



# Inpatient Quality Reporting Program

## Support Contractor

### SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock Part II

#### Questions and Answers

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**September 21, 2015**

**2 p.m. ET**

*The answers contained in this document were answered using the Specifications Manual for National Inpatient Quality Measures, Version 5.0a (Discharges 10/01/2015 through 06/30/2016). Please note that as the manual and the SEP-1 specifications are updated, these answers may no longer be valid. Please review the most recent specifications manual for the reporting period on QualityNet.*

#### **Antibiotics**

**Question 1:** Is documentation of infection limited to bacterial sources of infection? Are infections of fungal or viral sources included and expected to be treated with antibiotics?

**Answer 1:** The focus of SEP-1 is bacterial infections. As such, fungal and viral infections are excluded. Language changes to address this are forthcoming.

**Question 2:** A physician is concerned with the antibiotic list available in the specifications manual. If you follow the suggested antibiotic treatments from up-to-date, some of these antibiotics are not available to choose from the list in the Specifications Manual. Even if you look at Dr. Townsend's research for specific antibiotic treatment when source is known, they do not match the options in the Specifications Manual.



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**Answer 2:** Keep in mind the antibiotics listed in Table 5.0 and 5.1 in Appendix C are for Broad Spectrum application. Because of this, they will not necessarily match antibiotic treatment options when the source is known. These tables are ONLY used when the patient's only dose of antibiotics is received in the 3 hours following severe sepsis presentation.

### Crystalloid Fluids and IV Infusion

**Question 3:** Tissue hypoperfusion in the hour after crystalloid fluid is defined by the measure specification as systolic blood pressure (SBP) < 90, or mean arterial pressure (MAP) < 65, or a SBP drop > 40 from patient normal, or lactate level > 4. Is the lactate level referenced here the initial lactate or one after the fluid, as suggested by the definition?

**Answer 3:** The lactate level to use is the *Initial Lactate Level Result*.

**Question 4:** There appears to be some conflicting information regarding the septic shock definition. The *CMS Specification's Manual for Severe Sepsis/Septic Shock*, in the "Septic Shock Present" data element under "Notes for Abstraction," indicates "The criteria for determining that Septic Shock is present are as follows:

- a. There must be documentation of severe sepsis present.
- b. Tissue hypo perfusion persists after crystalloid fluid administration, evidenced by either SBP < 90, or MAP < 65, or a decrease in systolic blood pressure by > 40 points or Lactate level is > 4 mmol/L; example 1: Patient A met all criteria for Severe Sepsis (answered Value "1" to Data Element Severe Sepsis Present). Initial lactate level was 4.4. Choose Value "1" for Septic Shock Present." In these criteria, severe sepsis in the presence of a lactate level greater than 4 constitutes septic shock. However, in the "Frequently Asked Questions- SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock" from *QualityNet* (QNET), it is stated "By definition, septic shock is severe sepsis with hypotension or lactate  $\geq$  4 not responding to administration of crystalloid fluids (30 ml/kg). The 30 ml/kg of crystalloid fluids are only required to be administered if hypotension (or lactate  $\geq$  4) is actually present." According to this explanation, septic shock is not defined by the mere presence of a lactate greater than or equal to 4, but by a lactate level greater than or equal to 4 that does not respond to fluid resuscitation.

**Answer 4:** This represents a typographical error in the *QualityNet* FAQ response. This has been corrected.



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- Question 5:** I thought that "Septic Shock Present" requirements were either persistent hypotension after crystalloid fluid administration or Lactate  $\geq 4$ . When are the fluids supposed to be administered? If the Lactate is  $< 4$ , then the only other thing that shows that the patient has septic shock would be hypoperfusion after fluid administration.
- Answer 5:** Correct, septic shock is identified based on clinical criteria of severe sepsis with persistent hypotension (hypotension not responding to 30 ml/kg of crystalloid fluids) OR severe sepsis with an initial lactate  $\geq 4$ . For a case where septic shock is present based on persistent hypotension, the 30 ml/kg of crystalloid fluids must be given in order to identify persistent hypotension and septic shock. For a case where septic shock is present based on an initial lactate  $\geq 4$ , the crystalloid fluids are given after the presence of septic shock is identified.
- Question 6:** In patients that have congestive heart failure (CHF) with ejection fraction (EF)  $< 35\%$ , are Crystalloid Fluids of 30 ml/kg still recommended?
- Answer 6:** Yes, the measure does not exclude cases from the 30 ml/kg crystalloid fluid infusion. Trials of fluid administration for severe sepsis and septic shock have included cases with co-morbidities, such as CHF, and have not noted any deleterious effects from the fluid infusion. We are not aware of any studies of severe sepsis and septic shock indicating that fluids should not be given for cases with co-morbidities such as these. There are two points to keep in mind. First, the measure does not specify the infusion rate or duration for the 30 ml/kg, other than it must be greater than 1000 ml over 8 hours (125 ml/hour). As such, fluids could be given at a more conservative rate and still be equivalent to 30 ml/kg. Secondly, SEP-1 is not a mandate for care. If the physician feels, in their best judgment, that 30 ml/kg, even given at a conservative rate, is not appropriate for a given patient, they should exercise their best clinical judgment.
- Question 7:** Can you address fluid bolus in patients with known CHF or End Stage Renal Disease (ESRD) and when fluids may be contraindicated?
- Answer 7:** The measure does not exclude cases from the 30 ml/kg crystalloid fluid infusion. Trials of fluid administration for severe sepsis and septic shock have included cases with co-morbidities such as these, and have not noted any deleterious effects from the fluid infusion. We are not aware of any studies of severe sepsis and septic shock indicating that fluids should not be given for cases with co-morbidities such as these. There are two points to keep in mind. First, the measure does not specify the infusion rate or duration for the 30 ml/kg other than it must be greater than 1000 ml over 8 hours (125 ml/hour).



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As such, fluids could be given at a more conservative rate and still be equivalent to 30 ml/kg. Secondly, SEP-1 is not a mandate for care. If the physician feels, in their best judgment, that 30 ml/kg even given at a conservative rate is not appropriate for a given patient they should exercise their best clinical judgment.

**Question 8:** Are there any restrictions or exclusions for the volume requirements for patients with CHF on the fluid resuscitation? My physicians are concerned with giving 30 ml/kg for patients who are at risk for volume overload.

**Answer 8:** The measure does not exclude cases from the 30 ml/kg crystalloid fluid infusion. Trials of fluid administration for severe sepsis and septic shock have included cases with co-morbidities such as these and have not noted any deleterious effects from the fluid infusion. We are not aware of any studies of severe sepsis and septic shock indicating that fluids should not be given for cases with co-morbidities such as these. There are two points to keep in mind. First, the measure does not specify the infusion rate or duration for the 30 ml/kg other than it must be greater than 1000 ml over 8 hours (125 ml/hour). As such, fluids could be given at a more conservative rate and still be equivalent to 30 ml/kg. Secondly, SEP-1 is not a mandate for care. If the physician feels, in their best judgment, that 30 ml/kg even given at a conservative rate is not appropriate for a given patient, they should exercise their best clinical judgment.

**Question 9:** A patient has Severe Sepsis. The BP dropped to 62/39 @ 1400, Dopamine was started at 1430 and Levophed at 1443; an NS 500 ml bolus was given at 1753. What do I answer to Crystalloid Fluid administration? If MD aggressively starts the patient on vasopressor instead of administering crystalloid fluids initially, would we answer crystalloid fluid NOT administered at/after presentation of septic shock?

**Answer 9:** That is correct; you would answer crystalloid fluid NOT administered at/after presentation of septic shock. Guidelines recommend starting crystalloid fluids as first line.

**Question 10:** For hypoperfusion the rules say to abstract 1 hour after crystalloid fluid end time. Is that after the first bolus given or at the end of ALL crystalloid fluids given?

**Answer 10:** This would be the time after 30 ml/kg was given, which would likely correspond to the end of ALL crystalloid fluids given for fluid resuscitation.



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- Question 11:** If the crystalloid infusion time frame indicates 'bolus,' is that adequate or does the order need to give a time frame for infusion?
- Answer 11:** The order needs to specify a time frame over which to infuse, or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 12:** Does "bolus" count as a rate for crystalloid fluid administration?
- Answer 12:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 13:** Can the crystalloid fluid bolus be greater than 30cc/kg and still meet the measure for fluid administration?
- Answer 13:** Yes, 30 ml/kg is the target volume recommended in the guidelines. In some cases, more than this volume may be given.
- Question 14:** Regarding crystalloid fluids: 1) Does the order have to include time frame if it is clear by the medical record, nurse note, or intake and output (I&O) sheet that it can be demonstrated as given as bolus over short time? 2) Can fluids given with meds be included?
- Answer 14:** 1) As the specifications are currently written, the order must include a time frame over which to infuse the fluids or an administration rate. The term "bolus" is not acceptable.  
2) Fluids given to dilute meds or flush lines are not acceptable. The fluids to include are those given for the purpose of fluid resuscitation.
- Question 15:** If the order for the crystalloid fluid is written as a "bolus" and we have a start time and a completion time, can we select allowable value "1" (yes) since we have a start and stop time?
- Answer 15:** Yes, as the specifications are currently written, the order must include a time frame over which to infuse the fluids or an administration rate. The term "bolus" is not acceptable.
- Question 16:** What if MD order just says "bolus" for crystalloid fluids and on medication administration record (MAR) it specifies time of start/completion?
- Answer 16:** Yes, as the specifications are currently written, the order must include a time frame over which to infuse the fluids or an administration rate. The term "bolus" is not acceptable.



