



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.3a Measure Updates

Questions and Answers

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Webinar attendees submitted the following questions and subject matter experts provided the responses. Questions and answers may have been edited.

Organ Dysfunction/Systemic Inflammatory Response Syndrome (SIRS)/Hypotension

Question 1: Do the “2 hypotensive blood pressures criteria” also apply to hypotension used to determine organ dysfunction?

Two hypotensive blood pressures (BPs) are required to determine initial hypotension. However, only one hypotensive blood pressure is required for organ dysfunction. As a result, one of the two hypotensive blood pressures used to determine initial hypotension may be used to meet organ dysfunction.

Question 2: Do the two low vital signs need to be in the same time frame or can one be in six hours before and one in the six hours after severe sepsis presentation?

For initial hypotension, the time frame is six hours prior to severe sepsis presentation to six hours after severe sepsis presentation. This means the two hypotensive blood pressures need to occur within that 12-hour span. Blood pressures obtained prior to or after the 12-hour span should not be included.

Question 3: Should the first hypotensive blood pressure be when the fluids are started?

Initial hypotension will be when the second hypotensive blood pressure is documented within the time frame. Therefore, use the time of the second hypotensive blood pressure which represents initial hypotension as the basis for crystalloid fluid administration (CFA) time.



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Question 4: **What if there is documentation of chronic renal disease and the baseline is reported as 1.3? Would a reading of 1.8 still count as organ dysfunction or does it have to be over 2?**

To clarify, only creatinine values greater than 2.0 are acceptable for *Severe Sepsis Present* criteria C. Per the scenario in this question, with a baseline creatinine of 1.3, the reported creatinine value must be greater than 2.0 to meet organ dysfunction criteria. Therefore, although a reported creatinine greater than 1.8 is greater than 0.5 above the baseline, the reported creatinine must still be greater than 2.0 to meet organ dysfunction criteria.

Question 5: **With initial hypotension, the required intravenous fluid (IVF) must be initiated within three hours of initial hypotension. In regard to septic shock being met clinically, or with an initial lactic acid (LA) of 4.0 or greater or physician/advanced practice nurse (APN)/physician assistant (PA) documentation of septic shock, 30 mL (milliliter)/kg (kilogram) IVF is required within three hours of presentation. The noted statement on slide 18 states, “Complete infusion does not need to occur within the appropriate time frame.” Clarification is greatly needed as to what this statement is specially referencing.**

The intent is that the infusion needs to be started within that appropriate time frame, which is within three hours following initial hypotension. However, the IVF doesn't have to be completely infused within this time frame. For example, it could be started 2.5 hours after initial hypotension time. It is acceptable if the infusion goes over two hours because it was started in the appropriate time frame.

Question 6: **Slide 37, is that is a “Yes” for SIRS criteria being present?**

The physician documentation, that the patient has SIRS, would not be used to meet the SIRS criteria. The SIRS criteria and *Severe Sepsis Present* data element are looking for the actual abnormal values that are documented within six hours of the other two criteria and *Severe Sepsis*



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Present; therefore, the physician documentation, which only states the patient has SIRS, would not be used.

Severe Sepsis or Septic Shock Present on Admission

Question 7: Does the emergency department (ED) note need to say, “severe sepsis or septic shock present on admission (POA),” or can there be documentation of severe sepsis or septic shock as a diagnosis in the ED note and it qualify as present on admission?

1. If severe sepsis is documented as present on admission, then the admission date and time to the floor unit would be used. If severe sepsis is simply documented within the ED note, not saying present on admission, then the date and time severe sepsis was documented in the ED note would be used.
2. If the documentation of severe sepsis or septic shock within the ED note does not say present on admission, use the specified time that severe sepsis or septic shock is documented. If a specified time is not available, use the time the note was opened. If it is documented as present on admission, using the admission time to the floor or unit is acceptable.

Question 8: Why are direct admissions who present from nursing homes with infections, severe sepsis, or septic shock not considered a transfer?

The data related to transfer from another hospital or ambulatory surgery center (ASC) are to identify patients that were in a setting, such as a hospital, which may have received some treatment prior to the transfer. When patients are identified in a nursing home, this scenario aligns more closely with patients identified in the community.

Question 9: Slide 46. Severe sepsis present on admission. The slide notes to use the earliest documented hospital admission time. Are we always to use the documented patient arrival to floor [time] rather than the admit



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order time or admission registration time? If we have two times of arrival to floor, which time do we use? Do we use the earlier time?

Use the time that the patient arrived to the floor or unit or the time that most accurately reflects when the patient arrived to the floor or unit rather than the order time. If two times are documented that reflect when the patient arrived to the floor or unit, abstract the earliest of those times to get the earliest *Severe Sepsis Presentation Time* possible.

Sepsis Benchmarks

Question 10: Are there any benchmarks for the SEP-1 metric?

Currently, we do not have any benchmarks published. CMS is working on developing a benchmarks report that will have the overall performance for the measure and eventually a breakdown by the bundle.

Medications

Question 11: Slide 36. If it is a home medication, do you need the last dose given time or date?

If a medication is documented on the home medication record, it is not necessary to identify the exact time the last dose was given.

Documentation that the patient takes the medication at home is sufficient. However, if the home medication was given in the hospital, the date and time that it was last given needs to be documented and noted.

Hypotension

Question 12: If we have six hours to start a vasopressor, why do we only have an hour to assess for persistent hypotension? It seems to me that if the patient is still hypotensive in the hour post fluid, it should not be a miss but a pass if the vasopressor is started within the six-hour time frame. Most patients are not hypotensive an hour post fluid but are two hours post fluid. They still need a vasopressor.



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To clarify, the measure allows six hours from septic shock present time; assessment for persistent hypotension happens once fluids are completely infused which could be multiple hours after septic shock present time. The assumption above is correct. If the patient is hypotensive one hour post fluid, it would not be a miss if vasopressors are started within six hours of septic shock present time. The measure specifications include a one-hour time window to assess for hypotension that persists after the completion of the target ordered volume of crystalloid fluids because patients with persistent hypotension during that time are required to get a vasopressor. Evidence demonstrates administration of a vasopressor for hypotension that persists in the hour after the target ordered volume of crystalloid fluids has decreased mortality.

Question 13: **With two hypotension readings for initial hypotension, is there a maximum limit on the time between the two consecutive readings? For example, do they have to be 15 minutes apart or can they be greater than an hour? What's the time limit between the two consecutive readings?**

For manual version 5.3a, *Initial Hypotension* requires two hypotensive blood pressures within six hours prior to through six hours after the *Severe Sepsis Presentation Time*. Hypotensive readings for *Initial Hypotension* are not required to be consecutive, nor are they required to be within a particular time distance from each other. In summary, for v5.3a, there is no maximum limit on time between the two consecutive readings.

Question 14: **Can you clarify exactly what the definition of initial hypotension is? Is it either two hypotensive readings six hours prior to or two hypotensive readings six hours after severe sepsis? Must two hypotensive readings be within six hours of each other or two hypotensive readings within (what essentially is) a 12-hour time frame (i.e., Can one reading be up to six hours before and can the second be up to six hours after severe sepsis presentation?)?**



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For manual version 5.3a, *Initial Hypotension* requires two hypotensive blood pressures within six hours prior to through six hours after the *Severe Sepsis Presentation Time*. Hypotensive readings for *Initial Hypotension* are not required to be consecutive, nor are they required to be within a particular time distance from each other. In summary, for v5.3a, there is no maximum limit on time between the two consecutive readings.

Question 15: **If a patient has a low BP five hours prior to severe sepsis presentation, another low BP five hours after presentation time, and the patient received a 30 ml/kg mL/kg bolus ending four hours after presentation time, would that mean the patient did not meet the criteria for initial hypotension since the second low BP was after the completion of the IVF bolus?**

Correct. If the target ordered volume of crystalloid fluids completes prior to the second hypotensive reading, value 2 (No) would be selected for *Initial Hypotension*. Hypotension that is found after the target ordered volume of crystalloid fluids is complete is considered hypotension that persisted.

Question 16: **If fluids are started within the trigger window, but not completed within the six hours after presentation, and there is persistent hypotension upon fluid completion (i.e. at seven hours), is it correct that the vasopressor and focused exam requirements would not need to be addressed?**

If value 1 (Yes) is selected for *Septic Shock Present* based on an initial lactate level result ≥ 4 or *Documentation of Septic Shock and Persistent Hypotension* was present, vasopressor administration and the repeat volume status or tissue perfusion assessment would still be required.

Question 17: **If the patient has initial hypotension at 1745 and 30 mL/kg bolus was ordered at 1800 and started at 1810, then do we check the BP at 1910–2010 to assess for persistent hypotension?**



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To determine the exact hour to assess for *Persistent Hypotension*, further details would be required. However, if a 30 mL/kg bolus was ordered over one hour, and the infusion was started at 1810, unless further documentation indicates a different end time, the 30 mL/kg bolus would be completed at 1910. Therefore, *Persistent Hypotension* would be assessed between 1910 through 2010.

Question 18: **If there are two hypotensive blood pressures taken, both with the same time documented, theoretically to check validity of the reading, would the two hypotensive blood pressures be considered one reading? For example, BP 85/48 1300 and BP 86/50 were also documented at 1300. Would this be considered two low blood pressures for initial hypotension or only one?**

As long as the blood pressures are two different measurements, this would be considered two different readings. In this scenario, the two systolic hypotensive readings documented at the same time would suffice for *Initial Hypotension*.

Question 19: **For cases with septic shock based on severe sepsis and initial lactic acid (LA) >4 (with no initial hypotension and no documentation of septic shock), they get the target ordered volume of fluids, but they fail *Persistent Hypotension* as there are no BPs in the hour; however, the BPs right before, right after the hour, and all the BPs in this episode of care are normal. Cases like these should be made exceptions. Is this being looked at?**

No, this scenario is not being reviewed. Septic shock cases with an initial lactate ≥ 4 , who also receive the target ordered volume of fluids, should be assessed for *Persistent Hypotension*. This assessment determines if vasopressor administration is required for the septic shock patient. It is required because septic shock patients that require and receive a vasopressor have been shown to have decreased mortality.



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Question 20: **Is there a time frame to assess for persistent hypotension?**

Persistent Hypotension should be assessed one hour after completion of the target ordered volume of crystalloid fluids. A time frame in which *Persistent Hypotension* must be assessed following severe sepsis or septic shock is not specified in the manual. At the completion of the target ordered volume of crystalloid fluids, *Persistent Hypotension* should be assessed.

Question 21: **It really does not seem logical to have a 12-hour window for initial hypotension, especially if the infection source, two SIRs, and one organ dysfunction criteria all must be met within six hours of each other. Please explain how this makes sense for a three-hour and six-hour treatment bundle. So, even though a patient would receive all aspects of the treatment bundles in a timely manner, we would potentially fail the measure because a fluid bolus wasn't given within three hours of a hypotensive reading that is six hours after severe sepsis presentation and severe sepsis treatment and 12 hours after the first hypotensive reading?**

For manual version 5.3a, *Initial Hypotension* requires two hypotensive blood pressures within six hours prior to through six hours after the *Severe Sepsis Presentation Time*. The timing of *Initial Hypotension* is not necessarily relative to the three-hour and six-hour bundle, as this data element is simply indicating the event that would trigger crystalloid fluids administration for the severe sepsis/septic shock patient. However, CMS appreciates this concern and is looking to potentially update this guidance.

Question 22: **More clarification is needed on why two hypotensive measures are needed for initial hypotension but only one is needed for organ dysfunction. This seems inconsistent if you are defining hypotension as organ dysfunction.**

Evidence of organ dysfunction for *Severe Sepsis Present* and *Initial Hypotension* serves two different purposes. Therefore, the number of



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blood pressures sufficient to meet either one is different. For the severe sepsis patient with an infection, SIRS criteria, and signs of organ dysfunction, one hypotensive blood pressure or one abnormal lab value is sufficient to move forward with abstraction of the severe sepsis patient.

Initial Hypotension is looking for sufficient evidence to initiate fluid resuscitation with the target ordered volume of crystalloid fluids. If a patient with severe sepsis has two hypotensive blood pressure readings, this serves as a trigger to initiate crystalloid fluids for the purpose of resuscitation.

Question 23: Does persistent hypotension have to be after fluid resuscitation has been given?

