



# Inpatient Quality Reporting (IQR) Program

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## Support Contractor

### **The Clinician Perspective on Sepsis Care: Early Management Bundle for Severe Sepsis/Septic Shock**

#### **Questions & Answers**

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### Vasopressors

**Question 1:** If a patient has persistent hypotension after the initial 30 ml/kg fluid bolus but is treated effectively with additional smaller fluid boluses to maintain SBP > 90 or MAP > 65, are vasopressors still necessary? We've had a few patients who have responded well to additional fluids before nurses would have had time to start vasopressors. According to the measure, they would be noncompliant when the clinical care seems appropriate.

We recognize there may be times where physician clinical judgment based on specific patient response reflects additional fluids are indicated instead of vasopressors. Measure revision discussions are underway to address this in a future version of the *Specifications Manual for National Hospital Inpatient Quality Measures*.

### Examination Assessment

**Question 2:** On slide 12, it states all the elements of the tissue perfusion and fluid volume status exam must be performed by a LIP. Is this a change from the July 2016 update?

Slide 12 is a general reference to the focused exam data elements. Specific requirements are contained within the respective data elements.

In version 5.1 of the specifications manual (discharges 7/1/16 – 12/31/16), the fluid volume status exam data elements (Vital Signs Review Performed, Capillary Refill Examination Performed, Peripheral Pulse Evaluation Performed, Skin Examination Performed) have to be documented by a physician, advance practice nurse (APN), or physician assistant (PA). The Cardiopulmonary Evaluation Performed data element must be performed and documented by the physician/APN/PA.

In the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), all the fluid volume status exam data elements have to be documented by the physician. Additional options are also available that suffice for physician documentation in version 5.2a.



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**Question 3:** If patient has a lactate > 4, but does not have persistent hypotension, do we need to do a focused exam/diagnostic assessment of fluid resuscitation? If yes, what is the value of this exam? Especially if the repeat lactate shows improvement.

If the initial lactate level is greater than or equal to 4, the focused exam data elements would have to be answered. Lactate is one measure of sepsis-induced tissue hypoperfusion. The measure takes into account a variety of ways in which tissue hypoperfusion may be demonstrated.

**Question 4:** Slide 11: Is persistent hypotension determined only by MAP < 65 or do the other parameters still apply, e.g., SBP < 90 or decrease of 40 points from baseline?

The parameters are abbreviated for slide 11.

The other parameters still apply: systolic blood pressure (SBP) less than 90, **or** mean arterial pressure (MAP) less than 65, **or** physician documentation of decrease in SBP by greater than 40 mmHg occurring due to infection, severe sepsis, or septic shock.

**Question 5:** You say in slide 12 that the repeat focus exam is after initial fluid resuscitation. The spec manual states the time window beginning at the crystalloid fluid administration date and time, and ending six hours after the presentation of septic shock date and time. Can you clarify?

Slide 12 provides general guidance for when a physician should perform the focused exam. The data elements that make up the focused exam provide the specific parameters for abstraction.

For abstraction, the SEP-1 measure time frame to complete the focused exam is from the time you identified for crystalloid fluid administration date and time, and ends six hours after the presentation of septic shock date and time.



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**Question 6:**                    **Slide 17: Can the tissue perfusion assessment be done after fluid administration, but before vasopressor initiation?**

Slide 17 provides an example for when different interventions must be started to meet the measure.

The SEP-1 measure time frame for this assessment starts at the crystalloid fluid administration date and time, and stops at six hours after the presentation of septic shock date and time. It can be completed prior to vasopressors, but must be performed within six hours after septic shock presentation, to meet the measure.

**Question 7:**                    **We were told in an initial CMS webinar that if the patient is on a vent/mechanical respirations, these respirations should not count for SIRS criteria as SIRS criteria is based on spontaneous respirations, not on mechanical. *QualityNet* is now telling us that any respiration should count toward SIRS even if on vent. Can we please get some clarification of which is correct? Thank you.**

The Severe Sepsis Present data element indicates that respirations greater than 20 per minute would be considered systemic inflammatory response syndrome (SIRS) criteria.

In the *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure, Version 5.1*, a bullet point states, “If there is physician/APN/PA documentation that SIRS criteria or a sign of organ dysfunction is normal for that patient, is due to a chronic condition, is due to an acute condition that is not an infection, or is due to a medication, it should not be used. Inferences should not be made; physician/APN/PA documentation is required.”

If physician documentation indicates that the patient is on a vent and the rate is noted, then the respiratory rate would not be used in abstraction as a SIRS criterion.

**Question 8:**                    **Regarding slide 17, isn’t reassessment of volume status/tissue perfusion required for all patients with septic shock, not just those who are persistently hypotensive after fluids?**

The volume status/tissue perfusion data elements are required for septic shock patients; it is not limited to those who are persistently hypotensive.



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**Question 9:** Is a focused exam still required if patient has lactate > 4 but no initial and no persistent hypotension?

Yes, if the initial lactate is greater than or equal to 4, the focused exam data element is required.

### Intravenous (IV) Fluid

**Question 10:** Slide 14 says that crystalloid fluid is not required for severe sepsis. Is this a change?

Slide 14 is a visual summary of what is required to meet the bundles of care: Severe Sepsis three hour and six hour bundles, Septic Shock three hour and six hour bundles. The Crystalloid Fluid Administration data element defines what fluids to abstract. It states to only abstract crystalloid fluids given for the presence of severe sepsis with hypotension, **or** for the presence of severe sepsis with a lactate greater than or equal to 4 mmol/L, **or** physician/APN/PA documentation of septic shock. Fluids given for severe sepsis could be counted towards the 30 mL/kg volume.

**Question 11:** Slide 10 states fluids need to be in within three hours for hypotension? I understood that only the septic shock patients had the three-hour time requirement. Do you mean persistent hypertension?

Slide 10 is in reference to persistent or new-onset hypotension after fluids. Crystalloid fluids need to be given within three hours of persistent hypotension or a lactate that is greater than or equal to 4.

**Question 12:** If the patient meets the criteria for severe sepsis and SBP is less than 90 mmHg and I begin the bolus but the SBP goes to > 90 after just one liter, am I required to finish the full 30 mL/kg fluid bolus in order to meet the measure requirement?

Yes, if 30 mL/kg was indicated, the full 30 mL/kg must be administered.



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**Question 13:**      **If the patient does not get a complete 30 mL/kg bolus, but the physician documents a reason for not administering the complete 30 mL/kg bolus, will this pass the measure?**

In the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), if 30 mL/kg was indicated and 30 mL/kg was not administered, then the case will not pass the measure.

In the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), volumes up to 10% less than the 30 mL/kg target volume calculated by weight are acceptable.

In either version, physician-documented reasons for administering less than identified in the specifications are not acceptable.

**Question 14:**      **We still get a lot of concern from our physicians regarding giving the full 30 mL/kg for patients with heart failure or acute renal failure. If the full 30 mL/kg is not given, does the measure fail?**

For the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), if 30 mL/kg was indicated and 30 mL/kg was not administered, the case will not pass the measure.

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), an exclusion was added for patients who have a VAD. Additionally, volumes up to 10% less than the 30 mL/kg target volume calculated by weight are acceptable for all other cases. There were no changes made specifically for heart failure or acute renal failure patients. Therefore, if the patient does not have a VAD, or 30 mL/kg is not given and the volume administered is not within 10% lower than the 30 mL/kg, the case will fail.

**Question 15:**      **If fluids running at > than 125 mL/hr count for fluid resuscitation, then the patient may not receive the total amount of fluids within three hours of shock presentation. Will this cause us to fail the measure?**

The crystalloid fluids must be started within three hours of septic shock presentation time.



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**Question 16:** For severe sepsis with single hypotension episode, is 30 mL/kg mandatory?

For the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), if 30 mL/kg was indicated and 30 mL/kg was not administered the case will not pass the measure.

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), an exclusion was added for patients who have a ventricular assist device (VAD).

Additionally, volumes up to 10% less than the 30 mL/kg target volume calculated by weight are acceptable for all other cases.

Therefore, if the patient has initial hypotension and does not have a VAD, or 30 mL/kg is not given and the volume administered is not within 10% lower than the 30 mL/kg, the case will fail.

**Question 17:** On slide 14, it says that the crystalloid fluids must be completed within three hours of septic shock, but in slide 17 it says that the resuscitation should be started within three hours of septic shock. Which is correct? Is the three-hour requirement for starting the fluids, or completing all of the fluids?

The crystalloid fluids must be started within three hours of septic shock presentation time.

**Question 18:** If we count fluids administered by EMS toward the 30/ml requirement, do we still need a protocol/order to coincide with this administration of fluids? Often EMS documents how much fluid was given, the type, and a time, but does not include rate, or start and end time, or a protocol/order.

For the SEP-1 measure, physician/APN/PA orders are required for the fluids. The order must include the type of fluid, the volume of fluid, and a rate or time over which the fluids are to be given. Bolus or wide open is also acceptable as a rate.



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**Question 19:** On slide 15, we were told that the patient did not respond to the fluid bolus, therefore we had a diagnosis of shock and the shock clock started. Then on slide 17 we were told that the fluids should be started by 8 p.m. This patient should have already received their 30 mL/kg. Just to be clear, you are not asking that we give the fluids two times, correct?

Correct, the 30 mL/kg only needs to be given once.

**Question 20:** Is the SEP-1 bundle measure failed if crystalloid bolus is not completed within three hours of septic shock?

The crystalloid fluids must be started, not necessarily completed, within three hours of septic shock presentation time.

**Question 21:** If fluids are ordered as bolus or wide open, the end time of the fluids is not documented, but no stop infusion documentation is present, does that meet the criteria?

Crystalloid fluids, ordered as bolus or wide open, are acceptable for the order. To determine whether 30 mL/kg were actually given (version 5.1 required for Persistent Hypotension; version 5.2a required for Crystalloid Fluid Administration), an infusion rate or infusion end time is required.

**Question 22:** Regarding slide 23, the documentation of prehospital records, are IV fluids given en route by EMS considered part of the 30 mL/kg?