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- Question 17:** What allowable value should be selected regarding Crystalloid Fluid Administration? Is the term bolus or wide open but not a specific rate?
- Answer 17:** The *Crystalloid Fluid Administration* Notes for Abstraction indicate if a fluid volume is ordered, but there is no order for the time over which the IV fluids are to be given, choose Value "2."
- Question 18:** If the patient target crystalloid fluid amount is 1950 ml and the physician documents possible septic shock and orders 2L normal saline (NS) IV bolus, and the IV fluid record indicates the total 2L was infused 1.5 hours after the order, would this pass the measure, even without a time duration given, but the physician ordered bolus (wanting it in as fast as the patient can tolerate) and more than the target volume that was given?
- Answer 18:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 19:** The Frequently Asked Questions on the *QualityNet* website state: "Q: If there is documentation of actual fluid administration, does there need to be a corresponding order to consider the fluid as part of the 'crystalloid fluids administered'? Can the documentation of fluid administration within the nurses' notes be used to determine if the appropriate amount of crystalloid fluids were administered? The crystalloid fluid administration data element's Notes for Abstraction indicate the measure is considering clear documentation in the medical record as evidence the crystalloid fluids were actually administered. This would include volume given, date, and time of administration. Since the nurses' notes include a date and time, and states normal saline was given as IV bolus, and the amount is equivalent to 30 ml/kg, this documentation would be acceptable for selecting "Yes" for this data element." Therefore, is a provider order necessary or not?
- Answer 19:** There must be a physician order for crystalloid fluids. The order must reflect a total of 30 ml/kg was ordered. The order, however, is not used to confirm whether or not 30 ml/kg were actually given. The documentation in the nurses' notes or IV flow sheet is what is used to determine whether or not 30 ml/kg of crystalloid fluids were actually given.
- Question 20:** Page 4 of the Centers for Medicare & Medicaid Services' (CMS') FAQ has a question about whether you can use nursing documentation of actual fluid administration in the absence of a physician order to be able to answer "Yes" for the data element Crystalloid Fluids Administered. The answer states that "since the nurse's note includes a date and time, and states normal saline was



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given as IV bolus, and the amount is equivalent to 30 ml/kg, this documentation would be acceptable for selecting “Yes” for this data element.” This seems to be in contradiction to the requirement that the physician order must specify a rate or duration for the crystalloid fluid administration, specifically because it indicates that you can answer “Yes” in the absence of a physician order. Please clarify.

**Answer 20:** There must be a physician order for crystalloid fluids. The order must reflect a total of 30 ml/kg was ordered. The order, however, is not used to confirm whether or not 30 ml/kg were actually given. The documentation in the nurses’ notes or IV flow sheet is what is used to determine whether or not 30 ml/kg of crystalloid fluids were actually given.

**Question 21:** For the Focused Exam component, does crystalloid fluid administration time refer to when the fluid bolus starts or the time the 30 ml/kg infusion had ended?

**Answer 21:** Crystalloid fluid administration time, for purposes of the Focused Exam, refers to when the fluids were started.

**Question 22:** Many of our patients are already on pressors at the time of presentation for septic shock, which are then titrated to increase blood pressure. Are they still required to administer 30 ml/kg crystalloids, especially since many had already given fluid boluses prior to initiation of the pressors but outside time zero?

**Answer 22:** The measure does require the administration of 30 ml/kg of crystalloid fluids. These fluids can be administered prior to septic shock presentation. The latest they can be started and count for the measure is within 3 hours of septic shock presentation. It is conceivable that crystalloid fluids could be given and vasopressors started prior to septic shock presentation, and still meet the intent of the measure. It will all depend on the timing of events.

**Question 23:** Our MAR lists: sodium chloride 0.9% bolus infusion 1,000 mls. Is this considered the same as Normal Saline? Are there any other descriptions for Normal Saline or Lactated Ringers?

**Answer 23:** Normal Saline is a 0.9% solution of sodium chloride, so it is the same thing as sodium chloride 0.9%. You will need to check with your pharmacy to see if there are other terms in your formulary or medical record that correspond to normal saline or Lactated Ringers.



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- Question 24:** Does the IV bolus infusion of 30 ml/kg need to be completed by the end of the 3 hours of presentation or just initiated?
- Answer 24:** The 30 ml/kg infusion needs to be started within 3 hours of septic shock presentation, not completed.
- Question 25:** Administer 30 ml/kg wide open nurses' documentation lists bolus started at 1300 infusion completed 1445. Will this answer "Yes" because you have amount and a start and end time?
- Answer 25:** For *Crystalloid Fluid Administration*, there must be a physician order or orders equivalent to 30 ml/kg. Each order must include an infusion duration or infusion rate. There must also be documentation that the infusion was started within 3 hours of septic shock presentation.
- Question 26:** Does 'bolus' count towards duration of administration?
- Answer 26:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 27:** Is "BOLUS" an acceptable way to order IV fluids?
- Answer 27:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 28:** In fluid bolus, can a fluid bolus that was given before presentation time of severe sepsis be the start time of fluid administration? If started prior to presentation time, until how many hours before can it be abstracted?
- Answer 28:** Yes, crystalloid fluids started prior to severe sepsis or septic shock presentation can count. There is not a specific time limit.
- Question 29:** Slide 54 makes no sense. An earlier slide said fluid bolus is >125 ml/hour. Shock time is 0900. The patient on this slide gets 2.5 ml up within 5 hours. That meets bolus rate per prior definition. Please clarify.
- Answer 29:** Slide 54 is referring to a situation where the 30 ml/kg is ordered and given over a series of fluid boluses. The third order is when it is apparent the physician is ordering 30 ml/kg. Prior to the third order, it is not known whether or not the orders will be equivalent to 30 ml/kg. As such, the date and time this infusion is started is the date and time that should be entered for the start of the 30 ml/kg bolus. Because the third order, which is equivalent to 30



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ml/kg, is written and given more than 3 hours after presentation of septic shock, the algorithm will assign category D. This case will fail the measure.

**Question 30:** Is the ER-stated weight okay for calculating fluid resuscitation? Also, if patient blood pressure improves after partial bolus, will he/she be required to receive the entire amount or needs to be stopped in a patient with CHF?

**Answer 30:** An ER-stated weight is acceptable for calculating the target fluid volume. The entire 30 ml/kg is required to pass the measure. There are no exclusions for patients with co-morbidities such as CHF.

**Question 31:** Are multiple bolus orders of IV fluid totally the necessary amount of fluid acceptable, e.g., patient 50 kg, necessary total is 1500 ml, two orders for 1000 ml NS bolus ordered and given?

**Answer 31:** This is acceptable, as long, as each order contains a time frame over which to infuse it or an infusion rate.

**Question 32:** If a patient comes in with an urinary tract infection (UTI) and vital signs (VS)/MAP is within normal parameters but they give 1-2 L of NS and then the patient's MAP drops <65, do they finish the order and add a bolus to the original initial bolus to reach 30mg/kg or do they begin with a new order of 30mg/kg? Is there a time limit of how far apart the fluids are given?

**Answer 32:** The original bolus given prior to septic shock presentation can be included to reach the total target volume of 30 ml/kg. There really is not a time limit for how far apart the fluid boluses are, with the exception that in the case of multiple orders and infusions, the last one ordered to meet the equivalent of 30 ml/kg must be ordered and started within 3 hours of septic shock presentation to pass this part of the measure.

**Question 33:** Can we use the start time for the next fluid bag as the stop time for the bolus?

**Answer 33:** If you do not have a stop time and are not able to determine it based on the infusion duration time or rate in the order, the start time for the next fluid bag could possibly be used. However, there is not enough information in this question to provide a definitive response.

**Question 34:** Fluid challenge: Is the wording "fluid" required for the fluid challenge? For example, is "bolus" alone acceptable?

**Answer 34:** For the *Fluid Challenge Performed* data element, an order for a fluid challenge, fluid bolus, rapid fluid infusion, or similar terminology followed by



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specification of the IV fluid, volume, and time to infuse is acceptable. In addition, there must be documentation this order was actually carried out.