Yes, *Persistent Hypotension* can only be assessed and determined in the one hour after completion of the target ordered volume of crystalloid fluids.

Question 24: Please, can you clarify initial hypotension and crystalloid fluids to include fluids that are “started” within the specified time frame and that we should include the amounts that were indeed started but continued to run after the three hours? Also, per a *QualityNet Q&A* with Bob Dickerson, he advised that we could continue to abstract fluids for each subsequent hypotensive BP for the 30 mL/kg until the correct amount was ordered.

The time frame for administering crystalloid fluids based on *Initial Hypotension* is six hours prior through three hours after *Initial Hypotension*. This means that crystalloid fluids must be started within six hours prior through three hours after *Initial Hypotension*. The referenced Q&A is guidance from a previous version of the manual that no longer applies in v5.3a.

Question 25: What is the definition of persistent hypotension?

The definition of persistent hypotension is documentation of the presence of persistent hypotension or new onset of hypotension following the complete administration of the target ordered volume of crystalloid fluids.



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Question 26: Shouldn't there be an initial hypotension date and time data element required and part of the algorithm since the time window in which to accept fluids is so specific?

For manual v5.3, the guidance under the Notes for Abstraction provides the specified time frame in which crystalloid fluids should be started. An *Initial Hypotension Date and Time* data element has been added to the next version of the manual, v5.4, for discharges July 1–December 31, 2018, which is published on *QualityNet.org*.

Question 27: Since initial hypotension is hypotension that is present prior to the target ordered volume of crystalloid fluids being completely infused, what if target fluids are given for lactate acid >4 and, following completion of these fluids, the patient becomes hypotensive within six hours following severe sepsis. Would this be No to initial hypotension?

Allowable value 1 (Yes) can only be selected for *Initial Hypotension* if the two hypotensive readings are documented prior to the completion of the target ordered volume of crystalloid fluids. In this case, value 2 (No) should be selected for *Initial Hypotension*.

Question 28: To clarify persistent hypotension post fluid bolus, can we possibly use the same vital signs measurements as the initial hypotension measurements?

No, *Initial Hypotension* can only be present prior to the completion of the target ordered volume of crystalloid fluids. Hypotension present in the hour after completion of the target ordered volume of crystalloid fluids would be used for *Persistent Hypotension*.

Question 29: Slide 30. If there are two hypotensive blood pressures but one is prior to IVF and the second is after IVF completion, do we say “No” to initial hypotension? If the second is while the IVF is infusing, do we say “Yes” to initial hypotension?



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Correct. If the second hypotensive reading that potentially identified *Initial Hypotension* is after the completion of the target ordered volume of crystalloid fluids, value 2 (No) should be selected for *Initial Hypotension*. If the target ordered volume is not completed prior to the second hypotensive reading, value 1 (Yes) should be selected for *Initial Hypotension*.

Question 30: **Slide 30. Is the time frame to determine initial hypotension actually 12 hours?**

For manual version 5.3a, *Initial Hypotension* requires two hypotensive blood pressures within six hours prior to through six hours after the *Severe Sepsis Presentation Time*. Hypotensive readings for *Initial Hypotension* are not required to be consecutive, nor are they required to be within a particular time distance from each other. Rather, two hypotensive readings within the overall 12-hour time frame (six hours prior through six hours after *Severe Sepsis Presentation*) are sufficient.

Question 31: **Slide 52. The specifications manual says persistent hypotension or new onset of hypotension. Please define “new onset.”**

The term “new onset” is provided in the *Persistent Hypotension* data element for cases that did not have *Initial Hypotension*. If the patient was given the target ordered volume of crystalloid fluids based on an initial lactate ≥ 4 or *Documentation of Septic Shock* and then had two consecutive hypotensive readings in the hour after the completion of the target ordered volume of crystalloid fluids, this case would meet the definition of “new onset.”

Question 32: **Slide 53. If the crystalloid fluid is ordered at 150 cc and it takes 12 hours to get the target volume infused, you would look for persistent hypotension after 12 hours even though it is more than six hours after the presentation time of severe sepsis?**



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Correct. *Persistent Hypotension* would be assessed in the hour after completion of the target ordered volume of crystalloid fluids. If *Persistent Hypotension* was found greater than six hours after the *Severe Sepsis Presentation Time*, severe sepsis with *Persistent Hypotension* would be used to select value 2 (No) for *Septic Shock Present*.

Question 33: **Slide 53. There seems to be some challenges to get two BPs within the hour due to transport to the unit. Is there any talk of considering 1.5 hours after IVF infusion?**

At this time, we are not planning revisions to the one hour to assess for the *Persistent Hypotension* element.

Question 34: **For slide 53, regarding the time frame for the hour to assess for persistent hypotension, can you clarify the difference between completion of crystalloid fluids versus crystalloid fluids are completely infused?**

There is no difference between “completion of crystalloid fluids” and “crystalloid fluids are completely infused.” They mean the same thing.

Question 35: **Can we use BPs in the operating room (OR) or post-anesthesia care unit (PACU) for reassessment after crystalloid fluid administration?**

The *Persistent Hypotension* data element provides guidance **not** to use hypotensive blood pressures obtained in the operating room. This guidance only applies to the operating room and does not apply to other units such as the PACU.

Question 36: **Can you clarify if we should use blood pressures documented while the patient is on dialysis or during a dialysis treatment when looking for organ dysfunction?**

Yes, hypotensive blood pressures documented while the patient is on dialysis may be used as evidence of organ dysfunction.



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Question 37: **If only one low BP is needed for organ dysfunction, how does that help the transient low reading issue?**

Evidence of organ dysfunction for *Severe Sepsis Present* continues to only require one hypotensive blood pressure reading. If the physician/APN/PA documents this reading is normal for the patient due to a chronic condition or due to a medication, the blood pressure may be disregarded. Also, if there is physician/APN/PA or nursing documentation that the reading is invalid, erroneous, or questionable, the hypotensive blood pressure can be disregarded. Otherwise, the hypotensive blood pressure reading should be used.

Question 38: **If the provider documents that the skilled nursing facility (SNF) reported a systolic blood pressure (SBP)<90 prior to transfer, but there are no records from the SNF to determine time, can or should it be used to determine if end organ dysfunction is present if there were no SBP<90 after arrival?**

No, to use the prior to arrival blood pressure, the actual blood pressure value, as well as the date and time the reading was obtained, would be needed. Without a value, it is not possible to determine if the blood pressure meets criteria and, without a date and time, it is not possible to determine if the blood pressure was within the specified time frame.

Question 39: **Can you please clarify the bullets in the manual that relate to the multiple BP readings, using only the last two BPs?**

For the *Persistent Hypotension* data element, when multiple blood pressure readings are documented within the hour, the guidance states to assess the last two blood pressures documented in the hour. The last two blood pressures in the hour are assessed to determine if hypotension persists, in which case a vasopressor would be required, or if the blood pressure is normalizing.



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Crystalloid Fluid

Question 40: Am I correct in my understanding that the crystalloid fluid bolus must now be completed, not only initiated, within three hours of presentation of initial lactic acid >4 or hypotension?

No, the target ordered volume simply needs to be initiated within the specified time frame based on the appropriate trigger for fluids.

Question 41: What about crystalloid fluids that are ordered as boluses? Can I take 10% of those boluses? Example: Patient fluid requirement is 1800 milliliter (mL). The orders are one liter (L) bolus followed by 500 mL bolus. Would that suffice for targeted volume received?

Regarding the allowance for being within 10% of 30 mL/kg, this is specific to the physician's order of the fluids. If the patient required 1800 milliliters to equal a target ordered volume, administering 1500 milliliters would not be sufficient. The physician could order 1700 milliliters which would suffice to meet the volume within 10% of the 30 mL/kg. However, it is not acceptable to independently calculate a lesser volume outside of the ordered volume.

Question 42: If presentation time is 0730 and the initial hypotension time is 0710 (prior to presentation) does the clock for fluid start ticking at 0710?

With *Initial Hypotension* present at 0710, the specified time frame for initiating the target ordered volume would be six hours prior through three hours after 0710.

Question 43: Is there a certain amount of time that the crystalloid fluids must be infused after initial hypotension or as long as it's running >125 mL/hr?

No, a time frame to complete the target ordered volume is not specified in the measure. As long as the fluids were started within the specified time frame and administered at >125 mL per hour, the fluids could be used.



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Question 44: Now that we can use emergency medical service (EMS) fluids, if a patient received 500 ml bolus by EMS and, after arrival to ED, a 30 mL/kg bolus is ordered and administered, how would we determine fluid bolus end time in order to determine persistent hypotension? Would it be the end time of the entire volume of the 30 mL/kg bolus or would we need to calculate the end time including the 500 mL bolus from EMS. Required bolus 2700 mL, would the end time be when 2200 mL of bolus has been administered or when the 2700 mL has completed?

The fluids administered via EMS and the fluids administered in the ED should be used toward the target ordered volume. Therefore, the 30 mL/kg completion time would be calculated using both fluids administered by EMS and the ED. In this case, *Persistent Hypotension* would be assessed in the hour following the completion of 2700 mL.

Question 45: Regarding crystalloids for initial hypotension, if there are multiple low blood pressures six hours before and six hours after severe sepsis time, what is the time frame for fluid administration?

The time of *Initial Hypotension* would be the second earliest hypotensive blood pressure documented within the time frame and would serve as the trigger. Then, crystalloid fluids administered six hours prior through three hours after the trigger should be used toward the target ordered volume.

Question 46: When determining if 30 mL/kg fluids were given, at what point do you use fluids with medications? If you have a bolus going and it has a start and stop time and during the bolus the antibiotics were given, how do you determine stop time? Do you have to add the antibiotic volume and calculate an earlier stop time? This makes determining when to check for persistent hypotension very difficult.



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If crystalloid fluids used to dilute a medication are administered within the time frame, the fluids should be used toward the target ordered volume. However, in order to use any fluids toward the target ordered volume, the documentation must be complete, including a start time. If crystalloid fluids used to dilute a medication do not have an ordered rate or duration and there is no further documentation of a rate, duration, or end time for the infusion, the fluids would not be used toward the target ordered volume.

Question 47: **If a physician orders a crystalloid fluid bolus with the order statement, “30 mL/kg fluid bolus,” can you take 90% of the fluid? The reason for taking the 90% of the fluid is to obtain vital signs within the hour after completion of fluid.**

No, the entire ordered volume must be administered.

Question 48: **Is there a reference for the change in crystalloid fluid administration to ideal body weight for 30 mL/kg fluid administration? My physicians are asking, and I can’t find anything.**

A reference was not added to the manual for this update. This update is only applicable in instances where the patient is obese, and the Physician/APN/PA has the option to indicate IBW instead of the actual body weight.

Question 49: **Slide 17 and 18. I thought the order also needs to include the volume of fluids to give, not just 30 mL/kg. This is not defining exactly how much fluid to hang.**

The inclusion of “30 mL/kg” within a physician/APN/PA order for crystalloid fluids is acceptable for the volume requirement.

Question 50: **Slide 17. What if the patient already received the 30 cc/kg prior to the physician stopping the fluid? Sometimes more fluid has been ordered.**



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In order to provide an accurate response, further information regarding this question is necessary.

Question 51: **Slide 17. Just wanted to clarify that the initial hypotension on 1/5/2018 16:45 was the time of the second hypotensive episode.**

Yes, crystalloid fluids administered within six hours prior through three hours after the second hypotensive blood pressure that indicates *Initial Hypotension*, should be used.

Question 52: **Please re-explain the example on slide 17. If it is greater than six hours after severe sepsis can it still be used to exclude the case?**

If there is a refusal prior to or within six hours of the *Severe Sepsis Presentation Time*, value 1 (Yes) would be selected for the *Administrative Contraindication to Care, Severe Sepsis* data element. If the refusal of crystalloid fluids is greater than six hours after the *Severe Sepsis Presentation Time*, value 4 would be selected for *Crystalloid Fluid Administration* and the case would be excluded.

Question 53: **Slide 18. When there is conflicting documentation on fluid administration (e.g., the rate is documented at 999 mL/hr on the medication administration record [MAR], but the start and stop times indicate the fluids were infused faster), which rate takes precedent? The documented rate or the rate calculated off the start/stop times?**

The documented start and stop times indicating the time fluids actually infused would be used per the bullet point below from the *Crystalloid Fluid Administration* data element:

- If an ordered rate or duration time frame to infuse fluids and the rate or duration time frame the fluids were actually administered over are different, use the rate or duration time the fluids were actually administered over.



