

### **Support Contractor**

### SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.6 Measure Updates and FAQs

### **Questions and Answers**

Speaker(s)

Noel Albritton, MSN, RN Lead Solutions Specialist Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance Support Contractor (SC)

### Jennifer Witt, RN

Senior Health Informatics Solutions Coordinator Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance SC

### Moderator

Candace Jackson, ADN Project Lead, Hospital IQR Program Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education SC

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Subject-matter experts researched and answered the following questions after the live webinar. The questions and answers may have been edited for grammar.

Administrative Contraindication to Care, Severe Sepsis, and Septic Shock

# Question 1: Slide 10 and 11. To clarify, would a nurse's documentation be allowable if within the appropriate timeframe or is physician documentation required?

Nurse documentation only within the appropriate timeframe is allowable. If there is physician/advanced practice nurse (APN)/physician assistant (PA) **or** nursing documentation that the patient or authorized patient advocate has refused either blood draw, intravenous (IV) fluid administration, or IV antibiotic administration, select Value "1" (Yes) for the *Administrative Contraindication to Care, Severe Sepsis* and *Administrative Contraindication to Care, Septic Shock* data elements.

# Question 2: Slide 11. If there is any documentation of uncooperative behavior that might indicate staff is unable to do labs or IV fluids in the timeframe, can we say "Yes" to *Administrative Contraindications to Care*?

Yes, if there is physician/APN/PA **or** nursing documentation indicating the patient's non-compliance with care resulted in not being able to collect blood draws, administer IV antibiotics, or administer IV fluids, select Value "1" (Yes) for the *Administrative Contraindication to Care*, *Severe Sepsis* and *Administrative Contraindication to Care*, Septic Shock data elements.

# Question 3: Slide 11. Is this documentation allowable? "Patient is refusing to allow staff to take her vital signs."

No, documentation of the patient's refusal to allow staff to take vital signs is not sufficient for selecting Value "1" (Yes) for the *Administrative Contraindication to Care, Severe Sepsis* or the *Administrative Contraindication to Care, Septic Shock* data elements. The refusal of vital signs alone does not reflect the inability to collect blood draws, administer IV antibiotics, or administer IV fluids. If a physician/APN/PA or nurse documents that a patient is refusing blood draws, IV antibiotics, or IV fluids, select Value "1" (Yes).

Question 4:	Slide 11. The documentation that a patient was uncooperative and screaming and security was called does not seem like it should be "Yes" to <i>Administrative Contraindication to Care</i> , as it does not seem to exactly specify that a patient is refusing care. Before the question, it was stated the documentation must be clear that the patient is not complying to care, and that includes blood draws, fluid administration, or antibiotics. Can you explain why that statement is acceptable?
	Nurses would likely not be able to draw blood or start an IV for fluids or antibiotics if security has been called and the patient is uncooperative and yelling at nurses. The updated guidance for Specifications Manual version (v)5.6 takes this into account by allowing selection of Value "1" (Yes) if there is physician/APN/PA or nursing documentation of patient non- compliance with care that would result in not being able to collect blood draws, administer IV antibiotics, or administer IV fluids within the specified timeframe.
Question 5:	Is a Registered Nurse's documentation of refusal or noncompliance acceptable?
	Yes, a registered nurse's documentation is acceptable. If there is physician/APN/PA <b>or</b> nursing documentation that the patient or authorized patient advocate has refused either blood draw, IV fluid administration, or IV antibiotic administration, select Value "1" (Yes) for the <i>Administrative Contraindication to Care, Severe Sepsis</i> and <i>Administrative Contraindication to Care, Septic Shock</i> data elements.
Question 6:	If a patients' family refuses a central line, but a vasopressor was administered peripherally for a short time, is the case excluded?
	Yes, if a physician/APN/PA or nurse documents that the patient or authorized patient advocate refused a central line, select Value "1" (Yes) for the <i>Administrative Contraindication to Care, Septic Shock</i> data element, regardless of whether vasopressors were administered peripherally. This will result in the case being excluded from the measure.
Question 7:	If the patient refuses a blood culture, is that enough to count as "Yes" for Administrative Contraindication to Care?

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Yes, if there is physician/APN/PA or nursing documentation that the patient refused a blood culture within the specified timeframe, select Value "1" (Yes) for the *Administrative Contraindication to Care, Severe Sepsis* data element.

#### Broad Spectrum or Other Antibiotic Administration Selection

Question 8:Slide 13. For *Clostridium difficile* (C. diff) we are to select "Yes" if oral<br/>(PO) vancomycin is given. However, the prior question asked if the<br/>patient received IV antibiotics. Do I answer "No" and never make it to<br/>the selection question? Isn't PO vancomycin appropriate for C. diff?

The exception for C. diff, which allows PO vancomycin, applies only to the *Broad Spectrum or Other Antibiotic Administration Selection* data element. The *Broad Spectrum or Other Antibiotic Administration* data element, which must be answered first, requires all Severe Sepsis patients receive an IV antibiotic within the specified timeframe. If the patient did not receive an IV antibiotic, Value "2" (No) would be selected for the *Broad Spectrum or Other Antibiotic Administration* data element, the case would not meet the measure requirements, and it would not reach the *Broad Spectrum or Other Antibiotic Administration Selection* data element.

### Question 9: To clarify, is PO vancomycin acceptable only if the infectious source is C. diff? If our patient comes in with a wound infection and suspected C. diff, would we still need IV antibiotics because the wound infection could be the cause of the sepsis?

Yes, PO vancomycin is only acceptable for the *Broad Spectrum or Other Antibiotic Administration Selection* data element if the infectious source is C. diff. The *Broad Spectrum or Other Antibiotic Administration* data element, which comes earlier in the algorithm flow, requires all patients receive an IV antibiotic. The case will not meet measure requirements if the patient did not receive an IV antibiotic, and abstraction will not continue. The rationale for requiring an IV antibiotic is that, in most cases, the causative organism for Severe Sepsis is unclear and starting with broadspectrum IV antibiotics provides the greatest coverage against the most likely organisms. In the example provided, it is unclear whether the C. diff or wound infection is the cause.

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### **Question 10:** If C. diff is documented prior to Severe Sepsis Present, why doesn't PO vancomycin meet the requirement for antibiotic administration since it meets the requirement for antibiotic selection? The exception for C. diff, which allows PO vancomycin, applies only to the Broad Spectrum or Other Antibiotic Administration Selection data element. The Broad Spectrum or Other Antibiotic Administration data element, which must be answered first, requires all Severe Sepsis patients receive an IV antibiotic within the specified timeframe. If the patient did not receive an IV antibiotic, select Value "2" (No) for the Broad Spectrum or Other Antibiotic Administration data element. The case would then fail the measure, and it would not reach the Broad Spectrum or Other Antibiotic Administration Selection data element. **Question 11:** Why is IV vancomycin not acceptable for C. diff? If the physician suspects C. diff and orders Flagyl, is this acceptable? Are both vancomycin and Flagyl required or just one or the other? The Broad Spectrum or Other Antibiotic Administration Selection data element addresses this specific patient population based on guideline recommended treatment for C. diff. Intravenous vancomycin is not included as recommended antibiotic therapy for moderate to severe C. diff. Therefore, the Broad Spectrum or Other Antibiotic Administration Selection data element includes PO vancomycin, rectal vancomycin, and IV metronidazole (Flagyl). If physician/APN/PA documentation identifies the presence of C. diff and IV Flagyl was administered within three hours after the Severe Sepsis Presentation Time, select Value "1" (Yes) for the Broad Spectrum or Other Antibiotic Administration Selection data element. Administration of PO vancomycin or rectal vancomycin within three hours after the Severe Sepsis Presentation Time would also be acceptable for this data element. **Question 12:** If a patient with C. diff did not have an IV antibiotic prior to the PO vancomycin, it will still fail the measure as the IV antibiotic is first in the algorithm. Will this be changed in further updates? The Broad Spectrum or Other Antibiotic Administration data element requires all Severe Sepsis patients receive an IV antibiotic. If the patient did not receive an IV antibiotic, Value "2" (No) would be selected for this data element, and the case would fail the measure. We appreciate your comments and question, and we will share them with the measure stewards and measure writers for consideration in future manual updates.

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Question 13:	Is a physician order for a C. diff test enough to show that it was suspected?
	No, an order for C. diff testing is not acceptable documentation identifying C. diff is suspected. The documentation needs to use terms such as "suspected" or "likely" to confirm it actually is suspected or likely. A comment to this effect within a C. diff test order would be acceptable.
Question 14:	The emergency department (ED) physician documents, upon patient arrival, that an outpatient lab result came back as positive for C. diff. The physician orders vancomycin oral solution that was started less than three hours after the <i>Severe Sepsis Presentation Time</i> . However, since no IV antibiotic was initiated 24 hours prior to or less than three hours after the <i>Severe Sepsis Presentation Time</i> , would I say "No" to the <i>Broad Spectrum or Other Antibiotic Administration</i> data element?
	That is correct, you would select Value "2" (No) for the <i>Broad Spectrum or Other Antibiotic Administration</i> data element, and the case would fail the measure.
Question 15:	If a patient was receiving PO vancomycin for known C. diff greater than 24 hours prior to <i>Severe Sepsis Presentation</i> with no other source of infection, would this case be excluded because the patient was on antibiotics for greater than 24 hours?
	No, the <i>Broad Spectrum or Other Antibiotic Presentation, Date</i> and <i>Time</i> data elements all require an IV antibiotic be started within 24 hours prior through three hours following <i>Severe Sepsis Presentation Date</i> and <i>Time</i> . In specific situations, intramuscular (IM) or intraosseous (IO) antibiotics are acceptable. Oral antibiotics are not acceptable and should be disregarded. If the patient only received oral antibiotics within this time frame, the case would fail the measure

Directive for Comfort Care or Palliative Care, Severe Sepsis and Septic Shock

Question 16:Slides 15 and 16. Do we still count "Comfort Measures only" from a<br/>Physician Orders for Life-Sustaining Treatment (POLST) signed by<br/>the provider as "Yes" for Directive for Comfort or Palliative Care?