**Question 35:** Does the total volume of crystalloid fluids need to be infused within 3 hours (i.e., 4500 ml to infuse over 3 hours)? This could have started prior to the presentation of septic shock.

**Answer 35:** The equivalent of 30 ml/kg must be started within 3 hours of septic shock presentation, but does not need to be totally infused. Yes, it could be started prior to presentation of septic shock. Within 3 hours of septic shock presentation identifies the latest time it can be started and still pass this part of the measure.

**Question 36:** Slide 14 indicates resuscitation with 30 ml/kg crystalloids fluids needs to be completed within 3 hours of presentation of septic shock. However, slide 53 (What About Multiple Crystalloid Infusions?), example 2 states “1 added to counter and case continues.” In this example, the last order is 1000 ml over 1 hour started at 12:40, which means the 30 ml/kg would be completed by 13:40. Septic shock presentation time is 10:00; so, it would be over 3 hours for completion of the 30 ml/kg.

**Answer 36:** Slide 14 states "Within 3 hours of presentation of Septic Shock, resuscitation with 30 ml/kg of crystalloid fluids." This is the wording in the numerator statement. It does not state the fluids must be totally infused within 3 hours of Septic Shock presentation. As further clarified in other slides and in the calculations within the algorithm, the infusion must be started within 3 hours of septic shock presentation to pass this part of the measure.

**Question 37:** If the total 30 ml/kg is 3000 cc and the patient receives 1000 in ambulance prior to arrival, then physician orders and an additional 2 liters are given after arrival and within 3 hours of septic shock, would that be acceptable?

**Answer 37:** Yes.

**Question 38:** There are others symptoms of organ dysfunction that meet the definition of severe sepsis. If 30cc/kg is administered after severe sepsis presentation without previous hypotension (e.g., fluid given for elevated lactate), would an episode of hypotension within the hour following 30 cc/kg fluid administration still be considered persistent hypotension? Or does the patient also have to have hypotension prior to fluid resuscitation?

**Answer 38:** Clinically the situation you describe would represent septic shock. The measure however does not currently account for this because it references



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hypotension not responding to 30 ml/kg of crystalloid fluids. Based on the current wording in the manual, this would not be considered a case of septic shock for purposes of the measure.

**Question 39:** Septic shock presentation, per the manual, is based on the presence of severe sepsis, persistent hypotension after crystalloid therapy, or a lactate level  $\geq 4$  mmol/L. It does not need the administration of vasopressors to determine the presence of septic shock that slide 14 indicates.

**Answer 39:** Slide 14 does not state that the presence of septic shock is dependent on vasopressor administration. It indicates that within 3 hours of presentation of Septic Shock, 30 ml/kg of crystalloid fluids are given; AND ONLY if hypotension is persistent, then vasopressors are given with 6 hours of septic shock presentation; AND ONLY if hypotension persists or the initial lactate  $\geq 4$ , then a repeat volume status and tissue perfusion assessment must be performed.

**Question 40:** If during the crystalloid fluid administration the patient was hypotensive and the physician orders a vasopressor to start prior to completion of the crystalloid fluid administration; so, with the vasopressor infusing, there is not a SBP  $< 90$  or a MAP  $< 65$ .

**Answer 40:** This is a difficult question to respond to without specific times and physiologic parameters associated with those times. It is possible for a patient to be receiving crystalloid fluids and vasopressors prior to the presentation of septic shock and still pass this part of the measure.

**Question 41:** In the SEP-1 Specification Manual (5.0a), the “Persistent Hypotension” section under the 'N' algorithm indicates abstraction of allowable values 2, 3, or 4 should progress to “Initial Lactate Level Result,” and then the cases with a lactate result  $\geq 4$  (allowable value 3) bypass the remainder of 'N' and proceed to 'O'. Conversely, under the 'Persistent Hypotension' section of the 'W' algorithm, allowable values 3 and 4 automatically fall into the 'D' portion of the measure population and only allowable values 1 and 2 progress to either 'Shock Vasopressor Six Hour Counter' or 'Initial Lactate Level Result'. Refer to slides 55 and 59 of this presentation. Can you please clarify how the initial lactate relates to the persistent hypotension algorithm? Can you repeat what “O” means? What are the implications of a patient who has an initial lactate greater than 4, who receives the appropriate volume of crystalloid fluids and responds well (BP goes up, no hypotension, lactate decreases to  $< 4$ , does one pass or fail the measure for this type of scenario?



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- Answer 41:** If persistent hypotension is not present, the initial lactate can be used to identify whether or not septic shock is present. If the lactate result is  $\geq 4$  (value 3) the case is directed to "O." "O" is an off-page connector that directs the case to focused exam data elements. If a patient has septic shock, the reassessment of volume status and tissue perfusion is required. If the patient does not have septic shock (persistent hypotension not present and lactate  $< 4$ ), then they are directed to the end of the algorithm and do not need to have the reassessment of volume status and tissue perfusion. If a patient has an initial lactate  $\geq 4$  (regardless of BP), they have septic shock and should receive 30 ml/kg of crystalloid fluids. If they get the fluids, the case needs to have the reassessment of volume status and tissue perfusion. Assuming this is done correctly, the case should pass this part of the measure. The value for the repeat lactate is not factored into the SEP-1 measure.
- Question 42:** For persistent Hypotension – Crystalloid Fluid Conclusion, do we need to see an end time for crystalloid or can we "assume" that if it started at 10 a.m. and was ordered for 3000 ml at 1000/ml per hour, that will be done at 1300?
- Answer 42:** You do not need a specific end time documented. If one is not documented, you can estimate the end time using the data and logic in your question.
- Question 43:** Slide 69: would only go to category D if persistent hypotension in one hour after crystalloid fluid administration was completed and vasopressor not given within 6 hours of that time, correct?
- Answer 43:** Correct.
- Question 44:** When you stated on slide 25 that if crystalloid fluids were not administered after the presentation date and time of severe sepsis, select allowable value 2, does that also apply to patients with initial lactate levels of  $> 4$  even though these patients do not need the persistent hypotension after fluids to determine septic shock?
- Answer 44:** As the specifications are currently written, yes this would be the case. Patients should, however, be given the crystalloid fluids if they have severe sepsis with an initial lactate  $\geq 4$ , because this represents a state of hypoperfusion.
- Question 45:** For cases of severe sepsis with hypotension where the intravenous fluids (IVF) at 30 ml/kg are not ordered but vasopressors are started early on, if 'septic shock' is not documented by a provider, the abstraction for the shock presentation question would be 'no' and the crystalloid question 'No,' correct? And, the measure would be excluded or failed? The abstractor cannot determine shock without the IVF being given, correct?



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- Answer 45:** Correct, for purposes of the measure, if a patient has severe sepsis with hypotension and 30 ml/kg are not given they are not considered to have septic shock. In cases with hypotension, it is the lack of response to the crystalloid fluids that defines the presence of septic shock.
- Question 46:** If a patient meets the criteria for severe sepsis and becomes hypotensive at 80/52 but never receives crystalloid fluids, how would you assess for septic shock? (Assuming lactate is less than 4)
- Answer 46:** You could not assess the patient for septic shock. The lack of response to crystalloid fluids for a patient with severe sepsis and hypotension is what determines the presence of septic shock. If they were hypotensive but never received fluids, they would not have septic shock.
- Question 47:** Do you mean within the hour after infusion of fluids (i.e., fluids in at 2 p.m. and between 2–3 p.m. patient is still hypotensive) or must they be hypotensive after 3 p.m.?
- Answer 47:** Persistent hypotension, for the purposes of SEP-1, is identified within the hour following infusion of fluids. If fluids were completed at 2 p.m., then hypotension must be present in the hour following, from 2–3 p.m., to be considered septic shock for the purposes of the measure. Clinically, patients exhibiting hypotension later should still be treated for septic shock.
- Question 48:** I understand septic shock must develop within 1 hour of fluid infusion. I have a patient who had severe sepsis that did not progress to shock but two days later had persistent hypotension that did not respond to fluids. Would that restart the clock for a new severe sepsis/septic shock or does septic shock have to follow the initial severe sepsis used for the core measure?
- Answer 48:** The episode of septic shock needs to be within 6 hours following severe sepsis presentation. A patient would not be abstracted for septic shock if the septic shock occurred more than 6 hours after severe sepsis presentation. You would select value "2 (No)" for Septic Shock Present.
- Question 49:** There are other symptoms of organ dysfunction that meet the definition of severe sepsis. If 30 cc/kg is administered after severe sepsis presentation without previous hypotension (e.g., fluid given for elevated lactate), would an episode of hypotension within the hour following 30 cc/kg fluid administration still be considered persistent hypotension, or does the patient also have to have hypotension prior to fluid resuscitation?
- Answer 49:** Same as question #48



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- Question 50:** Can we count fluids given by EMS prior to arrival to count towards the 30 ml/kg?
- Answer 50:** Fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 51:** Last meeting did you all say that fluids given by EMS prior to arrival to ER do not count towards the total fluid required by the sepsis protocol?
- Answer 51:** Fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 52:** Previous presentations of specs suggested fluids administered by EMS, such as paramedics in ambulance transport, could be included for total volume infusion towards target 30 ml / kg. Is this still accurate? What are criteria?
- Answer 52:** Fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 53:** For presentation in the ED, can fluids given by EMS be used?
- Answer 53:** Fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 54:** Our facility tracks fluids administered by EMS for sepsis patients. Would this be allowed as fluid prior to septic shock dx?
- Answer 54:** Fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 55:** Can we use volume infused by EMS when determining fluid total?
- Answer 55:** Fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 56:** Can EMS fluid boluses be used for Crystalloid Fluid administration volume?
- Answer 56:** Yes, fluids given by EMS prior to arrival can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 57:** If the patient becomes septic days into the admission, would the time the sepsis is identified be our start time for data collection or is this only on admission for these patients?