Yes, if they are considered to be part of the medical record and requirements from the Crystalloid Fluid Administration data element are met.

**Question 23:** Can the +/- 10% fluid volume required apply to cases being abstracted now or only starts January 1?

Guidance in this bullet point is effective starting January 1 with the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17).





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**Question 24:** Is it acceptable now to complete a fluid resuscitation when needed at 10% less for all patients, or is this just for patients with a VAD?

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), the allowance for 10% less than the target fluid volume based on weight is for all patients. Patients with VADs are excluded from crystalloid fluid administration.

**Question 25:** Since the crystalloid fluid administration begins with the physician ORDER for the fluids which is required to contain the TYPE of fluid, VOLUME of fluid, & RATE or TIME over which the fluids are to be given. Within the operative room suite, typical written ORDERS are seen in a different format. The TYPE of fluids are seen listed, with the START & STOP of the fluids during the surgical procedure, but typically DOES NOT follow a blanket RATE. The RATE can fluctuate during the procedure according to the clinical response of the patient during the procedure. Fluids rates can increase, then decrease, then increase again, etc. The START & STOP times display a MEDIAN RATE at the end of the procedure. How does CMS look at this RATE for operative room administration of fluids, given this knowledge? Is this ORDER (signed and dated by the physician) on the document acceptable to use? Is the median RATE acceptable to use for the fluids given throughout the procedure start/stop time?

There are two elements that both must be fulfilled for crystalloid fluid administration: 1) an order for 30 mL/kg and 2) fluid administration documentation. If the order does not contain the elements required in the Crystalloid Fluid Administration data element, it cannot be used. All fluids must be documented as given at a rate of greater than 125 mL/hr to be counted toward the 30 mL/kg. A median rate would not be acceptable.



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#### Antibiotic (ABX)/Blood Culture

**Question 26:** If a patient has a UTI and the physician starts the patient on Cipro. If the cultures grown, E. Coli with Cipro sensitivities, should Cipro be abstracted as the appropriate antibiotic?

Yes, if there is a lab report or physician/APN/PA documentation indicating the causative organism and susceptibility is known, and an IV antibiotic identified as appropriate to treat the causative organism is given within three hours following presentation of severe sepsis, it would be appropriate for the Broad Spectrum or Other Antibiotic Administration Selection data element.

**Question 27:** If the source is appendicitis, is Invanz appropriate for antibiotic selection?

The documentation provided would not be acceptable for the Broad Spectrum or Other Antibiotic Administration Selection data element, because the causative organism is not identified and antibiotic sensitivities are not documented.

**Question 28:** In regard to the administration of broad spectrum antibiotics, if a patient is presumed to have sepsis due to (+) ehrlichiosis, and doxycycline is ordered, will this continue to be a fallout?

Based on the documentation, the organism is not known. The documentation would not be sufficient to select Value "1" for the Broad Spectrum or Other Antibiotic Administration Selection data element. You would choose Value "1" if an IV antibiotic from Table 5.0 or an appropriate combination of IV antibiotics from Table 5.1 is not started or given within the three hours following presentation of severe sepsis; but there is a lab report or physician/APN/PA documentation indicating the causative organism, and susceptibility is known, and an IV antibiotic identified as appropriate to treat the causative organism is given within three hours following presentation of severe sepsis.



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**Question 29:** Could you clarify the time window for the obtained cultures and subsequent sensitivities that can be utilized for the broad spectrum antibiotic selection question – for those antibiotics that are prescribed other than those on the monotherapy or crosswalk tables?

In the *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure, Version 5.2a*, this is clarified. The cultures must be obtained in the time period of 24 hours prior to antibiotic administration through three hours after severe sepsis presentation. The results do not need to be available prior to antibiotic administration.

**Question 30:** Is there a need to draw blood culture when the physician already knows the source of infection? For example, patient arrives from primary care physician with a positive diagnosis of C. diff after serial stool studies, and upon arrival, patient meets the criteria for severe sepsis.

The measure requires that blood cultures be drawn regardless of suspected infection source. Blood cultures have to be drawn within the allowable time frame to continue with abstraction.

**Question 31:** Slide 26, with the antibiotic exclusion, it seems that with July 2016 discharges, in Premier, where we submit our abstractions, it no longer excludes patients on ABX > 24 hours of sepsis presentation if initial lactate was not collected. Is this correct that it will no longer be excluded?

A change for the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), removed the requirement to continue data collection after an algorithm fail point has resulted in cases no longer being excluded. If there was not an initial lactate level collected, the case will fail the measure even if the patient was on an IV antibiotic more than 24 hours prior to severe sepsis presentation. This is being addressed in a future version of the specifications manual.



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**Question 32:**      **What are the reasons accepted for why blood cultures might be drawn after antibiotics are given? I didn't see that specified.**

For the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), if the blood culture is drawn after antibiotics are received, then the case will not pass the measure.

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), the new Blood Culture Collection Acceptable Delay data element includes the reasons where obtaining a blood culture following antibiotic administration is considered acceptable.

**Question 33:**      **Currently, if a patient comes in through the ED with an infection, but not severe sepsis, is appropriately given an antibiotic in the ED. Then hours later, within 24 hours, patient worsens, meets severe sepsis and blood cultures are drawn, etc. The antibiotic given in the ED is causing failures related to blood culture before antibiotic even though this was appropriate care. Are there any changes being made to specs to prevent this from occurring? Thank you.**

This will be addressed in the next version of the specifications manual (version 5.2a) for discharges 01-01-17 (1Q 2017) through 12-31-17 (4Q 2017), with the addition of the Blood Culture Collection Acceptable Delay data element.

**Question 34:**      **The slide on page 35 for exclusions details, third criteria down states, "Received an antibiotic within 24 hours prior to severe sepsis presentation and received a dose of the same antibiotic more than 24 hours prior to presentation." Is the requirement for it to be the same antibiotic new for 2017 discharges, or is that in effect for July 1, 2016 discharges; or is it for any antibiotic?**

The Broad Spectrum or Other Antibiotic Administration Time states that if antibiotics were administered intravenously (IV) within 24 hours prior to Severe Sepsis Presentation Time, abstract the earliest time that a dose of IV antibiotic was given. This identifies the time frame to look for an IV antibiotic, which would then indicate that the IV antibiotic would have to be in the 24 hours prior to and greater than 24 hours prior to severe sepsis to exclude the case.



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### Abstraction

**Question 35:**      **Abstraction guidelines require to abstract the time of the last sign of severe sepsis. Slide 9 states the “earliest” chart annotation. Which one?**

The earliest set of criteria within six hours of each other should be used to determine the earliest severe sepsis presentation time. Then, the time the last criterion was met would be considered the severe sepsis presentation time.

**Question 36:**      **If physician documents severe sepsis present on admission, do we use triage time or the time patient became an inpatient?**

Per the *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure, Version 5.1*, if the note states severe sepsis was present on admission, use the earliest documented hospital admission date/time.

**Question 37:**      **It has been my understanding that when all S&S of severe sepsis are present at triage, we should abstract time zero as end triage time. Is this still acceptable?**

Per the Severe Sepsis Presentation Time data element, if severe sepsis is present on arrival to the emergency department (ED) or severe sepsis is identified in triage, the Severe Sepsis Presentation Time is the time the patient was triaged in the ED. If more than one triage time is documented, e.g., “triage started” and “triage completed,” use the later time reflecting triage is completed.

**Question 38:**      **Slide 13: If patient arrives via ED but patient doesn’t meet all three criteria in triage and ED physician doesn’t document severe sepsis; but the next day, a different physician documents severe sepsis present on admission, would we use the triage time based on this new documentation?**

Per the *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure, Version 5.1*, if the note states severe sepsis was present on admission, use the earliest documented hospital admission date/time.



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**Question 39:**      **So, if a patient doesn't meet the criteria for severe sepsis, but there is documentation for septic shock, then the time would be the same for both severe sepsis and septic shock?**

Correct, the presentation time would be the same. Based on the following bullet points, Value "1" (Yes) could be selected for both Severe Sepsis Present and Septic Shock Present data elements.

Per Severe Sepsis Present data element:

If criteria for severe sepsis are not documented and there is not physician/APN/PA documentation of severe sepsis, but there is physician/APN/PA documentation of septic shock, choose Value "1" (Yes).

Per Septic Shock Present data element:

If criteria for septic shock are not met, but there is physician/APN/PA documentation of septic shock, choose Value "1" (Yes).

**Question 40:**      **On occasion, we have a single low BP recorded in chart, with marginally blood pressure just before and after normal readings, i.e., often spurious, not real, are we compelled to use that single, transiently low BP as "time zero?"**

Unless there is physician/APN/PA documentation or nursing documentation indicating a low blood pressure (BP) reading is invalid, erroneous, or questionable, the documented low BP should be used.

**Question 41:**      **The example of sepsis being present at triage mentions a red, hot, swollen leg as qualifying for an infection source, I assume. However, if that was documented by a nurse at triage, but a provider does not document possible infection, cellulitis, etc., until two hours later, wouldn't the abstracted start time actually be two hours later?**

Correct, for the purposes of the measure, signs and symptoms are not acceptable for a suspected infection. Therefore, the later documentation by a physician, APN, or PA of the infection would be used.



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**Question 42:** Regarding the crystalloid fluids. One option for septic shock is severe sepsis AND hypotension following 30 mL/kg, which your chart on page 14 says is not needed until septic shock is present, yet it is used to decide septic shock. Also, if a patient has initial hypotension, and you don't give the 30 mL/kg, but they don't meet septic shock criteria, I believe the case fails. Again it should be yes on the chart in the timing of three hours after severe sepsis. Please clarify if I am misunderstanding this. Thanks so much.

Slide 14 is a visual summary of what is required to meet the bundles of care: Severe Sepsis three hour and six hour bundles, Septic Shock three hour and six hour bundles. To pass the Septic Shock three hour bundle, 30 mL/kg of crystalloid fluids must be initiated within three hours of presentation of septic shock.