	Yes, as long as "Comfort Measures only" is selected on the POLST form that is dated and signed prior to arrival, Value "1" (Yes) is selected for the <i>Directive for Comfort Care or Palliative Care, Severe Sepsis</i> data element.
Question 17:	Slide 15. With state authorized POLST forms, there are three paragraphs to be filled out by providers:
	1. Cardiopulmonary Resuscitation (CPR)
	• DNAR (Do Not Attempt Resuscitation) box is checked. Choosing DNAR will include appropriate comfort measures and may still include the range of treatments below.
	2. Medical Interventions
	• Limited additional interventions are checked. There are also full treatment and comfort-focused boxes.
	3. Signatures/Dates
	Will the checked box with DNAR and statement below it qualify for <i>Directive for Comfort or Palliative Care</i> even if "limited interventions" is subsequently checked under the Medical Interventions paragraph?
	Yes, if a box that includes "comfort measures" is checked, selecting Value "1" (Yes) is appropriate for the <i>Directive for Comfort Care or Palliative Care, Severe Sepsis</i> data element.
Question 18:	Slide 15. If the first documentation shows the physician ordered a Social Services consult for possible hospice, is this acceptable for comfort care?
	Yes, select Value "1" (Yes) for the <i>Directive for Comfort Care or Palliative Care, Severe Sepsis</i> data element if there is an order for a hospice consult.
Question 19:	Slide 15. We often see the following: "Palliative care consult to determine goals of care." Although "determine goals" means no plan has been determined, does the palliative care consult override that, and would we would still answer "Yes"?
	Yes, select Value "1" (Yes) for the <i>Directive for Comfort Care or Palliative Care, Severe Sepsis</i> data element in this case since there is a palliative care consult.

Question 20:	Slide 15. Does this still include State Authorized Portable Orders (SAPO) for comfort measures?
	Yes, select Value "1" (Yes) for the <i>Directive for Comfort Care or Palliative Care, Severe Sepsis</i> data element if there is a SAPO dated and signed prior to arrival with an inclusion term selected.
Question 21:	Slide 16. For "palliative care ordered," palliative care is not on the list on slide 15. Why would Value "1" (Yes) be selected?
	Value "1" (Yes) would be selected if "palliative care ordered" was documented within the specified timeframe because "palliative care" is listed in the Inclusion Guidelines for Abstraction within the <i>Directive for</i> <i>Comfort Care or Palliative Care, Severe Sepsis</i> data element. Slide 15 provides the context in which the inclusion terms must be documented.
Question 22:	If the order for palliative consult results in no comfort care given, do we still select "Yes" for <i>Directive for Comfort or Palliative Care</i> ?
	Yes, even if the order for a palliative consult did not result in the initiation of palliative or comfort care, you would select Value "1" (Yes) for the <i>Directive for Comfort Care or Palliative Care, Severe Sepsis</i> data element.
Question 23:	Does the following documentation count as a recommendation? "Comfort care should be discussed with family."
	No, a discussion of comfort care would not be acceptable documentation of a recommendation or plan for comfort care.
Question 24:	For <i>Directive for Comfort or Palliative Care</i> , would it be acceptable for the documentation to be "was discussed and considered but family had not decided yet" or "family declines comfort care but accepts palliative care consultation"?
	Documentation that comfort or palliative care "was discussed and considered but family has not decided yet" is not acceptable because it is not consistent with the contexts listed in the Notes for Abstraction (e.g., recommendation, order, consultation, evaluation, request, plan, or referral) for this data element. In this situation, select Value "2" (No) for <i>Directive for Comfort Care and Palliative Care, Severe Sepsis</i> .

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Documentation that the "family declines comfort care but accepts palliative care consultation" is acceptable because the documentation is within the context of a palliative care consultation. In this situation, select Value "1" (Yes).

# Question 25: If a palliative care consult is done and the patient family or patient still wants aggressive care, would you select "Yes" for palliative care?

Yes, if the palliative care consult was documented within the specified timeframe, select Value "1" (Yes) for the *Directive for Comfort Care and Palliative Care, Severe Sepsis* data element, even if the patient or family still wants aggressive care.

### Question 26: Is the following physician documentation an inclusion for comfort care? "Does not want aggressive care. This is a comfort care type admission."

Yes, this is acceptable physician/APN/PA documentation reflecting a plan for comfort care, and you would select Value "1" (Yes) for the *Directive for Comfort Care and Palliative Care, Severe Sepsis* data element.

# Question 27: Can an order for a palliative care consult, without any mention in the physician note, still count?

Yes, select Value "1" (Yes) for the *Directive for Comfort Care and Palliative Care, Severe Sepsis* data element if there is an order for a palliative care consult, even if the consult is not mentioned in the physician note.

### Question 28: If palliative care is ordered upon admission to ED and *Severe Sepsis Present* happens 12 hours later, would you select Value "1" (Yes)?

Yes, because the order for palliative care was documented prior to the *Severe Sepsis Presentation Time*, select Value "1" (Yes) for the *Directive for Comfort Care and Palliative Care, Severe Sepsis* data element. The definitions for the Allowable Values include a time frame of prior to or within six hours of the presentation of Severe Sepsis within which the physician/APN/PA documentation of comfort measures only or palliative care must occur for selection of Value "1" (Yes).

# Question 29: Does a palliative care consult have to be within six hours of the *Severe* Sepsis Presentation Time to answer "Yes"?

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The physician/APN/PA documentation of a palliative care consult must be prior to or within six hours after the *Severe Sepsis Presentation Time* to select Value "1" (Yes) for the *Directive for Comfort Care and Palliative Care, Severe Sepsis* data element. The palliative care consult does not need to be performed within the specified timeframe.

# Question 30: Does comfort, palliative, or selective care only need to be discussed or recommended and not ordered?

No, documentation of comfort or palliative care needs to be within one of the contexts listed in the Notes for Abstraction (e.g., recommendation, order, consultation, evaluation, request, plan, or referral) for the data element. Documentation of a discussion of comfort or palliative care would not be acceptable because a discussion is not one of the contexts.

The documentation of "selective care" is not acceptable because it is not one of the terms considered synonymous with comfort or palliative care listed in the Inclusion Guidelines for Abstraction. The first bullet point in the Notes for Abstraction indicates to only accept terms identified in the list of inclusions, and no other terminology will be accepted.

### Question 31: Would a palliative care consult for pain management count?

Yes, the reason for a palliative care consult is irrelevant. If there is physician/APN/PA documentation of a palliative care consult within the specified timeframe, select Value "1" (Yes) for the *Directive for Comfort Care and Palliative Care, Severe Sepsis* data element.

### Crystalloid Fluids

# Question 32: Slide 20. If, prior to the 2000 milliliters (mL) being ordered, boluses of 500, 500, and 1000 mL were ordered, would the 2000 mL bolus be the only fluid considered toward fulfilling the bolus?

No, all the infusions ordered and started within the timeframe of six hours prior through three hours following the crystalloid fluid trigger event (e.g., initial hypotension or septic shock) would be used to determine the completion time of the target ordered volume of crystalloid fluids. If the two 500 mL infusions and the 1000 mL infusion were ordered and started within the timeframe, and prior to the 2000 mL, the earlier infusions would be used toward the target ordered volume.

Question 33:	Slide 22. Is this correct? The only time the entire target ordered volume must be infused to meet the measure is if the target ordered volume is within the 10 percent less range.
	The entire target ordered volume must be infused if it is 30 mL/kilogram (kg) or if it is within 10 percent of 30 mL/kg.
	If the ordered volume is greater than 30 mL/kg then, for purposes of the measure, at least 30 mL/kg must be infused. In clinical practice, the entire volume should be infused if ordered, but the measure is only interested in the point at which 30 mL/kg is infused.
Question 34:	Slide 22. Do I calculate to the 1890 mL or the full 2000 mL?
	You would calculate the completion time of the target ordered volume (which is 2000 mL in this scenario) because this is the volume that was actually ordered. Ten percent less of 30 mL/kg is 1890 mL and that is the lower bound of the acceptable fluid volume order range.
Question 35:	Slide 22. For the 10 percent rule, does the physician order have to be ordered as a one-time order displaying the 30 mL/kg volume?
	No, the "10 percent rule" applies when the total fluid volume ordered equals a volume that is within 10 percent of the 30 mL/kg volume based on the documented weight. The total fluid volume ordered may be in a single order or multiple orders.
Question 36:	Slide 22 and 23. At what point is the 10 percent value of fluids given acceptable? Can you use the 10 percent rule with ideal body weight (IBW)?
	A fluid volume ordered that is within 10 percent of 30 mL/kg determined by the patient's documented weight is acceptable, even if the volume is based upon IBW.
	If the physician/APN/PA documents they used IBW to determine the crystalloid fluid volume and the total volume of crystalloid fluids ordered was within 10 percent of 30 mL/kg based on the patient's documented IBW, then that volume of fluids ordered would be acceptable.

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# Question 37: Slide 24. If the physician ordered 2500 mL and the nurse administered 2160 mL (10 percent), would we would fail the measure because the patient did not receive 2400 ml?

Yes, the nurse needs to administer the volume ordered by the physician. If less than the volume ordered is infused, then the target ordered volume was not completely infused and Value "2" (No) would be selected for *Crystalloid Fluid Administration*. This would result in the case failing the measure.

### Question 38: Is an initial lactate of greater than 4 also a trigger for fluid?

An initial lactate greater than or equal to 4 is not necessarily a trigger for fluid administration. *Initial Hypotension* and Septic Shock are the trigger events identified in the *Crystalloid Fluid Administration* data element. One of the ways SEP-1 defines Septic Shock is Severe Sepsis with an initial lactate greater than or equal to 4. If Septic Shock is identified this way and the lactate level result time represents the time of Septic Shock, then it could serve as the crystalloid fluid trigger because it represents the time of Septic Shock. An initial lactate level greater than or equal to 4 alone is not a required triggering event for fluid administration.

# Question 39: For crystalloid fluids, the fluids must run at a rate greater than 125 mL/hour. Does the order have to say "bolus," or can I count an infusion that is ordered as Lactated Ringers IV at 150 mL/hour?

The crystalloid fluid order must include the type of fluid, the volume, and a rate or duration. Because the example in the question includes a rate of 150 mL/hour, this would be an acceptable order assuming a volume is also ordered. Terms such as "bolus" or "wide-open" are acceptable in place of a rate or infusion duration.

#### Question 40: Does the rate have to be at greater than 125 mL/hour?

Yes, the *Crystalloid Fluid Administration* Notes for Abstraction state, "Only those crystalloid fluids given at a rate greater than 125 mL/hour should be used towards the target ordered volume. Do not use crystalloid fluids given at 125 mL/hour or less toward the target ordered volume."

# Question 41: Are we allowed to use IV medications if they are running at 126 mL/hour or greater?

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Yes, crystalloid fluids mixed with or used to dilute a medication are acceptable if the required documentation is included in the physician/APN/PA order and there is acceptable documentation of fluid administration. (Start time is required as either rate, duration, or end time.)

# Question 42: Must the target volume of crystalloid fluids be infused in the given timeframe?

No, the *Crystalloid Fluid Administration* data element does not specify a timeframe in which the target ordered volume of crystalloid fluids must be completely infused.

Question 43: Is it acceptable to infuse more than 30 mL/kg?

Yes, fluids should be administered as ordered by the physician/APN/PA. For purposes of the measure, the time at which 30 mL/kg is fully infused is used to determine if fluid resuscitation occurred per the SEP-1 specifications. Additionally, abstractors must look for *Persistent Hypotension* beginning one hour after 30mL/kg of fluids is fully infused.

