guidelines and the SEP-1 specifications within the CMS specifications manual. It is important to keep in mind that the CMS SEP-1 specifications, within the specifications manual, are not guidelines. The measure specifications are utilized to help identify the extent hospitals follow the guidelines from the SSC. The specifications manual reflects the content of the guidelines. One can structure templates for data collection based upon guidance in the specifications manual to capture that information more easily, but they are not guidelines for patient care. The specifications are the parameters for identifying how care is provided and are consistent with the actual SSC guidelines.

Question 2: **When will these recommendations be reflected in the specifications manuals?**

There is a process for integrating guideline updates and changes into the chart abstraction guidance in the measure specification that takes time. Many of the 2021 SSC recommendations or suggestions have already been incorporated into the SEP-1 measure. We are continually looking at updates as literature becomes available. We cannot speak to any changes that may be pending for any future versions of the specifications manual that have not been published yet. The most recent version of the manual, effective for discharges starting January 1, 2023, already includes most of the guideline updates.

Question 3: **Where can we get a copy of the 93 recommendations?**

The recommendations discussed during the webinar are available on the Surviving Sepsis Campaign web site. The Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2022, published in *Critical Care Medicine* and *Intensive Care Medicine*,

provides the 93 recommendations for effective identification and treatment of Sepsis and Septic Shock.

Question 4: **Slide 16. Must fluid volume still be given at a rate greater than or equal to 126 mL/hour (hr)?**

The guidance in the manual has not changed and still requires that, to count fluids towards your resuscitation volume, they must be given at a rate of 126 mL/hr or greater. You cannot count anything less than 126 mL/hr toward the resuscitation fluid volume. This guidance was incorporated in the original specifications to differentiate between fluids for replacement or resuscitation and fluids for maintenance.

Question 5: **Are we no longer required to give 30 milliliters (mL)/kilogram (kg)? If not, what is the new requirement?**

The standard or default for SEP-1 is still 30 mL/kg unless there is a compelling reason not to give 30 mL/kg, including comorbidities such as end-stage renal disease or end-stage heart failure. You do not want to under resuscitate the patient, but, at the same time, you may want to have a cautious approach to fluid administration. The key point is how you give the fluids. The SEP-1 guidance does not dictate how fast the fluids should be given other than they must be given at a rate of 126 mL/hr or greater. The SEP-1 abstraction guidance does not dictate that you have to give all the fluid in one bolus; the fluids could be given over 30 minutes, in one hour, in two hours, or in a couple of different boluses, based on how the patient responds. The measure is utilizing the standard volume of 30 mL/kg. The specifications manual guidance allows giving volumes less than 30 mL/kg in scenarios where the patient may be responding to a lower volume of fluids or there are concerns about fluid overload.

From a measure requirement perspective, 30 mL/kg is still the default. However, if a physician, advanced practice nurse, or physician's assistant, documents that they are giving a volume less than that and documents the reasons for giving the lesser volume, then that is the target volume for that patient. This allows for some flexibility based on individual patient needs.

Question 6: **If the provider documents a reason why less than 30mL/kg should be administered and documents that 0 mL should be administered, does that meet the *Crystalloid Fluid Administration* data element criteria for Value 1?**

This situation would not meet the criteria for selecting Value 1 because the abstraction guidance does not have any allowances for no volume.

The abstraction guidance reflects that some amount of fluid is being given, either 30 mL/kg or less than 30 mL/kg; there is no guidance in the measure specifications about 0 volume.

Question 7: **Slide 27. What data element is abstracted prior to the *Severe Sepsis Present* data element that includes the abstraction of pregnancy?**

The data element *Pregnant 20 Weeks Through Day 3 Post-delivery* is in the algorithm right before the *Severe Sepsis Present* data element. You would also abstract the *Transfer From Another Hospital or ASC* and *Clinical Trial* data elements, then the *Pregnant 20 Weeks Through Day 3 Post-delivery* prior to abstracting the *Severe Sepsis Present* data element.

The value selected for the *Pregnant 20 Weeks Through Day 3 Post-delivery* data element will be used to determine which clinical criteria you should use to establish whether severe sepsis is present when abstracting the *Severe Sepsis Present* data element. The *Pregnant 20 Weeks Through Day 3 Post-delivery* data element will not exclude the case from the measure denominator.

Question 8: **If lactate continues to rise, should it be repeated until it is trending down?**

The SEP-1 measure does not require that you continue to trend lactic acid levels until a downward trend is identified. The measure is looking for an initial lactate level that, if elevated, would then drive whether a follow-up lactate was drawn. If a follow-up lactate is indicated and obtained, the measure does not look for the value of that follow-up lactate. From that point clinical judgement should be used to determine if you continue to monitor lactate levels.

Question 9: **Slide 30. Why do you use lactic acid instead of procalcitonin to diagnose sepsis?**

Neither lactic acid nor procalcitonin are used to diagnosis sepsis. For the measure specifications, procalcitonin is not acceptable because it is not an equivalent test to lactic acid. Lactic acid has been used since the SSC guidelines were developed and continues to be suggested by the SSC guidelines. It is suggested because of the association between high lactic

acid levels in patients with an infection and higher rates of severe sepsis and septic shock.

Question 10: **For the phrase "antibiotics given" within three hours, does "given" mean the antibiotic infusion started within three hours, or it was completely infused within three hours?**

The SEP-1 measure looks to see if the antibiotic was started within the three-hour timeframe. We recognize that different antibiotics may require different infusion times. For example, some antibiotics are going to be given over an hour, while other antibiotics can be given by intravenous (IV) push. The key point is starting the antibiotic within the three-hour timeframe. The infusion end or completion time is not used because the infusion start time is consistently documented, but the time it ends and is completely administered is inconsistently documented or difficult to find.

Question 11: **Slide 26. In regards to the COVID-19 exclusion, if there is documentation of COVID-19 and the polymerase chain reaction (PCR) test is negative, could this be discounted in the future?**

With the onset of the COVID-19 pandemic, it was recognized that fluid resuscitation for patients with sepsis secondary to COVID-19 received a different treatment approach than a bacterial infection. As such, the measure specifications were adjusted to exclude those patients suspected or confirmed as having COVID-19 so that cases would not unintentionally fail the measure. We now know much more about COVID-19 and have better tests to identify whether it is present. CMS continues to monitor the impact of COVID-19 on the SEP-1 measure to determine if any guidance changes will need to be made in future versions of the specifications manual. We appreciate this question and will share this question with the measure stewards for consideration.