If severe sepsis and initial hypotension are present, 30 mL/kg of crystalloid fluids are required to determine if persistent hypotension is present, and therefore, septic shock. This is not measured in the Septic Shock three hour bundle. The Initial Hypotension data element simply provides a "triggering event" for 30 mL/kg of crystalloid fluids to be administered. There is not a time frame from the presence of initial hypotension within which the 30 mL/kg must be given, but it must be given. In a case where a patient has severe sepsis, and initial hypotension, and does not receive 30 mL/kg of crystalloid fluids, the case will fail the measure.

**Question 43:** What if a patient presents to the ED and is severe sepsis, not hypotensive. Three days later, the patient becomes septic; hypotensive fluids given and no improvement. What is the time zero?

Since initial hypotension may only be found six hours prior to through six hours after severe sepsis presentation, hypotension documented three days after severe sepsis would not be relevant. Likewise, since Value "1" cannot be selected for Septic Shock Present if septic shock is found greater than six hours after severe sepsis presentation, the criteria for septic shock found three days after severe sepsis would not be relevant.



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**Question 44:** If patient does not get 30 mL/kg bolus, but there is documentation that states, “AKI, creat was 0.7 last month. Pt reports poor fluid intake. Repleting fluid cautiously, started with 2 units PRBCs, s/p 1L IVF in the ED, giving another bolus now slowly.” Would this count as a reason for not administering?

No, the measure does not provide an exclusion nor exception for not administering 30 mL/kg of crystalloid fluids when 30 mL/kg is required.

**Question 45:** If the time zero started at 3 p.m. The three hour ends at 6 p.m. and the six hour bundle ends at 9 p.m., right?

Correct, if the severe sepsis presentation time was 3 p.m., elements such as “broad spectrum or other antibiotics” and the “initial lactate” would need to be completed by 6 p.m., and the “repeat lactate” would need to be completed by 9 p.m.

**Question 46:** Lactate was 5.0 at 1 p.m., but patient did not meet suspicion of infection (last criteria for severe sepsis) until 3 p.m. Repeat lactate at 4 p.m. was 3.1, but it now is initial lactate as closer to time of presentation. Does this patient have septic shock based on first lactate – or not as based on second (initial) lactate, assuming patient met severe sepsis criteria at 3 p.m. If yes to septic shock – is time 3 p.m.?

Since the initial lactate level result is used to determine the presence of septic shock, and the initial lactate is less than 4 (result was 3.1), septic shock would not be present in this case.

**Question 47:** If the only chart documentation that makes the case coded as septic shock is a progress note, which contains the magic words, sepsis shock – no elevated lactate or hypotension – would the shock clock start with the time of that dictation as, “The time of presentation? is defined as the time of earliest chart annotation consistent with all elements of severe sepsis or septic shock ascertained through chart review?” Thank you.

If there is a specific time associated in the note with when septic shock was present, that can be used. If not, then the time the note was written or opened should be used.





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**Question 48:** In regards to slide 15 discussing the example, if the patient presented with PN on day 1 and got appropriate treatment on day 1 with blood cultures, ABX, lactic acid measures, etc. If patient on day 3 develops some SIRS criteria, and provider states severe sepsis in progress note on day 3, but does not get a lactic acid drawn on day 3, is day 3 considered time zero for severe sepsis, even though initial infection identified on day 1 and no new infection is noted?

Yes, the severe sepsis presentation time will be when all three criteria are met within six hours of each other **or** when the physician/APN/PA documents severe sepsis. If the criteria were not all met within six hours of each other prior to the physician's documentation of severe sepsis on day 3, the severe sepsis presentation time would be on day 3. Therefore, a lactate is expected to be collected within six hours prior to through three hours after the severe sepsis presentation time.

**Question 49:** Since the crystalloid fluids order may be up to 10% lower than the target 30 mL/kg volume, then we may then take a 10% lower than 30 mL/kg administered?

Crystalloid fluids, which are ordered, administered, and are within 10% of the calculated target volume of 30 mL/kg, are acceptable.

**Question 50:** If the documentation on the causative organism that is susceptible to the antibiotic ordered within the three hours and after blood cultures done is not available until after cultures come back, do you still count these results, or do the results have to be known before that antibiotic can be counted, i.e., Cipro alone is ordered, which is not a mono drug and 3 days later you find out that the causative organism is susceptible to it, can it be counted even though there wasn't another combo drug ordered along with it?

It is understood that susceptibility testing results typically take time to report. Therefore, a time frame for the susceptibility report is not specified in the measure. If the susceptibility results demonstrate the IV antibiotic that was administered within three hours of severe sepsis was appropriate, "Yes" could be selected for the Broad Spectrum or Other Antibiotic Administration Selection data element.



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**Question 51:**      **If providers state, “severe sepsis present on arrival,” do we use triage time? And if a provider states, “severe sepsis present on admission,” do we use the time of admission to an inpatient bed?**

If the note states severe sepsis was present on arrival, refer to the *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure, Version 5.1* that address severe sepsis present on arrival (bullet point below).

If the note states severe sepsis was present on admission, use the earliest documented admission date/time.

If severe sepsis is present on arrival to the ED or severe sepsis is identified in triage, the Severe Sepsis Presentation Time is the time the patient was triaged in the ED.

If more than one triage time is documented, e.g., “triage started” and “triage completed,” use the later time reflecting triage is completed.

**Question 52:**      **For the focused eval, if the provider has in his documentation that he performed the focused eval one hour post fluid administration, does that meet the time frame for this data element, or am I limited in using the note date/time?**

If the physician’s documentation contains the required documentation for each of the focused exam data elements, and refers to the completion of the exam at an earlier time, that earlier time could be used.

**Question 53:**      **If a provider inappropriately documents severe sepsis when the patient does not have SIRS criteria to meet definition of sepsis, is this case required to be reported to CMS since it fails the initial screen but included an erroneous diagnosis?**

Since Value “1” (Yes) can be selected when the physician/APN/PA documents severe sepsis, the case would be included in abstraction regardless of whether specific clinical criteria are met.



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**Question 54:** Just so we understand, can you confirm that for focused exam, does abstraction only need to see that an exam is attested to, or do they still need to go into the chart to validate that this was documented somewhere by staff?

Physician/APN/PA documentation attesting to the review or performance of specific focused exam data elements, or attest to performing a physical exam, perfusion assessment, sepsis focused exam, etc., will suffice. Further documentation or validation of the focused exam is not required.

**Question 55:** Slide 23 basically says that even if we have criteria met for severe sepsis, if the physician says it's not, we go with the physician and say no to severe sepsis. This is a change that will take place in January? Does that mean that we are currently going with the criteria and not with physician documentation?

The *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure, Version 5.1* indicate that, if there is documentation of clinical criteria being met or physician/APN/PA documentation of severe sepsis, and within six hours, additional physician/APN/PA documentation indicate the patient does not have severe sepsis, choose Value "2" (No). This was added to version 5.2a of the specifications manual (discharges 1/1/17 – 12/31/17).

This is effective for version 5.1 (discharges 7/1/16 – 12/31/16) and version 5.2a (discharges 1/1/17 – 12/31/17).

**Question 56:** Severe Sepsis Present Date/Time, if the patient meets clinical criteria at 9 a.m. for severe sepsis and the physician documents in the Impression/Plan the diagnosis of severe sepsis, but there is no specific time. The note time for the ED record is 6 a.m. Do we use the 9 a.m. clinical criteria time or the open time of the ED note at 6 a.m.?

Since the physician documented severe sepsis within a note without a time specified for the documentation of severe sepsis, the note-opened time (6 a.m.) would be used for the Severe Sepsis Presentation Time. Also, since the time the clinical criteria were met (9 a.m.) was later than the note-opened time (6 a.m.), the earlier note-opened time would be used for the Severe Sepsis Presentation Time.



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**Question 57:**      **Regarding the three hour bundle, if a patient has an isolated incidence of MAP < 65 and subsequent values over 65, does that still count for organ dysfunction?**

Yes, unless there is physician/APN/PA documentation that the low BP or MAP is erroneous, questionable, or invalid, the low BP or MAP would be abstracted at face value and would suffice for evidence of organ dysfunction.

**Question 58:**      **If nursing documents “yes” to suspicion of infection, and the SIRS criteria, and organ dysfunction are also met within the three hours, we abstract as severe sepsis. However, we may not see anywhere in the physician documentation that there is an infection. They may or may not start an antibiotic. Do we still consider this to be severe sepsis? This doesn’t seem right without a physician’s saying so.**

Yes, per the Severe Sepsis Present data element, nursing documentation referencing a suspected infection is acceptable. Therefore, further physician documentation confirming an infection or ordering treatment for an infection is not required to suffice criteria “a,” documentation of a suspected infection.

**Question 59:**      **“Bolus” or “wide open” acceptable for crystalloid fluid order: in version 5.2a, if there is no infusion rate or end time documented, is it a fail?**

Yes, it would be a fail. If a rate or time over which the IV fluids are to be given, were given **or** the fluid bolus completed time or end time is not documented in the medical record, “No” would be selected for Crystalloid Fluid Administration.

**Question 60:**      **If a patient meets two or more SIRS criteria and has no evidence of organ dysfunction, but the physician documents severe sepsis, do we abstract as sepsis or severe sepsis?**

Yes, with the physician/APN/PA documentation of severe sepsis, “Yes” could be selected for Severe Sepsis Present.



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**Question 61:** Physician documents severe sepsis at 22:00 due to lactate and UTI without SIRS being present. Initial lactate at 21:30 was 4.3. Does the patient meet shock at 22:00 when the physician documented severe sepsis due to the lactate?

Yes, since the criteria to meet Septic Shock Present include severe sepsis presentation and an initial lactate greater than or equal to 4, the septic shock would be considered present when both severe sepsis and the initial lactate greater than or equal to 4 are present. Therefore, the septic shock presentation time in this case would be 22:00, when the last septic shock criteria (severe sepsis presentation) is met.

**Question 62:** Patient is admitted to floor and vital signs flow sheet has one BP with MAP < 65. Patient meets severe sepsis criteria. Does this one BP value require the patient receive the fluid bolus volume of 30 mL/kg? There is no documentation provider was notified.