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- Answer 57:** Data collection for the SEP-1 measure is for the first episode of severe sepsis or septic shock, regardless of when it occurs during the hospital stay.
- Question 58:** Could you please clarify: one slide indicates crystalloid administration can be calculated based on the order that states start time, rate, and duration (allowing you to estimate end time) while another of your slides indicates documentation must be clear that crystalloid fluids that were actually administered, i.e., documented end time?
- Answer 58:** Documentation must be clear the crystalloid fluids were actually administered and indicate a date and time documented when they were started. If the completion time or the infusion end time was not documented, you can estimate this based on the time the infusion was started and the infusion duration or rate stated in the order.
- Question 59:** Can you use an actual time of crystalloid fluid conclusion time that is charted or do you always calculate the end time?
- Answer 59:** If there is an end time documented, you should use that. You would calculate an estimated time if the end time was not documented.
- Question 60:** What time do we use if there is no end time for crystalloid fluids?
- Answer 60:** As illustrated in slides #22 and #58, if a time is not documented when the crystalloid fluids were completed, this can be estimated based on the start time of the fluids and the infusion duration or rate specified in the order. If the order states to give 2000 ml over 1 hour, add 1 hour to the time the 2000 ml infusion was started to estimate an end time.
- Question 61:** For the focused exam (e.g., Cap Refill) the suggested question indicates the time window beginning at crystalloid fluid administration date and time and ending 6 hours after sepsis shock presentation date and time. Is that crystalloid fluid admin start date and time or completion date and time? Can the focused exam be performed prior to completion of crystalloid fluid admin?
- Answer 61:** The time window for the Focused Exam elements starts when the crystalloid fluids are started. Ideally the focused exam should be completed after fluids are completely infused. It would be appropriate, however, to be assessing the patient as fluids are being infused. As such, a focused exam completed prior to the fluids being completely infused would be acceptable.



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- Question 62:** We have been told that if multiple crystalloid infusions are ordered, that we should use the date and time of the first infusion, not the last infusion as mentioned on slide 51. When did this information change?
- Answer 62:** This is based on a more thorough evaluation of the specifications and intent of the crystalloid fluid administration data elements. We recognize the wording in the data elements is currently not very clear on this point, and we are working to clarify for a future version of the manual.
- Question 63:** How much time prior to septic shock presentation can we use the crystalloid volume? Is this 3 hours prior to septic shock presentation?
- Answer 63:** There currently is not a time frame for how much time prior to septic shock presentation the fluids can be used. However, any fluids given prior must be given at a rate of greater than 125 ml/hour. Fluids running at a rate slower than this are not acceptable to count toward the 30 ml/kg volume.
- Question 64:** Regarding slide 81, the notes for abstraction in the Specifications Manual v5.0a does not indicate abstraction of CVP and ScvO<sub>2</sub> after crystalloid fluid administration. The notes for abstraction of these measures indicate "abstract the first one that occurs after the time and date of septic shock presentation." The suggested data collection question is "what is the earliest time at which a central venous oxygen measurement was obtained after the presentation of septic shock?" Please indicate if this is an error in the Specifications Manual.
- Answer 64:** There is not an error in the manual or in the slide. Slide 81 is a general slide identifying the general time frame within which to look for information and the allowable values for all of the "Any Two" data elements (CVP, ScvO<sub>2</sub>, Bedside Cardiovascular Ultrasound, and the Passive Leg Raise or Fluid Challenge). You will note on subsequent slides (#86 and 87) that are specific to CVP and ScvO<sub>2</sub>, there is a point to "... abstract the first one after Septic Shock presentation date and time."
- Question 65:** Regarding physician Focus Exam calculated from crystalloid fluid administration date and time or time IV fluids started, if the patient received more than one IV to meet the fluid amount requirement, do we use the time that the first IV was started or the time that the last IV was started?
- Answer 65:** You will use the time the infusion that completes the 30 ml/kg total volume was started.
- Question 66:** Is there any time limit as to the crystalloid administration is allowed PRIOR to septic shock presentation?



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- Answer 66:** There currently is not time frame for how much time prior to septic shock presentation the fluids can be used. However, any fluids given prior must be given at a rate of greater than 125 ml/hour. Fluids running at a rate slower than this are not acceptable to count toward the 30 ml/kg volume.
- Question 67:** When should the crystalloid fluid administration be used, as opposed to the fluid challenge guidelines in Spec Manual?
- Answer 67:** A fluid challenge occurs after the 30 ml/kg of crystalloid fluids for fluid resuscitation are given. If a patient with septic shock does not respond to the initial fluids, a fluid challenge will assess the patient's response to additional fluids.
- Question 68:** He said that the time for multiple infusions is when the third order is written, but then below that statement is it says when the last IV fluid order is started and ordered are rarely ever the same time. So it is time ordered or time started by the nurse?
- Answer 68:** Crystalloid infusion time is always the time the infusion is actually started, not when the order was placed.
- Question 69:** Do I take it that if there is a documented time of infusion completed, that would be used instead of a calculated one?
- Answer 69:** If there is a time documented at which the 30 ml/kg infusion was completed, that should be taken over a calculated end time.
- Question 70:** If the IV infusion is ordered as “wide,” how do you determine end time?
- Answer 70:** The order needs to specify a time frame over which to infuse or a rate. You will not be able to determine end time if the time the infusion is completed is not documented or if there is not a rate or duration over which to infuse the fluid in the order.
- Question 71:** How do you estimate the infusion end time in the example of 100 ml to be given wide open?
- Answer 71:** The order needs to specify a time frame over which to infuse or a rate. You will not be able to determine end time if the time the infusion is completed is not documented or if there is not a rate or duration over which to infuse the fluid in the order.



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- Question 72:** Slide 58 states that if a rate is ordered, then we can calculate the duration and then an end time. However, specs state if no time over order, then select “No” to fluids.
- Answer 72:** Correct, if there is not an infusion duration or rate in the order, you will select "No" to Crystalloid Fluid Administration. The case will then fail the measure and you are done with abstraction. You will not need to try to determine end time because that is done for the Persistent Hypotension data element.
- Question 73:** So, per slide 53, fluids can start more than 3 hours before time of septic shock, as long as given sequentially and last IV up or order is within the 3 hours? Please confirm.
- Answer 73:** Yes.
- Question 74:** So, we can calculate the fluid end time even though it is not documented in the medication record with an exact end time?
- Answer 74:** Correct, the end time can be estimated for purposes of the measure if there is a rate or time over which to infuse the fluids in the order.
- Question 75:** What if fluids have been administered and completed before the shock time but within a few hours?
- Answer 75:** This is acceptable for fluid administration. Note, however, if septic shock presentation time is more than 6 hours after severe sepsis, the case is excluded from the septic shock portion of the measure.
- Question 76:** If you have two peripheral lines, you can give 2 L of fluid at same time. The third l would go in when one is finished. This means you could give 3 L of fluid in 2 hours, not 3. You can't just assume it takes 3 hours for all 3 L to infuse.
- Answer 76:** Correct, you would adjust your calculation of infusion end time accordingly.
- Question 77:** Does the patient have to receive (fully administer) weight based fluid within the 3 hours, or does the appropriate volume have to be ordered in the timeframe?
- Answer 77:** The appropriate volume must be ordered and started within 3 hours. The total volume does not need to be completely infused within 3 hours.
- Question 78:** Some practitioners state the time of fluid completion is to be recorded in the review as the same time the fluids are ordered. However, in order to satisfy



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the measure, we need to enter the time the fluid finished infusing into the patient. Is this right?

**Answer 78:** Correct, start of infusion and end of infusion cannot be the same time because of the amount of time it actually takes for the fluids to infuse. If infused rapidly and the volume is small, the start and end times can be close together, but never the same time.

**Question 79:** The fluids need to be running at the time of septic shock, correct? So, if the order is 2500 ml over 1 hour, started at 10:00 for a 70 kg patient, if septic shock is identified at 11:30 (after fluid), you would say “No” for fluid, correct?