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Question 54: **Slide 18. Total fluid bolus does not have to be infused over a certain time frame?**

Yes, that is correct. There is the time frame and crystalloid fluid administration is specific to the start of the fluids. It does not specify a time frame for when those fluids must be completed. However, the fluids must be completely infused and the completion time determined in order to use the volume toward the target ordered volume.

Question 55: **Slide 18. If the nurse only documents 30 mL/kg infused, does this count toward target volume infused even though a total volume number was not stated?**

Nursing documentation alone for 30 mL/kg infused would not be sufficient. There would need to be a volume ordered or a volume within the physician's order. Additionally, the nurse would have to document a start time and either a rate and duration over which fluids were given or an end time.

Question 56: **Slide 18. Can CFA fluids be started, then a break, then more given to make up the total amount? Any limit to the time lapse between fluids given to make up CFA?**

As long as crystalloid fluids are started within the time frame and administered at >125 mL/hr., the fluids are acceptable.

Question 57: **Slide 18. Isn't there a specified rate of at least 150/hr to meet this measure?**

Only crystalloid fluids administered at >125 ml is acceptable for the measure.

Question 58: **Slide 18. Do we need a stop time to use a specific bag of fluids?**

A rate, duration, **or** stop/end time must be documented in order to determine the fluids completely infused.



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Question 59: Slide 18. On the same line as registered nurse (RN) documenting 30 mL/kg given, what if the physician documents 3000 cc given, no order and no rate. Would this be sufficient?

No, physician/APN/PA orders and documentation of actual administration are required for all crystalloid fluids used toward the target ordered volume.

Question 60: Slide 18. In version 5.3a, is the term “wide open” acceptable for a fluid bolus order as a rate of infusion?

For the physician/APN/PA crystalloid fluid order requirement, the terms “bolus, wide open, or open” are acceptable for a rate or infusion duration.

Question 61: Slide 18. IVF was ordered at 30 mL/kg over one hour, but nurse notes ended at two hours. What time do we use for determining the persistent hypotension?

The documented start and stop times indicating the time fluids actually infused would be used per the bullet point below from the *Crystalloid Fluid Administration* data element:

- If an ordered rate or duration time frame to infuse fluids and the rate or duration time frame the fluids were actually administered over are different, use the rate or duration time the fluids were actually administered over.

Question 62: Slide 23. If fluids are ordered at 30 mL/kg, and a nurse’s note reflects discussion with the physician to stop fluids due to fluid overload, and the infused amount is within 10% of the ordered volume, does the element pass?

No, the entire ordered volume must be administered. The 10% allowance is only acceptable for fluids ordered.



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Question 63: Slide 23. If the physician orders 2400 mL and the full amount is not given, it does not count, correct? We do not take 10% off the 2400 mL and count the infusion as acceptable if the patient receives 2160 of the 2400 ordered? However, if the patient's weight requires 2400 ml and the physician ordered 2160 mL, which is the required amount less 10%, and it was completely infused, that would meet the fluid requirement because the order was within the 10% variance?

Yes, this is correct. If the 30 mL/kg is ordered, the complete 30 mL/kg volume must be infused. If a volume that is within 10% of 30 mL/kg is ordered, the complete ordered volume that is within 10% of 30 mL/kg must be infused.

Question 64: Slide 26. Crystalloid fluids given to dilute medications. Would this apply only to rate of 125 mL/hr?

Yes, it would only apply to fluids given at greater than or equal to 125 milliliters per hour as well as meeting the other requirements of the crystalloid fluid administration data element such as a complete order and documentation of the infusion.

Question 65: Slide 26. Would the vancomycin example that was provided be acceptable to use for crystalloid fluid administration? I had thought that the fluid rate must be >125 mL/hr, not greater than or equal to 125 mL/hr? In this example, it would appear that the vancomycin was given at 125 mL/hr.

Yes, the example on slide 26 demonstrating crystalloid fluids used to dilute vancomycin would be acceptable because the rate is 250 mL over one hour. Only crystalloid fluids administered at a rate greater than 125 mL/hr are acceptable.

Question 66: Slide 26. If you have an order for 30 mL/kg ordered by weight and, during this infusion, an antibiotic is also given, can you use the



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weight-based CFA end time, or do you have to add in antibiotic time and make the weight-based CFA end time earlier?

The completion time of the target ordered volume, including all acceptable crystalloid fluids administered within the time frame, should be calculated. Therefore, if crystalloid fluids used to dilute medications were administered within the time frame, those fluids should be used to determine the appropriate end time.

Question 67: **Slide 26. So, now we may include normal saline (NS) administered with antibiotics?**

Yes, at this point, the inclusion is not specific to antibiotics, but it is only specific to medications in general. Crystalloid fluids given to dilute medications, including antibiotics, should be used towards the target ordered volume. If they are given in line with the order and administration requirements, they are acceptable.

Question 68: **Slide 29. If we limit the time frame to the earliest triggering event, there are times when the three-hour window has closed before the patient even meets criteria for severe sepsis. How can we hold our physicians accountable to follow a measure before the patient even qualifies for that measure?**

If *Initial Hypotension* is present, acceptable crystalloid fluids should be started within six hours prior through three hours after *Initial Hypotension*. Crystalloid fluid resuscitation is based on the triggering event, *Initial Hypotension*; it is not based on the severe sepsis presentation.

Question 69: **According to slide 29, if a patient comes in to the ED with initial hypotension immediately upon arrival, but infection is not suspected immediately, and severe sepsis criteria is not met until three or four hours later, then we can fail the measure for not giving a 30 mL/kg**



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bolus within the first three hours, before the patient has even met severe sepsis criteria. Is that correct?

If *Initial Hypotension* is present, acceptable crystalloid fluids should be started within six hours prior through three hours after *Initial Hypotension*. Crystalloid fluid resuscitation is based on the triggering event, *Initial Hypotension*; it is not based on the severe sepsis presentation.

Question 70: **Any medication infusing in crystalloid fluids may be used as the IV fluid bolus if the IV rate is >125 cc/hr?**

Yes, as long as the order and documentation of administration meets the requirements of the data element, including given at >125 mL/hr, the fluids should be used.

Question 71: **Are the IV shortages present, throughout the nation at this time, affecting crystalloid fluid administration amounts?**

No. CMS is aware of potential shortages in some areas, but no changes have been made to the measure because of crystalloid fluid shortages.

Question 72: **Are we still expected to do those two pages of calculations to determine exactly when the 30 cc/kg is infused?**

Yes, the completion time of the target ordered volume should be calculated to determine the hour to assess for *Persistent Hypotension*.

Question 73: **Can fluids that are ordered without rate or duration or term “bolus” be used if there is documentation of a start and stop time?**

If the type of fluid, volume of fluid, rate, or infusion duration is missing, do not use the order toward the target ordered volume.

Question 74: **Can we use the rate and duration for IVF completed or must there be a completed or stop time?**



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The ordered or documented rate or duration may be used if an end/stop time is not documented for the infusion.

Question 75: Does documentation of fluids in the intake and output (I&O) count toward the total fluid infused?

If the documentation on the I&O flow sheet identifies the type of crystalloid fluid, the start time of the infusion, and documentation that the infusion was completed via a documented rate, duration, or end time, the documentation on the I&O flow sheet would be acceptable.

Question 76: For pre-hospital fluids, if the ED physician documents that 2000 mL of fluids were administered in the field, would that be allowed to be counted towards the 30 mL/kg?

No, documentation of fluids administered prior to arrival must contain the type, volume, start time, and either a rate, duration, or end time of the fluid infusion.

Question 77: If the order for crystalloid fluids is written as IV NS 30 mL/kg bolus, and required fluid amount is 3,200 mL, is it acceptable to have administration of the entire bolus documented with one start time and one end time for the entire 3,200 mL, or do we need a start and end time for each bag of fluids administered to achieve that bolus?

For a single order for the complete 30 mL/kg volume, a documented start and stop/end time for the complete infusion is acceptable. Further documentation of each bag or liter is not required since the order is for the complete 30 mL/kg volume.

Question 78: If the physician orders crystalloid fluids at a rate of 126 mL/hr but does not specify a total volume to be infused, does this count towards the total volume of crystalloid fluids.



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No, in order to meet the requirements for *Crystalloid Fluid Administration*, a volume must be included in the order.

Question 79: **If the provider uses clinical judgement when giving fluids to heart failure and end stage renal disease (ESRD) patients and does not order the appropriate amount, is it still a failed case? Will this be considered for future updates to accept this?**

Yes, the complete target ordered volume must be infused if initial hypotension or septic shock is present. No updates are being considered at this time regarding these specific patient populations.

Question 80: **Is there no definite time frame for completion of fluids? If a patient is getting a 30 mL/kg bolus at 126 mL/hr, it could take over eight hours. Is that acceptable?**

The time frame to abstract *Crystalloid Fluid Administration* is provided in the data element. However, the data element does not specify a time frame in which the target ordered volume must be completely infused.

Therefore, as long as the single order for 30 mL/kg at 126 mL/hr is started within the specified time frame for *Crystalloid Fluid Administration*, the fluids would be acceptable.

Question 81: **Please clarify what “completion of crystalloid fluids regardless of when crystalloid fluids are completely infused” means. Does this completion refer to the actual initiation of 30 mL/kg fluids?**

In order to determine that the target ordered volume was completely infused, a rate, duration, or end time must be documented. If one of these is documented, the completion time of the target ordered volume can be determined. The data element does not specify a time frame in which the target ordered volume must be completely infused.

Question 82: **Please define Isolyte.**



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Isolyte is an IV solution that is acceptable when in the form of a crystalloid solution.

Question 83: **Would sodium bicarbonate added to NS at a rate of 150 cc/hr be counted towards fluid requirement? What about albumin administered?**

No, the *Crystalloid Fluid Administration* data element provides a list of acceptable electrolytes, including potassium, magnesium, calcium, lactate, acetate, or gluconate. Sodium bicarbonate and albumin are not included on the list of acceptable electrolytes.

Question 84: **Will there ever be an exception to the 30 mL/kg bolus for patients who are fluid overloaded? We have had intubated patients develop flash pulmonary edema and pink froth coming from the endotracheal tube, yet CMS says we need to keep loading them with fluids even if their BP stabilizes. Are there any plans to address this?**

At this time, there are no further updates to the *Crystalloid Fluid Administration* data element to address this scenario. The measure is designed to encompass the majority of severe sepsis/septic shock cases and not outlier cases. Therefore, physician discretion should continue to be used when administering crystalloid fluids.

Laboratory Values

Question 85: **Does the provider need to include all values when documenting an acute condition? Plus, what is the source if the cause is not an infection (e.g., all low BPs due to hypovolemia or bleeding)?**

In order to not use SIRS criteria or a sign of organ dysfunction there must be physician/APN/PA documentation linking the acute condition to a non-infectious source.

The physician/APN/PA documentation “hypotensive BP due to hypovolemia secondary to bleeding” or physician documentation “hypotensive BP due to hypovolemia” and PA documentation



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“hypovolemic due to bleeding” would be acceptable to not use the hypotensive blood pressures.

Question 86: **If an arterial blood gas (ABG) or a venous blood gas (VBG) is obtained, can the lactate result, included with the results, be used as the initial or repeat lactate result if obtained in the appropriate time frame?**

Yes, the manual does not specify the source/method for obtaining the lactate level.

Question 87: **If the patient has severe sepsis and their initial lactate acid is ≥ 4 , then do they also have septic shock? Some patients have elevated lactic acid, but their blood pressure is normal. Do they not need the vasopressors, which is part of the septic shock bundle? How do we handle those cases?**

If the lactic acid is greater than or equal to 4, this is correct; they have septic shock and should receive fluids. The patient should be assessed for persistent hypotension in the hour after the completion of fluids even if they were not initially hypotensive. For cases where value 1 (Yes) is selected for the *Persistent Hypotension* data element, proceed to *Vasopressor Administration*. Therefore, if *Persistent Hypotension* is not present, the case will not proceed to the *Vasopressor Administration* data element.