With organ dysfunction being met by hypotension and/or hypotension documented within six hours prior to through six hours after severe sepsis presentation, “Yes” would be selected for Initial Hypotension. With “Yes” selected for Initial Hypotension, this would lead to the Crystalloid Fluid Administration data elements in which 30 mL/kg of crystalloid fluids would be required.

**Question 63:** If the patient has initial hypotension, gets an appropriate 30 mL/kg fluid bolus, but there are no BPs documented in the hour after the fluid bolus ends, how do we answer the question regarding septic shock (when no physician documentation of septic shock)?

If no BPs were documented in the one hour following 30 mL/kg of crystalloid fluids, septic shock would not be considered present based on persistent hypotension. For Septic Shock Present based on persistent hypotension, a “Yes” would only be selected if Value “1” (Yes) could also be selected for Persistent Hypotension. Therefore, if the initial lactate is not greater than or equal to 4, there is no persistent hypotension, and there is no documentation of septic shock, “No” would be selected for Septic Shock Present.



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**Question 64:** Does the new revision that states a provider can override earlier documentation of severe sepsis negate an abstractor determining severe sepsis based on the criteria?

If physician documentation within six hours of the would-be severe sepsis presentation time indicates severe sepsis is not present, “No” could be selected for Severe Sepsis Present. This applies to Severe Sepsis Presentation by meeting criteria or Severe Sepsis Presentation met by physician/APN/PA documentation of severe sepsis.

**Question 65:** When determining presentation of severe sepsis time, would we use the note-creation time in our EHR (Epic) or the time that the note was revised? (Epic has a view where you can view the time the note was revised by the writer.)

If a time is not specified for the documentation of severe sepsis, the note-opened time should be used for the severe sepsis presentation time. If the revised time reflects a specified time the physician documents severe sepsis, it could be used.

**Question 66:** If there is a documentation of no severe sepsis within the six hours of clinical criteria, do we have to keep abstracting for new episodes of severe sepsis?

No, if physician/APN/PA documentation indicates severe sepsis is not present within six hours of severe sepsis presentation, Value “2” (No) would be selected for Severe Sepsis Present. Upon selecting “No” for Severe Sepsis Present, the case would be excluded at that point.

**Question 67:** Regarding severe sepsis cases, if the patient has initial hypotension and does not receive 30 mL/kg crystalloid fluid, will this fail the measure?

Yes, with “Yes” selected for Initial Hypotension and less than 30 mL/kg of crystalloid fluids administered, Value “2” (No) would be selected for Crystalloid Fluid Administration.



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**Question 68:**      **How do you assess for persistent hypotension if the assessment has to be done within the period of six hours after septic shock when if the rate is > 125cc/hr, the total volume of crystalloids will not be done until after the six hours? Does that case fall out of the measure or get excluded? Thank you.**

While the septic shock presentation time must be within six hours of severe sepsis presentation to select “Yes” for Septic Shock Present, persistent hypotension is not required to be met within six hours of severe sepsis or septic shock presentation. Therefore, if “Yes” was selected for Septic Shock Present based on an initial lactate greater than or equal to 4 or documentation of septic shock and persistent hypotension was found later due to fluids being administered at 125 mL/hr, “Yes” could be selected for Persistent Hypotension at that time.

**Question 69:**      **One of our data abstractors has asked, “if MD indicates in exam for volume status and tissue perfusion that skin appearance was pale, cool, and dry, would this pass the measure, or does capillary refill have to be specifically mentioned? Can you provide guidance?”**

For the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), with the inclusion of “pale,” this documentation would suffice the Skin Examination Performed data element since this references a skin color.

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), with the reference to skin color, appearance, or condition, this documentation would suffice the Skin Examination Performed data element.

However, this documentation would not suffice the Capillary Refill Examination for either version of the specifications manual as it does not reference the capillary refill or peripheral perfusion.



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**Question 70:** For CVP Measurement, we have an EMR that has a CVP tab in the vital signs. It doesn't say "via CVC" or via anything. We have a critical care paper flow sheet if the patient is in the ICU, and it has hemodynamic monitoring and a CVP column, but nowhere on the flow sheet does it say "via CVC" or "via CVP." Can we not use these CVP readings since there is no mention of "via CVC?"

With the Central Venous Pressure (CVP) Measurement being documented under the area designated for CVP readings, this would suffice the Central Venous Pressure Measurement data element.

**Question 71:** I remain very confused about fluid resuscitation and determining septic shock. Per the manual, 30 ml/kg are administered after initial hypotension; however, septic shock is not determined until patient's meeting severe sepsis criteria, and have persistent hypotension (or lactate  $\geq 4$ ), defined as two or more consecutive hypotensive BPs after initial fluid resuscitation. Slide 14 states 30 ml/kg fluids are NA under Severe Sepsis. When we are abstracting, what event determines septic shock?

Slide 14 is a visual summary of what is required to meet the bundles of care: Severe Sepsis three hour and six hour bundles, Septic Shock three hour and six hour bundles. To pass the Septic Shock three hour bundle, 30 mL/kg of crystalloid fluids must be initiated within three hours of presentation of septic shock.

If severe sepsis and initial hypotension are present, 30 mL/kg of crystalloid fluids are required to determine if persistent hypotension is present, and therefore septic shock. This is not measured in the Septic Shock three hour bundle. The Initial Hypotension data element simply provides a "triggering event" for 30 mL/kg of crystalloid fluids to be administered. There is not a time frame from the presence of initial hypotension within which the 30 mL/kg must be given, but it must be given. Therefore, patients with severe sepsis present **and** initial hypotension, initial lactate greater than or equal to 4, or documentation of septic shock, should be administered 30 mL/kg.





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**Question 72:** Can you address how prehospital administration of IV fluid by paramedics needs to be documented in the record? I received a response from *QualityNet* identifying that all IVF needed to have a provider order to be included in the crystalloid fluid volume. In this case, the provider documented, “Patient with 40-point drop in systolic blood pressure from 1/30/1999 during course of treatment; I have already given the patient antibiotics, therefore I will give the patient the remaining fluid when you add the 1000 mL’s from prehospital to my 1 L here in the emergency department, and then an additional 500 equals the 2490 mL’s recommended for 30 mg’s per kilogram sepsis bolus.” Based on this information, can I answer, 1. Yes, 30 mL/kg of crystalloid fluids were ordered and administered prior to, at the time of, or after the presentation of initial hypotension, initial lactate  $\geq 4$ , or documentation of septic shock?” Any assistance to better understand this is greatly appreciated.

While prehospital fluid administration could be applied to the 30 mL/kg crystalloid fluid administration, a physician’s order for fluids remains a requirement. If the physician ordered, “NS 0.9% IV 30 mL/kg (2490 mL) bolus, 1000 mL administered via emergency medical service (EMS), bolus 1500 mL now,” the prehospital fluids could be used. However, if the physician documents the prehospital fluids rather than ordering, the prehospital fluids would not be applied toward the 30 mL/kg infusion.



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#### Laboratory Values/Oxygen/Lactate

**Question 73:** Is an ScvO<sub>2</sub> obtained via a central line that is placed in the femoral artery or internal jugular vein an accurate assessment? Will it count toward the measure?

The point of insertion of the central line is not taken into consideration. There must be documentation reflecting the oxygen reading was obtained via central venous catheter (CVC).

**Question 74:** When I am reading the chart, I see several labs and they are daily; if I see a note on day 1 saying patient's lab values reveal renal failure, which is chronic, this excludes the first lab I look at. Does it exclude each lab after that of that one set of labs if they continue to be abnormal, or do I need to have a note everyday regarding each day's ordered lab? Thanks.

In the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), there is no time frame for this documentation to occur. If there is physician documentation indicating that a lab result is due to a chronic condition, an acute condition that is not an infection, or a medication, then the lab result would not be used in abstraction.

**Question 75:** We had a patient who expired after the three-hour limit for severe sepsis, but before the six-hour limit, so the case failed repeat lactate, even though the patient died before the six hours were up. Since severe sepsis has both three-hour and six-hour measures, can there be two expiration questions for severe sepsis – one for three hours and one for six hours – rather than just one for three hours? Has there been any discussion about this? Thank you.

The Sepsis Discharge Time calculation in the algorithm will be changed in the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17). The change will allow for cases to be excluded from the measure if the discharge time is within six hours of severe sepsis presentation.



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**Question 76:** Our hospital has a SNF that uses the same lab system, so usually when these patients are transferred to an inpatient unit due to sepsis, most of the time, blood cultures, lactate, and antibiotics are already done or started at this SNF. So our physicians would not reorder blood cultures or lactate acid. Can we use these BCs, lactate drawn prior to inpatient admission?

If the blood cultures and lactate draw times and results are present within the medical record, and within the allowable time frame for the specific data element, they could be used.

**Question 77:** With lactate representing the organ failure – it is time of result, correct? Not drawn time?

Lab value results, not the draw time, are used to determine organ dysfunction.

**Question 78:** Concerning slide 23: More and more EMS agencies are using I-STAT machines with lactic acid capability; does a lactic acid drawn en route count as lactic acid #1?

If there is documentation in the medical record that the lactate was drawn within the specific data elements' allowable time frame, they could be used in abstraction.

**Question 79:** If a patient's initial lactate is, say 2.3, and the second lactate ordered turned out to be 4.1, does this repeat lactate level take the patient into the septic shock category?

To determine septic shock based on a lactate, it would have to be the initial lactate level. The Initial Lactate Level Collection data element indicates that if there are multiple lactates, the one drawn closest to severe sepsis presentation would be considered the initial lactate level. It will depend on when severe sepsis presented to determine which of the lactates listed would be considered the initial lactate level and to determine if septic shock was present.



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#### Contraindications

**Question 80:**      **Version 5.1: In regards to administrative contraindication to care, severe sepsis, a patient requires mechanical ventilation, but is refusing; is this appropriate for administrative contraindication of care?**

No, the refusal must be for blood draw, fluid administration, antibiotic administration. Documentation of refusal of care, treatment, or medications that would result in blood draws, IV fluids, or IV antibiotics not being administered is acceptable.