**Answer 79:** The fluids can be running before, at the same time as, or after the presentation of septic shock. In the scenario you describe you would select "Yes" for Crystalloid Fluid Administration, assuming the order included the rate or duration over which to infuse the fluids.

**Question 80:** Is it in the literature to infuse 1000 over 8 hours?

**Answer 80:** The measure is not stating to infuse 1000 ml of crystalloid fluids over 8 hours (125 ml/hour). This is a rate below which the measure stewards indicated the fluids are being given, too slow for purposes of fluid resuscitation, and would be more representative of an IV maintenance rate.

**Question 81:** Over what period of time should the fluids be infused?

**Answer 81:** There is not a required time frame or rate for infusing the crystalloid fluids, other than a minimum rate or time frame equivalent to 1000 ml over 8 hours (125 ml/hour). Below this rate, the fluids are considered for IV maintenance rather than for fluid resuscitation.

**Question 82:** Will the abstractor have to calculate for crystalloid volume or does the order have to be written specifically as 30 ml/kg?

**Answer 82:** This depends on how the physician writes the order. If they write an order for the total volume, the abstractor will need to determine the target total volume based on the patients weight to identify whether or not the order is equivalent to 30 ml/kg. If they write an order for 30 ml/kg, the abstractor will still need to determine the target total volume based on the patient’s weight. In this situation, the target total volume is used to determine whether or not 30 ml/kg were actually given for determining presence of Persistent Hypotension.



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- Question 83:** For septic shock present, did you mean if no crystalloids were given at all or if the crystalloids were given but not at 30 ml/kg to answer “No” to septic shock present?
- Answer 83:** To answer "No" to *Septic Shock Present* would indicate no crystalloid fluids were given at all.
- Question 84:** The severe sepsis time zero is 03:00. An order for 30 ml/kg crystalloid fluid over 2 hours is placed at 05:00. Fluid administration begins at 05:45. Is this compliant?
- Answer 84:** I cannot answer this question based on the information provided. Whether or not the timing of the crystalloid fluids is compliant depends on *Septic Shock Presentation Time* (Septic Shock time zero), not *Severe Sepsis Presentation Time* (Severe Sepsis time zero).
- Question 85:** Are there any exceptions to the 30 ml/kg infusion?
- Answer 85:** There is not an exclusion or exception for the 30 ml/kg volume.
- Question 86:** Can vasopressors administered prior to conclusion of 30 ml/kg of fluid administration be acceptable?
- Answer 86:** Yes, vasopressors administered prior to conclusion of 30 ml/kg are acceptable.
- Question 87:** If fluids are given prior to presentation of septic shock, do you still give an additional 30 ml/kg?
- Answer 87:** Fluids given prior to presentation of septic shock can count toward the total volume, as long as they were given at a rate >125 ml/hour.
- Question 88:** What if fluids were given but were below the recommended rate of 30 ml/kg?
- Answer 88:** If the volume of fluid is less than 30 ml/kg, the case will not meet the criteria for this part of the measure.
- Question 89:** Do the fluids need to start within 3 hours of presentation or must they be started and infused 30 ml/kg within the 3 hours?
- Answer 89:** They must be started. They do NOT need to be completed within 3 hours.
- Question 90:** I am confused about the content of slides 39 and 43. I don't understand how 1 L of IVF at 125/hour can pass the measure, if the total volume did not meet the 30 ml/kg amount?



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- Answer 90:** 1000 ml over 8 hours (equivalent to a rate of 125 ml/hour) itself cannot pass the measure if the patient requires more than 1000 ml to meet the 30 ml/kg total target volume. 1000 ml over 8 hours (125 ml/hour) is the rate below which the fluids are running for maintaining an IV line and not for fluid resuscitation.
- Question 91:** What about giving fluids to patients with renal failure (ESRF)? Is it ok to give fewer fluids than the 30 ml/kg?
- Answer 91:** If the volume of fluid is less than 30 ml/kg, the case will not meet this part of the measure. There is no exclusion for patients with ESRF.
- Question 92:** We have been working with EMS to start fluid boluses when a patient presents with symptoms of septic shock. If there is documentation of the amount of fluid given to a patient prior to arrival, can this be included as part of the total amount of fluid given to the patient in order to reach 30 ml/kg?
- Answer 92:** Yes.
- Question 93:** Re: 30 ml/kg, if a patient has MD/PA, or NP documentation of heart failure or renal failure as reason to give less than 30 ml/kg, is that acceptable? The patient may receive 20 ml/kg.
- Answer 93:** If the volume of fluid is less than 30 ml/kg, the case will not meet this part of the measure. There is no exclusion for patients with HF or ESRF.
- Question 94:** Not all elevated lactates with low BP can be attributed to Sepsis. For example, decompensated heart failure patients may have a low BP and elevated lactates. In this case, crystalloids are not advised. How do you deal with this?
- Answer 94:** Please note, the patient must have severe sepsis with an elevated lactate (septic shock) or severe sepsis with hypotension (precursor to septic shock) to receive crystalloid fluids. So if the patient does not have a suspected infection, or does not meet SIRS criteria, or does not have a sign of organ dysfunction, they do not have septic shock. If they do not have severe sepsis with elevated lactate or severe sepsis with hypotension, you would not treat them for severe sepsis or septic shock.
- Question 95:** Will we meet the measure for crystalloid infusion if rate of IVF is ordered at 30 mg/kg but patient does not receive the full amount? Will we pass the measure?
- Answer 95:** No, to determine the presence of persistent hypotension, the total volume equivalent to 30 ml/kg must be totally infused.



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**Question 96:** So, if we were in the process of giving crystalloid fluid but a lactic acid result  $>4$  comes during administration of fluid, would we use the time of the lab result?

**Answer 96:** If this represents the initial lactate level result, it could be used as a sign of organ dysfunction and can be used in the determination of septic shock presentation. Of course, the timing of entire clinical criteria and picture must be taken into consideration when determining presence of severe sepsis and septic shock.

**Question 97:** Do we want to achieve a small numerator?

**Answer 97:** A small numerator would reflect you had few cases that met the measure. A larger numerator would reflect you had more cases that met the measure. As such, a larger numerator reflects high compliance with the measure specifications.

**Question 98:** How far prior to the presentation of septic shock can we use the crystalloid prior to presentation?

**Answer 98:** The measure does not specify how far prior to presentation crystalloid fluids are considered acceptable for inclusion. Note that you can only use fluids that were given for fluid resuscitation, so they must be given at a rate greater than 125 ml/hour or 1000 ml over 8 hours and meet other criteria as indicated in the *Crystalloid Fluid Administration* data element.

**Question 99:** If not administering crystalloid fluids after presentation of Severe Sepsis excludes patients from the septic shock measure, what would be the best way to encourage the crystalloid fluid administration? Should we be encouraging our physicians to go ahead and administer these with the 30 ml/kg dosing while only severe sepsis is known, or just let it be upon their discretion?

**Answer 99:** If a patient presents with severe sepsis and hypotension, crystalloid fluids should be given to treat the hypotension. This is appropriate medical care per severe sepsis and septic shock guidelines. If the patient is given 30 ml/kg of crystalloid fluids and the hypotension does not respond, the patient has septic shock.

If a patient presents with severe sepsis and an initial lactate  $\geq 4$  mmol/L, the patient has septic shock and they should be treated with 30 ml/kg. This is appropriate medical care per severe sepsis and septic shock guidelines. SEP-1 is a measure of appropriate clinical patient care, not a set of guidelines or mandate for care. If patients are treated according to the guidelines, they



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will pass the measure. Patients should not be treated only from a perspective of meeting a measure.

**Question 100:** Can you clarify the crystalloid fluid type? Are balanced salt solutions, like Normosol allowed (similar to LR)?

**Answer 100:** Currently the only acceptable crystalloid fluids are normal saline (0.9% saline solution) and Lactated Ringers. This will be addressed in a future version of the manual.

**Question 101:** How long prior to the presentation of septic shock is fluid administration acceptable to meet the crystalloid fluid administration data element?

**Answer 101:** There is not a specific time frame. The fluids, however, must be given at a rate greater than 125 ml/hour (1000 ml over 8 hours). The intent is to capture fluids given for fluid resuscitation to treat hypotension or an initial lactate  $\geq 4$  mmol/L.

**Question 102:** If the patient with documented Severe Sepsis but with a lactate  $< 4$  has an order for Crystalloid fluids at  $> 125$  ml/hour, but the total volume ordered after an hour does NOT equal 30mg/kg, but the patients BP drops  $> 40$  points, would septic shock be present?

**Answer 102:** In order to say septic shock is present in the scenario you describe, 30 ml/kg of crystalloid fluids would need to be given and hypotension would need to persist within the hour following administration of the fluids.

