Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Sepsis Efforts at Bellevue Hospital and SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock v5.0b through v5.2a Analysis Results

Questions and Answers

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Responses to the questions posed during the November webinar, *Sepsis Efforts at Bellevue Hospital and SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.0b through v5.2a Analysis Results,* only reflect CMS guidance on implementing the SEP-1 measure in the Hospital IQR Program. For audience members with questions concerning SEP-1 implementation at Bellevue Hospital, please contact Dr. Uppal at amit.uppal@bellevue.nychhc.org.

Question 1: **I am interested in obtaining national fluid bolus compliance over time. I did not see fluid bolus included in the graphs contained in the presentation. Thanks!**

Fluid bolus administration is represented in the septic shock three-hour bundle for which performance is displayed on slide 60 titled, "Breakdown by SEP-1 Bundles: Septic Shock 3-Hour Bundle."

Question 2: **When will data for SEP-1 be reported on *Hospital Compare*?**

CMS is currently discussing options for the display of SEP-1 data on *Hospital Compare* and therefore, has not yet determined when the *Hospital Compare* release will display the report for SEP-1.

Question 3: **Is there any plan to change initial population of SEP-1 to cases with severe sepsis and/or shock and not simple sepsis?**

This has been discussed in the past and there are no plans at this time to exclude these patients. The performance data demonstrates that, on average, about 61 percent of the SEP-1 initial patient population are patients with simple sepsis. Of those, 48 percent of cases met the clinical criteria for severe sepsis and septic shock and a Value "1" (Yes) was selected. This means that about 29 percent of the SEP-1 initial patient population consists of cases with a simple sepsis diagnosis code that are eligible for the measure and have severe sepsis or septic shock.

Question 4: **Is there any way CMS will consider having process measures broken out like was presented today? It will help hospitals see where they need to work on and what is going well.**

CMS is currently discussing options for the display of SEP-1 data on *Hospital Compare*.

Question 5: **What is the overall pass rate of the SEP-1 measure?**

The overall pass rate varies by quarter. The overall pass rate for the most recent quarter of data available (first quarter 2017) is about 47 percent.

Question 6: **What version of the specifications manual indicates that a clinician only has to "attest" to volume status/tissue perfusion exam? I can't find it and my vendor doesn't have "attestation" as an option when submitting SEP-1 data.**

This was introduced in version 5.2a of the *Specifications Manual for National Hospital Inpatient Quality Measures* (aka specifications manual) and is included in the "Exceptions" under the second bullet point in the Notes for Abstraction of each "Focused Exam" performed data element.

Question 7: **Slide 35: Is it acceptable for the provider to review the focused exam performed by the nurse within the required six hours but document their reassessment focused exam review at a later time?**

Yes, this is acceptable as long as the physician/advanced practice nurse (APN)/ physician assistant (PA) documentation later references the date and time at which they conducted the focused exam or reviewed elements of the focused exam per the measure specifications.

Question 8: **Slide 50: The initial lactic acid is greater than 2, then why not repeat lactic acid within the next three hours?**

That is acceptable. The table on slide 50 is an overview depicting which actions must be performed within each bundle to meet the measure specifications. If the initial lactate is greater than 2 mmol/L the severe sepsis six-hour bundle calls for a repeat lactate within six hours of severe sepsis.

Question 9: **If lactic acid is greater than 2 in the first three hours, why is it not repeated within that time frame?**

That is acceptable. The table on slide 50 is an overview depicting which actions must be performed within each bundle to meet the measure specifications. If the initial lactate is greater than 2 mmol/L the severe sepsis six-hour bundle calls for a repeat lactate within six hours of severe sepsis.

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Question 10: **Question for Bob: We find an issue when a patient has not met severe sepsis criteria but had a lactate level drawn because sepsis was suspected. When the patient reaches severe sepsis shortly after, it causes a fallout because the first lactate was drawn outside the three-hour time frame from start of severe sepsis. Can you speak to this scenario?**

Current specifications also allow lactate levels to be drawn within six hours prior to severe sepsis presentation time. If there are multiple lactates drawn within the appropriate window, current specifications identify the initial lactate as the one drawn closest to the time of severe sepsis presentation because it most closely reflects the lactate level at the time of severe sepsis.