**Question 81:**      **If a patient is not very agreeable to treatment and refuses any type of care, is that considered a fallout? She was aggressive both verbally and physically towards staff, but also Alert and Oriented Times 3 (A/Ox3), able to make decisions on her own.**

For the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), the only acceptable sources are physician/APN/PA documentation or a witness-signed consent form marked “refused.” The physician documentation of refusal of care would have to be in the allowable time frame for the specific data element. If within the allowable time frame, there is physician documentation that the patient refused care, then allowable Value “1” (Yes) could be selected for the data element.

**Question 82:**      **If the patient is confused or unable to communicate with the provider, and does not have family present, can the provider refuse the fluids on behalf of the patient and document contraindication to care?**

A provider refusing the fluids on behalf of the patient would not be acceptable for the data elements.

**Question 83:**      **Is a hospice consult considered “palliative care?”**

The only terms accepted are identified in the list of inclusions. No other terminology will be accepted. Hospice is an inclusive term and would be acceptable as Directive for Comfort Care or Palliative Care, if documented within the acceptable time frame.



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### Documentation

**Question 84:**      **On the skin examination: is skin=Normal acceptable, or does the note have to be specific about skin coloration? For example, pink, yellow, jaundiced?**

As per the specifications manual, reference to skin color, appearance, or condition is required. The term “normal” is inclusive of all of these.

**Question 85:**      **If infection is suspected, can the LIP just document the symptoms, for example, swollen hot leg? Or would they need to document suspected cellulitis, etc.?**

As per the specifications manual, documentation of signs or symptoms is not acceptable for a suspected infection. Therefore, this documentation would not be acceptable, as it is considered symptoms of a possible infection.

**Question 86:**      **Slide 12: To meet the requirements, does the LIP need only to document that the focused exam was performed, and include no specifics, like vitals, capillary refill, etc., in the note or H&P?**

Slide 12 is a general reference to the focused exam data elements. Specific requirements are contained within the respective data elements.

In the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), the fluid volume status exam data elements (Vital Signs Review Performed, Capillary Refill Examination Performed, Peripheral Pulse Evaluation Performed, Skin Examination Performed) have to be documented by a physician/APN/PA. The Cardiopulmonary Evaluation Performed data element must be performed and documented by the physician/APN/PA.

In the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), all the fluid volume status exam data elements have to be documented by the physician. Additional options are also available that suffice for physician documentation in version 5.2a.



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**Question 87:** Is “vital signs stable” acceptable for the physicians to document instead of the specific vital signs?

For the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), documentation of vital signs review needs to include the four vital signs being reviewed: temperature, pulse or heart rate, respirations, blood pressure. The values are not required.

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), documentation indicating a physician/APN/PA has reviewed, performed, or attested to reviewing or performing a vital signs review is acceptable. If documented this way, listing each vital sign element (Temperature, Pulse or Heart Rate, Respirations, Blood Pressure) is not required.

**Question 88:** Slide 21: If MD documents vital signs reviewed, is that sufficient?

For slide 21, which references the specifications manual, version 5.1 (discharges 7/1/16 – 12/31/16), the vital signs specified in the data element must indicate heart rate, respiratory rate, temperature, and blood pressure were reviewed. Documentation of actual values is not required. “Vital signs reviewed” is not sufficient.

**Question 89:** ED provider note time represents first contact with the patient; if severe sepsis is identified during the ED stay, the note time may become time zero per data definition specifications. As a result, we are missing some time windows by a few minutes due to the artificially early time zero since the earliest time must be abstracted. Can a sepsis-specific template be used as a priority over note time?

If there is a specific time documented within the note for severe sepsis time, that should be used instead of the note-open time. How that is addressed is up to the individual facility or physician.

**Question 90:** The provider can document that septic shock exam was done and this will be acceptable for the focused exam component?

This would be acceptable for the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17).



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**Question 91:** Does the LIP have to link the specific disease process to the abnormal SIRS/organ dysfunction? “Creatinine 3.2 due to ESRD, not sepsis.”

The specifications do not require the physician to explicitly document the creatinine is elevated due to end state renal disease (ESRD). The requirement is that there must be some association between the condition and the elevated level in the physician note. If the physician documented that the patient has ESRD and in the same note referenced the elevated creatinine level, included the elevated level, or indicated the level is elevated, this is sufficient to establish a link or association.

**Question 92:** With regard to MAP < 65 as an indication of severe sepsis presentation requiring bundle intervention:

- 1) If there are < 2/4 SIRS criteria present at the time a MAP of < 65 is recorded, is the MAP relevant/applicable within the six-hour window to demonstrate severe sepsis?
- 2) If physician documentation notes sepsis, not severe sepsis, on admission with appropriate antibiotic and other supportive treatment, is that single low MAP relevant?

**Is further physician documentation required to address a single < 65 MAP occurrence?**

All three criteria must be met within six hours of each other: two or more SIRS criteria, suspected infection, and a sign of organ dysfunction. A MAP less than 65 is considered a sign of organ dysfunction. If this is present, you still need two or more SIRS criteria in the same six-hour period. Documentation of sepsis can count as an infection, but is not sufficient to say the patient has severe sepsis without the other criteria present in the same six-hour time period.

**Question 93:** For version 5.2a, is physician documentation of “repeat focused exam performed” acceptable for all evaluations, e.g., cap refill, cardiopulmonary, peripheral pulse?

This would be acceptable.



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**Question 94:**      **Beginning 1/1/17, it will no longer be necessary for the practitioner to include the results of the focused exam to pass this portion of the six hour bundle? Documentation that the focused exam was performed or reviewed fulfills this component?**

Documentation indicating a physician/APN/PA has performed, or attested to, performing a physical examination, perfusion (reperfusion) assessment, or sepsis (severe sepsis or septic shock) focused exam is acceptable. The physician/APN/PA cannot review someone else's focused exam.

Documentation indicating a physician/APN/PA has reviewed, performed, or attested to, reviewing or performing one of the specific focused exam data elements is acceptable, but the name of the data element must be documented.

**Question 95:**      **If the MD/APN/PA did not perform the repeat focused exam, do they need to document within the six-hour window that they reviewed the results of the focused exam?**

Documentation indicating a physician/APN/PA has performed, or attested to, performing a physical examination, perfusion (reperfusion) assessment, or sepsis (severe sepsis or septic shock) focused exam is acceptable. The physician/APN/PA cannot review someone else's focused exam.

Documentation indicating a physician/APN/PA has reviewed, performed, or attested to, reviewing or performing one of the specific focused exam data elements is acceptable, but the name of the data element must be documented.

Regardless, the physician documentation must occur within the specified time frame.

**Question 96:**      **Does that attestation statement have to be done within that time frame of the focus exam requirements?**

Yes, this must still be documented in the time frame specified in the data elements.





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**Question 97:** For SEP-1 version 5.2a update, to clarify with the physician reassessment note, is one note stating that all the focused exams were reviewed and performed by a physician acceptable or it needed to be stated each focused exam was reviewed or performed by a physician?

Documentation that a focused exam was performed by a physician would suffice for all elements, e.g., skin exam, vital signs review, cardiopulmonary eval, peripheral perfusion assessment, capillary refill exam. Documentation that each element of the focused exam was reviewed or performed by a physician would suffice, if each element is identified.

**Question 98:** With the coming updates to the SEP-1 measure for January 2017, provider documentation of “sepsis focused exam performed” will fulfill the requirement for the reassessment of volumes status and tissue perfusion?

Yes, “sepsis focused exam performed” would suffice for the reassessment of volumes status and tissue perfusion.

**Question 99:** Regarding the focused exam, do the actual values have to be documented, and do all elements have to be mentioned in the note?

For the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17), if there is physician/APN/PA documentation that a focused exam was performed, actual values do not need to be documented. Reference to the focused exam being performed would suffice.

**Question 100:** Is this a correct statement? As of January 2017, Physician PA or APN documentation of “focused assessment performed” is adequate, not requiring for the individual elements to be addressed specifically as was required previously.

This is correct.



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**Question 101:** If a physician documents, “I performed a septic shock focused exam at 23:00,” and that focused exam is within six hours of septic presentation and following initiation of 30 mL/kg crystalloids, does this fully meet focused exam requirements?

Yes, this will meet documentation requirements for the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17).

**Question 102:** Slides 20, 22: On the focused exam, if a nurse documents the assessment within three hours, then physician/APN/PA attests to this by signature, but does so after the three-hour time frame, is this acceptable?

The physician documentation must be within the time frame specified in the data elements.

### Data

**Question 103:** What about national mortality from severe sepsis/septic shock? Within our division, we compare shock mortality rates, but I always wonder how ours compare to the national mortality rates.

We have reviewed absolute sepsis mortality between cases that passed the measure versus those that failed the measure. Data revealed an 8.3% lower absolute mortality rate for cases that passed the measure. This lower mortality rate resulted in 6,054 fewer deaths in the first quarter of reported data.

**Question 104:** Are you tracking mortality or any other significant patient outcomes measure (as well as hospital LOS or ICU LOS) based on completion or lack of completion of the bundles?

It is important to note that the measure is a process measure, and that the primary aim is to promote evidence-based, protocolized care. A secondary analysis that we are conducting aims to identify the difference in mortality between cases that pass and fail the measure, and also the associated number of averted deaths.



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**Question 105:** Have you seen any improvement or worsening in sepsis mortality with this result?

We have reviewed absolute sepsis mortality between cases that passed the measure versus those that failed the measure. Data revealed an 8.3% lower absolute mortality rate for cases that passed the measure. This lower mortality rate resulted in 6,054 fewer deaths in the first quarter of reported data.

**Question 106:** Any baseline data available for compliance with the measure?

The first quarter of data was shown. Because of ongoing refinements to the specifications manual in the first three quarters, there is not yet a baseline for performance.

**Question 107:** What scores are you seeing from hospitals across the US for SEP-1? We lack a benchmark and it would be helpful to know how others are doing outside of our organization.