**Question 103:** Given the confounding conditions during surgery, can vitals and fluids taken/given in the OR be used to meet criteria for severe sepsis/shock criteria and crystalloid fluids?

**Answer 103:** This is very possible. It will, in part, be dependent upon the timing and rate they are administered.

**Question 104:** If an IV cannot be accessed can crystalloids be given by intraosseous infusion (IO)?

**Answer 104:** IO is not an acceptable route as currently defined in the SEP-1 specifications.

**Question 105:** For septic shock: did I understand that if the initial Lactate is  $\geq 4$  this would indicate septic shock if severe sepsis is present, regardless of if crystalloid fluids were given?

**Answer 105:** Yes, this is correct.



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- Question 106:** Are you saying that septic shock can be present if a patient has severe sepsis and a lactate of 4, even without low SBP? Are you saying crystalloids have to be given even if SBP is not low or the measure fails?
- Answer 106:** Yes, one manifestation of septic shock is severe sepsis with a lactate  $\geq 4$ . In this situation, crystalloid fluids are not given to identify the presence of septic shock, but are necessary for the treatment of septic shock.
- Question 107:** If a physician documents severe sepsis with shock and crystalloid fluids are given but under 30 ml/kg, how would you answer the septic shock present element?
- Answer 107:** The thing to keep in mind is that the *Septic Shock Present*, *Crystalloid Fluid Administration*, and *Persistent Hypotension* data elements are in part dependent upon one another. If the patient did not receive 30 ml/kg of crystalloid fluids, even if they continue to have hypotension, by specifications in both the *Crystalloid Fluid Administration* and *Persistent Hypotension* data elements, one cannot indicate that septic shock is present. So if crystalloid fluids are ordered but are less than 30 ml/kg, you would need to select Value "2 (No)" for *Septic Shock Present*.
- Question 108:** What if patient is not fluid responsive and harm would be a risk by giving these fluid volumes?
- Answer 108:** Fluid responsiveness would be determined based upon the patient's response to giving fluids. In the event the physician feels there are patient safety concerns associated with giving 30 ml/kg to a specific patient, physician judgment should be used to determine the most prudent course of action for that patient.
- Question 109:** Must the order state give fluids over one hour, or can you use your hospital policy for rapid fluid infusion?
- Answer 109:** The order or hospital policy that is used must specify a rate or duration over which to give the fluids.
- Question 110:** Does the infusion need to be started in three hours or finished in three hours to meet the measure (being 30 ml/kg, of course)?
- Answer 110:** Crystalloid fluid infusion needs to be started within 3 hours of septic shock presentation, not finished.
- Question 111:** On page 42, would an example pass, if the nurse charted when the 2000 ml infusion was completed even though order doesn't give duration?



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- Answer 111:** This would not be sufficient. Per the *Crystalloid Fluid Administration* data element, the order must contain an infusion duration or rate.
- Question 112:** Can a fluid infusion be stopped for reason prior to meeting guidelines, such as "Infusion stopped due to recovered BP and patient becoming fluid overloaded?"
- Answer 112:** If a physician has patient safety concerns based upon a specific patient's response to the 30 ml/kg crystalloid infusion, they should use their judgment in determining the most prudent course of action. For purposes of the measure, if the full 30 ml/kg of fluids are not infused, the case will not pass the measure.
- Question 113:** Does IV antibiotic count as part of the infusion, such as Vanco 250 cc in NS?
- Answer 113:** No, the total volume of fluids includes only those fluids ordered for fluid resuscitation, not for delivery of medications or to flush lines.
- Question 114:** When will the abstraction tool be available for this measure?
- Answer 114:** A universal SEP-1 paper abstraction tool is posted on *QualityNet* under Data Collection Abstraction Resources.  
<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775357005>.
- Question 115:** What happens if an initial lactate level is not associated with septic shock IE admission lab but two days later had septic shock with another lactic acid level done?
- Answer 115:** This will depend on the timing of septic shock in relation to when the patient first presented with severe sepsis. According to the revised specifications in version 5.0b of the manual, if septic shock presentation is more than six hours after severe sepsis presentation, you would choose Value "2" for *Septic Shock Present*.
- Question 116:** Does the IV need to be charted as completed to count the fluids?
- Answer 116:** It depends on the data element your question is referencing. For *Crystalloid Fluid Administration*, you are looking for an order that is equivalent to 30 ml/kg and a time indicating when the crystalloid fluids were started. For this data element, the fluids do not need to be completely infused. For *Persistent Hypotension*, you need to know when the fluids were infused and the volume infused must be 30 ml/kg. If the time the IV was completed is not



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documented, you can estimate it based on the time it was started and the duration or rate in the order.

**Question 117:** We are a small hospital. Any inpatient that develops severe sepsis or septic shock would be transferred out to another hospital. How does this transfer affect our values for actions that may be needed an hour or more after the patient is discovered to have severe sepsis or septic shock? Will we fail measures because we regularly transfer patients for better care?

**Answer 117:** Currently SEP-1 does not exclude transfers out that occur prior 3 hours of presentation of severe sepsis. We will take this concern forward for consideration in a future version of the manual.

**Question 118:** Having just one BP to indicate vasopressor is required is not clinically appropriate. There should be at least two BPs?

**Answer 118:** Thank you for raising this concern. Version 5.0b of the manual changes the number of blood pressure measurements to two or more consecutive readings.

**Question 119:** Is there a consideration being explored to give a range for fluid resuscitation. For example, physician gave 2000cc NS. Based on weight, patient should have received 2016cc NS. Clinically, I do not think that 16cc of fluid would make a difference in patient's outcome and it is difficult to have a serious review of case with a physician when we are talking about 1 tsp. of fluid.

**Answer 119:** Thank you for raising this concern. Currently variations such as this are not accounted for. We will take this forward for consideration in a future version of the manual.

### Treatment Documentation

**Question 120:** A patient arrives to the ED via EMS and requires immediate intubation and initiation of pressors, labs, including blood cultures and lactate level, are drawn upon arriving to ED. The results of the lactate level come back over 4; however, the ED physician has not documented a note and there is no documentation of possible source of infection, so severe sepsis criteria are not met. Would time of septic shock be the time the lactate level results are reported?

**Answer 120:** In order for septic shock to be present, severe sepsis must also be present. If criteria for severe sepsis is not met because there is not documentation of a suspected infection you would select "No" for *Severe Sepsis Present* and would not need to abstract information for septic shock.



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- Question 121:** If a nurse documents source of infection in nurses' notes, can we utilize that as criteria for severe sepsis or would PA/MD/ANP documentation only suffice? Please elaborate.
- Answer 121:** Nursing documentation is acceptable and is specified in v5.0b of the manual.
- Question 122:** Example: Temp documented by nurse on flow sheet was taken at 1700 with the rest of VSs taken at 1730. The doctor copied VSs and placed in the note omitting the time these were taken. That doesn't matter?
- Answer 122:** Correct, the physician note really shouldn't matter because you will be taking the earliest times for these noted in the medical record.
- Question 123:** Is nurse documentation of source of infection considered a valid source of documentation? Documentation says it must be a Physician, APN, or PA.
- Answer 123:** Nursing documentation is acceptable and is specified in v5.0b of the manual.
- Question 124:** Is there an exclusion from the 30 ml/kg of fluids for dialysis, CHF, etc. patients? Is physician documentation allowed to exclude these patients?
- Answer 124:** There is no exclusion for the 30 ml/kg of crystalloid fluids. However, if a physician feels that giving 30 ml/kg of crystalloid fluids would be detrimental to a specific patient, they should use their medical judgment in determining the most prudent course of action for that patient.
- Question 125:** If clinical criteria are met at 14:00 but doctor documentation of septic shock or severe sepsis 18:00, which time do we take?
- Answer 125:** The specifications indicate that if there are multiple times documenting the presence of severe sepsis, to use the earliest time. In this situation, since the clinical criteria are met at 14:00, that time should be used since it is earlier than the physician documentation at 18:00.
- Question 126:** Does physician documentation of septic shock take precedent over the clinical indicators? In other words, if there is physician documentation, can you go to the next step or do you still have to check for the clinical indicators?
- Answer 126:** You need to look for both the clinical criteria and physician documentation. Whichever of the two occurs earliest is the time you use for septic shock presentation or time zero.
- Question 127:** If septic shock presents is documented in the first note by MD but not in triage documentation, is the MD documentation time zero?