Question 11: **Slide 50: Does the 30 mL/kg crystalloid fluids need to be completely infused within the required three hours? If the fluids need to be initiated but not completely infused within the three-hour window, is there a time limit on how long it takes for the 30 mL/kg to be completely infused?**

The crystalloid fluids need to be initiated within the three hours after initial hypotension or septic shock presentation time. There is no time limit for completing the infusion once it is initiated within the appropriate time window. Please note that fluids infused at a rate of 125 mL/hour or less cannot be used to count toward the 30 mL/kg total volume.

Question 12: **Is the slight improvement over time due to actual changes in care or changes in the specifications?**

This is difficult to differentiate because changes to some data elements have occurred over time. We believe the increase is most likely a combination of actual improvements in patient care, improved documentation, and specification changes.

Question 13: **Are you not including the bolus order for the initial three-hour bundle?**

The 30 mL/kg crystalloid fluid bolus is part of the septic shock three-hour bundle.

Question 14: **Is the graph on slide 64 correct? It appears that sepsis cases that did not pass the measure had better mortality rate!**

A correct interpretation of slide 64 is that SEP-1 cases that did not meet the requirements of the measure have a higher or worse mortality rate than SEP-1 cases that did meet all applicable requirements.

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Question 15: **Please provide details on how you are determining performance on the breakdown bundles and individual processes of care based on the abstracted SEP-1 bundle data. And by details, I mean that we'd like to be able to replicate how CMS is determining numerators and denominators from the abstracted data.**

Each bundle was defined based upon the data elements and algorithm calculations that make up the requirements for that bundle within the algorithm flow. For each bundle, the denominator is equivalent to the number of cases that qualified for all data elements and calculations, and were not excluded prior to reaching the beginning of the current bundle or during the current bundle. The numerator for each bundle is the number of cases that met (passed) all data elements and calculations for that particular bundle.

Question 16: **Where did Bob obtain the percentages? *QualityNet* feedback reports have not been populating.**

The data presented during the webinar is based upon SEP-1 data submitted by hospitals to the CMS data warehouse, which is not currently publicly available. CMS conducted a preliminary analysis of this data for the presentation. Additionally, the results of the mortality analysis are not risk-adjusted.

Question 17: **What is the measure missed most associated with mortality?**

This question is not very clear. Assuming "the measure missed the most" is referring to SEP-1 bundles, we do not have a detailed analysis available that compares bundle pass rates to mortality rates.

Question 18: **Are the data sets used for this analysis of SEP-1 available for download; if so, where?**

The data sets are currently not available for download.

Question 19: **How did you determine the N=that number where that element was evaluated (before that element had not yet "falled out")? Thanks.**

The "N" for each bundle is based upon the number of cases that progressed through the algorithm (passed and were not excluded) to the point where the elements for the given bundle started.

Question 20: **I want to make sure that I am reading the data correctly; is it approximately 50 percent of all coded cases are excluded? Thank you.**

Yes, approximately 50 percent of the cases in the initial patient population is excluded for a variety of reasons, including transfers, antibiotic exclusion, and comfort care.

Question 21: **When will possible benchmarks for the SEP-1 metric be available?**

CMS is currently exploring options to include SEP-1 in the quarterly benchmark reports posted on *QualityNet*. A date when it will be available has not been determined.

Question 22: **Regarding the last slide; the *QualityNet* Q&A website is often hard to navigate. It does not seem to produce many results, despite the fact that you likely receive questions every day. Are there any plans to make the Q&A database more robust based on questions that clinicians have submitted?**

The team that responds to SEP-1 questions submitted through *QualityNet* is currently developing additional sets of questions and responses for posting on the *QualityNet* Hospital Inpatient Questions and Answers (Q&As) web page.