# Question 44: If the physician orders a 500 mL bolus, can you assume that the rate is 1000 mL/hour?

No, the rate of fluid administration cannot be assumed based on a "bolus" order. The term "bolus" in the fluid order is acceptable in place of a rate or duration. However, a rate or duration must be documented for the fluid administration to confirm it was infused at a rate greater than 125 mL/hour and to help determine when the infusion was completed.

### Question 45: For fluids, are we allowed to round to the nearest mL?

Yes, per the guidance in the *Crystalloid Fluid Administration* data element for determining the target ordered volume, round the IV fluid volume in mL to the nearest whole number.

### Question 46: How do you abstract if the rate for the IV fluids was documented by emergency medical services as drops (gtt)/min? There is no mention of this method in the specifications manual.

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For SEP-1, drops per minute is not an acceptable fluid rate determination. Unless there is further documentation within the medical record indicating the mL/hour rate or equivalent to gtt/min, this infusion would not be used toward the target ordered volume.

# Question 47: Can you accept an order for crystalloid fluid administration that states, "3200 cc IV NS bolus"?

Yes, this fluid order would be acceptable because it includes the requirements for physician/APN/PA orders: the type of fluid, volume of fluid, and rate or infusion duration. The term "bolus" is acceptable in place of a rate for the fluid order.

Question 48: When will the guidance be updated to include acceptable crystalloid administration to be less than the target ordered volume when noninvasive stroke volume assessment prior to or during the initial 30 mL/kg demonstrates that the patient has a non-therapeutic response to the initiation or ongoing fluid administration?

> Currently, no revisions to the guidance based on the use of non-invasive stroke volume assessment are planned. We continue to monitor the evidence and update the measure when new evidence warrants revisions to the measure.

Question 49: If the targeted volume was ordered and hung but not completely infused at the end of the three hours of the trigger event, can we say "Yes"?

Yes, select Value "1" (Yes) in this situation. The target ordered volume of crystalloid fluids does not need to be completely infused within three hours after the triggering event. The specifications only require the target volume of fluids be ordered and started within six hours prior to through three hours after the triggering event.

### Question 50: To assess for hypotension, does the hour after fluids start when the target volume is completed or when the ordered amount is completed?

The timeframe to assess for *Persistent Hypotension* is within one hour following the completion of the target ordered volume of crystalloid fluids.

Question 51:	It was stated that crystalloid fluids do not have to completely infuse within a specified timeframe. In the following scenario, would the case fall out because the vasopressors were started after six hours of <i>Septic</i> <i>Shock Presentation</i> , although <i>Persistent Hypotension</i> was present after fluids? Septic Shock at 1200; target fluids given at 1300 and finished at 1900. In the hour after fluids are completed, the patient presents with two hypotensive blood pressure (BP) readings and is positive for <i>Persistent Hypotension</i> . A vasopressor is started at 2100.
	Yes, in this case select Value "2" (No) for the Vasopressor Administration data element. The case will fail the measure. The Vasopressor Administration Time would need to be within six hours after the Septic Shock Presentation Time to answer Value "1" (Yes) for the Vasopressor Administration data element.
Question 52:	Why is Dextrose (5 Lactated Ringers (D5LR) or Dextrose 5 Normal Saline (D5NS) not acceptable IV fluids for the target volume?
	Only crystalloid or balanced crystalloid solutions are acceptable for the <i>Crystalloid Fluid Administration</i> data element. The solutions D5LR and D5NS are not balanced crystalloid solutions.
Question 53:	The crystalloid fluid data element says there is no specified timeframe for completion of fluids but, if it is not completed in a timely way, doesn't that cause a fallout for not determining <i>Persistent Hypotension</i> and giving vasopressors in a timely way?
	Yes, this can happen. Because the guidance does not require the target ordered volume of crystalloid fluids to be completed within a specified timeframe, fluids infused at a slower rate could be completed more than six hours after <i>Septic Shock Presentation Time</i> . In this situation, if <i>Persistent</i> <i>Hypotension</i> is identified in the hour after the infusion is completed and vasopressors are started, the <i>Vasopressor Administration Time</i> will be more than six hours after <i>Septic Shock Presentation Time</i> . The <i>Vasopressor</i> <i>Administration</i> data element and SEP-1 algorithm require the vasopressors be started within six hours after <i>Septic Shock Presentation Time</i> . Value "2" (No) would be selected for the <i>Vasopressor Administration</i> data element, and the case would fail the measure. We appreciate your comments and question, and we will share them with the measure stewards and measure writers for consideration in future manual updates.

Question 54:	Does the physician need to specify what the IBW is, or can they refer to using IBW and have the number in the medication administration record (MAR) order? Does the physician need to state that the targeted fluids are based on IBW?
	The physician does not need to specify the ideal body weight (IBW) value in the order as long as the IBW value is documented clearly in the medical record. The order does need to specify that fluid volume is based on IBW.
	Per the <i>Crystalloid Fluid Administration</i> data element, the physician/ APN/PA can use IBW to determine the target ordered volume if they document the patient is obese (defined as body mass index greater than 30) and document that IBW is used to determine the target ordered volume. IBW must be present in the medical record, but the IBW does not need to be included in the order. Abstractors should not calculate the IBW.
Question 55:	Does the BMI (Body Mass Index) and IBW need to be in the same note? Can BMI be time/date stamped on another part of the chart?
	Documentation of the BMI and IBW does not need to be within the same note. As long as the IBW is documented in the medical record, it is acceptable to use. Keep in mind that there are other requirements for the order listed in the <i>Crystalloid Fluid Administration</i> data element, but the IBW does not need to be included in order.
Question 56:	I recently received a response from CMS regarding a fluid bolus that was started 10 minutes outside the allowable timeframe. The patient did receive almost 600 mL during the timeframe from this bolus. I was told I could not use the 600 mL toward the patient's total fluid requirement. The patient was a Do Not Resuscitate (DNR) and Do Not Intubate (DNI) patient and needed to be resuscitated gently. Is this response correct?
	Yes, only fluids ordered and initiated within the specified timeframe determined by the triggering event would be used toward the target ordered volume of crystalloid fluids. Crystalloid fluids ordered or started outside of the specified timeframe would not be used toward the target ordere volume.
Question 57:	Since we can use IBW for BMI of greater than 30, would it not be prudent to change the measure from 30 mL/kg to a standard of two liters within three hours prior to or up until three hours following time zero?

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The use of the IBW to determine the target ordered volume is specific to patients with obesity that was documented by a physician/APN/PA to avoid requiring infusion of very large volumes for this patient population. Therefore, the use of the IBW to determine the target ordered volume is not universal to all patients. Determining the target ordered volume using IBW does not always result in a standard volume of two liters for all patients. Additionally, for some smaller elderly patients, two liters may be greater than 30 mL/kg.

Question 58: In a septic patient with active heart failure, low BPs, and an elevated lactate level (i.e., distended neck veins, rales, pulmonary congestion by x-ray, elevated B-type natriuretic peptide), why not use dobutamine and good judgment before beginning the protocol's fluid recommendations? Is the correct response to intubate the patient, give the resuscitation per protocol, and carefully monitor intake and output thereafter?

> The physician's best clinical judgement should always be used for treatment of individual patients. Measures and guidelines upon which measures are based are designed for the majority of patients with a specific condition. The measure is not intended to be used as a clinical protocol for treatment of all patients with Severe Sepsis or Septic Shock. The measure provides guidance for retrospective reviews of medical records for patients with Severe Sepsis or Septic Shock to determine if the recommended interventions for Severe Sepsis or Septic Shock were implemented. Some patients may not meet the measure because they required variations in treatment based on a physician's best clinical judgement.

Question 59: Does CMS realize how difficult it is to keep up with all the sepsis updates and keep it all straight when abstracting? Isn't there a way they could simplify all of this? Also, I hear constant complaints from practitioners that CMS is not keeping up with current literature regarding fluid administration and that several studies have shown that bolusing large amount of fluids into patients is not beneficial, especially for the congestive heart failure (CHF) and end stage renal disease (ESRD) population. Would it be possible to share the literature or studies that were used to determine the IV fluid volume requirements for this measure? Is there a plan on having a clinical exclusion criterion for fluid resuscitation for patients at risk for fluid overload, pulmonary edema, CHF, and ESRD, for example?

**Support Contractor** 

Thank you for your questions and comments. CMS is aware of the complexity of the SEP-1 measure and continues to focus on burden reduction when reviewing measure updates.

References for the measure can be found in the Severe Sepsis and Septic Shock (SEP) Measure Information Form in the specifications manual on *QualityNet* at <u>https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1141662756099</u>.

Fluid resuscitation for purposes of the measure is specific to Severe Sepsis and Septic Shock patients. The measure does not exclude populations from crystalloid fluid administration based on comorbidities. The evidence continues to suggest resuscitation with 30 mL/kg of crystalloid fluids for the Severe Sepsis patient with hypotension or the Septic Shock patient is beneficial for the majority of patients regardless of these comorbidities due to the severity of Severe Sepsis and Septic Shock. We continue to monitor evidence; however, no updates related to excluding patients from crystalloid fluid administration based on comorbidities is planned.

### Initial Hypotension

Question 60:	Slide 25. Have BPs taken during dialysis been considered for exclusion?
	Because the updated guidance does not exclude hypotensive BP readings obtained in dialysis, you would only exclude such readings if there was physician/APN/PA documentation attributing the hypotensive reading(s) to a chronic condition, medication, acute condition with a non-infectious source, or documented as normal for the patient. We appreciate your question and will consider this during the next update to the specifications.
Question 61.	Slide 25 Does procedural/conscious sedation, such as propofol, apply to

Question 61: Slide 25. Does procedural/conscious sedation, such as propofol, apply to intubation procedures? The medications used are often the same as conscious sedation and providers are required to file a procedural note, even if in an ED.

Yes, it can. The updated guidance does not provide specific examples of procedures or sedating medications that would allow you to disregard the hypotensive BP readings due to procedural or conscious sedation. However, if there is documentation in the medical record indicating procedural or conscious sedation was used for intubation, you would disregard hypotensive BP readings obtained during intubation.