Question 88: **What about patients whose initial lactate is < 4 , but subsequent lactate > 4 ? Can we use the second value for septic shock?**

For the *Septic Shock Present* clinical criteria, only the *Initial Lactate Level Result* is evaluated. Subsequent lactate levels are not used to determine *Septic Shock Present*. In this situation, additional clinical criteria or physician/APN/PA documentation of septic shock would need to be documented.



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Question 89: I understand that initial LA is the LA drawn closest to severe sepsis time. However, these patients fail, especially those who develop severe sepsis later in their stay. These patients have many LAs drawn that will not fit into the time frame for either initial LA or repeat LA. These patients have many LAs drawn as clinically appropriate. Cases like these should be made exceptions. Is this being looked at?

Thank you for the comments. Determining which lactate should be used for the *Initial Lactate Level Collection* data element, is being reviewed for potential updating in a future version of the manual.

Question 90: Can we use “pancytopenia” or “neutropenia” without having the laboratory results included, and will we still be able to exclude the elevated or low results?

Pancytopenia or neutropenia are terms referencing the abnormal lab value. If the reference to the abnormal lab value is documented as due to a chronic condition or medication or is documented as normal for the patient, these abnormal lab values are excluded. The terms pancytopenia or neutropenia alone would not be used to meet the criteria. The laboratory values must be included along with the terms to be used in the measures.

Question 91: Will a procalcitonin become part of this measure in the future? Our physicians are using this as a marker instead of lactic acid since lactic acid can be elevated for numerous other reasons.

Procalcitonin is currently not part of the measure. At this time, there are no plans to add this unless there is some literature that surfaces indicating that this is a better marker for sepsis. The Surviving Sepsis Campaign Guidelines, published in early in 2017, referenced the use of procalcitonin for determining when it’s appropriate to either de-escalate or stop antibiotics. However, those guidelines do not recommend procalcitonin as a marker for identifying the presence of severe sepsis or septic shock.



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Question 92: Referring to slide 31 and then slide 38, why is the elevated lactate due to seizures, not accepted (to exclude that lactate level)?

Slide 31 is providing guidance for the *Initial Lactate Level Result* data element. Slide 38 is providing guidance for the *Severe Sepsis Present* data element. Slide 38 demonstrates an elevated lactate that is documented as due to an acute condition. Therefore, the elevated lactate would continue to be used to meet organ dysfunction criteria.

Question 93: Slide 31. ED states, “Severe sepsis criteria met, two SIRS, Lactate 2.3, and pneumonia.” Within 24 hours pulmonologist states, “Lactate elevated due to respiratory failure.” Does that physician still need to include wording stating, “Not due to infection, due to respiratory failure?”

The inclusion of the wording, “Not due to an infection” is not required. However, the sign of organ dysfunction documented as due to an acute condition (respiratory failure) would continue to be used unless the acute condition is further documented as due to a non-infectious source (e.g., traumatic injury).

Question 94: Slide 31. What is the time frame for physician to document elevated lactic acid due to another cause?

The time frame for physician/APN/PA documentation that SIRS criteria or a sign of organ dysfunction is normal, due to a chronic condition, or due to a medication, is prior to or within 24 hours of the *Severe Sepsis Presentation Time*.

Question 95: Slide 33. If the physician does not speak of baseline creatinine and creatinine is elevated, is this useable or should not be used for *Severe Sepsis Present* because baseline is not referenced?

If the physician/APN/PA documentation does not include chronic kidney disease with a baseline creatinine **or** consider the elevated



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creatinine to be due to the chronic condition, the elevated creatinine values should be used.

Question 96: **Slide 33. Can we disregard creatinine levels if the patient has chronic kidney disease (CKD) with no baseline mentioned?**

If the physician/APN/PA documentation does not state the elevated creatinine to be due to the chronic condition, the elevated creatinine values should be used.

Question 97: **Slide 33. Only in the ED or entire medical record?**

Slide 33. Physician/APN/PA documentation of CKD with a baseline creatinine must be documented within the entire medical record.

Question 98: **Slide 38 and 39. If there is documentation in the history and physical (H&P) earlier in the stay that the patient has epilepsy and, later (a few days) in the stay, the patient has a seizure, and the physician documents elevated lactic acid due to seizure, can the elevated lactic acid be excluded?**

Unless the acute condition (seizure) is documented as due to the non-infectious source (epilepsy), the elevated lactate would be used. The measure specification guidance does not allow inferences to be made.

Question 99: **Does the physician documentation of “severe metabolic acidosis” allow for the exclusion of the lactic acid as a result for organ dysfunction?**

Since there is no specific reference to the lactate level, documentation of "severe metabolic acidosis" would not be sufficient to exclude the lactate level.

Question 100: **I do not see anything about repeat lactic acid. We recently had a patient that went emergently to the OR and the second lactic acid was outside of the six-hour range. Is there any exclusion in place to prevent missing the measure?**



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No, the measure does not provide an exception for not obtaining a repeat lactate level within the specified time frame.

Question 101: **If the physician documents acute kidney injury, patient with ESRD on dialysis, and the creatinine is elevated, should it be used or are no elevated creatinine levels allowed to be used if there is documentation of ESRD on dialysis?**

With the inclusion of the documentation “ESRD on dialysis,” all elevated creatinine values would be disregarded.

Question 102: **In the elevated lactic acid example does the physician need to state the result or just say it is elevated?**

The physician documentation including “elevated lactate” will suffice as this provides a reference to the abnormal sign of organ dysfunction.

Question 103: **Is lactic acid time drawn or time resulted to be used?**

For *Severe Sepsis Present*, criteria C, organ dysfunction, the reported/ resulted time of the lab should be used. For the *Initial Lactate Level Collection* data element, the time the lab is collected/drawn should be used.

Question 104: **This was not covered in a slide. A patient comes into the ED with LA >4 at 1500. However, severe sepsis presentation time isn't found later until 1800. Another LA level is collected at 1730 (which is the one we use since we have to use the one closest to severe sepsis presentation time). Then, do we use the second LA level to also determine our septic shock criteria, since we used that as our initial LA?**

For v5.3a, the lactate collection time that is closest to the *Severe Sepsis Presentation Time* should be used for the *Initial Lactate Level Collection* data element. In this scenario, the lactate collected at 1730 would be



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considered the initial lactate. If the *Initial Lactate Level Result* was elevated, a *Repeat Lactate Level Collection* would be required.

Question 105: **What about using queries to ask the physician if lactic acidosis was related to other conditions other than infection (e.g., acute kidney injury)? Can that be used to help with abstraction?**

If there is physician/APN/PA documentation prior to or within 24 hours of the *Severe Sepsis Presentation Time* indicating the elevated lactate was normal or due to a chronic condition or medication, the elevated lactate should be disregarded.

Septic Shock/Severe Sepsis

Question 106: **Septic shock is determined if the patient has persistent hypotension after the fluids were completed. Say the patient had severe sepsis at 1200. Initial hypotension happened at 1500 and fluids were started in the time frame but not finished until 1900. In the hour after fluids were complete, the patient still has hypotension. This would qualify them as being in shock. However, 1900 is greater than six hours after severe sepsis. So, the patient would have shock according to the criteria. It seems wrong to answer “no” to this based on a technicality. How would we answer this?**

For the purposes of the measure, if the *Septic Shock Presentation Time* is greater than six hours after the *Severe Sepsis Presentation Time*, value 2 (No) should be selected for *Septic Shock Present*. In this example, with the *Severe Sepsis Presentation Time* at 1200 and *Persistent Hypotension* identified at 1900, value 2 (No) would be selected for *Septic Shock Present*.

Question 107: **What if there is documentation that the patient had hypotension, elevated white blood count (WBC), elevated heart rate, and lactate of 2.1, but was diagnosed with gastrointestinal bleed and esophageal varices but was not diagnosed with severe sepsis, as there were no**



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infections. Later, while in the intensive care unit (ICU), the physician states shock. Are they excluded and do not meet the criteria if they have a history of urinary tract infection (UTI) on antibiotics prior to admission?

Further information is needed to accurately respond to this question.

If an infection is not documented within six hours of two SIRS criteria and a sign of organ dysfunction, *Severe Sepsis Present* would not be met by the clinical criteria. Also, the documentation of “shock” without a reference to “septic” would not be used as documentation of septic shock. The documentation of “history of UTI infection” would not be used to meet *Severe Sepsis Present* criteria A unless the infection was documented as currently present, suspected, or antibiotics were continued into the hospitalization, supporting the infection remains present or suspected.

Question 108: Do all three criteria have to be met within six hours of each other or six hours from each other? For example, WBC: 20.5 at 2000; respiratory rate: 22 at 1400; documentation of infection at 1000; and elevated lactate at 2000. When would the severe sepsis be present?

All three *Severe Sepsis Present* clinical criteria must be met within six hours of each other. Per the example in the question, the clinical criteria are not within six hours of each other. These criteria alone would not meet *Severe Sepsis Present*.

Question 109: The patient has a lactate level of >4 and the provider relates it to diabetic ketoacidosis (DKA) due to diabetes type 1. Should this value be used in determining *Severe Sepsis Present* and/or septic shock present?

With the physician/APN/PA documentation considering the elevated lactate level to be due to DKA and further documentation that DKA is due to a chronic condition, the elevated lactate level would not be used as evidence of organ dysfunction for *Severe Sepsis Present*.



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Question 110: If a provider documents severe sepsis, should that date and time supersede the calculated severe sepsis date and time if they are different?

The earliest *Severe Sepsis Presentation Time* should be abstracted. Therefore, if the physician documentation of severe sepsis occurred prior to the clinical criteria being met, the date and time of the physician's documentation of severe sepsis should be abstracted.

Question 111: Do we stop abstracting when it is documented by a doctor that the patient does not have severe sepsis?

If severe sepsis has not presented prior to the physician documentation of "patient does not have severe sepsis," this physician documentation would be disregarded, and abstraction of severe sepsis would continue. If the physician documented "patient does not have severe sepsis" within six hours after severe sepsis has presented, then value 2 (No) would be selected for *Severe Sepsis Present*.

Question 112: Documentation states severe sepsis was present on admission. The admission/discharge/transfer (ADT) event log shows patient departed ED on 1/2/2018 at 1000 and was admitted to the ICU on 1/2/2018 at 1000. The ICU flowsheet reads arrival of patient to ICU on 1/2/2018 at 1015. What time would you use as admission time?

The earliest hospital observation/inpatient admission time should be abstracted for the *Severe Sepsis Presentation Time*. Therefore, the earliest time that reflects the arrival to the inpatient floor or unit would be abstracted, which would be 1000.

Question 113: Slide 32. Is continuous veno-venous hemodialysis (CVVHD) an acceptable form of hemodialysis?

Yes, as long as hemodialysis or peritoneal dialysis is documented with ESRD, it is acceptable.



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Question 114: On slide 35, Lovenox is not listed on Table 5.3. Is Lovenox considered a heparin?

Only the anticoagulants provided on Table 5.3 are being considered at this time.

Question 115: Slide 35. Does documentation of any anti-coagulant given exclude the coagulant? For example, what about a heparin line flush?

Only documentation that the patient was given one of the anti-coagulants on Table 5.3 would exclude an elevated international normalized ratio (INR) or activated partial thromboplastin time (aPTT) value from being used as evidence of organ dysfunction. A heparin flush would not be acceptable, only therapeutic doses of anti-coagulants can be used to exclude INR or aPTT value.

Question 116: Slide 35 and 36. The anticoagulant is noted as a home medication. Does this apply to any time during the encounter or only when severe sepsis or septic shock criteria is present at admission?

If an anticoagulant from Table 5.3 is documented as a home medication, an elevated INR or aPTT value should be disregarded regardless of when severe sepsis presented.

Question 117: Slide 38. If SIRS or organ dysfunction values are due to a condition that is not an infection, or is due to a medication, and it is documented, does the value have to also be included within the same note? Are qualifiers such as elevated or low SIRS/organ dysfunction values acceptable?

Yes, the abnormal value or reference to the value must also be included in the same physician/APN/PA documentation as the chronic condition or medication. Documentation of a term defining an abnormal SIRS criterion or sign of organ dysfunction is acceptable.



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Question 118: **Slide 38. When referencing acute respiratory failure, what about vapotherm? We have had physicians document “acute respiratory failure” when the patient was placed on a vapotherm set up.**

The organ dysfunction criterion acute respiratory failure as evidenced by a new need for invasive or non-invasive mechanical ventilation no longer requires documentation of “acute respiratory failure” as part of this criterion. Documentation the patient is on mechanical ventilation includes invasive mechanical ventilation which requires an endotracheal or tracheostomy tube or non-invasive mechanical ventilation.