Question 23: **If lactic acid is greater than two in the first three hours, why is it not repeated within that time frame?**

If the initial lactate is greater than 2 mmol/L, the severe sepsis six-hour bundle calls for a repeat lactate within six hours of severe sepsis. The repeat lactate can be repeated at any time within that period. The time frame for the repeat in the SEP-1 measure specifications is six hours because the lactate may take longer than three hours to demonstrate a meaningful response to treatment.

Question 24: **When do you expect payment determination to be attached to SEP-1 performance?**

CMS has not announced when this will happen. This will be announced through notice and comment rulemaking.

Question 25: **When will this measure be moved to pay for performance?**

CMS has not announced when this will happen. This will be announced through notice and comment rulemaking.

Question 26: **Why "all or nothing"? Individual measure rates would provide better info for performance improvement.**

Research demonstrates that outcomes are better for patients when all applicable evidence-based elements of care are provided rather than just some. An "all or nothing care" and "measure of care" approach supports the full scope of evidence-based care measures that result in the best outcomes for the majority of patients with severe sepsis and septic shock.

Question 27: **If the physician documents "not sepsis," is this enough to be excluded from the measure?**

For version 5.2a of the specifications manual, documentation of "not sepsis" is not sufficient documentation to exclude this case. Abstractors should continue looking for clinical criteria to establish the presence or absence of severe sepsis or septic shock.

Question 28: **If a history and physical examination (H&P) is done by a physician in the time period of six hours after the septic shock time, will that suffice for sepsis reperfusion exam? I asked *QualityNet* this question and they said an H&P will suffice.**

The presence of an H&P without physician/APN/PA documentation stating they performed a physical exam, sepsis-focused exam, etc., is not sufficient for the physician/APN/PA attestation exception. Examples of acceptable physician/APN/PA documentation include "I performed a physical exam," "review of systems completed," "shock-focused exam performed," etc.

Documentation within an H&P that meets the requirements of the focused exam data elements may be used.

Question 29: **Is there any talk about using procalcitonin as part of the measure for early sepsis recognition?**

Currently, there are no plans to change the clinical criteria used to establish severe sepsis or septic shock, including the addition of a procalcitonin test to the measure specifications.

Question 30: **If the emergency department (ED) physician has strong indications that the patient has severe sepsis related to Clostridium *difficile* (C. *diff*), how can we be compliant when the physician orders vancomycin intravenously (IV) only without cultures?**

IV vancomycin will meet the Broad Spectrum or Other Antibiotic Administration data element if given in the 24 hours prior to severe sepsis presentation time. However, if IV vancomycin is the only antibiotic given, and it is started within the three hours after the severe sepsis presentation time, IV vancomycin alone will not meet the Broad Spectrum or Other Antibiotic Selection data element.

The Broad Spectrum or Other Antibiotic Selection data element requirements must be met if the only IV antibiotic given is in the three hours following severe sepsis presentation. Since IV vancomycin is on the combination therapy table, aminoglycoside, aztreonam, or ciprofloxacin must also be given to meet the Broad Spectrum or Other Antibiotic Selection data element.

Question 31: **When a patient is admitted with an infection, but does not yet have severe sepsis, and receives an antibiotic, this is best practice. However, if the patient develops severe sepsis a couple of hours later, they will fail the SEP-1 measure, because they did not receive the antibiotic three hours after the severe sepsis presentation time. Will CMS be amending the definition to allow for these types of sepsis patient presentations?**

Receiving antibiotics within three hours after severe sepsis presentation is not a requirement to pass the broad spectrum or other antibiotic administration component if the patient received an IV antibiotic within 24 hours prior to severe sepsis presentation. The case scenario described in this question should pass the broad spectrum or other antibiotic administration portion of the measure.