Question 62:	Slide 25. Often nerve blocks are performed in the post-anesthesia care unit (PACU) or the pre-operative holding area, utilizing mild sedation and or narcotics. What do we do for this?
	If documentation within the medical record indicates the patient was under procedural or conscious sedation while the nerve block was being performed, disregard the hypotensive BP readings. Otherwise, you should use these readings.
Question 63:	Slide 28. For the guidance "due to medication," wouldn't that be the situation in the PACU? PACU patients are immediately in the waking-up stage. Shouldn't that count as the operating room (OR)?
	No, the patient's location in the Post-anesthesia Care Unit (PACU) alone would not attribute the hypotensive BP reading(s) to a medication. Also, the PACU would not be considered the same as the operating room. According to the guidance on slide 28, if there is physician/APN/PA documentation attributing hypotension to a medication while the patient was in the PACU, then you should not use the hypotensive reading(s) documented in the PACU.
Question 64:	Slide 28. If documentation says, "hypotension normal for this patient due to CHF," would we not use any low BP values?
	Correct. If the term "hypotension" is documented as normal for the patient and due to a chronic condition, such as CHF, disregard all hypotensive blood pressure readings.
Question 65:	Slide 29. Are we unable to use the physician documentation for hypotension because we need two low BPs?
	Correct, the documentation of the term "hypotension" would not meet the requirements of the <i>Initial Hypotension</i> data element. Documentation of
	actual BP readings (i.e. systolic blood pressure (SBP) less than 90 or mean arterial pressure (MAP) less than 65) are required to meet the criteria of the data element.

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No, the same guidance to not use hypotensive BP readings obtained in the operating room, interventional radiology, during active delivery, or procedure/conscious sedation also applies to the *Persistent Hypotension* data element.

Question 67:What if the Initial Hypotension episode is in the ER during a procedure<br/>in which conscious sedation is being administered?<br/>What about hypotensive BPs obtained during anesthesia for a<br/>gastrointestinal procedure? Are they used?

No. If there is documentation in the medical record indicating the patient was under procedural or conscious sedation in the ED or during the gastrointestinal procedure when the hypotensive reading(s) were obtained, do not use the hypotensive readings.

Question 68: When it comes to crystalloid fluid for *Initial Hypotension*, one bullet point says to only abstract the fluids six hours prior to and three hours after the *Initial Hypotension*. Does that mean we can count the fluids three hours after, as we do not have the time limit?

No. Only crystalloid fluids ordered and **started** within the six hours prior through three hours after the *Initial Hypotension Time* count towards the target ordered volume. Fluids ordered or started more than three hours after *Initial Hypotension* cannot be used. The target ordered volume of crystalloid fluids does not need to be completely infused within three hours after *Initial Hypotension*.

Question 69:Is Initial Hypotension two low BPs within three hours of each other?Yes, Initial Hypotension is defined as two hypotensive BP readings within<br/>three hours of each other that are documented within six hours prior through<br/>six hours after the Severe Sepsis Presentation Time.

# Question 70: If there was just one systolic BP less than 90 documented and the physician documents hypotension, would it exclude the case for *Initial Hypotension*?

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Physician/APN/PA documentation of "hypotension" is not acceptable in place of the actual BP reading. The actual BP value must be documented and be an SBP less than 90 or MAP less than 65 to meet *Initial Hypotension* criteria. If a single hypotensive reading is documented within the specified timeframe for *Initial Hypotension*, select Value "2" (No). This will not result in exclusion of the case from the measure. In this situation the algorithm flow will take you to the *Septic Shock Present* data element.

### Question 71: Would "Yes" be answered for *Initial Hypotension* if there are two systolic BPs less than 90 within six hours of *Severe Sepsis Presentation*, but fluids greater than 30 mL/kg were not ordered?

Yes, if two hypotensive blood pressure readings are documented within the specified timeframe for *Initial Hypotension*, select Value "1" (Yes), even if crystalloid fluids were not ordered. If the target ordered volume of crystalloid fluids was completely infused prior to the *Initial Hypotension Time*, select Value "2" (No) for *Initial Hypotension*.

# Question 72: The patient had Severe Sepsis at 1800 and the fluid bolus was given by 1830. Then, the patient has two low BPs within three hours. Does the patient have *Initial Hypotension* even though the 30 mL/kg was given prior to the BP dropping?

No, if the target ordered volume of crystalloid fluids was completely infused prior to the *Initial Hypotension Time*, select Value "2" (No) for *Initial Hypotension*.

Question 73: Regarding *Initial Hypotension* six hours prior to time zero, I do not understand why we must give 30 mL/kg for hypotension when sepsis has not been diagnosed and could be six hours prior to time zero. Can you explain this?

*Crystalloid Fluid Administration* is initiated based on the event that triggers the need for fluid resuscitation (i.e., *Initial Hypotension* or *Septic Shock Present*). *Crystalloid Fluid Administration* is not based on Severe Sepsis presentation because Severe Sepsis alone does not trigger the need for crystalloid fluid resuscitation. Therefore, if *Initial Hypotension* is the earliest event that triggers the need for crystalloid fluid resuscitation, for purposes of the measure, acceptable crystalloid fluids should be ordered and started within six hours prior through three hours after the *Initial Hypotension Time*.

### Hospital Inpatient Quality Reporting (IQR) Program Support Contractor

### Persistent Hypotension

Question 74:	Slide 30. I have seen cases where the BP was checked multiple times within the hour following the bolus. There were not two consecutive low BPs, but the last one was low. Many times, the last BP is checked minutes before the end of the hour, giving little to no time to check another BP. If the BPs following the last low BP within the hour are normal, vasopressors may not have been clinically indicated. They were obviously monitored for <i>Persistent Hypotension</i> . Why does this fail?
	As you note, the guidance indicates if the hour to assess for <i>Persistent Hypotension</i> ends with a single hypotensive blood pressure reading, select Value "3" (No) or "UTD." Unable to determine (UTD) is associated with Value "3" because UTD does not fit with Value "1" (present) or Value "2" (not present). Value "3" will result in the case failing the measure.
	New guidance, as noted in slide 32, indicates that, if <i>Persistent Hypotension</i> is unable to be determined, but a vasopressor was administered, select Value "1." Administration of a vasopressor reflects that, despite the difficulty in identifying presence of <i>Persistent Hypotension</i> based on retrospective review of the medical record, at the time the physician was providing care they thought <i>Persistent Hypotension</i> was present. Therefore, select Value "1" (Yes) in these situations.
	We appreciate your comments and question and continue to work with the measure stewards to refine abstraction guidance for this data element.
Question 75:	Slide 32. Does the vasopressor have to be started after the low BP or can it already be running?
	No, the vasopressor does not have to be started after the low BP. The updated guidance on slide 32 for the <i>Persistent Hypotension</i> data element does not include a specified timeframe in which the vasopressor must be started for selecting Value "1" (Yes). To select Value "1" (Yes) for <i>Persistent Hypotension</i> in this scenario, only documentation of <i>Vasopressor Administration</i> is required.
Question 76:	Slide 32. I use the CMS Abstraction Reporting Tool (CART) to abstract this data. Is Value "1" (Yes) referenced on this slide the same for CART?
	Yes, Allowable Value "1" referenced on slide 32 corresponds with "Yes" within the data element, and the same Allowable Value is available in CART.

Question 77:	Slide 33. By what timeframe does the vasopressor need to be initiated? Is it within the one hour, the same timeframe as usual, or at any time?
	The <i>Persistent Hypotension</i> data element does not specify a timeframe in which the vasopressor must be started. To select Value "1" (Yes) for <i>Persistent Hypotension</i> , only documentation of <i>Vasopressor Administration</i> is required.
Question 78:	Slide 33. If the vasopressor was initiated at 1350, with BPs at 1410 of 97/63; at 1430 of 92/59; and 1445 of 85/50, can we still answer "Yes" to <i>Persistent Hypotension</i> ?
	Yes, although <i>Persistent Hypotension</i> cannot be determined in this scenario because there is documentation of <i>Vasopressor Administration</i> , you should select Value "1" (Yes).
Question 79:	Slides 35 through 41. These calculations are impossible. Given the complexity of the calculations presented here and the judicious delivery of fluids to frail patients with multiple comorbidities, is CMS expecting clinicians in critical situations to utilize these calculations?
	No, the specifications manual and calculation examples are not intended for use in clinical care; rather, they provide guidance to medical record abstractors for retrospective chart abstraction.
Question 80:	Slide 40. Is the mLs in the last example (Infusion 2, 3, and 4) correct? Should it be 16.67 [30 minutes x (8.33 + 2.78 + 8.33)]?
	Correct, beside "Infusions 2, 3, 4" on slide 40, the mL per minute of Infusion 4 should be 16.67 mL per minute rather than 8.33 mL per minute.
Question 81:	If we have one liter running at 100 mL/hour and another medication running at 200 mL/hour, do we include the 100 mL/hour since the entire rate is greater than 125 mL/hour?
	No, the infusion running at 100 mL/hour would not be used toward the target ordered volume due to the rate below 126 mL/hour. Infusions running at rates less than 126 mL/hour should not be combined with other infusions for a combed rate of 125 mL/hour or greater. The rate of each infusion should be considered separately.

Question 82:	For purposes of accessing <i>Persistent Hypotension</i> , what do you select if there is normotensive BPs recorded in the OR within the one-hour timeframe following a fluid bolus?
	If all BPs in the hour following the fluid infusion are obtained in the OR, select Value "2" (No) for <i>Persistent Hypotension</i> .
Question 83:	How would we abstract <i>Persistent Hypotension</i> if all the BPs were above 90 systolic, but the physician started a vasopressor?
	<i>Persistent Hypotension</i> can be determined in this scenario since the documented BPs are all "normal." Select Value "2" (No). Updated guidance regarding the inability to determine the presence of <i>Persistent Hypotension</i> when a vasopressor was administered would not apply to this situation.
Question 84:	What would we select for <i>Persistent Hypotension</i> if the vasopressor is started prior to the completion of the fluids?
	Determining the appropriate Allowable Value to select for <i>Persistent Hypotension</i> will depend on the documented BPs and documentation of <i>Vasopressor Administration</i> . If <i>Persistent Hypotension</i> is present based on BP readings, select Value "1" (Yes). If not present, select Value "2" (No) regardless of <i>Vasopressor Administration</i> . If you are unable to determine presence of <i>Persistent Hypotension</i> based on the documented BPs and a vasopressor was administered, select Value "1" (Yes). The <i>Persistent Hypotension</i> data element does not include a specified timeframe in which the vasopressor must be started for selecting Value "1" (Yes).
Question 85:	To clarify, must <i>Persistent Hypotension</i> be after completion of the target fluids and within six hours of Severe Sepsis? If so, then target fluids administered to completion which finish greater than six hours will never pass for <i>Persistent Hypotension</i> . Is this accurate?
	<i>Persistent Hypotension</i> must be assessed in the one hour following the completion of the target ordered volume of crystalloid fluids. There is no requirement for assessment of <i>Persistent Hypotension</i> within six hours after the <i>Severe Sepsis Presentation Time</i> . Additionally, there is not a specific timeframe within which crystalloid fluids must be completely infused.