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- Answer 127:** You need to look for both the clinical criteria and physician documentation. Whichever of the two occurs earliest is the time you use for septic shock presentation or time zero.
- Question 128:** Regarding physician documentation of "severe sepsis" or "septic shock," it appears as though the data dictionary states the documentation must be within the same six hours of the SIRS and organ dysfunction determining criteria for severe sepsis. Is it okay for the physician to document outside of the six hours, but refer to that time frame in the documentation? For example, if the patient demonstrates severe sepsis and/or septic shock in the middle of the night, the physician may not be at the hospital, but can give orders per telephone.
- Answer 128:** Physician documentation of severe sepsis or septic shock does not need to be within 6 hours of the clinical criteria. The clinical criteria must all be met within 6 hours of each other, and if documentation of a suspected infection is based on physician documentation that must be within 6 hours of the other clinical criteria.
- Question 129:** How would you know that you have septic shock before you've administered the fluids and have persistent hypotension? Is it only in the case of physician documentation and/or lactate greater than 4?
- Answer 129:** Correct, septic shock is present if severe sepsis is present with a lactate  $\geq 4$ . Fluids are not needed to determine the presence of septic shock in this situation, but should be given for the treatment of septic shock. The fluids would therefore be given after septic shock presentation. In the case of physician documentation, the fluids may be given before or after presentation time, depending on the timing of the physician documentation in relation to when fluids were started.
- Question 130:** What if the fluids were finished before septic shock presentation and the criterion for septic shock is physician documentation? If appropriate fluids were completed at 10 and physician writes "septic shock" at 10:30, is that still compliant?
- Answer 130:** Yes, this is acceptable. The updated version of the manual v5.0b clarifies that crystalloid fluids given before, at the time of, or after presentation of septic shock are acceptable.
- Question 131:** Would physician documentation of leukocytosis be acceptable as infection present?



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- Answer 131:** Leukocytosis is an increase in the total number of WBCs and may be a sign of an infection or inflammation. It is not an infection itself. It is not acceptable documentation that the physician suspects an infection, as it is non-specific.
- Question 132:** When both are present, does physician documentation of time zero take precedence over clinical specifications determination of time zero? For instance, is time zero when the physician declares the presence of severe sepsis/septic shock (at 10:00) even if there is clinical/lab documentation at an earlier date/time that establishes the presence of severe sepsis/septic shock (08:45)?
- Answer 132:** No, you need to look for both and you will use whichever occurs earliest. In the example you provided, since clinical criteria (08:45) are met earlier than physician documentation (10:00), you would use the earlier time which corresponds with when the clinical criteria were met (08:45).
- Question 133:** Does the documentation of suspected infection have to be documented within the time frame of the presentation of severe sepsis?
- Answer 133:** The documentation of infection needs to be within 6 hours of the other clinical criteria.
- Question 134:** If there is documentation by the APN/PA/MD for suspected/possible infection, can the nurse documentation of suspected infection be used to meet the presentation date and time of severe sepsis?
- Answer 134:** Documentation of a suspected infection from a physician, APN, PA, or nurse is acceptable. This has been clarified in version 5.0b of the Specifications Manual.
- Question 135:** In the previous webinar we were specifically told that nursing documentation of suspected infection is acceptable. Today you mentioned that only an MD, PA, or APN is allowed. Please clarify.
- Answer 135:** Nursing documentation of a suspected infection is acceptable and revisions recently published in version 5.0b of the manual specify this. Today's session was focused on septic shock. Only physician, APN, or PA documentation of septic shock is acceptable.
- Question 136:** With regards to time zero, do you use two positive SIRS with suspected infection, meaning for a patient that presents with two positive SIRS at 0800 and RN suspects infection at 0800 and ER MD documents PN at 0900, is time zero at 0800 or by provider at 0900?



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**Answer 136:** Time of severe sepsis presentation (time zero) is based on when the last of the clinical criteria were met. Clinical criteria include two SIRs, a sign of organ dysfunction, and a suspected infection. Based on your question and assuming there was also a sign of organ dysfunction at or before 0800, then 0800 would be time zero.

**Question 137:** If the physician/APN/PA documentation is the latest item in determining "time zero," do we use the date and time of dictated documentation of this, or do we search the nursing notes for the actual time the clinician saw the patient? In other words, do we use the documentation time (as shown by the dictation time) or the time the clinician saw the patient and presumably made the decision?

**Answer 137:** You will use the time documented that indicates an infection is suspected. If this is reflected in documentation associated with the time the physician saw the patient, that time can be used. If it is associated with the time of the physician note, that should be used. You cannot make an assumption the physician suspected an infection at the time they examined the patient if they do not document that is when they suspected an infection.

**Question 138:** In cases where a practitioner is observing the patient via vid-link and "performing" a focused exam, how should documentation appear, since they are dependent on observation of nursing action and patient responses?

**Answer 138:** To meet the criteria established in the current wording of the manual, documentation reflecting the physician performed the focused exam with nursing assistance, or something to that effect, would be acceptable.

**Question 139:** Does the physician have to document the CVP, ScvO<sub>2</sub> measurements to evaluate volume status, or can it be abstracted from the nursing documentation?

**Answer 139:** It can be abstracted from nursing documentation.

**Question 140:** For the focused MD exam, the vital signs (Temperature, Pulse, Respiratory Rate, and Blood Pressure) need to come from the same entry. Is this referring to the doctor's notes or the doctor taking the info from the nursing documentation? Can he obtain vital signs from nursing notes that are separate entries? Is this specifically referring to abstracting of info by coders?

**Answer 140:** The Temperature, Pulse, Respiratory Rate, and Blood Pressure need to be all in the same, single physician note. The physician can use vital signs from



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more than one set of nursing vitals when composing that note. I am unclear on your question regarding coders.

**Question 141:** Time frame is an issue when ordering a bolus. In the ER they order 2 or 3 bolus and they document the volume in and the start and end time in the nursing I&O. Could I use that?

**Answer 141:** The order for the 30 ml/kg of crystalloid fluids can be in a single order or a series of orders. The orders must include a duration over which to infuse the fluids or an infusion rate. If an infusion duration or rate is not included in the order, you will need to select "No" for Crystalloid Fluid Administration.

**Question 142:** Can CVP measurement and CV O2 measurement be documented by nursing?

**Answer 142:** Yes.

**Question 143:** Why does a Focused Exam need to be documented by a licensed independent practitioner (LIP), yet CVP, Central Venous Oxygen, and Bedside Cardiac Ultrasound do not? The Focused Exam elements are foundational elements of nursing assessment. How is it proven that the MD reviewed the CVP, etc.?

**Answer 143:** The Focused Exam involves the physical assessment of the patient. The expectation is that the provider responsible for the care of the patient has conducted an exam of the patient following administration of the crystalloid fluids to help determine the patient's response to the fluids, further care, and treatment needs. The studies indicating that using EGDT (CVP and ScvO2) was not superior to usual care and from which the components of the Focused Exam were derived, had physicians performing the usual care patient exams. Since the addition of the Focused Exam as an option to the CVP and ScvO2 is based upon findings from these studies, it would follow the "usual care" or focused exam should be consistent with the studies. The values for CVP and ScvO2 are documented readings that do not require performance of a physician assessment of the patient.

**Question 144:** I read that a risk assessment is to be documented on nursing admission, what does the risk assessment consist of exactly?

**Answer 144:** There is no requirement in the SEP-1 specifications for a "risk assessment."

**Question 145:** On the SEP-1 Core measure there is confusion on where to get source of infection for both severe sepsis and septic shock criteria. Can source be lab results, nursing documentation, radiology findings, or ED provider documentation only?



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- Answer 145:** The suspected source of infection must be documented from a physician, APN, PA, or nurse that an infection is suspected, possibly present, or present. The documentation must specify the name of an infection or include the word infection. A lab result may not truly be reflective of an infection. Depending on the lab and the results, there are a variety of conditions that could be causing the results. Simply stating signs and symptoms are not sufficient either, because they may not be caused by an infection.
- Question 146:** Does the physician have to be present at that time? Can he make an entry from using the nurse's information?
- Answer 146:** It is unclear which data element this question is referencing. As such, I am unable to respond.
- Question 147:** Do Medical Orders for Life-Sustaining Treatment (MOLST)/ Physician Orders for Life-Sustaining Treatment (POLST) forms dated prior to arrival, which contain the correct wording for comfort measures only (CMO), count in excluding the patient for CMO? Or does there need to be new documentation by provider for CMO?
- Answer 147:** The Directive for Comfort Care, septic shock, and severe sepsis data elements indicate that if there is a State-Authorized Portable Order (SAPO) in the record that is dated and signed prior to arrival, with an option in which an inclusion term is found that is checked, to select Value "1 (Yes)."
- Question 148:** For a patient that doesn't meet clinical criteria for septic shock is documentation of septic shock in the discharge (d/c) summary sufficient? Is the documentation of sepsis hypotension sufficient?
- Answer 148:** Version 5.0b of the specifications manual includes a bullet point in the Notes for Abstraction for severe sepsis and septic shock Presentation data elements that indicates if the only documentation indicating presence of severe sepsis (septic shock) is after the discharge time, choose Value "2 (No)."
- Question 149:** Peripheral pulse evaluation-Provider documents distal pulses present. Can I accept this documentation?
- Answer 149:** This is acceptable.
- Question 150:** If there is documentation that the patient has a central line, is that considered indication that the CVP or SvO2 was obtained via central line?
- Answer 150:** Documentation that a central line is present does not mean the SvO2 was obtained via the central line. SvO2 is a venous blood oxygen saturation, which



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can be obtained from any venous blood sample. There would need to be some documentation supporting the SvO2 was obtained from the Central Line. CVP is a central venous pressure. As such, it can only be obtained via a central line.