Slides 29 – 33 in the presentation show the performance of hospitals in the fourth quarter of 2015. The percentages listed are the average rates for each bundle and the overall rate. These numbers can be used for relative external comparison to national performance averages. Benchmarks have not been established at this point for SEP-1.

**Question 108:** Slides 25 – 34: Over what time frame was this information collected?

The data came from cases discharged in the fourth quarter of 2015 (10/1/2015 – 12/31/2015).

**Question 109:** The data on slides 29 – 34 are taken from what time period?

The data came from cases discharged in the fourth quarter of 2015 (10/1/2015 – 12/31/2015).

**Question 110:** What is the date range for the data on slide 34?

The data came from cases discharged in the fourth quarter of 2015 (10/1/2015 – 12/31/2015).



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#### Future Sepsis/Feedback

**Question 111:** In the future, will there be exceptions to the large fluid volume requirements for septic shock patients also diagnosed with pulmonary edema?

To our knowledge, no trial has demonstrated that this population suffers adverse effects when treated initially with a crystalloid fluid bolus. In fact, observational studies showed an association between an early fluid challenge and improved mortality.

**Question 112:** Any plans to exclude dialysis patients from the 30 mL/kg requirement?

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure. There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

**Question 113:** Are there any plans to exclude the burn population given the burn community's specific guidelines for caring for this patient population?

The SEP-1 specifications manual excludes trauma patients, including burn patients. This topic has been added to our agenda to review during the next manual-revision discussions.

**Question 114:** Will fluid administration amounts ever be at the discretion of the treating provider who is examining the patient and not 30 mL/kg?

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure.



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**Question 115:** Will there be any exclusion of the amount of fluid needed for morbidly obese patients? Some require more than six liters of fluid which is not safe for the patient.

An upper limit for the 30 mL/kg crystalloid fluid infusion based on BMI is planned for discussion during the next manual-review process. At this time, no adjustment to the required 30 mL/kg volume is specified in the specifications manual. Clinical judgment in this case should prevail if physician/APN/PA felt that 30 mL/kg of crystalloid fluids are not indicated or could be detrimental. This may result in a case not meeting the measure. As mentioned previously, we are aware that variations in presentation may exist for which clinical judgment dictates following the guidelines is not in the best interest of the patient.

**Question 116:** Has there been consideration given for an acceptable reason for < 30 mL/kg for fluid requirement, such as CHF exacerbation, flash pulmonary edema, etc.?

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure. There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

**Question 117:** We have an issue with crystalloid fluid orders; a patient with renal failure or CHF, the physicians do not feel comfortable ordering 30 mL/kg. Will there ever be an exclusion for those circumstances?

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure. There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.



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**Question 118:** Do you have any plans to revise the 30 mL/kg crystalloid fluids requirement for those patients with documented fluid overload? If no, why is this not being considered?

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure. There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

**Question 119:** Has there been any thought to build into SEP-1 for the 30 mL/kg crystalloid administration exclusion of a patient on dialysis, in heart failure, etc.?

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure. There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

**Question 120:** In regards to fluids, do you foresee HD or CHF patients being excluded for 30 mL/kg; if MD documents rationale for giving 2L as opposed to required 4L.

To our knowledge, no trial has demonstrated that this population suffers adverse effects when treated initially with a crystalloid fluid bolus. In fact, observational studies showed an association between an early fluid challenge and improved mortality. On the contrary, in the early goal-directed therapy (EGDT) trial, and other published observations, patients with heart or renal failure who received a fluid bolus and EGDT had a lower rate of intubation for respiratory compromise compared to those patients who did not.



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**Question 121:** Is there a plan to allow for physician discretion related to amount of IV fluids administered in special situations? For example, a hemodialysis patient, or patient with PMH of CHF, whose BP responds to less than 30 mL/kg, and administering the full amount puts them at risk of fluid overload.

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure.

There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

**Question 122:** Would you consider removing 30 ml/kg requirement for initial hypotension and maybe make it only 20 ml/kg? Many patients respond well to this volume.

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure.

**Question 123:** Has it been considered to exclude dialysis patients from the requirement for 30 mL/kg fluid resuscitation?

There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.



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**Question 124:** **Has there been any discussion for 2017 on patients with fluid restrictions like fluid overload and CHF patients to be excluded, or any other alternative, if documentation supports the reason on limited fluid volume? Thank you.**

To our knowledge, no trial has demonstrated that this population suffers adverse effects when treated initially with a crystalloid fluid bolus. In fact, observational studies showed an association between an early fluid challenge and improved mortality. On the contrary, in the EGDT trial, and other published observations, patients with heart or renal failure who received a fluid bolus and EGDT had a lower rate of intubation for respiratory compromise compared to those patients who did not.

**Question 125:** **Don't you think there needs to be a MD/PA/APN documented "reason" to exclude the patient for this measure as we have had for many other measures? Say, for instance, a patient that comes in and is coded three times, all while trying to diagnose, and save a patient, the last thing a clinician is thinking about is a repeat lactate. Even the PCI element had a reason as intubation in the ED to exclude that patient from the PCI measure, as long as it was documented by the clinician. Will this possibly considered in the future?**

Patients that discharge/expire within six hours of severe sepsis presentation are excluded from the measure, starting with the specifications manual, version 5.2a (discharges 1/1/17 – 12/31/17). Therefore, a repeat lactate would not be required as the case would be excluded prior to reaching the repeat lactate data element.

**Question 126:** **Has there been thought to reporting measure compliance split by data element, i.e., initial lactate, repeat lactate, antibiotic compliance, etc., or by three- and six-hour compliance rates?**

Hospitals can get this bundle-level data from their own internal analysis. Like other Hospital IQR Program measures, when the measure is publicly reported, the overall measure pass rate will be reported.





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**Question 127: What about qSOFA? How does this effect the SEP-1 core measure?**

There remains considerable controversy about the Sepsis-3 proposed definitions, including that they have not been prospectively validated, and could result in missing the early identification of sepsis. For a more detailed response, please review our letter to the editor of the *Journal of the American Medical Association (JAMA)*. The letter is on the *QualityNet* web page, [Fact Sheets for Measure Changes](#) or on the *JAMA* web page, <http://jamanetwork.com/journals/jama/fullarticle/2536619>.

**Question 128: This update does not reflect the Sepsis-3 definition. When will SEP-1 core measure adapt the Sepsis-3 definition?**

There remains considerable controversy about the Sepsis-3 proposed definitions, including that they have not been prospectively validated, and could result in missing the early identification of sepsis. For a more detailed response, please review our letter to the editor of *JAMA*. The letter is on the *QualityNet* web page, [Fact Sheets for Measure Changes](#) or on the *JAMA* web page, <http://jamanetwork.com/journals/jama/fullarticle/2536619>.

**Question 129: If and when do you expect the Sepsis-3 International Conference to influence these measures?**

There remains considerable controversy about the Sepsis-3 proposed definitions, including that they have not been prospectively validated, and could result in missing the early identification of sepsis. For a more detailed response, please review our letter to the editor of the *JAMA*. The letter is on the *QualityNet* web page, [Fact Sheets for Measure Changes](#) or on the *JAMA* web page, <http://jamanetwork.com/journals/jama/fullarticle/2536619>.

**Question 130: How are we going to integrate Sepsis-3 (new) definition with the current SEP-1 core measure?**

There remains considerable controversy about the Sepsis-3 proposed definitions, including that they have not been prospectively validated and could result in missing the early identification of sepsis. For a more detailed response, please review our letter to the editor of the *JAMA*. The letter is on the *QualityNet* web page, [Fact Sheets for Measure Changes](#) or on the *JAMA* web page, <http://jamanetwork.com/journals/jama/fullarticle/2536619>.



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**Question 131:** Will the data ever be categorized into ED cases vs. inpatient cases?

No, the primary aim is to promote evidence-based protocolized sepsis care, which should be consistent when severe sepsis or septic shock are identified.

**Question 132:** Physicians are citing evidence that fluid boluses should be given in smaller increments, 500ml, followed by evaluation of the patient's response before giving more fluid. In addition, fluid boluses should be stopped whenever there is an adequate response to the fluids even if the 30 mL/kg goal is not met. In addition, a vasopressor should be started before the 30 mL/kg fluid goal is met if the patient does not respond to the boluses. Are you aware of this evidence? Is it good evidence? Will it be worked into the measure?

Please share the evidence your physicians are citing for our review. Thanks!

**Question 133:** Are there any updates to the status of the exclusion of patients who have been on IV ABX greater than 24 hours prior to onset of severe sepsis/septic shock? I specifically refer to the hard stop in the July 1 revised algorithm that no longer allows the abstractor to get past the initial lactic acid question to answer IV ABX question that would exclude from the population. Prior to July 1, we were able to answer "no" to initial lactic, and then enter ABX details, and not be penalized. Currently, however, hospitals are being penalized for patients already on IV ABX because no lactic was done. I have seen hospitals nationwide submit this question to *QualityNet* and the response is that the measure stewards "realize this is a valid concern by many and they are taking it into concern for a future update to the current specs manual."

Changes to address this are still under consideration. Because a final decision has not been made yet, we are unable to share additional information at this time.



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**Question 134:**      **Given the large numbers of people who exclude, will the Code Tables be changed? For example, removing A41.9 Sepsis, unspecified organism?**

Not at this time. Initial data analysis reflects that about 60% of the total number of cases in the population are those with uncomplicated sepsis codes. Of those, about 46% actually have severe sepsis or septic shock, but do not have severe sepsis or septic shock International Classification of Diseases, Tenth Revision, (ICD-10) codes. This represents about 28% of the total population that have severe sepsis or septic shock, but do not have ICD-10 codes for severe sepsis or septic shock.

**Question 135:**      **With the very large percent of cases that do not meet severe sepsis criteria, will the measure sampling be revised to include only those patients with severe sepsis and septic shock ICD-10 codes?**

Not at this time. Initial data analysis reflects that about 60% of the total number of cases in the population are those with uncomplicated sepsis codes. Of those, about 46% actually have severe sepsis or septic shock, but do not have severe sepsis or septic shock ICD-10 codes. This represents about 28% of the total population that have severe sepsis or septic shock, but do not have ICD-10 codes for severe sepsis or septic shock.