Question 119: **Slide 38. Does there have to be physician documentation of acute respiratory failure along with documentation of a new need for invasive or non-invasive mechanical ventilation to determine organ dysfunction?**

The organ dysfunction criterion acute respiratory failure as evidenced by a new need for invasive or non-invasive mechanical ventilation no longer requires documentation of “acute respiratory failure” as part of this criterion.

Question 120: **Slide 39 and 40. What if there is conflicting physician documentation, where one says the condition is due to a non-infectious source, but another physician says it is severe sepsis or septic shock? In this scenario, does the clock start then?**

If there is physician/APN/PA documentation prior to or within 24 hours of *Severe Sepsis Presentation Time* indicating SIRS criteria or a sign of organ dysfunction is due to or possibly due to an infection, severe sepsis or septic shock, the value should be used. Without further information for this scenario, including the times other severe sepsis clinical criteria were met, it is difficult to determine when the “clock starts” or the *Severe Sepsis Presentation Time*.



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Question 121: **Slide 40. What if the dehydration is caused by fever from sepsis, but it is not mentioned in that sentence, but it can be suspected from other documentation?**

If additional documentation shows the source of the dehydration is the fever from sepsis, that would, essentially, mean that the source is infectious after all. This sign of organ dysfunction would be used to meet severe sepsis criteria.

Question 122: **Slide 40. If one provider says, “Creatinine 2.4 due to acute kidney injury related to dehydration” and another provider says, “Severe sepsis with tachycardia, tachypnea, elevated creatinine with acute kidney injury” and this results in different documentation, should we accept creatinine for organ dysfunction or not?**

If there is physician/APN/PA documentation prior to or within 24 hours of *Severe Sepsis Presentation Time* indicating SIRS criteria or a sign of organ dysfunction is due to or possibly due to an infection or severe sepsis or septic shock, the value would be used.

Question 123: **The differential diagnosis is a listing of all potential causes of the patient symptoms. Differential diagnosis is listed as a positive qualifier, but doesn’t this contradict the third bullet point on slide 41?**

The third bullet point on slide 41 provides direction for determining if a documented condition has an infectious source. If a condition is listed on the differential diagnosis list and is not included in the “Inclusion Guidelines for Abstraction,” the three bullet points on slide 41 should be followed to determine if the source of an acute condition is a non-infectious source.

Question 124: **Slide 41. What is the stance on pancreatitis?**

The third bullet point on slide 41 provides direction for determining if a documented condition is infectious. If a condition is listed on the



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differential diagnosis list that is not included in the “Inclusion Guidelines for Abstraction,” the three bullet points on slide 41 would be followed to determine if the condition source of an acute condition is a non-infectious source.

Question 125: **Slide 41. Is there a time frame on the last bullet point or can it be documented any time during their admission?**

No, the bullet point does not provide a time frame in which supporting documentation must be found in the medical record.

Question 126: **Slide 42. The APN documentation on this slide could be considered due to an infection (i.e., Clostridium difficile [C. diff]). I don’t understand why that is allowed, but elevated lactate due to seizure is not.**

The documentation on slide 42 provides supportive documentation that the condition is an infection. The seizure example does not.

Question 127: **On slide 43, it was noted that if a physician documents severe sepsis due to influenza, that we should answer with value 2 or No to severe sepsis. However, it was also noted that, if we could meet criteria, we would use that that time, otherwise selecting value 1 or Yes to severe sepsis. On slide 44, it has patient meeting criteria in the example at 0800. Then, it shows physician documentation of severe sepsis due to influenza at 0845 and tells us to select value 2 or No. Which is the correct answer?**

If the only physician/APN/PA documentation of severe sepsis considers severe sepsis to be due to a viral, fungal, or parasitic infection, this documentation of severe sepsis is not considered and abstraction continues.

If severe sepsis is documented or met by clinical criteria and then, within six hours after the *Severe Sepsis Presentation Time*, there is physician documentation indicating severe sepsis is not present or severe sepsis



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is due to a viral, fungal, or parasitic infection, then value 2 (No) should be selected.

Question 128: **Slide 43. If the physician documents severe sepsis related to influenza but is also documenting a UTI and meets clinical criteria, is this considered severe sepsis related to viral infection or do we still abstract as if there is a bacterial infection documented?**

If the clinical criteria for severe sepsis is met and, within six hours after the *Severe Sepsis Presentation Time*, there is physician/APN/PA documentation severe sepsis is due to influenza, then value 2 (No) would be selected for *Severe Sepsis Present*.

If severe sepsis is documented as being due to a viral infection and then the severe sepsis clinical criteria are met at a later time, the later time when severe sepsis clinical criteria were met would allow value 1 (Yes) to be selected for *Severe Sepsis Present*.

Question 129: **Slide 43. Did I hear that if severe sepsis is met by physician documentation only, and there is documentation of “severe sepsis due to influenza,” I would disregard the documentation of severe sepsis and continue to the review record to see if it meets severe sepsis? This is compared to slide 44 which states severe sepsis clinical criteria met and then within six hours physician documents severe sepsis due to influenza to select No to severe sepsis present. Then, am I done?**

If the only physician/APN/PA documentation of severe sepsis considers severe sepsis to be due to a viral, fungal, or parasitic infection, this documentation of severe sepsis is not considered, and abstraction continues.

If severe sepsis is documented or met by clinical criteria and then, within six hours after the *Severe Sepsis Presentation Time*, there is physician documentation indicating severe sepsis is not present or severe sepsis is due to a viral, fungal, or parasitic infection, then value 2 (No) would be selected.



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- Question 130:** Slide 43. Severe sepsis is noted as “possible due to viral or pneumonia source.” Do we include this as the documentation of severe sepsis or infection?
- With the consideration that severe sepsis is possibly due to an infection, value 1 (Yes) would be selected for *Severe Sepsis Present*.
- Question 131:** Slide 44. For the examples, why would the case be excluded? Wouldn't we need to continue to look for the next time when criteria were met?
- Since the measure only evaluates the first and earliest presentation of severe sepsis, if the earliest presentation of severe sepsis is negated or considered to be due to a viral, fungal, or parasitic infection, value 2 (No) would be selected.
- Question 132:** Slide 44. “Severe sepsis is not present.” How do we extract antibiotic compliance related to viral illnesses that do not require antibiotics?
- If value 2 (No) is selected for *Severe Sepsis Present*, the case is excluded, and abstraction does not continue to the *Broad Spectrum or Other Antibiotic Administration* data elements.
- Question 133:** Slide 44. The specifications instruct us to choose value 1 for *Severe Sepsis Present* if criteria for severe sepsis are not documented and there is not documentation of severe sepsis, but there is physician documentation of septic shock. However, there is an issue with the following bullet: “If there is documentation of clinical criteria being met or physician/APN/PA documentation of Severe Sepsis and within 6 hours after there is additional physician/APN/PA documentation indicating the patient is not septic, does not have Sepsis, Severe Sepsis, or Severe Sepsis is due to a viral, fungal, or parasitic infection, choose value 2.” There is no mention of septic shock within this bullet. So, if we use documentation of septic shock as *Severe Sepsis Present*,



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then six hours later a physician documents septic shock is not present, there is no mention of septic shock in this bullet to select value 2.

In this scenario, the documentation within six hours of the *Severe Sepsis Presentation Time* indicating septic shock is not present indicates the patient is not septic. Therefore, value 2 (No) is selected for *Severe Sepsis Present*.

Question 134: Slide 44. Is it ok to only say “sepsis not present?” Do they not have to specifically say “severe” sepsis?

For the bullet point on slide 44, documentation indicating the patient does not have sepsis within six hours of the *Severe Sepsis Presentation Time* is sufficient to allow value 2 (No) to be selected. The word “severe” does not need to be used.

Question 135: Slide 44. If severe sepsis is met with the criteria of infection, SIRS, and organ dysfunction, but one of the SIRS criteria was an elevated heart rate and documentation states atrial fibrillation with rapid ventricular rate, would we exclude the heart rate and select “No” for severe sepsis presentation?

If the SIRS criterion is documented as normal for the patient, due to a chronic condition, or due to a medication, this criterion may be excluded.

Question 136: Slide 46. If severe sepsis/septic shock are documented present on admission in the ED, can we use the time seen from the ED note? For example: ED note: Time seen 1900, *Severe Sepsis Present* on admission. Later on, the patient was admitted to ICU at 2300. Shouldn't we use the “time seen” at 1900 since severe sepsis is mentioned in the ED?

If severe sepsis is present on admission to the ED, documentation would have to explicitly reflect that. Per the manual, documenting “present on admission” implies severe sepsis was present on admission when the



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patient changes to inpatient status. If severe sepsis is documented as present on admission, the earliest hospital observation/inpatient admission time would be used. In this case, 2300 would be abstracted since “severe sepsis is documented as present on admission.” For documentation of “severe sepsis present on arrival,” the earliest arrival time to the hospital would be abstracted.

Question 137: **Slide 46. If a patient has an admission order but there are no beds for admission and the patient is considered a “boarder” in the emergency department, what would be the appropriate present on admission time if the patient does not arrive to the admission unit for 16 hours?**

Per slide 46, the time the patient is admitted to the hospital observation/inpatient unit would continue to be abstracted if severe sepsis was documented as present on admission.

Question 138: **Slide 47. Regarding admission time, if we only have the admission order in the electronic medical record (EMR) and not the time they arrived to the unit, could we use the admission order time?**

Since the guidance directs use of the earliest hospital observation/inpatient admission time, using the time of the admit order would not suffice unless this documentation reflected earliest hospital observation/inpatient admission time.

Question 139: **Regarding present on admission, if the ED physician documents “sepsis on admission” within the ED note, wouldn’t that mean the patient had sepsis when they initially presented to the ED and not to the floor?**

If severe sepsis is present on admission to the ED, documentation would have to explicitly reflect that. Per the manual, documenting “present on admission” implies severe sepsis was present on admission when the patient changes to inpatient status. If severe sepsis is documented as



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“present on admission,” the earliest hospital observation/inpatient admission time should be used.

Question 140: **Is it acceptable for the physician to collaborate with the nurse regarding the three- and six-hour reassessments for a stable patient or should it still be face-to-face assessments to be able to document?**

It depends on the physician/APN/PA documentation of the required elements. Without further information, it is not possible to determine whether documentation will suffice some or all the requirements.

Question 141: **Why isn't Enoxaparin on the list for anti-coagulants?**

Currently, only the anti-coagulants provided on Table 5.3 were selected as they have the greatest impact on signs of organ dysfunction. We thank you for the question and will consider possibly updating the list of anticoagulants in Table 5.3 in the future.

Question 142: **We frequently have differential diagnoses listed as high probability, moderate probability, and low probability. Would the diagnoses listed under “low probability” be considered to fall under the negative qualifier of “unlikely?”**

The data element does not distinguish between “levels of probability.” Therefore, documentation of an infection or severe sepsis on the differential diagnosis list would be used.

Question 143: **Why is it that patients transferred from urgent care with severe sepsis or septic shock are not considered an exclusion?**

Acceptable facilities in which value 1 (Yes) may be selected for the *Transfer from Another Hospital or ASC* data element include facilities that should have the ability to treat the severe sepsis/septic shock patient per the measure. Urgent care is not currently an acceptable facility.



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Vasopressors

Question 144: Should the vasopressor time frame be similar to fluid resuscitation for initial hypotension, that it is based on when the persistent hypotension is instead of when septic shock time starts? This is in the cases where physician calls for septic shock and persistent hypotension results much later.

Administration of a vasopressor for the septic shock patient is based on the *Septic Shock Presentation Time* because, per the treatment recommendations, a vasopressor should be administered within six hours after septic shock presentation.

Question 145: Is there still a six-hour time frame to start vasopressors after presentation of septic shock?

Yes, the vasopressor time frame starts at the *Septic Shock Presentation Time* and ends six hours after the *Septic Shock Presentation Time*.

Vital Signs/Assessment

Question 146: Why are we still abstracting pre-hospital arrival vital signs? As triage time is not severe sepsis time and the provider has not seen the patient yet, it would make sense not to use pre-arrival vital signs.