Question 86:	Is a vasopressor only allowed to be given within the one hour following BP evaluation for assessment of <i>Persistent Hypotension</i> ? If that is correct, would a vasopressor given within the six-hour timeframe from Septic Shock count?
	The <i>Persistent Hypotension</i> data element does not include a specified timeframe in which the vasopressor must be administered. Select Value "1" (Yes) for <i>Persistent Hypotension</i> if you are unable to determine presence of <i>Persistent Hypotension</i> and there is documentation of <i>Vasopressor Administration</i> .
Question 87:	If the patient has two consecutive low BPs, meeting the need for vasopressors, and they bring the BP up enough to not need vasopressors, is this considered a fail?
	No, this would not necessarily cause the case to fail.
	If the two consecutive low BPs were the last two in the hour, select Value "1" (Yes) for <i>Persistent Hypotension</i> and continue abstraction of the <i>Vasopressor Administration</i> data elements. If vasopressors were not given, the case will fail.
	If the two consecutive low BPs were not the last two in the hour and the hour ended with one or more than one normal BP, select Value "2" (No) for <i>Persistent Hypotension</i> . Vasopressors are not required. The case will not fail based upon whether or not vasopressors were administered.
Question 88:	If there are no fluids given, how can you determine <i>Persistent Hypotension</i> ?
	You cannot. Presence of <i>Persistent Hypotension</i> is dependent upon infusion of crystalloid fluids. If no crystalloid fluids were administered, select Value "3" (No) for the <i>Crystalloid Fluid Administration</i> data element. This will result in the case failing the measure prior to reaching the <i>Persistent Hypotension</i> data element in the algorithm.
Question 89:	If there is no completion time required, how do you determine for <i>Persistent Hypotension</i> ?

Support Contractor

While the target ordered volume of crystalloid fluids does not need to be completely infused within a specified timeframe, you must determine the time the infusion is completed to identify when the hour to assess for *Persistent Hypotension* begins. To determine when the target ordered volume was completely infused, you must have documentation of the infusion start time and rate, duration, or completion time.

# Question 90: If you answer "No" to *Initial Hypotension*, per the guidelines, can you answer "Yes" to *Persistent Hypotension*?

Yes. Select Value "1" (Yes) for the *Persistent Hypotension* data element if there is *Persistent Hypotension* or new onset of hypotension in the hour following the administration of the target ordered volume of crystalloid fluids. This remains true even if the patient does not have *Initial Hypotension*.

Question 91: Four blood pressure readings, every 15 minutes, are documented after fluid resuscitation. All blood pressures are above 90 systolic, except the last BP. If you abstract as Value "3" (UTD), the measure is failed. Can an additional BP be taken outside of the one hour to assess for *Persistent Hypotension*?

No, only BP readings documented within the one hour after completion of the target ordered volume of crystalloid fluids should be used to determine *Persistent Hypotension*.

# Question 92: If the definition of *Persistent Hypotension* is defined as two BP recordings less than 90, why would you choose Value "3" (UTD) if there was only one?

As you note, the guidance indicates, if the hour to assess for *Persistent Hypotension* ends with a single hypotensive BP reading, select Value "3" (No) or (UTD). UTD is associated with Value "3" because UTD does not fit with Value "1" (present) or Value "2" (not present). Value "3" will result in the case failing the measure. We appreciate your comments and question and continue to work with the measure stewards to refine abstraction guidance for this data element.

Question 93: The patient had two low BPs recorded in the chart, one at 0308 and one at 0352. The *Severe Sepsis Presentation Time* was at 0308. This meets the criteria for the *Initial Hypotension*, but what would be the correct answer to the last hypotension question? It doesn't seem that it is persistent or new onset within the hour of the conclusion of the fluids. Value "1" (Yes) and Value "2" (No) both cause the case to be compliant, but we would like clarification.

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Without further information, we are unable to provide an accurate response to this question. Please submit your question via the *QualityNet.org* online Q&A tool for further assistance.

# Question 94: What is the timeframe to reassess for another BP if we have two normal BPs followed by a low BP?

For the *Persistent Hypotension* data element, only use BPs documented within the one hour after completion of the target ordered volume of crystalloid fluids.

Question 95: If *Persistent Hypotension* is present because the patient was started on a vasopressor with only one hypotensive BP present or the last BP in the one-hour window was hypotensive, what time would we use for *Septic Shock Presentation Time*, the earlier time of the one hypotensive BP or the later time when "septic shock" was documented?

Criterion "a" in the *Septic Shock Present* data element identifies the presence of Septic Shock based on the patient having Severe Sepsis and *Persistent Hypotension*, which requires two consecutive hypotensive BP readings. Unlike the updated criteria in the *Persistent Hypotension* data element, this criterion does include an allowance for vasopressor administration to determine presence of *Persistent Hypotension*.

Therefore, if you select Value "1" (Yes) for *Persistent Hypotension* because you were not able to determine presence of *Persistent Hypotension* based on the BP readings, but a vasopressor was administered, you cannot use this as a determination of the presence of persistent hypotension to meet *Septic Shock Present* criteria.

# Question 96: Did the hypotension readings change from consecutive to any two BP readings in six hours?

No, BP timeframes for *Initial Hypotension* and *Persistent Hypotension* did not change in v5.6.

Low BP readings do not need to be consecutive for the *Initial Hypotension* data element. To select Value "1" (Yes) for this data element, there must be two low BPs within three hours of each other and between six hours prior through six hours after *Severe Sepsis Presentation Date* and *Time*.

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To select Value "1" (Yes) for the *Persistent Hypotension* data element, the las two consecutive BP readings within the one hour after completion of the target ordered volume of crystalloid fluids must both be hypotensive. According to updated guidance, select Value "1" (Yes) if the last two BPs are a normal reading followed by a low reading but a vasopressor was given.

Question 97: We have an electronic medical record (EMR) issue where the same BP rate is occasionally duplicated within two seconds of each other (e.g., 80/50 at 8:01 and 80/50 at 8:02). When this is a hypotensive result, it is causing numerous failures for Intravenous Fluid Resuscitation (IVF). Many cases only have one duplicate reading and no others, so the physician doesn't order IVF. From a policy standpoint, can we address this for abstractors?

If there is physician/APN/PA or nursing documentation indicating that a hypotensive reading is erroneous or questioning the validity of a hypotensive reading, disregard that reading for determining the presence of persistent or new onset of hypotension. If no such documentation exists, the Introduction to the Data Dictionary indicates the medical record must be abstracted as documented or taken at "face value." We recommend you discuss this issue with your EMR vendor.

# Question 98:If the hour to assess for *Persistent Hypotension* falls outside of the six<br/>hours after time zero, how do we answer that question? How do we<br/>assess for vasopressors when not done until after *Persistent Hypotension*<br/>when they were not initiated during the six-hour window?

*Persistent Hypotension* must be assessed in the one hour following the completion of the target ordered volume of crystalloid fluids. There is no requirement for assessment of *Persistent Hypotension* within six hours after the *Severe Sepsis Presentation Time*.

The Septic Shock Present data element is prior to Persistent Hypotension in the algorithm. Therefore, if Persistent Hypotension is identified greater than six hours after the Severe Sepsis Presentation Time and Septic Shock presentation is based upon Severe Sepsis with Persistent Hypotension, select Value "2" (No) for Septic Shock Present. Guidance in the Septic Shock Present data element indicates that, if Septic Shock Present is more than six hours after Severe Sepsis Presentation Time, choose Value "2" (No). This will result in the case passing the measure and abstraction will end.

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However, if presence of Septic Shock is not based upon *Persistent Hypotension* and the timing of *Persistent Hypotension* is such that vasopressors are administered greater than six hours after the *Septic Shock Presentation Time*, select Value "2" (No) for the *Vasopressor Administration* data element. This will result in the case failing the measure.

Question 99: If the patient has Severe Sepsis, does not have *Initial Hypotension*, does not have an initial lactic acid greater than or equal to 4, but did get the 30 mL/kg fluids proactively, do you still look for hypotension in the hour after the 30 mL/kg even though the fluids were not technically required? If so, do you answer "Yes" to *Septic Shock Present* and/or "Yes" to *Persistent Hypotension*?

> Yes, upon reaching the *Septic Shock Present* data element, you would assess *Persistent Hypotension* to determine if Septic Shock was met by clinical criteria of Severe Sepsis with *Persistent Hypotension*. If the hour to assess for *Persistent Hypotension* ends with two consecutive hypotensive readings, *Septic Shock Present* would be met by Severe Sepsis with *Persistent Hypotension*. In this situation, select Value "1" (Yes) for *Septic Shock Present* and *Persistent Hypotension*.

Question 100: Do we automatically select "Yes" for *Persistent Hypotension* if we don't see the BPs, but the patient received a vasopressor? The *Persistent Hypotension* data element states that we can now select Value "1" (Yes) if we are unable to determine *Persistent Hypotension*, but a vasopressor was administered. What timeframe does the vasopressor have to be administered to qualify for this new update?

No, you would not automatically select Value "1" (Yes) for *Persistent Hypotension* based on *Vasopressor Administration* alone. Allowable Value 1 or 2 may be appropriate for the *Persistent Hypotension* data element depending on the BPs documented in the hour to assess for *Persistent Hypotension*. The updated guidance only applies to situations where the last two BPs are a low BP preceded by a normal BP and a vasopressor was administered.

The *Persistent Hypotension* data element does not include a specified timeframe in which the vasopressor must be started, only that a vasopressor was administered.

### Hospital Inpatient Quality Reporting (IQR) Program Support Contractor

### Repeat Volume Status and Tissue Perfusion Assessment Performed

# Question 101:Slide 42. Would an exam or review of systems (ROS) done by the ED<br/>physician, after start of crystalloids or a history and physical (H&P), in<br/>the appropriate timeframe count for *Repeat Volume Status and Tissue*<br/>*Perfusion Assessment Performed* even if didn't list out five of the eight<br/>needed elements?

This will, in part, depend on physician/APN/PA documentation. For example, it would be acceptable if the ED physician documented that they "completed a review of systems," "performed a sepsis exam," "completed a physical exam," or included synonymous documentation. However, if an H&P was completed, it would need to include five of the eight elements or the physician would need to document in the H&P that they completed a review of five of the eight elements. It would also be acceptable if the physician documented within the H&P that they performed "a review of systems," "sepsis exam," or "physical exam," or if they included synonymous documentation. Presence of an H&P in the medical record alone may not meet requirements if it does not contain this information.

# Question 102: Slide 42. If the physician documents that he could not perform a ROS but, in his notes, you can find five out of the eight parameters, would this be acceptable?

Yes, documentation of five of the eight parameters within the specified timeframe is acceptable.

# Question 103: Slide 42. Why doesn't a physical exam or ROS documented in the correct timeframe count? I do not understand why an attestation of the exam or review is allowed, but the documented ROS or physical exam is not allowed.

Physician/APN/PA documentation that they performed a "review of systems," "sepsis exam," or "physical exam" is acceptable. Presence of a H&P in the medical record alone is not acceptable due to wide variations in H&P documentation. Physician/APN/PA documentation in the H&P of the findings from a physical exam or review of systems that includes five of the eight parameters is acceptable. It would also be acceptable for the physician to document within the H&P that they performed "a review of systems," "sepsis exam," or "physical exam," or if they included synonymous documentation.