**Question 136:**      **Based on the number of patients excluded from the initial patient population, is CMS considering changing the patient population criteria?**

This has been discussed and a decision was made not to change the population at this time. Initial data analysis reflects that about 60% of the total number of cases in the population are those with uncomplicated sepsis codes. Of those, about 46% actually have severe sepsis or septic shock, but do not have severe sepsis or septic shock ICD-10 codes. This represents about 28% of the total population that have severe sepsis or septic shock, but do not have ICD-10 codes for severe sepsis or septic shock.



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**Question 137:** At my hospital, we had 150 to 200 cases of severe sepsis or septic shock cases per month. However, our metrics are based on 10 charts per month. Are there plans to improve such sampling errors?

The sample sizes are based upon standard sampling methodology used by CMS. For a monthly population of 150 – 200 cases, the Sepsis Sample Size Requirements identified in the SEP-1 Measure Information Form indicate your facility's sample size is 20 cases. If cases are excluded, they are not replaced, which could account for ten charts per month.

**Question 138:** I am wondering if you can tell me if there are plans to revise the element or query entitled, "Broad Spectrum or Other Antibiotic Administration Selection?" The definition clearly states that the appropriate antibiotic must be administered in the three hours following severe sepsis/septic shock presentation in order to meet measure requirements. We have had several failed numerators for this, as the patient presents with an obvious infection, and the appropriate antibiotic is started quickly, as it should be, but the antibiotic start time is prior to the severe sepsis/septic shock time. This is due to the fact that the documentation of infection by the ED provider is later than the time that the antibiotic was administered. The ED documentation of infection was the last piece in place to determine the severe sepsis/septic shock time. In these cases, the patient received correct treatment with early administration of an appropriate antibiotic, but failed the measure requirements for SEP-1. This is an inequitable situation, and we are hopeful that it will be corrected.

There is not sufficient information in this question to identify where the issue is located or exactly what the issue is. If IV antibiotics are started in the 24 hours prior to severe sepsis or septic shock presentation, the Broad Spectrum or Other Antibiotic Administration Selection data element does not need to be answered. The only time this data element needs to be answered is if the **only** antibiotics given were in the three hours following severe sepsis or septic shock presentation. Any IV antibiotic given in the 24 hours prior to severe sepsis or septic shock presentation will meet the antibiotic administration requirements.



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**Question 139:** Specs manual states that patients who were started on antibiotics more than 24 hours prior to onset of severe sepsis are excluded from measure, but the initial lactate question is asked first in the algorithm. So if initial lactate fails, then the algorithm stops without answering the antibiotic timing questions so you wouldn't know the patient was already on antibiotics > 24 hours before. Are there going to be any changes to correct this?

Changes to address this are still under consideration. Because a final decision has not been made yet, we are unable to share additional information at this time.

**Question 140:** Will the measure be updated such that if the patient had two consecutive low BPs in the hour after, then after that hour, no further hypotension (still within the six hours) will not be a fallout for not starting vasopressors?

We are not aware of any updates under consideration like this.

**Question 141:** I have had a patient who should have been excluded as per the denominator statement, "Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis" actually fail, since there was no lactate drawn within the time frame, and it fails, and then there is no opportunity to answer the antibiotic question that should then exclude the patient. Will this be corrected?

Changes to address this are still under consideration. Because a final decision has not been made yet we are unable to share additional information at this time.

**Question 142:** Why are we still abstracting prehospital records, such as ambulance and nursing homes, for severe sepsis presentation; and when will this change? Thanks.

Allowance of prehospital records for SEP-1 data elements was introduced at the request of multiple hospitals. Currently, there are no plans to remove prehospital records as a source of information.



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**Question 143:** Is there going to be any consideration of possibly separating the sepsis bundle into either three hour and six hour bundles, or separate elements, i.e., initial lactate, blood culture, antibiotic?

We are not aware that this is currently under consideration.

**Question 144:** Currently, patients who received antibiotics > 24 hours prior to severe sepsis are not being excluded in our Midas data tool and opportunities are occurring for “initial lactate.” Has logic for 2017 been updated or will this continue in 2017?

For discharges 01-01-17 (1Q 2017) through 12-31-17 (4Q 2017), the algorithm (logic) remains the same. If the initial lactate criteria were not met, the case will not pass, even if antibiotics were received greater than 24 hours prior. Changes to address this are still under consideration. Because a final decision has not been made yet, we are unable to share additional information at this time.

**Question 145:** We’re having some issues with lactate testing fallouts (as is everyone), however in many cases, we are testing the lactate > six but < 12 hours prior to the documentation of severe sepsis, and in these cases, the lactate has been normal. Given the previously normal lactate, clinicians are not retesting lactate in these cases (no clinical indication to do so). What guidance can you offer for these cases? Would you consider increasing the time window for appropriate lactate screening?

The time frame of only allowing use of lactates within six hours prior to presentation is based upon concern that as sepsis progresses, lactate levels older than six hours may no longer be valid. We thank you for your recommendation and will take it under review and consideration. However, we are not aware that expanding the time frame to allow lactates more than six hours prior to presentation is currently under consideration.



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**Question 146:** Is there any discussion on looking at the abstraction notes for initial lactate? Currently, the Initial Lactate Level Collection data element requires that, “If there are multiple lactate levels, only abstract the level drawn closest to the time of presentation of severe sepsis. That lactate level is the initial lactate level for purposes of this data element.” It’s been my finding that sometimes a lactic acid level is drawn early within the course of care but within six hours prior to severe sepsis presentation, and is repeated by protocol; however, we must take our second serial lactate as the first because of a timing issue, which causes a core measure failure for repeat lactic acid.

The lactate closest to the presentation time is used because it is the level that most accurately reflects the patient’s condition at the time of presentation. The specifications take into account that if a lactate level is elevated (regardless of which one), it would be appropriate to draw serial lactates until it is normalized.

**Question 147:** Has CMS considered changing the all-or-nothing, pass-fail of the 63 points currently abstracted?

We are not aware that this is currently under consideration.

**Question 148:** Attempts to draw blood cultures without success can be abstracted as being collected. Will an exception be built into abstraction when dealing with antibiotic administration and crystalloid fluid administration when IV access is lost and central lines are needed?

We are not aware of any exceptions under consideration related to this situation.

**Question 149:** Do you expect a major update to the guidelines in the next few months?

With regard the specifications manual update, revisions are currently under consideration for version 5.3, which will be published mid-year 2017 and take effect for cases discharged January 1, 2018.



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**Question 150:** Great presentation, Dr. Townshend, Mr. Dickerson, and Dr. Tefera; would love to continue seeing these SEP-1 webinars. They are extremely helpful! Would be even better if we could leave more time for questions at the end; perhaps have a webinar for SEP-1 questions only? That would be so valuable and appreciated!

Thank you for the feedback. We will work to decrease the webinar administrative slides and provide more time for questions and answers.

**Question 151:** Consider changing “initial lactate” to “lactate closest to time zero.” This is very confusing to the staff because sometimes the initial lactate is not really the initial lactate based on the current definition in the specs manual, since some initial lactates are not closest to time zero. In some patients, we need to be getting three lactates, which is making our cases fallout.

The initial lactate, defined for purposes of the measure, as the lactate drawn closest to the severe sepsis presentation time, may not be the first lactate actually drawn. We will take your recommendation to rename the data element under consideration.

**Question 152:** Please consider changing this measure to using only the coded diagnosis of sepsis like the other core measures. The requirement of searching for the SIRs and infection in a lengthy patient chart is very burdensome, and apt to not be done correctly due to interpretation. Watching the chat lines, there are many interpretations to identifying the Sepsis. Thanks.

This has been discussed, and a decision was made not to change the population at this time. Initial data analysis reflects that about 60% of the total number of cases in the population are those with uncomplicated sepsis codes. Of those, about 46% actually have severe sepsis or septic shock, but do not have severe sepsis or septic shock ICD-10 codes. This represents about 28% of the total population that has severe sepsis or septic shock, but do not have ICD-10 codes for severe sepsis or septic shock.





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#### Why

**Question 153:** If a fluid challenge is used as one of the four requirements for the repeat volume status assessment, what exactly is to be measured by the provider giving the fluid challenge? For example, the fluid is given as per? Notes for abstraction? What is the measurement of responsiveness? Is it merely an improvement in blood pressure or HR with that fluid challenge, or is it more specific measurement done by other means such as stroke volume?

For purposes of the SEP-1 measure, all that is required is a fluid challenge be ordered and completed. A response is not abstracted and not required.

**Question 154:** You give 30 mL/kg fluid bolus and the patient is still hypotensive, and the physician wants to give another liter of fluid before vasopressors. If that worked, it generates a fallout for no vasopressor. Why?

Based on the measure criteria and logic, vasopressors should be started if the patient has persistent hypotension as denoted by not responding to 30 mL/kg of crystalloid fluids. If vasopressors are not given to treat persistent hypotension, the case will fall out of the measure. This will occur regardless of whether the hypotension resolves with additional fluids (more than 30 mL/kg) instead of vasopressors. While cases occur where it may be clinically appropriate to give more fluids rather than start vasopressors, the measure is designed to address how the majority of cases should be treated based upon guidelines. In clinical practice, physician judgement should be used if there are concerns following the guidelines may be detrimental to a given patient. We recognize there may be times where physician clinical judgment based on specific patient response reflects additional fluids are indicated instead of vasopressors. Measure revision discussions are underway to address this in a future version of the specifications manual.



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**Question 155:** So, if the patient has severe sepsis with one or two episodes of hypotension at onset, which resolves without fluid intervention and does not progress to shock, we would still have to give 30 mL/kg of fluids? If so, what is the reasoning behind this? Especially in the case of dialysis and CHF patients.