Pre-arrival documentation may be used if the criteria are met within the specified time frame. For example, if the patient has vital signs meeting criteria documented by EMS and within six hours has an infection documented and further organ dysfunction criteria, severe sepsis would be present. The goal is to include pre-arrival vital signs as appropriate and not discount them solely because they are prior to arrival.



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Question 147: If we are to abstract pre-arrival vitals in the EMS, we should be able to abstract EMS fluids without all the hospital-given requirements. It seems unreasonable to ask EMS to give us a start time and end time of fluid given when the patient is normally in the ambulance under an hour. What if we were able to use the start time and end time of the ride itself, as EMS is trained to document those times, not the actual start and end time of fluid?

Thank you for the input. This will be brought to the attention of the measure stewards for further discussion.

Question 148: Are vital signs (VS) taken in the PACU included in the “OR documentation” or is this limited to those done in the actual OR?

Vitals documented in the operating room (OR) should not be used. This does **not** include vital signs documented in other units such as the PACU. Vital signs obtained in units other than the OR should be used.

Question 149: Does a vital sign sheet need to have mean arterial pressure (MAP) labeled in order to take a number as a MAP value? Our form has BP heading and number showing BP with number in parenthesis following which indicates a MAP, but not labeled as such. Do I use it?

In order to use the value as a MAP, it needs to be identified as such. When the medical record is abstracted at face value, if the value listed is not identified, it is difficult to determine if the value is the MAP or another value.

Question 150: Any update on focused exam for version 5.3a of the specifications?

Language has been revised within each data element of the repeat volume status and tissue perfusion assessment. Please see the individual data elements for specific updates.



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Question 151: **Slide 45. Are vital signs in the cath lab utilized for severe sepsis presentation?**

Yes, vital signs documented in the cath lab are used.

Question 152: **Slide 45 states do not use VS from OR for severe sepsis. Slide 53 speaks to using persistent hypotension documented in the OR. Is this contradictory?**

The *Severe Sepsis Present* data element provides guidance for not using vital signs documented in the operating room. The *Persistent Hypotension* data element provides guidance for not using hypotensive readings documented in the operating room. For *Persistent Hypotension*, as slide 53 states, when the patient is in the OR during the hour to assess for *Persistent Hypotension*, value 2 should be selected because the values are not used to establish *Persistent Hypotension*. This is not contradictory because the hypotensive values are not used; it's instructive as to the value that should be selected for *Persistent Hypotension*.

Question 153: **Can we use the calculated venous oxygen saturation (SO₂) for mixed venous oxygen saturation (SvO₂)?**

As long as the documentation reflects the oxygen saturation was obtained via a central catheter, this documentation is acceptable.

Question 154: **For the reperfusion note, does the licensed individual practitioner have to perform the parameters as opposed to just reviewing them?**

The repeat volume status and tissue perfusion assessment data elements provide multiple ways in which physician/APN/PA documentation may be acceptable. The physician/APN/PA may document their performance of a physical exam, reperfusion exam, etc. The physician/APN/PA may also document their performance OR review of an individual repeat volume status or tissue perfusion assessment data



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element. The data elements provide examples for each of these methods of acceptable documentation.

Question 155: **For documentation of atrial fibrillation (AF), does there need to be documentation of AF with rapid ventricular response (RVR) or AF with tachycardia to exclude the heart rate, or is documentation of atrial fibrillation alone enough to exclude the heart rate as SIRS criteria?**

In order to disregard/not use the elevated heart rate(s), AF with tachycardia or RVR must be documented. The documentation of “AF” alone describes the irregularity of the heart beat but does not confirm a rapid heart rate in and of itself.

Question 156: **For the reperfusion note, if the licensed individual practitioner documents that the sepsis focused exam is completed, do the values need to be found throughout the charting to substantiate that statement?**

No, the physician/APN/PA documentation “sepsis focused exam completed” within the specified time frame is acceptable documentation to select value 1 (Yes).

Question 157: **How often should the patient be reassessed on acute care?**

The measure does not provide guidance related to how often a severe sepsis or septic shock patient should be reassessed. The repeat volume status and tissue perfusion assessment provide a specific time frame for which the patient should be reassessed after crystalloid fluid administration. However, this reassessment is specific to reassessment after fluid administration and not meant to provide guidance as to how often the patient should be reassessed in general. Please refer to your facility’s policies and procedures for assessment frequency requirements within acute care units.



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Question 158: **Is the sepsis reassessment gone from the core measure?**

No, the repeat volume status and tissue perfusion assessment data elements remain in the measure.

Question 159: **With the updates, can a qualified RN perform the focused re-assessment after the fluid bolus?**

Each data element of the repeat volume status and tissue perfusion assessment provides guidance regarding who may document the element. Data elements that require physician/APN/PA documentation also provide guidance indicating physician/APN/PA documentation of their review of nursing documentation of an element is acceptable. Therefore, a nurse may perform an exam, but physician/APN/PA documentation of their review of the exam is still required for these specific data elements.

Question 160: **Would physician documentation of “bedside reassessment completed” be accepted as documentation of a completed sepsis focus exam?**

Yes, this documentation is acceptable for physician/APN/PA documentation attesting to their performance of an exam.

Ideal Body Weight (IBW)/Body Mass Index (BMI)

Question 161: **Can the IBW be part of the order for the fluids? Example: 2,000 mL NS based upon IBW due to BMI >30. Is that acceptable?**

Yes, the IBW can be included in the order for fluids. Per the bullet point, physician/APN/PA documentation clearly indicating the IBW will be used to determine the target ordered volume is required. This physician/APN/PA documentation may be in the fluid order, or in further physician/APN/PA documentation.

Question 162: **Does the 10% lower apply to the IBW calculation also?**



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The 10% threshold would apply to the IBW calculation if the physician bases the target ordered volume from the IBW and then orders a volume that is within 10% of the target ordered volume. Physician documentation should reflect appropriate use of IBW in determining the target ordered volume.

Question 163: Can the IBW be taken from the nutrition assessment if the physician documents the IBW will be used for fluid administration but does not specify the IBW he/she used?

If the physician's documentation clearly indicates the IBW will be used to determine the target ordered volume, the IBW must be documented in the medical record. The guidance does not specify who must document the IBW value. As such, the IBW on the nutrition assessment can be used to determine the IBW value.

Question 164: Can you use IBW for any patient, or does the patient need to be obese?

In order to use the IBW to determine the target ordered volume, the following documentation is required:

- Physician/APN/PA documentation clearly indicating the IBW will be used to determine the target ordered volume of crystalloid fluids
- Physician/APN/PA documentation identifying the patient has obesity or BMI>30
- The IBW must be documented in the medical record

Question 165: On IBW fluid, the physician documents "BMI >30 will give 30 mL/kg per IBW." Is this sufficient to meet both the obesity component and IBW, if BMI and IBW are documented in the EMR?

The documentation "BMI >30 will give 30 mL/kg per IBW" will suffice the physician/APN/PA documentation requirements to use the IBW to determine the target ordered volume. The IBW value needs to be



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documented in the medical record in order to use the IBW to determine the target ordered volume.

Question 166: **Could “average” body weight be used for the IBW value?**

Yes, if there is physician/APN/PA documentation indicating that the patient has obesity and “average body weight” will be used to determine the target ordered volume, this weight may be used.

Question 167: **Was it stated that “adjusted body weight” reference can also be used if the circumstances and documentation exist for BMI >30, obesity, and the criteria for IBW?**

Yes, the “adjusted body weight” may be used in place of the IBW if the physician/APN/PA documentation meets all the requirements within the bullet point.

Question 168: **Does a BMI have to be documented by a provider or be in the medical record, or can obese be used to utilize IBW?**

The IBW value must be included in the medical record and may be documented by the physician/APN/PA, but it is not required to be documented exclusively by the physician/APN/PA.

Question 169: **Is it acceptable if a clinical pharmacist documents the following statement? “Per Dr. Smith, patient has BMI >30; therefore, IBW of 60 kg will be used for fluid resuscitation and 1800 mL of LR will infused.”**

No, per the bullet point, physician/APN/PA documentation identifying the patient has obesity or BMI >30 is required. Therefore, pharmacist documentation referencing a physician would not suffice for physician documentation.



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- Question 170:** **If the ED physician orders the target volume by IBW but does not document that, can the hospitalist document in the focus exam that IBW was used?**
- If there is physician/APN/PA documentation clearly indicating the IBW will be used to determine the target ordered volume of crystalloid fluids and physician/APN/PA documentation identifying the patient has obesity or BMI>30, the IBW may be used to determine the target ordered volume.
- Question 171:** **Does the IBW need to be documented before the fluids are started to be able to use it?**
- The data element does not provide guidance indicating when the IBW must be documented. Therefore, if there is physician/APN/PA documentation meeting the requirements of the bullet point and the IBW is documented in the medical record, the IBW may be used.
- Question 172:** **Regarding the obesity documentation, slide 19 reads either obesity documentation or BMI >30 can be used.**
- Yes, the physician/APN/PA may document that the patient has obesity or BMI >30.
- Question 173:** **Slide 19. To be clear, IBW used for the determination of fluid administration amount is considered appropriate treatment for severe sepsis?**
- The *Crystalloid Fluid Administration* data element makes an allowance for the physician/APN/PA to use the IBW to determine the target ordered volume for patients with obesity (BMI >30) if they prefer. Using the IBW to determine the target ordered volume is appropriate but not required. It is at the discretion of the physician/APN/PA.
- Question 174:** **Slide 19. Does the physician have to document “obesity” or can this be assumed from a documented BMI that is automatically calculated within the chart?**



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Physician/APN/PA documentation that the patient has obesity or BMI >30, as well as documentation that the ideal body weight is being used, is required. A BMI listed in the medical record that is not physician/APN/PA documentation is not sufficient.

Question 175: **Slide 21. Do they have to document both that the patient is obese AND that they are using IBW, or can they document one or the other?**

Physician/APN/PA documentation that the patient has obesity OR a BMI >30 AND documentation that the ideal body weight is being used are required.

Question 176: **Slide 21 and 22. For IBW, does the clinician have to document the actual BMI or, if the order states BMI >30, is that sufficient if the actual BMI is documented elsewhere in the EMR?**

The physician/APN/PA may document the patient is “obese,” has “BMI >30,” or document the actual BMI that is >30.

Question 177: **If the IBW is calculated in an order set, is that sufficient documentation for using IBW?**

The required documentation may be in an order set but must continue to meet the requirements of the bullet point to use the IBW. In order to use the IBW to determine the target ordered volume, the following documentation is required:

- Physician/APN/PA documentation clearly indicating the IBW will be used to determine the target ordered volume of crystalloid fluids
- Physician/APN/PA documentation identifying the patient has obesity or BMI>30
- The IBW must be documented in the medical record

Question 178: **If the patient has a documented BMI of 29 in the EHR, but the physician documents patient is obese and IBW was used for fluid volume, would this pass the measure since the BMI was not >30?**



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The physician/APN/PA documentation identifying the patient has obesity is sufficient to meet that specific requirement of the bullet point.

Question 179: In our EMR, there are two different values for IBW. One is termed “bariatric” and the other is termed “calculated.” Are one of these two values the appropriate IBW to be used for determining target ordered volume? If not, how do we account for two different IBWs listed for the patient if the provider merely documents the patient is obese? Do we administer IV NS 30 mL/kg, based on IBW?

The guidance within the data element only refers to using the IBW and does not delineate the terms “bariatric” versus “calculated.” Therefore, the medical record would need to clearly indicate which value is the IBW or which IBW value should be used to determine the target ordered volume.

Antibiotics

Question 180: Are there plans to provide further clarification when abstracting cases where oral vancomycin is the antibiotic choice without broad spectrum IV antibiotic in severe sepsis with *C. diff* as the known causative organism?

No, for the severe sepsis patient admitted to inpatient acute care, an IV antibiotic is the recommended treatment even though oral vancomycin can be used to suffice the *Broad Spectrum or Other Antibiotic Selection* data element.

Question 181: Slide 11. If an antibiotic is given prior to obtaining a blood culture, will it still fall out?

Unless the case meets the *Blood Culture Acceptable Delay* data element, the blood culture is required to be collected prior to the IV antibiotic administration.

Question 182: Slide 11. Can we enter antibiotics greater than 24 hours before severe sepsis presentation time? What if the only dose is given before



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the 24 hours, and no other dose is given due to the loss of the IV access, and the provider is unable to obtain the IV access within the three hours of severe sepsis, and patient had dose just prior to the 24-hour pre-time?