**Support Contractor** 

### Slide 43. If the H&P says, "unable to perform ROS due to patient being **Question 104:** obtunded," could we still use the H&P even if it has the exam section done? No, this would not be acceptable physician/APN/PA documentation attesting to performing or completing an exam because it does not indicate that an exam was performed. The Repeat Volume Status and Tissue Perfusion Assessment Performed data element requirements are not dependent upon the patient's level of consciousness or mental alertness. **Question 105:** Is the physician documentation of "hemodynamically stable" acceptable for the sepsis exam? No, this documentation alone would not be acceptable. As the example on slide 42 and in the data element demonstrates, physician/APN/PA documentation reflecting "I have reassessed the patient's hemodynamic status" would be acceptable. This documentation reflects that the physician/APN/PA performed an exam or reassessment. **Question 106:** Would you consider accepting documentation of refusal for repeat vital signs (VS) after crystal fluid bolus administration in the future? This occurs on occasion. Thank you for your comment. Given the various methods available to meet the Repeat Volume Status and Tissue Perfusion Assessment Performed data element requirements, this is not something currently under consideration. We appreciate your comments and question, and we will share them with the measure stewards and measure writers for consideration in future manual updates. **Ouestion 107:** The physician opens his note, documents "sepsis reassessment completed after fluid bolus" in the plan portion, and signs the note without a timestamp. The fluid bolus is completed within the threehour timeframe. Does this meet the reassessment requirement? The physician/APN/PA documentation of "sepsis reassessment completed" is acceptable documentation attesting to performing an exam. However, since there is not a specific time associated with the documentation, the note-opened time would be used for the Repeat Volume Status and Tissue Perfusion Assessment Performed Time. If the note-opened time is between the crystalloid fluid administration date and time and six hours after the presentation of Septic Shock date and time, then this documentation would be acceptable.

Question 108:	For focused reassessment, the physician H&P has a "Review of Systems" heading and the physical exam is documented underneath. Is this acceptable for the sepsis reassessment without further provider documentation that the ROS is specific to sepsis reassessment?
	No, the heading of "Review of Systems" alone is not acceptable for physician/APN/PA documentation attesting to performing an exam or review of systems. If the physician documented five of the eight parameters within the physical exam notes, then this documentation would be acceptable for the <i>Repeat Volume Status and Tissue Perfusion Assessment Performed</i> data element.
Question 109:	Please comment on the timing of documentation for the review of systems in reference to fluid resuscitation. If the note is timed after the fluid bolus start time, is that enough?
	Review of systems documentation for the <i>Repeat Volume Status and Tissue</i> <i>Perfusion Assessment Performed</i> data element needs to occur within a specific time window, which begins after the crystalloid fluids start time and ends six hours after <i>Septic Shock Presentation Time</i> . If this documentation occurs within this time window, it is acceptable.
Question 110:	The physician documented, "After fluid resuscitation I did the sepsis reassessment." However, the abstractor said this was a miss because there was no date or time associated with the attestation. In other words, the abstractor said "after fluid resuscitation" was not a correct date/time and the physician should put "assessment done at XX date/YY time." Is this correct? Must the attestation include a date and time?
	Yes, that is correct. Documenting "after fluid resuscitation" is not acceptable in place of a specified time for performing a sepsis reassessment for the <i>Repeat Volume Status and Tissue Perfusion Assessment Performed</i> data element. If a date and time is not specified for the attestation documentation, the note-opened time would be used.
Question 111:	Does the six-hour timeframe for perfusion assessment documentation by a physician begin at the start or end of crystalloid fluid administration?

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The time window for the *Repeat Volume Status and Tissue Perfusion* Assessment Performed data element starts at the Crystalloid Fluid Administration Time and ends six hours after the Septic Shock Presentation Time.

#### Severe Sepsis Present

Question 112:Slide 45. What if the anticoagulant is started after the International<br/>Normalized Ratio (INR) or activated partial thromboplastin time<br/>(aPTT) is elevated? Would you still use this as organ dysfunction?

The guidance in the *Severe Sepsis Present* data element does not specify a timing relationship between when the anticoagulant was given and the elevated INR or aPTT. Because of this, you would not use an elevated INR or aPTT regardless of when the anticoagulant was given.

Question 113: Slide 46. This wording is confusing: "Documentation of a term that represents or is defined by a SIRS criteria or sign of organ dysfunction is acceptable in place of an abnormal value when documented as normal for the patient." Should it say, "not acceptable"?

No, for purposes of negating the systemic inflammatory response syndrome (SIRS) criterion or organ dysfunction, a physician/APN/PA note that includes a term defined by an abnormal value is acceptable in place of the abnormal value. For example, a physician note that indicates thrombocytopenia due to a medication is acceptable in place of a platelet count less than 100,000 due to a medication.

Question 114: Slide 46. Can you clarify if documentation of the terms that represent SIRS or organ dysfunction (OD) can be used as criteria to determine Severe Sepsis start time or can only be used to exclude criteria?

Documentation of a term that represents or is defined by an abnormal SIRS criterion or sign of organ dysfunction cannot be used to determine presence of SIRS or organ dysfunction. The actual value must be used. The terms can only be used to exclude SIRS or organ dysfunction.

# Question 115: Slide 46. Please clarify why a heart rate (HR) of 90 would not be used as a SIRS criterion since tachycardia is defined by a HR greater than 100.

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A HR of greater than 90 is one of the criteria for determining the presence of SIRS. Documenting tachycardia is not acceptable in place of a HR value for determining the presence of SIRS. Documentation of the term tachycardia is acceptable for excluding a HR greater than 90 if the documentation indicated that tachycardia was normal for the patient, due to a chronic condition or medication, or due to an acute condition with a noninfectious source.

### Question 116: Slide 46. If the patient has a HR of 108 and the physician documents "patient with chronic sinus tachycardia," would I use the HR of 108 or disregard the HR of 108?

You may disregard the heart rate of 108 based on the physician/APN/PA documentation stating tachycardia is a chronic condition for this patient.

Question 117: Slide 46. Based on previous discussion of *Severe Sepsis Present*, the following statement seems contradictory to discussions that the terms are not acceptable when documented as normal for a patient: "Documentation of a term that represents or is defined by a SIRS criteria or sign of organ dysfunction is acceptable in place of an abnormal value when documented as normal for the patient, due to a chronic condition, due to a medication, or due to an acute condition that has a non-infectious source/process." Please clarify.

This bullet point is indicating if a physician/APN/PA documented a term, such as thrombocytopenia, as being due to a medication or non-infectious condition, that using the term is acceptable instead of using the abnormal value that defines the term for purposes of negating the SIRS criterion or organ dysfunction (e.g., platelet count less than 100,000). For determining the presence of SIRS criteria or organ dysfunction, the term is not acceptable; rather, the abnormal value must be documented.

# Question 118: Slide 47. How would we abstract if the note just stated, "History of A-fib"?

You cannot use documentation of a chronic condition alone, such as "History of A-fib," for negation of a SIRS criterion or a sign of organ dysfunction. The documentation must indicate that the SIRS criterion or sign of organ dysfunction was due to the chronic condition.

Question 119: Slide 47. Regarding the statement "Hx of A-fib with tachycardia" and the exclusion of elevated HRs greater than 90, if the patient was noted to be in normal sinus rhythm, would we use the elevated HRs greater than 90? Patients with a "history of A-fib" are not always in

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# chronic/persistent A-fib. Please verify that we are to use the above statement alone to disregard the elevated HRs greater than 90.

If the physician/APN/PA documents "Hx of A-fib with tachycardia" and the heart rate is elevated, you should not use the elevated heart rates. This documentation attributes the elevated heart rates to A-fib. Additional documentation such as "in normal sinus rhythm" should be taken into consideration based upon the context in which it is used and actual heart rates.

# Question 120: Slide 48. Why would you not use the elevated HR if the patient only has a history of A-fib? Are they currently in A-fib? If not, why wouldn't you use the elevated HR?

You should not disregard elevated heart rates if the only documentation is "history of A-fib." You should disregard elevated heart rates if the physician/APN/PA documentation attributes the patient's elevated heart rate to a chronic condition.

### Question 121: Slide 48. Do we still not use the value if the patient is not in A-fib but has a HR above 90? What if the physician documents "Hx of A-fib heart rate controlled at this time"? Do we exclude the documented HR of 97?

If there is physician/APN/PA documentation attributing the elevated heart rate to a chronic condition, you should not use the elevated heart rate. Physician/APN/PA documentation "Hx of A-fib - heart rate controlled" indicates the heart rate of 97 is not due to A-fib and may be used for SIRS criteria.

### Question 122: Slide 48. Does "Hx of" mean the same as a chronic condition?

No, "Hx of" just means the patient has a history of the condition that this documentation describes. Whether or not the condition is chronic will depend on the condition itself.

# Question 123: Slide 49. Can we use the VS taken during the OR procedure to meet the data element for reassessment after crystalloid fluid infusion to check for *Persistent Hypotension*?

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Yes. The restrictions on SIRS criteria or a sign of organ dysfunction obtained within the OR, interventional radiology, during active delivery, or procedural/conscious sedation are specific for determining presence of Severe Sepsis. The *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element does not include these restrictions.

### Question 124: Slide 49. Is the catheter laboratory considered "OR"?

No, "OR" is limited to locations of the hospital identified as an "operating room."

#### Question 125: Slide 49. Is dialysis considered a procedure?

The updated guidance does not identify specific procedures, it refers to procedures during which procedural or conscious sedation was used. If documentation in the medical record indicates that procedural or conscious sedation was used, SIRS criteria or evidence of organ dysfunction met during the time of procedural or conscious sedation should not be used.

Question 126: Slide 49. Conscious sedation occurs in the ED and critical care when the patient is being intubated. This often causes hypotension with the drugs used. Should we exclude the hypotensive reading based on that?

Yes, you may disregard hypotensive readings taken during the time conscious sedation was used for intubation.

Question 127: Slide 49. Since procedural sedation can take place in many areas of the hospital, who can document start and stop times of procedural sedation?

The guidance does not specify who can document the start and stop times of procedural sedation. The documentation within the medical record must simply indicate the patient was under procedural sedation when a SIRS criterion or sign of organ dysfunction was obtained.

# Question 128: Slide 49. What is your definition of active delivery? Does it include pushing or is it during active labor?

The guidance does not define active delivery.