The International Guidelines for Management of Severe Sepsis and Septic Shock: 2012, upon which the SEP-1 measure is based, recommend administration of 30 mL/kg of crystalloid fluids for patients with sepsis-induced hypoperfusion/hypotension. We are looking into ways to more accurately identify episodes of hypotension that do not spontaneously resolve and truly do represent sepsis-induced hypoperfusion/hypotension requiring 30 mL/kg of crystalloid fluids. To our knowledge, no trial has demonstrated that this population suffers adverse effects when treated initially with a crystalloid fluid bolus. In fact, observational studies showed an association between an early fluid challenge and improved mortality. On the contrary, in the EGDT trial, and other published observations, patients with heart or renal failure who received a fluid bolus and EGDT had a lower rate of intubation for respiratory compromise compared to those patients who did not.

**Question 156:** Could you please provide a rationale why cap refill is a requirement in the focused exam components? Many providers feel that cap refill is not a valuable assessment in the adult population, based on evidence.

We believe that the action of clinicians reassessing a critically ill patient is standard of care and consistent with current practice norms. We will continue to review the focused exam data elements of the measure to minimize any clinician documentation burdens.

**Question 157:** Our physicians are challenging the value of documenting capillary refill and peripheral pulses in the focused exam. Can you please explain the rationale of this specific documentation?

We believe that the action of clinicians reassessing a critically ill patient is standard of care and consistent with current practice norms. We will continue to review the focused exam data elements of the measure to minimize any clinician documentation burdens.



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**Question 158:**      **Volume reassessment: Why two of the following four elements when bedside US in many EDs has become primary means of volume assessment in shock states? Seems to me that US alone should qualify.**

We agree that ultrasound is a valuable means of reperfusion assessment and will review this suggestion for the next specifications manual.

**Question 159:**      **When a patient requires fluids due to initial hypotension and the patient responds to the fluids prior to the entire 30 mL/kg is infused, why should fluids continue to be infused? What is the rationale for continuing the fluids?**

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure.

**Question 160:**      **Please advise why the crystalloid fluid requirement for severe sepsis with hypotension is not reflected in the SEP-1: Completing the Bundles slide or in the SEP-1 Numerator Statement.**

The bundles are time sensitive. There is no timing requirement for when the crystalloid fluids for severe sepsis with hypotension must be given. The Septic Shock three hour bundle requires that crystalloid fluids be administered within three hours of septic shock. At the time, a patient presents with severe sepsis and hypotension, one does not know they have septic shock until after the 30 mL/kg of crystalloid fluids are completely infused and the response to the fluids is assessed. If the patient doesn't respond and has persistent hypotension indicating presence of septic shock, the fluids have already been given.



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**Question 161:**      **If there is continual measure refinement going on, why is CMS validating SEP-1? Hospitals are set up to fail validation when there are so many changes to the measure, and oftentimes those changes are not updated timely within the specs manual either.**

Because SEP-1 is a challenging measure, we have instituted multiple specification changes in the year to simplify abstraction for hospitals and minimize documentation for clinicians. Because of these refinements, in 2016, we delayed the public reporting of SEP-1 on *Hospital Compare*. We will continue to review feedback from hospitals about their experiences and will only public report data when we are confident that the reported data are valid and reflect hospital performance.

**Question 162:**      **The term, severe sepsis, was eliminated during the Sepsis-3 meeting. Why are we still using the term, severe sepsis? It is confusing.**

There remains considerable controversy about the Sepsis-3 proposed definitions, including that they have not been prospectively validated, and could result in missing the early identification of sepsis. For a more detailed response, please review our letter to the editor of the *JAMA*. The letter is on the *QualityNet* web page, [Fact Sheets for Measure Changes](#) or on the *JAMA* web page, <http://jamanetwork.com/journals/jama/fullarticle/2536619>.

**Question 163:**      **Why do physicians have to document that creatinine level is elevated because of ESRD in order for us not to use the elevated creatinine as organ dysfunction? It is well understood that creatinine level in ESRD patients will usually or not always elevated, why physicians have to document?**

The specifications do not require the physician to explicitly document the creatinine is elevated due to ESRD. The requirement is that there must be some association between the condition and the elevated level in the physician note. If the physician documented that that patient has ESRD and in the same note referenced the elevated creatinine level, included the elevated level, or indicated the level is elevated, this is sufficient to establish a link or association.



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**Question 164:** Why doesn't CMS break the measure into the various bundles and data elements? Why is SEP-1 only one measure; and if you fail any piece of the bundles, then you fail the entire measure overall? SEP-1 essentially acts like a composite score instead of a single measure, which is not how we have seen measure data reported historically within the Hospital IQR Program for various other measure sets.

This is because SEP-1 is a composite measure. It is the first CMS composite measure for the Hospital IQR Program. More information is available in the *Fact Sheet SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock* posted on the *QualityNet* web page, [Fact Sheets for Measure Changes](#).

**Question 165:** If “any” antibiotic that is given, for example, one hour before the presentation of severe sepsis, i.e., not on the Table 5.0 or 5.1, but no antibiotic is given three hours after the presentation of severe sepsis, why wouldn't that fail the measure? The data element specifies “any” antibiotic and not a broad spectrum. This is confusing. I appreciate clarification. How can that not fail if we gave the wrong ABX prior to the diagnosis?

Typically, antibiotics given prior to presentation of severe sepsis are given for a known or suspected specific infection. The choice of antibiotics in this case is most likely guided by infection-specific recommendations or guidelines. If antibiotics are first started after severe sepsis is recognized, the patient condition is worse, and warrants potentially more aggressive antimicrobial management.

The International Guidelines for Management of Severe Sepsis and Septic Shock: 2012, upon which the SEP-1 measure is based, recommend the initial use of broad spectrum antibiotics to ensure all likely causative organisms are covered. The guidelines also recommend de-escalation of antibiotics once the causative organism is identified. This is beyond the scope and measurement period of antibiotics for SEP-1.



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**Question 166:** Can you address the rationale behind using the “initial lactate” value closest to the Severe Sepsis Presentation Time when multiple levels are drawn? My issue with this is that ED physicians often do not dictate diagnosis and treatment until after the patient is stabilized and care has been rendered. Dictation of the infection may be the last element needed to identify the severe sepsis presentation time. Lactate levels have been drawn...and possibly redrawn within this time period. By using the level closest to the presentation time, may exclude the “repeat level” being performed simply because the physician didn’t take time away from patient care to dictate the infection.

This is the level that most accurately represents the patient’s condition at the time presence of severe sepsis is identified.

**Question 167:** Initial antibiotic administration is recommended for sepsis; why is the measure only looking at severe sepsis? A lot of patients are excluded because they meet sepsis criteria but did not meet severe sepsis criteria (organ dysfunction)?

The scope of the measure was limited by the measure stewards to severe sepsis and septic shock because of the high mortality rates associated with these conditions.

**Question 168:** Why are you waiting for the patient to be in septic shock before giving fluids?

The Crystalloid Fluid Administration data element allows for inclusion of fluids given prior to, at the time of, or within three hours, following presentation of septic shock.

**Question 169:** Can you explain why 0.9% saline used to mix the antibiotics cannot be counted toward the fluid bolus?

The intent is to ensure fluids counted toward to 30 mL/kg of crystalloid fluids are given for fluid resuscitation. To do this, fluids given for other reasons are not counted toward the 30 mL/kg total volume.



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**Question 170:** Can you tell us why septic shock exclusion criteria come after fluid administration in the current algorithm of July changes? They remain in January 2017 and pose a real problem because they fail cases instead of excluding them appropriately.

This is being looked into for a future version of the specifications manual.

### Citations

**Question 171:** Our group has a question around giving 30 mL/kg to patients who are morbidly obese. We know that total circulating volume is decreased (50% morbidly obese vs. 75% for normal BMI) so it seems that the 30 mL/kg (we had a patient weighing 236 kg... requiring 7+ liters at base). Do you know of any studies that support an adjusted weight or adjusted volume for the morbidly obese?

An upper limit for the 30 mL/kg crystalloid fluid infusion based on BMI is planned for discussion during the next manual-review process. At this time, no adjustment to the required 30 mL/kg volume is specified in the specifications manual. Clinical judgment in this case should prevail if the physician/APN/PA felt that 30 mL/kg of crystalloid fluids are not indicated or could be detrimental. This may result in a case not meeting the measure. As mentioned previously, we are aware that variations in presentation may exist for which clinical judgment dictates that following the guidelines is not in the best interest of the patient.

**Question 172:** Is there any way to get a copy the article Dr. Townsend mentioned about the author of Sepsis-3 stating it still needs testing? This is a discussion I would like to have with the head of Critical Care. Thank you.

The letter can be located on the *QualityNet* web page, [Fact Sheets for Measure Changes](#) or on the *JAMA* web page, <http://jamanetwork.com/journals/jama/fullarticle/2536619>.



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**Question 173:**      **Is there any EBM that the exam is better than following lactate improvement? I believe the literature suggests lactate is a better measure.**

We agree that lactate is a marker of clinical improvement, but also believe that clinicians reassessing a critically ill patient is standard of care and consistent with current practice norms.

**Question 174:**      **Do you have any words or evidence/articles that we can give to providers who are resistant to the 30 mL/kg bolus for patients with other comorbidities, such as CHF?**

At this time, no revisions are planned allowing less than 30 mL/kg of crystalloid fluids to be administered, based on physician discretion. Since 30 mL/kg of crystalloid fluids are required in order to determine if hypotension persists, cases where patients receive less than 30 mL/kg will fail the measure.

There is no evidence that heart failure or dialysis patients have any negative outcomes related to the fluid bolus. Rather, extensive evidence indicates that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered. In the EGDT trial, and other published observations, patients with heart or renal failure who received a fluid bolus and EGDT had a lower rate of intubation for respiratory compromise compared to those patients who did not.

**Question 175:**      **Can you give the reference for the sepsis article in *JAMA* discussed during Q&A? Thanks.**

The letter can be located on the *QualityNet* web page, [Fact Sheets for Measure Changes](http://jamaneetwork.com/journals/jama/fullarticle/2536619) or on the *JAMA* web page, <http://jamaneetwork.com/journals/jama/fullarticle/2536619>.