Question 32: **If the provider documents not sepsis, and the criteria for severe sepsis or septic shock is evident after this documentation, is severe sepsis or septic shock present?**

Documentation of “not sepsis” is not sufficient documentation to exclude this case. In this case, if the patient meets clinical criteria, severe sepsis or septic shock would be present.

Question 33: **Does documentation by a physician with a reason the full 30 mL/kg is not given pass the measure?**

Physician/APN/PA documentation of a reason for not infusing the full 30 mL/kg is not acceptable. If there is physician/APN/PA documentation indicating less than 30 mL/kg of crystalloid fluids were given, choose Value "2."

Question 34: **If physician places an order for "vancomycin per pharmacy for pneumonia," then the pharmacist would calculate the dosage and place an order for vancomycin without the documentation "for pneumonia." Can we still use "pneumonia" as diagnosis if patient receives a dose of vancomycin?**

Nursing or pharmacist documentation indicating a patient is being treated with an antibiotic for an infection that is within six hours of criteria "b" or "c" is acceptable as a suspected infection (e.g., Levaquin is documented in medication administration record [MAR] for pneumonia and nursing documentation indicates a dose was given within six hours of criteria "b" and "c," pharmacy note that patient is on vancomycin for pneumonia).

Question 35: **If physician documents chronic kidney disease without a baseline creatinine, can we still exclude all elevated creatinine level?**

In version 5.2a of the specifications manual, if a baseline creatinine value is not included in the documentation of chronic kidney disease (CKD), an elevated creatinine should be used for determining organ dysfunction.

In version 5.3 of the specifications manual, if a baseline creatinine is not documented, elevated creatinine levels should be used for determining organ dysfunction.

Question 36: **Physician documents "acute thrombopenia due to chemo"; do we exclude the low platelet?**

If there is physician/APN/PA documentation indicating thrombocytopenia is due to a medication (chemotherapy), the platelet count should be disregarded. This is true for both specification manual versions 5.2a and 5.3. Both the platelet level and chemotherapy need to be in the same documentation.

Question 37: **If you have someone note "not sepsis" on ED disposition note, would that cancel the fluid boluses that were given in ED that may be counted towards a delayed presentation if identified within six hours after the initial fluid bolus?**

For version 5.2a of the specifications manual, the note "not sepsis" would not cancel the fluid boluses that were appropriately ordered and given in the ED.

Question 38: **Would the documentation of "not sepsis" count as not severe sepsis or septic shock and therefore would exclude the whole case? Or would "not sepsis" mean that there was no infection at that time and the abstractor should continue to look for another set of criteria to meet severe sepsis or septic shock?**

For version 5.2a of the specifications manual, documentation of "not sepsis" is not sufficient documentation to count as not severe sepsis or septic shock. Abstractors should continue looking for clinical criteria to establish the presence of severe sepsis or septic shock.

Question 39: **Ventricular assist device (VAD) patients are excluded; wondering, why transcatheter aortic valve replacement (TAVR) patients are not excluded, too?**

Thank you for your question. VADs were added as an exclusion in version 5.2a of the specifications manual only for the crystalloid fluid component; however, TAVR patients are currently not excluded. CMS appreciates the question and will consider this in future updates.

Question 40: **Will there be consideration in the future in altering the [system inflammatory response syndrome] SIRS criteria for pregnant patients?**

Thank you for your question. There are no plans at this time to alter criteria for these patients or to exclude them.

Question 41: **Will the newly released high blood pressure measurements be incorporated into the sepsis hypertension-related measures?**

None of the SEP-1 data elements assess hypertension. They do assess initial and persistent hypotension. The recent guidelines do not change the definition and guidance for patients with initial or persistent hypotension.

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Question 42: **Will there ever be a time when physician documentation of why a 30 mL/kg bolus was not given will be acceptable? Example, "The patient has renal failure and the nephrologist requests to not give the normal bolus for sepsis."**

At this time, there are no plans to allow for physician/APN/PA documentation of a contraindication to fluids as an acceptable exclusion. The latest evidence supports administration of the fluid bolus.