If an IV antibiotic was not administered within the 24 hours prior through three hours after the *Severe Sepsis Presentation Time*, value 2 (No) should be selected for the *Broad Spectrum or Other Antibiotic Administration* data element.

If the patient received an IV antibiotic in the 24 hours prior to the *Severe Sepsis Presentation Time* and also received the same IV antibiotic more than 24 hours before the *Severe Sepsis Presentation Time*, the earliest IV antibiotic time within the 72 hours prior to the *Severe Sepsis Presentation Time* would be abstracted.

If there is documentation indicating IV access could not be established and antibiotics administered via intramuscular (IM) or intraosseous (IO) started in the 24 hours prior to or three hours after the severe sepsis presentation, it is acceptable to select Value 1.

The measure does not provide an exception for not administering IV antibiotics within the time frame due to IV failure or inability to maintain IV access.

Question 183: **Slide 11. Does this mean, if the patient was on antibiotics prior to 24 hours before severe sepsis time, the case will be excluded?**

If the *Broad Spectrum or Other Antibiotic Administration Time* is greater than 24 hours before the *Severe Sepsis Presentation Time*, the case will be excluded.

Question 184: **Slide 11. There are times that the patient is getting antibiotics greater than 24 hours, but the last dose of the antibiotic does not fall into the window allowed. Example: 1/24 01:00 IV Zosyn; time zero for severe sepsis is 1/25 0600.**



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If an IV antibiotic was not administered within the 24 hours prior through three hours after the *Severe Sepsis Presentation Time*, value 2 (No) would be selected for the *Broad Spectrum or Other Antibiotic Administration* data element.

Question 185: **Slide 13. What about C. diff patients? Is it acceptable for oral vancomycin only or do you also need IV Flagyl?**

For the *Broad Spectrum or Other Administration* data element an IV antibiotic administered within 24 hours before through three hours after the *Severe Sepsis Presentation Time* is required.

For the *Broad Spectrum or Other Antibiotic Administration Selection* data element, if the causative organism is identified as C. diff, oral vancomycin administered within three hours after the *Severe Sepsis Presentation Time* is acceptable.

Question 186: **Slide 15. For antibiotic administration selection within three hours of severe sepsis, if the first antibiotic given is in the combo table with no other combo antibiotic from the table given within the three hours, but a mono-therapeutic is also given within the three hours, would antibiotic administration selection be consistent with antibiotic selection guidelines?**

If a monotherapy antibiotic was administered within three hours after the *Severe Sepsis Presentation Time*, value 1 (Yes) would be selected for the *Broad Spectrum or Other Antibiotic Administration Selection* data element.

Question 187: **Does this mean that IV antibiotics are not required to be given within three hours following presentation of severe sepsis/septic shock?**

If an IV antibiotic was not administered within the 24 hours prior through three hours after the *Severe Sepsis Presentation Time*, value 2 (No) would be selected for the *Broad Spectrum or Other Antibiotic Administration* data element.



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Question 188: At our hospital, physicians sometimes place orders like “vancomycin per pharmacy for pneumonia.” Then, the pharmacist will enter a different vancomycin order with dosage, route, and frequency, but the phrase “for pneumonia” is not on this actual order. Do we need to have “for pneumonia” on the vancomycin order entered by the pharmacist in order to use pneumonia as an infection when a dose of vancomycin is given?

Physician/APN/PA, nursing, or pharmacist documentation of pneumonia is acceptable for *Severe Sepsis Present* criteria A. With the physician documentation “vancomycin per pharmacy for pneumonia,” further documentation when the antibiotic is administered may be used for *Severe Sepsis Present* criteria A.

Question 189: Because blood culture bottles now contain substances that neutralize antibiotics, is it feasible that CMS will reconsider the recommendation that antibiotics are administered after blood culture collection?

There is potential for this to be a consideration in a future version of the manual. At this time, blood culture collection is expected to be prior to the IV antibiotic administration unless a *Blood Culture Acceptable Delay* applies.

Question 190: Can you please clarify the exceptions for *C. diff*? Does the patient need to have a dose of IV antibiotic within the antibiotic time frame in order to get to the antibiotic selection questions which permit an exception for oral vancomycin? There seems to be confusion on the ListServe.

For the *Broad Spectrum or Other Administration* data element, an IV antibiotic administered within 24 hours before through three hours after the *Severe Sepsis Presentation Time* is required. For the *Broad Spectrum or Other Antibiotic Administration Selection* data element, if the causative



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organism is identified as *C. diff*, oral vancomycin administered within three hours after the *Severe Sepsis Presentation Time* is acceptable.

Question 191: **Do we have a clearly defined example for the antibiotic exclusion? The latest example I can find is from an older webinar. Will this be in the alphabetical data dictionary?**

There is potential for further clarification in a future version of the manual. However, if the patient received an IV antibiotic in the 24 hours prior to the *Severe Sepsis Presentation Time* and received the IV antibiotic greater than 24 hours before the *Severe Sepsis Presentation Time*, the earliest IV antibiotic time within the 72 hours prior to the *Severe Sepsis Presentation Time* would be abstracted. Abstracting a *Broad Spectrum or Other Antibiotic Administration Time* greater than 24 hours before the *Severe Sepsis Presentation Time* would exclude the case.

Example:

IV Zosyn: 2/28/18 at 0600

IV Zosyn: 3/1/18 at 0600

IV Zosyn: 3/2/18 at 0600

IV Zosyn: 3/3/18 at 0600

- *Severe Sepsis Presentation Time*: 3/3/18 at 1200
- *Broad Spectrum or Other Antibiotic Administration Date and Time*: 3/1/18 at 0600

IV antibiotic dose on 2/28/18 at 0600 is greater than 72 hours before the *Severe Sepsis Presentation Time*. The case is excluded at the *Broad Spectrum Antibiotic Time* calculation in the algorithm.

Question 192: **Explain the look back of up to 72 hours for the antibiotics given prior to sepsis presentation.**

Please see response to question number 196.



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Question 193: In determining infection present, if a provider notes a condition that may or may not be an infection but orders antibiotics for empiric coverage, would this be considered a noted infection to meet criteria? For example, neutropenic fever has no obvious infection source; vancomycin and Zosyn started empirically.

With antibiotics started for the documented condition, this would be used for *Severe Sepsis Present* criteria A per the bullet point below:

- If an antibiotic is ordered for signs or symptoms of an infection, this may be considered documentation of an infection (e.g., ceftriaxone ordered for colitis, Zosyn 3.375 g IV q6hr for cough).

Question 194: What is the reason for not accepting oral antibiotics that have almost 100% bioavailability of IV antibiotic (i.e., levofloxacin)?

Treatment recommendations for the severe sepsis patient reflect the administration of IV antibiotics for the systemic condition. As further evidence becomes available, further considerations for other routes of antibiotic administration may be considered.

Other Abstraction Questions

Question 195: Is the cardiac cath lab considered a procedure area? Patients can be hypotensive there and not be septic.

No, the bullet point for exclusion areas only includes vital signs documented while the patient is in the operating room. This does not include the cath lab or other units that are not operating rooms.

Question 196: When are these changes effective?

The version 5.3a manual is effective for discharges starting January 1, 2018–June 30, 2018.

Question 197: Do we apply this update retrospectively to Quarter (Q) 4 2017 abstraction?



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No, do not apply retrospectively. Version 5.3a of the manual would only apply to patients discharged from January 1, 2018–June 30, 2018.

Question 198: **Is there an “additional notes for abstraction v5.3a” document with the additional information given today?**

No, there is not an additional note for abstraction for version 5.3a. At this time, we are not planning on releasing one.

Question 199: **There are several changes/clarifications with version 5.3a of the specifications manual. We are currently on validation. Do we need to go back and re-abstract these cases due to these clarifications, or is this going forward with the release of this 5.3a update?**

This webinar pertains to v5.3a, which includes all discharges January 1, 2018–June 30th, 2018. The decision to re-abstract medical records is at the discretion of the individual facility.

Question 200: **Slide 10. What is the signed consent for clinical trials?**

In order to suffice the *Clinical Trial* data element, the patient needs to provide a signed consent for the clinical trial and enroll in that same clinical trial during the same hospital stay. Also, the clinical trial must be for the same condition as the measure being studied.

Question 201: **Why is it necessary to enter the patient’s time of discharge when abstracting severe sepsis? Can this time be obtained from coding or does it have to be the exact documentation of when the patient left?**

The *Discharge Time* is abstracted to determine if the patient was discharged within six hours after severe sepsis or septic shock presented. The time the patient actually left should be used rather than a time obtained from coding.



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Question 202: We've already abstracted January and February severe sepsis cases. Does this mean we now need to re-abstract these cases with these new data element specifications?

This webinar pertains to v5.3a which includes all discharges January 1, 2018–June 30th, 2018. The decision to re-abstract medical records is at the discretion of the individual facility.

Question 203: Are all tick-borne diseases included in the parasitic infection category?

No. If a tick-borne infection is documented, the abstractor would follow the guidance under *Severe Sepsis Present* criteria A to determine if the condition is infectious or not.

Question 204: Are SEP-1 cases being validated? If so, how are the results? Are most facilities accurately abstracting SEP-1 per validation results?

Yes, SEP-1 is a validated measure. Validation results are not publicly available at this time.

Question 205: Are there any templates available for abstracting and submitting data for sepsis?

The specification manual does not provide templates for abstracting or submitting data.

Question 206: I had a patient that had a history of ESRD in 2015; they had a transplant in 2017. They came in with an initial creatinine of 2.11, which went back to 1.02 after hydration. Since they had a transplant, are they still considered to be ESRD?

The documentation of ESRD alone would not be relevant unless the physician/APN/PA documentation considered the elevated creatinine to be due to the chronic condition (ESRD). Also, in order to not use the creatinine as evidence of organ dysfunction, per the sub-bullet point regarding ESRD and documentation of dialysis, there would need to be



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documentation of ESRD and that the patient is on hemodialysis or peritoneal dialysis. If neither of these is documented, the elevated creatinine would be used as evidence of organ dysfunction.

Question 207: **If an ED note states that the physician had discussed palliative care, but there is not a consult order, are we able to exclude this case?**

Physician/APN/PA documentation of the inclusion term “palliative care” within the specified time frame is acceptable. An order for a consult is not required.

Question 208: **Is a long-term acute care hospital (LTACH) considered a transfer? They frequently are treated before transferred to an acute facility.**

Per the *Transfer from Another Hospital or ASC* data element:

- Select “Yes” in the following types of transfers:
 - Long term acute care (LTAC): Any LTAC hospital or unit (outside or inside your hospital)

Question 209: **Is bagging a patient (with an Ambu bag®) during a code considered to be an “artificial intervention,” and would respiratory rate documented while being “bagged” be excluded as SIRS criteria for the measure?**

Unless there is documentation that the respiratory rate is due to the Ambu bag® ventilation and the Ambu bag® ventilation is related to a non-infectious source (code), the respiratory rate would be used. The majority of the time, a set rate is not documented for what the respiratory rate should be when using the Ambu bag®. Therefore, the bullet point regarding artificial intervention, for most cases, does not apply to this scenario. The example provided in the *Severe Sepsis Present* data element demonstrates a documented ventilation rate and a documented respiratory rate for which can be determined to be caused by the artificial intervention. Documentation of the ventilation via Ambu bag® would need to be similar to this example to apply this bullet point.



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Question 210: **When will the updates for July 1, 2018, be available?**

Specification manual v5.4 for discharges July 1, 2018–December 30, 2018 was published on *QualityNet.org* December 29, 2017.

Question 211: **Will there be a webinar that addresses the most common validation mismatches and/or issues related to abstraction of the sepsis measure?**

Thank you for this suggestion. CMS does not currently have plans for a webinar addressing common validation mismatches or other issues related to SEP-1. However, webinar suggestions are welcomed and always considered for the future.

Question 212: **Would a transfer from a free-standing ED be considered a transfer from another acute care facility? These patients arrive having received antibiotics, fluids, etc.**

Per the *Transfer from Another Hospital or ASC* data element:

- If a patient is transferred in from any emergency department (ED) or observation unit OUTSIDE of the current hospital, select “Yes.” This applies even if the emergency department or observation unit is part of the current hospital’s system (e.g., the hospital’s free-standing or satellite emergency department), has a shared medical record or provider number, or is in close proximity.