Question 129:	Slide 51. What type of documentation would be required to show the BPs were during the conscious sedation? Do we need provider documentation to state this?
	The guidance does not specify who can document the start and stop times of procedural sedation. The documentation within the medical record must simply indicate the patient was under procedural sedation when a SIRS criterion or sign of organ dysfunction was obtained.
Question 130:	Side 52. Can an addendum in a progress note regarding Severe Sepsis or Septic Shock be used if the patient was already discharged?
	This may depend upon the context of the documentation. Some documentation related to Severe Sepsis and Septic Shock has timing requirements. If the physician/APN/PA documented Severe Sepsis or Septic Shock was present after discharge time, the documentation of Severe Sepsis or Septic Shock would not be used.
Question 131:	Slide 53. Our clinical document improvement staff do concurrent reviews. How do you abstract if the coding query is during the admission?
	Physician/APN/PA documentation responding to a coding query during the hospital admission is acceptable.
Question 132:	Slide 53. The rule regarding sepsis present on admission, determined in a query, makes no sense as a query response is considered part of the medical record and is a legal document that follows American Health Information Management Association compliance. Please clarify.
	For SEP-1 measure purposes, there are some restrictions on when documentation must occur. Physician/APN/PA documentation of Severe Sepsis or Septic Shock on a coding query is acceptable. However, if the only documentation of Severe Sepsis or Septic Shock is after discharge time, it is not used because this generally results in cases not meeting the timing relationships SEP-1 requires.

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Question 133: Slide 53. If there is no nursing note stating that the patient had arrived in the intensive care unit (ICU) Room 2 at this time, what is the next documentation that would be enough to take as the admission time when the physician documents "severe sepsis present on admission"? Would the admission, discharge, transfer (ADT) event log, with the Unit/Room number, be enough? For example:

- 5/27/19 1830 Emergency Services
- 5/27/19 1845 OR
- 5/27/19 2315 ICU/5A2 Transfer In

If Severe Sepsis is documented as "present on admission," the earliest documented arrival time to the inpatient floor or unit would be used for the *Severe Sepsis Presentation Time*. In this scenario, the documentation of "ICU/5A2 Transfer In" at 2315 would be acceptable.

Question 134: Slide 54. Would you use the result time for all lab values, including lactic acid, rather than the collection time? Can "verified" be used as the result time, or must it say "result"?

You should use the result time of the laboratory values to determine the time of SIRS criteria or evidence of organ dysfunction for the *Severe Sepsis Present* data element. A verified time would not be used as the laboratory result time.

Question 135: Slide 54. I have been abstracting sepsis since inception and have always documented my labs as time drawn not time resulted. Have I been wrong all this time? If I have a patient with an elevated lactate level that is the third criteria to meet *Severe Sepsis Present*, was drawn at 1500, but was not resulted until 1530, does that patient meet *Severe Sepsis Present* at 1530?

While the wording was revised over time, previous versions of the specifications manual reflect the use of the reported time for lab values. If the last Severe Sepsis clinical criteria was an elevated lactate drawn at 1500 and resulted at 1530, the *Severe Sepsis Presentation Time* would be 1530.

Question 136: Slide 54. The specifications manual states to use the draw time for several of the labs. Which data elements use the result time and which data elements use the draw time?

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Data elements that use the draw time of a laboratory value have "collection" in the name of the data element. For example, the *Initial Lactate Level Collection* or *Blood Culture Collection* data elements use the time these labs were collected or drawn rather than a resulted time.

Question 137: Slide 54. Our respiratory department will do the initial lactic acid (LA) reading in our ED. It is reported on the arterial blood gas (ABG) slip or under the VS graph as "LA collected at xxxx and reported to Dr. X at xxxx." The lab will also report this same value out, but it usually has a much later time noted for both collection and result. Should I use the lab result as a second LA even if it is just the original being reported in a different format?

No, if the lactate collection documented on the vital sign graph and the lactate collection reported by the laboratory are the same lactate, this would not be considered two different lactate collections.

Question 138: Slide 57. The patient has a BP of 88/47. The admit H&P, done within 24 hours, states, "hypotensive, normal for patient," without a reference of the numerical value. Three days later, when the BP is 60/30, documentation states "BP hypotensive" in the same note. Does this indicate that this is a new level of hypotension? Would we include this as criteria of organ dysfunction?

Because the physician/APN/PA documentation of "hypotensive, normal for patient" does not specify that it only applies to the BP reading of 88/47, all hypotensive blood pressure readings should be disregarded.

Question 139: Slide 57. The term "severe sepsis" is listed under the following title:

**Chronic Medical Problems: Patient active problem list** 

Would this be considered chronic or active?

We are not able to determine whether this is considered chronic or active based on the information you provided. The guidance in the *Severe Sepsis Present* data element states, "Documentation of an infection in an active problem list is acceptable if there is information in the medical record supporting the infection is current." Since the specifications indicate the term "sepsis" is acceptable for an infection, you would consider it current or active if there is additional information in the medical record indicating that Severe Sepsis or Sepsis is a current infection.

Question 140:	Slide 58. To clarify, if a patient is on hemodialysis, are we allowed to exclude the elevated creatinine?
	No, the documentation of hemodialysis alone would not exclude the elevated creatinine value. To disregard the elevated creatinine, there must be physician/APN/PA documentation that the patient has ESRD and on hemodialysis.
Question 141:	Slide 59. "Pancytopenia" is not listed in the specifications instructions as an acceptable term in place of a specific lab value. Please clarify.
	The list of examples in the guidance of terms that represent or define an abnormal SIRS criterion or sign of organ dysfunction is not an all-inclusive list. If there is physician/APN/PA documentation indicating "pancytopenia" is normal for the patient, due to a chronic condition or medication, or due to an acute condition with a non-infectious source, you would disregard the low white blood cell count and the low platelet count.
Question 142:	Slide 60. The examples presented about chronic diseases and lab values are inconsistent. The cirrhosis example did not link the bilirubin to the cirrhosis; they were two separate sentences. For slide 58, it was said that the chronic kidney disease with elevated creatinine had to be linked and in the same statement. Why is this different?
	The example on slide 58 illustrates a situation where the physician documentation indicates presence of a chronic condition (chronic kidney disease), but the documentation does not associate the chronic kidney disease with the elevated creatinine. In this situation, you should use the elevated creatinine.
	The example on slide 60 illustrates PA documentation that associates a chronic condition and acute condition with a non-infectious source (hx of cirrhosis and ETOH abuse) with the elevated bilirubin. In this situation, the elevated creatinine would not be used because the documentation associates it with the history of cirrhosis and alcohol abuse.
Question 143:	Slide 60 and 61. The examples have symptoms related to a chronic condition. Where would a non-clinical person go to find this information?
	We recommend you consult with clinical personnel in your organization for questions on the meaning of documentation in your medical record.

Question 144:	Slide 61. The connection between the bilirubin and the condition is "obvious," but should we not abstract it that way?
	The guidance does not require explicit documentation indicating the abnormal value is "due to" a chronic condition or acute condition with a non-infectious source. Therefore, physician/APN/PA documentation associating, relating, or linking SIRS criteria or evidence of organ dysfunction to a chronic condition or acute condition with a non-infectious source is acceptable.
Question 145:	Slide 61. The first line states that the patient has abdominal pain, which is an acute condition. How do you assume that the bilirubin is due to the chronic condition and not to the acute condition that is also listed?
	The guidance indicates you should not use the elevated bilirubin whether it is due to a chronic condition or an acute condition with a non-infectious source. You would disregard the elevated bilirubin because it is included in the same documentation as the chronic condition and acute condition with a non-infectious source.
Question 146:	Slide 61. Would elevated bilirubin levels on subsequent days need to have the history of cirrhosis documented each day to not use them, or would the initial documentation of the condition allow all elevated bilirubin levels to be disregarded?
	Since the bilirubin of 6.0 is associated with the chronic condition and/or the acute condition with a non-infectious source, you would disregard all bilirubin levels of 6.0 or less. You should use bilirubin levels greater than 6.0 unless there is further physician/APN/PA documentation attributing the more severe bilirubin values to the chronic condition or acute condition with non-infectious source.
Question 147:	Hypotension or tachycardia can be caused by dehydration and dehydration can be due to a decreased oral intake. Do I still use hypotension or tachycardia if the documentation states that the decreased oral intake is due to a strep throat infection?
	You should use the hypotension as a sign of organ dysfunction if the hypotension is documented as being caused by decreased oral intake and the decreased oral intake is noted as due to a strep throat infection. The documentation indicates the cause of the hypotension is due to an infection.

Question 148:	Regarding lab-dependent indicators for organ dysfunction (e.g., platelets, creatinine, bilirubin, INR, LA), most hospitals draw labs about 0500. Considering the criteria inclusion window, when all elements should come together within the six hours, are we then unable to use the early morning labs to assess for Severe Sepsis or Septic Shock later in the day (i.e., past 1100)?
	The time the lab values are resulted must be used when determining whether Severe Sepsis criteria are met based on SIRS criterion or sign of organ dysfunction. If the lab value results time is more than six hours from other criteria it cannot be used to determine presence of Severe Sepsis or Septic Shock.
Question 149:	The initial lactate can be drawn six hours prior to or three hours after Severe Sepsis; however, the repeat lactate needs to be drawn from Severe Sepsis to six hours after.
	In this case, the initial LA was drawn at 0100 with a result of 2.2. The repeat LA was drawn at 0250 with a result of 1.2. Severe Sepsis was at 0305. Will this case fail due to the time the repeat lactate was drawn? If so, why would we fail the repeat lactate when the second lactate is drawn before sepsis criteria are met? The physicians are initiating labs and assessing the patient's status before the patient reaches Severe Sepsis, which seems like proactive, good patient care.
	The case will fail because the specifications require the <i>Repeat Lactate Level Collection</i> to occur after <i>Severe Sepsis Presentation Time</i> . We appreciate your comments and question, and we will share them with the measure stewards and measure writers for consideration in future manual updates.
Question 150:	Per the <i>Severe Sepsis Present</i> Notes for Abstraction, "If documentation of an infection is in a physician/APN/PA, nursing, or pharmacist note without a specific date and time or documented using the acronym POA, use the date and time the note was started or opened." Can this be interpreted and used for source of infection using the first time the provider opened the ED record and started documenting? Would you be able to use it even if the first provider documentation is orders, not assessment notes?

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This guidance applies for situations where the infection or source of infection is documented in the note but without a specific time. If the ED provider documented the source of infection in the note but did not include a time associated with the source of infection, you should use the earliest time reflecting the provider opened or started the ED note for the infection (criteria a) time . If the provider documented an infection within an order and there was not a separate time associated with the infection, you may use the time the order was placed or written for the infection (criteria a) time.

Question 151: In the H&P, the physician has labs listed and, under impression, has "acute kidney infection, possibly secondary to diuretic, especially spironolactone, and liver enzymes elevated possibly secondary to congestive changes from CHF." Could we disregard the elevated creatinine and bilirubin based on this documentation of noninfectious reasons for elevated values if they didn't specifically reference elevated creatinine and bilirubin?

> No, the abnormal criteria (elevated creatinine and bilirubin) need to be referenced in the documentation of the acute condition with a noninfectious source. Based on this scenario, the elevated creatinine and bilirubin values should be used.