Question 213: **Many of our elderly patients (or transient patients) wait until they are very ill to come to the ER (e.g., having extremely elevated LA). In the past, the guidelines allowed us to make reference to comfort measures and that would count. These patients may not have family available at that time or may not be able to answer for themselves. Also, many of these families are not ready to make a decision within three hours of severe sepsis or septic shock (six hours) because they are not ready (despite the fact that the physician is certain that they will likely die). These patients are counted in our mortality stats. Why was this part**



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of the measure removed (i.e., the physician referring to the likelihood of the patient needing comfort measures or palliation rather than a specific order for comfort care or palliative care)?

Physician/APN/PA documentation of the inclusion term “palliative care” within the specified time frame is acceptable. An order for a consult is not required.

Public Reporting/Value-Based Purchasing

Question 214: **How does CMS justify publicly reporting this measure starting with Q1 2017 results when so many impactful changes to the measure (e.g., focused reassessment requirements, ideal body weight for fluids) have been made since Q1 2017?**

As stated in the FY 2015 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) Final Rule, in which the SEP-1 measure was finalized for the Hospital IQR Program, Section 5001(a) of the Deficit Reduction Act (DRA) requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital can review its data before they are made public. In the FY 2014 IPPS/LTCH PPS Final Rule, for the FY 2014 Hospital IQR Program and subsequent years, CMS finalized continuing the policy of publicly reporting data as soon as it is feasible on CMS websites, such as the *Hospital Compare* website (<http://www.medicare.gov/hospitalcompare>), after a 30-day preview period (78 FR 50776 through 50778). As such, CMS is required to publicly report the measure. The changes to SEP-1 to date have all been sub-regulatory changes which have provided clarifications to both clinicians and abstractors but have not substantively changed the measure.



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Question 215: Why are sepsis measure results being reported publicly when the specifications keep changing so dramatically? There should be stability in the measure before public reporting.

CMS believes the sepsis measure is stable and the changes to date have not been substantive. The changes have improved the measure but have not changed the overall intent of the measure or the intent of the bundle-level elements.

Question 216: Are any new measures on outcomes being considered? Will public reporting include comparison of outcomes to pre-SEP-1 outcomes?

CMS is not aware of any new outcome measures. Stakeholders are encouraged to submit measures to CMS during the JIRA open period for submitting candidate measures at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html>. The first public reporting of SEP-1 will be the overall performance result for Q1 2017 through Q3 2017.

Question 217: Is the “bundle” result going to be publicly reported?

At this time, only the overall performance results will be publicly reported.

Question 218: Related to the first publicly reported SEP-1 measure on *Hospital Compare*, what is the national average for this first time frame, Q1 2017 to Q3 2017? Do they provide top decile also?

At this time, national averages are not available for public reporting.

Question 219: Since SEP-1 is now being publicly reported through *Hospital Compare*, does this mean that SEP-1 is now included in the IQR Hospital Value-Based Purchasing (VBP) Program?

SEP-1 is not currently included in the Hospital VBP Program.

1. Hospital VBP Program measures may only be selected from the Hospital IQR Program measure set.



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2. Data must be publicly displayed on *Hospital Compare* for at least one year prior to inclusion in a Hospital VBP Program performance period.
3. Implementation in the Hospital VBP Program would further require CMS to undergo notice and comment rulemaking, publicly proposing the measure for adoption for that specific program beginning with a specific program year and subsequent years.

Additionally, SEP-1 has not been implemented in any other CMS value-based purchasing program; it is only implemented in the Hospital IQR Program, a quality data reporting program in which measure performance is not tied to payment.

Question 220: **What prompted the release of SEP-1 to *Hospital Compare*?**

As stated in the FY 2015 IPPS/LTCH PPS Final Rule, in which the SEP-1 measure was finalized for the Hospital IQR Program, Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital can review its data before they are made public. In the FY 2014 IPPS/LTCH PPS Final Rule, for the FY 2014 Hospital IQR Program and subsequent years, CMS finalized continuing the policy of publicly reporting data as soon as it is feasible on CMS websites, such as the [Hospital Compare website](#), after a 30-day preview period (78 FR 50776 through 50778). As such, CMS is required to publicly report the measure.

Question 221: **Where can we find state and national overall performance rates for SEP-1 for comparison with our facility?**

Hospital Compare will display the average performance for their facility, the state, and the nation for comparison.

Question 222: **When were hospitals first notified that public reporting would begin with Q1 2017 data? Please provide a link to that communication.**



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Hospitals were notified during the February 27 SEP-1 webinar, *SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.3a Measure Updates*, at this link: www.qualityreportingcenter.com/event/sep-1-early-management-bundle-severe-sepsis-septic-shock-v5-3a-measure-updates/

Comments

Question 223: I would like to add to the discussion that adding the ability to include crystalloid fluids that are given with antibiotics has made abstraction of fluids more cumbersome because often the provider will order the correct 30 mL/kg and it may have to infuse over a couple of hours, thus an antibiotic is given during this time frame. So, I have to now add in the antibiotic fluids which makes calculation more complicated. Very frustrating and time consuming. Also, clinical staff will be looking to assess vitals in the hour after the 30 mL/kg has infused and likely will not be adding in the fluids for the antibiotics, as that is not the intent of the antibiotic fluids.

Thank you for your comments. The inclusion of fluids used for antibiotics is not intended to complicate measure abstraction. It is intended to raise awareness for clinicians that infusing several antibiotics can alter the overall total volume significantly. Clinical staff should continue to follow the measure abstraction guidance regarding timing of vital sign assessment.

Question 224: A new 5.3a specifications manual really needs to be published for accuracy.

Thank you for the comments. CMS makes every effort to keep the specifications manual as accurate as possible. Please follow-up using the online tool available at *QualityNet.org* if there are specific concerns regarding the manual so CMS can address the concerns directly.

Question 225: Slide 38, 39, and 40 place a large amount of burden on the abstractor. Pulling documentation from different places seems to be inferring a lot.



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Thank you for the comments and bringing the burden on the part of the abstractor to the attention of CMS. Regarding those specific slides, per the specifications, if there is physician/APN/PA documentation prior to or within 24 hours after *Severe Sepsis Presentation Time* indicating SIRS criteria or sign of organ dysfunction is due to an acute condition or acute on chronic condition, the criteria value should be used. If, however, there is further physician/APN/PA documentation prior to or within 24 hours after *Severe Sepsis Presentation Time* indicating the acute condition is due to a non-infectious source/process, it would not be used.

This guidance provides a limited time frame for which acceptable documentation may be found, as well as specific guidance to use the SIRS criteria or sign of organ dysfunction that are documented as due to an acute condition. The only time SIRS criteria or sign of organ dysfunction would not be used in this case is when there is further specific physician/APN/PA documentation demonstrating the acute condition is due to a non-infectious source. As the guidance requires specificity in the physician/APN/PA documentation that SIRS criteria or sign of organ dysfunction are due to an acute condition and physician/APN/PA documentation that an acute condition is due to a non-infectious source, inferences may not be made.

Question 226: **Many of our elderly patients (or transient patients) wait until they are very ill (e.g., having extremely elevated LA) to come to the ER. In the past, the guidelines allowed us to make reference to comfort measures and that would count. These patients may not have family available at that time or may not be able to answer for themselves. Also, many of these families are not ready to make a decision within three hours of severe sepsis or septic shock (six hours) because they are not ready (despite the fact that the physician is certain that they will likely die). These patients are counted in our mortality stats. Why was this part of the measure removed (i.e., the physician referring to the likelihood of the patient needing comfort measures**



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or palliation rather than a specific order for comfort care or palliative care)?

The measure does not require an order for hospice, comfort care, or palliative care to be placed to suffice the *Directive for Comfort Care* data elements. In manual version 5.3, the acceptable time frame for documentation of comfort care was increased from three hours to six hours after the *Severe Sepsis Presentation Time*. Therefore, if documentation sufficing the *Directive for Comfort Care* data element(s) is not documented prior to or within six hours of the *Severe Sepsis Presentation Time*, the severe sepsis bundle is required.

Question 227: Any thoughts of retiring SIRS criteria and moving toward sepsis-related organ failure assessment (SOFA) or quickSOFA (qSOFA)?

At this time, there are no plans to retire the use of SIRS criteria nor implement SOFA or qSOFA.

Question 228: Are there any plans to make SEP-1 an eMeasure?

At this time, there are no plans to make SEP-1 an eMeasure.

Question 229: I disagree with the comment of nursing home patients being transfers. We have nursing homes within our community which use IV fluids and IV antibiotics to treat infections and send patients to a hospital if there is a decline in their condition. Example: We have a ventilator extended care facility (ECF) within a city block and they treat their patients and send them to the hospital when the current IVF and antibiotics don't seem to be working.

Thank you for your comments. CMS will take this comment into consideration for future measure updates.

Question 230: IVF administration time of 30 mL/kg at 126 mL/hr would pass the crystalloid fluids if the patient received the intended total IV fluids even if the end time is after the six hours, but a patient receiving the



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same amount of IV fluids (as individual IV fluid orders) fails because the last bag is hung outside the six hour range but received the correct amount of fluids based on his weight. Please rethink this data element to determine if patient failed IV crystalloid fluids. The patient fails based on a technicality.

Thank you for your comments. The *Crystalloid Fluid Administration Time* is abstracted in part based on how fluids are ordered. With multiple orders, it cannot be determined that the complete target ordered volume was given until the last order completing the target ordered volume is started. Hence, the start time of the order completing the target ordered volume is abstracted.

Question 231: Why is *QualityNet* no longer answering questions submitted, and/or is there a known date when they are going to restart addressing questions? I still have questions pending from November 2017.

Questions submitted via the online tool are typically responded to within seven days. If a response has not been received within this time frame, it is likely the questions were not submitted to the correct location. Please resubmit the question to the Inpatient Quality Reporting (IQR) option.

Question 232: My physicians have asked if there will ever be any exclusion added due to a contraindication listed by them. They have documented specific reasons as to why they did not administer the 30 mL/kg but continue to fail the measure. They feel that this is not allowing for them to use their clinical judgment on an individual basis to treat their patients.

At this time, there are no plans to add additional exceptions for not administering crystalloid fluids for patients that qualify for fluids.

Question 233: Please rethink the IV fluid times. Example: A patient with congestive heart failure (CHF) is given a total of fluids that was equal to 30 mL/kg but fails because the physician did not order it as one order at



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30 mL/kg but as separate fluid boluses or individual fluid orders. If the physician orders the 30 mL/kg at 126 mL/hr and it takes several hours to infuse but that patient meets because of the ruling on what time to accept as fluid administration time, and, if they received the correct fluids, they fail because the order did not say 30 mL/kg. If the physician would have ordered the IVF at 126 mL/hr and the patient received the fluids over the same time frame, then the doctor felt it was in patient's best interest.

Thank you for your comments. The *Crystalloid Fluid Administration Time* is abstracted in part based on how fluids are ordered. With multiple orders, it cannot be determined that the complete target ordered volume was to be given until the last order completing the target ordered volume is started. Hence, the start time of the order completing the target ordered volume is abstracted.

Question 234:

A few comments and questions regarding measure burden were submitted:

- 1. “So many physicians do not agree with the Surviving Sepsis Campaign. Is any consideration given to this? There is also such great difficulty getting the doctors to document the specifics required in the measure and the abstractors have a very hard time making sure we’re not trying to fit a round peg in a square hole when trying to match the physician documentation to the requirements. This measure is so very difficult from both ends.”**
- 2. “There are abstractors all over the country who have been unable to impress upon their higher-ups how crazy this measure really is because it’s impossible to describe unless you have to do it. CMS should stop the madness. This is too complicated.”**
- 3. “This measure is impossible. I can’t believe hospitals and hospital associations aren’t all screaming bloody murder.”**



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Thank you for your comments. This measure is important for the early detection and management of sepsis. Based on evidence-based guidelines, this measure was re-endorsed by the National Quality Forum (NQF) in July 2017 following a rigorous scientific review. However, CMS does understand concerns with abstraction and continues to work toward reducing abstraction burden and measure simplification with each measure update. CMS routinely incorporates feedback from clinicians and abstractors into each new version of the specifications manual and plans to continue evaluating feedback for further ways to improve upon the measure.