## Question 152: If the provider documents "acute kidney injury," but the creatinine is less than 2, is that organ dysfunction?

No, a creatinine value greater than 2.0 is necessary for evidence of organ dysfunction.

Question 153: A patient has an order for a bilevel positive airway pressure (BiPAP) as needed, and the BiPAP is placed on and off intermittently for several days as evidenced on the flowsheet. Would each time the BiPAP is reapplied constitute a "new need" and would that be used for organ dysfunction?

No, in this situation, only the first time is considered the new need for mechanical ventilation. You should use only the first time BiPAP is applied as a sign of organ dysfunction.

#### Question 154: Every time there is an abnormal value result (e.g., low BPs every 15 minutes for 24 hours) must the provider document each low BP in the narrative and state it is related to something other than sepsis?

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No, if the physician/APN/PA attributed a low BP reading (e.g. 80/50) to a chronic condition, medication, or non-infectious acute condition, you should disregard all SBP readings of 80 and less severe values (i.e., 81–89). If the documentation indicated "hypotension" was due to a chronic condition, medication, or non-infectious acute condition, you should disregard all hypotensive readings because "hypotension" includes all SBP values less than 90 and MAP values less than 65.

#### Question 155: If the patient meets all criteria for *Severe Sepsis*, but the ED or admitting physician documents the International Classification of Diseases (ICD)-10 code of "Sepsis A419," do we say "Yes" or "No" to *Severe Sepsis*?

If the clinical criteria for Severe Sepsis were met, documentation of the ICD-10 code "Sepsis A419" would not negate the presentation of Severe Sepsis based on the clinical criteria. You would select Value "1" (Yes) for *Severe Sepsis Present*.

## Question 156: If the patient was diagnosed with early sepsis three days prior, then a low BP is documented once without a documented cause, is it now considered Severe Sepsis and included in the SEP-1 measure?

All three Severe Sepsis clinical criteria must be met within six hours of each other or there must be physician/APN/PA documentation of Severe Sepsis. There is insufficient information in this question to identify whether the clinical criteria or the physician/APN/PA documentation criteria for *Severe Sepsis Present* were met.

## Question 157: The physician stated, "Does not meet sepsis criteria." However, the case does meet CMS criteria at the same date and time. Does this note exclude the case or do you continue abstracting?

Since the time that the clinical criteria for Severe Sepsis were met is the same time as the documentation negating the presence of Sepsis, select Value "1" (Yes) for *Severe Sepsis Present*. The Notes for Abstraction indicate to select Value "2" (No) if, within six hours **after** documentation meeting clinical criteria, there is additional physician/APN/PA documentation indicating Sepsis, Severe Sepsis, or Septic Shock is not present.

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Question 158:	Regarding <i>Severe Sepsis</i> criteria, the education comment on a recent validation report stated that the face-to-face time (when the provider first sees the patient) is an acceptable time over the ED physician open note time, as it is earlier if the physician note is documenting an infection like pneumonia. This does not make sense, as the face-to-face time is when the provider sees the patient and not when they determine
	time is when the provider sees the patient and not when they determine an infection. Which time is the correct time to use on the ED physician note?

For questions regarding validated cases, you will need to request an Educational Review.

Per the guidance, use the specified time an infection is documented within a note. If a specified time is not available, use the time the note was opened or started.

Question 159: Regarding the timing of infection or documentation of Severe Sepsis, the process at my local hospitals is to open a note when assigned to a patient. It may be some time before they see the patient. Once the patient is assessed, the assessment is entered and counted as the "perform" time. When adding new documentation to a note that has already been started, this is counted as "modify." "Verified" and "sign" timing occur when the note is finalized and closed out. In the guidelines, it states, "If documentation of an infection is in a physician/APN/PA, nursing, or pharmacist note without a specific date and time or documented using the acronym POA, use the date and time the note was started or opened." Since the physician doesn't start it until the "perform" time documentation, can I use the "perform" time instead of the time the note was opened?

> No, per the current guidance, if a time is not specified for the documentation of an infection within a note, use the time the note was opened or started. We appreciate your comments and question, and we will share them with the measure stewards and measure writers for consideration in future manual updates.

# Question 160: Based on the discharge summary and/or coding query, the discharge diagnosis is "sepsis." However, sepsis is not documented anywhere else in the chart. Infection, two SIRS criteria, and organ dysfunction are documented. Would you still assess for *Severe Sepsis*?

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Yes, the patient is in the initial patient population if the patient has a discharge code of Sepsis. The presence of Severe Sepsis; however, is not based on discharge coding. You should review the medical record. If *Severe Sepsis Present* clinical criteria a, b, and c were all met within six hours of each other, select Value "1" (Yes).

Question 161: For *Severe Sepsis Present*, can a physician, three days later, state "severe sepsis on presentation" to make time zero 72 hours prior?

No, the documentation of "Severe Sepsis on presentation" would not reflect an earlier specified presentation time of Severe Sepsis. You would use the specified time of this documentation. If a time is not specified for this documentation, use the note-opened time as the *Severe Sepsis Presentation Time*.

#### Septic Shock Present

Question 162: Slide 62. If I have two low BPs within three hours of each other and they occur within six hours after the *Severe Sepsis Presentation Time*, would we look at the hour after the infusion amount completed and abstract "Yes" to *Septic Shock Present* if it ends on two low BPs?

Yes, for the *Septic Shock Present* data element, if two hypotensive BP readings were documented at the end of the hour to assess for *Persistent Hypotension*, select Value "1" (Yes) based on Severe Sepsis with *Persistent Hypotension*.

Question 163: If there is both *Initial Hypotension* and *Septic Shock Present*, is the earliest or latest time used for fluids?

You should use the time of the earliest triggering event, *Initial Hypotension* or *Septic Shock Present*, to determine the timeframe for acceptable crystalloid fluids.

Question 164: If a patient has an LA of 4 or higher that is not the initial LA and the patient met *Severe Sepsis Present*, would we say "No" to *Septic Shock Present* since the initial LA wasn't 4 or higher?

Correct, if the *Initial Lactate Level Result* was not greater than or equal to 4.0, select Value "2" (No) for *Septic Shock Present*. Criteria would not be met based on Severe Sepsis with an *Initial Lactate Level Result* greater than or equal to 4.

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# Question 165: If lactate levels are disregarded for *Severe Sepsis Present* due to physician documentation that the elevated lactate is due to liver disease, would a lactate greater than 4 still be used as criteria for *Septic Shock Present*?

No, if all elevated lactate levels are disregarded because of documentation indicating they are due to a condition that is not an infection, select Value "1" (Yes) for the *Initial Lactate Level Result*. The initial lactate would then not be used to meet *Septic Shock Present* clinical criteria.

## Question 166: Where do you enter the physician documentation of Septic Shock? Is it under the *Septic Shock Present* data element?

Yes, if there is physician/APN/PA documentation of Septic Shock, select Value "1" (Yes) for the *Septic Shock Present* data element.

#### Other Data Elements/Questions/Comments

Question 167: If the physician reviews ED/admission notes and one to three days later, but before discharge, uses *Sepsis Present on Admission* as a problem, do we count these? They are being coded as Sepsis; however, no additional testing/interventions are done and the case falls out.

Having a Sepsis ICD-10 code makes the patient eligible for the initial patient population. Severe Sepsis must be present based on clinical criteria or physician/APN/PA documentation of Severe Sepsis as described in the *Severe Sepsis Present* data element. There is not sufficient information in this question to determine whether *Severe Sepsis Present* criteria were met.

Physician documentation of "sepsis present on admission" only meets *Severe Sepsis Present* criteria a (infection). You should use the earliest documented date and time the patient arrives to the floor or unit for admission as the time of the infection (criterion a). To meet all three criteria, there must also be two or more SIRS criteria (criterion b) and a sign of organ dysfunction (criterion c), all documented within six hours of each other.

Question 168:Why would a case fail "repeat lactate" when the second lactate is<br/>drawn before sepsis criteria are met? Physicians are initiating labs and<br/>assessing the patient's status before the patient reaches Severe Sepsis.<br/>For example, the initial lactate was 2.2 at 2340; the repeat lactate was<br/>1.2 at 0140; and Severe Sepsis criteria were met at 0305.

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The case would fail because the specifications require the *Repeat Lactate Level Collection* to occur after *Severe Sepsis Presentation Time*. We appreciate your comments and questions, and we will share them with the measure stewards and measure writers for consideration in future manual updates.

#### Question 169: If a patient receives antibiotics out in the field does that affect *Blood Culture Collection* in the hospital?

No, *Blood Culture Collection* must still occur within the specified timeframe. However, if the *Blood Culture Collection Time* is after the *Broad Spectrum or Other Antibiotic Administration Time*, the case will reach the *Blood Culture Collection Acceptable Delay* data element. Since antibiotics were started prior to hospital arrival and the blood culture was drawn after the pre-hospital antibiotics were started, select Value "1" (Yes) for the *Blood Culture Collection Acceptable Delay* data element.

#### Question 170: Where can antibiotic tables 5.0 and 5.1 be found?

Antibiotic tables 5.0 and 5.1 are in Appendix C of the specifications manual.

#### Question 171: Why is Lovenox not included in the anticoagulants list?

Lovenox is not included on Table 5.3 of anticoagulants due to the minimal impact of this medication on the INR or aPTT.

Question 172: We are reviewing the same types of questions and not new data elements at each webinar. These same questions are continuously being asked in the Q&As, as evidenced by the past webinar Q&A transcripts. This means that the current methods used to teach abstractors is not working for Sepsis. When can we have a live Q&A back-and-forth interactive training session or live in-person training?

> Due to the variety of scenarios and medical record documentation, as well as the continual influx of new abstractors, the webinars are intended to review measure updates and questions that address general scenarios and examples. We appreciate your comments and question and are exploring the potential for other types of training.

Question 173:	How can CMS publish SEP-1 scores and include them in pay-for- performance programs when these questions show there is little consistency in abstracting these cases?
	CMS has not yet made a decision regarding inclusion of SEP-1 in the Hospital Value-Based Purchasing (VBP) Program. SEP-1 data continue to demonstrate improvement in measure performance each quarter. CMS reviews and considers abstractor and provider feedback when making guidance updates, with the goal of improving clarity and reducing abstraction burden.
Question 174:	Will the SEP-1 measure be included in the Hospital VBP Program?
	CMS has not yet made a decision regarding inclusion of SEP-1 in the Hospital Value-based Purchasing Program.
Question 175:	Version 5.6 guidelines are effective for which discharge quarters?
	CMS Specification Manual v5.6 applies to discharges for third and fourth quarters 2019.
Question 176:	Do we need to wait until July 1, 2019 discharges to include these updates in abstractions?
	Yes, the updates provided in CMS Specification Manual v5.6 do not apply to discharges prior to July 1, 2019.