- Question 151:** For the Peripheral Pulse Evaluation Performed documentation is "intact distal pulses" or "pulses 2+ bilaterally" considered acceptable documentation?
- Answer 151:** Yes.
- Question 152:** A patient arrives to ED from a clinic and is told he has a knee infection. If the RN documents "Here for evaluation of infected knee" and all other criteria are met for severe sepsis, does the RN documentation of infection count as documentation of an infection?
- Answer 152:** Yes.
- Question 153:** If there is no documentation of severe sepsis/septic shock and the clinical specifications for severe sepsis/septic shock are not met, then does the timestamp on a physician order set for the "Severe Sepsis order set" or the "septic shock order set" count as time zero?
- Answer 153:** It could if there is documentation confirming the order set is used for treatment of severe sepsis or septic shock.
- Question 154:** Capillary refill is basic to RN training. What's the reason for not allowing their documentation to meet measure requirement?
- Answer 154:** In the studies upon which the inclusion of capillary refill as a component of the Focused Exam, physicians conducted the physical assessments. The measure stewards felt that to maintain consistency with the studies, and because a physician can write orders to address any immediate needs, it would be more appropriate for the Focused Exam to be performed by a physician in cases of septic shock.
- Question 155:** Can I use the documentation of sepsis as an infection for one of the criteria (not for severe sepsis)? Is sepsis an inclusion for clinical infection like in an SCIP measure, where sepsis was one of the inclusion terms] for infection?
- Answer 155:** Sepsis is not acceptable as documentation of a suspected infection. There must be documentation using the word infection or including a condition that is an infection.



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- Question 156:** What if the last two bullet points under notes for abstraction for septic shock Present are true? Example: Provider documents septic shock, but no fluids were administered. Is this a “Yes” or “No” to Septic Shock Present?
- Answer 156:** Regardless of how septic shock is identified in the medical record (by clinical criteria of physician documentation of septic shock), if crystalloid fluids are NOT given following presentation of severe sepsis, you will select Value "2 (No)" for septic shock.
- Question 157:** Does it make a difference if sepsis is documented instead of severe sepsis?
- Answer 157:** Yes, only severe sepsis is acceptable.
- Question 158:** If we have an automated sepsis alert, can we use the time of the alert activated as the start of our severe sepsis/septic shock clock when not documented by the provider (only the alert is)?
- Answer 158:** No, the specifications indicate the presentation time of severe sepsis is the earlier of either when the last of the clinical criteria are met, OR documentation of severe sepsis by a physician, APN, or PA.
- Question 159:** What if clinical indicators do not meet criteria for either severe sepsis or septic shock but MD documents wither condition?
- Answer 159:** It is unclear which data element this question is referencing. As such, I am unable to respond.
- Question 160:** This question concerns the data definition "Vital signs review performed." This concerns the interpretation of the word "review." Is the physician/APN/PA allowed to document vital signs completed at different times during the 6 hour window? For example, can he document a temp taken at 2 p.m. and other vitals taken at 3 p.m. or temp/pulse/resp. at 3 p.m. and take the BP reading from 4 p.m.? In essence, is he allowed to take any vitals he wants since he is documenting at one specific time or do all of the vitals he documents need to be completed at the same time?
- Answer 160:** The vital signs the physician is reviewing in their note can come from various locations or can be documented at different times in the medical record. The physician note must include reference to all four: temp, pulse, resp. rate, and BP.
- Question 161:** What can we use for infection? Does it have to say "infection" or can we take a known infection such as PN that is documented in the Active Problem List or other notes?



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- Answer 161:** The documentation must include the word infection or be a condition that is an infection.
- Question 162:** If the physician documents septic shock but fluids were not given at 30 ml/kg, we answer “No” to septic shock present? I thought you said earlier that if the physician documented septic shock without meeting the criteria.
- Answer 162:** If the clinical criteria for septic shock are not met but the physician documents septic shock, this documentation can be used to indicate the presence of septic shock. If crystalloid fluids are NOT given following presentation of severe sepsis (regardless of how septic shock is identified: clinical criteria or physician documentation), you will select Value "2 (No)" for *Septic Shock Present*.
- Question 163:** What do you do when there is not a stop time documented for the Crystalloid Fluid Administration (CFA)?
- Answer 163:** You can estimate the time the crystalloid fluid infused was completed based on the infusion duration or rate specified in the order and the volume ordered.
- Question 164:** Is it okay to scan all IV bags at once? For example, order written for 3000 ml of NS for a 100kg septic shock patient with no time frame, but nurse documents 3000 mls given at the conclusion within 3 hours of septic shock dx. Please, advise.
- Answer 164:** In order to select "Yes" for *Crystalloid Fluid Administration*, there must be an order for 30 ml/kg of crystalloid fluids and the order must include the duration over which to infuse the fluids or an infusion rate. If an infusion duration or rate is not included in the order, you must select "No."
- Question 165:** We use an EHR at our organization. If a physician documents severe sepsis absent no other specific time by the diagnosis, should we use ED note time which is when the note is started, or file time when the note is signed as the presentation time?
- Answer 165:** If there is documentation of severe sepsis within an ED physician note and there is not a specific time within the note associated with this documentation, you will use the time the note was started or opened.
- Question 166:** Is it acceptable for the physician to document “no change” for the focused exam from the initial assessment covering all required elements if there is no change with the reassessment? Please advise.



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- Answer 166:** No, the Focused Exam requirements include physician documentation of a vital signs review, peripheral pulse evaluation, cardiopulmonary exam, capillary refill evaluation, and skin exam. The performed data element for each of these specifies what the evaluation or exam consists of.
- Question 167:** If septic shock is documented in the d/c summary by the physician but the criteria is not met for septic shock, do you use the date and time the discharge summary was written?
- Answer 167:** Version 5.0b of the specifications manual includes a bullet point in the Notes for Abstraction for severe sepsis and septic shock presentation data elements that indicates if the only documentation indicating presence of Severe Sepsis (septic shock) is after the discharge time, choose Value “2 (No).”
- Question 168:** Our physicians do not document the individual times of each aspect of their physical exam. Will the time be what is documented on the progress note? We are also concerned about how we will know the actual time the lab values were first viewed.
- Answer 168:** If this is in reference to the individual components of the Focused Exam, the time of documentation or a note indicating they were done is sufficient. There is not requirement for recording the time lab values were viewed.
- Question 169:** If an LIP documents “Normal peripheral perfusion,” is this acceptable for peripheral pulse evaluation?
- Answer 169:** No, the documentation must make reference to "pulses" not perfusion.
- Question 170:** How should we document if the patient did NOT receive all of the IV fluid due to documented physician contraindication, e.g., pulmonary edema?
- Answer 170:** Documentation that a patient did not receive the full 30 ml/kg of crystalloid fluids will not result in excluding the case.
- Question 171:** On the refocused exam, if a physician documents regarding the skin exam as "warm and dry," is this sufficient?
- Answer 171:** No, the *Skin Examination Performed* data element specifically states there must be a reference to skin color.
- Question 172:** If the criteria for severe sepsis or septic shock are met and the physician documents it, as well, which time is used?



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- Answer 172:** You will use the earlier of either when the last of the clinical criteria are met, OR physician, APN, or PA documentation. If clinical criteria were met before physician documentation, you will use the clinical criteria met time. If the physician documentation occurred prior to clinical criteria being met, you will use the time of physician documentation.
- Question 173:** At the last presentation we were told an RN could document infection source and examples were given. Bob just said infection source needed to be documented by MD/APN/PA. Is this a change or did I hear incorrectly?
- Answer 173:** The documentation of a suspected infection can come from a nurse. This is clarified in version 5.0b of the Specs Manual.
- Question 174:** Physician documented an infection on active problem list. The history and physical (H&P) references this infection was pre-existing! Can we still collect the infection?
- Answer 174:** If the documentation reflects the infection is still present or suspected as still being present, this is acceptable.
- Question 175:** Can the elements of the Focused Exam be in different MD notes and or done by different MDs at different times?
- Answer 175:** Each element of the Focused Exam (vital signs review, cardiopulmonary exam, capillary refill evaluation, peripheral pulse evaluation, and skin exam) can be in the same note, noted at different times, in separate notes, or in notes from different physicians.
- Question 176:** Why does the Tissue Perfusion exam require the physician to "list" vitals rather than noting "reviewed?"
- Answer 176:** Noting "reviewed" does not indicate which vitals were reviewed. Minimally it is expected the temp, heart rate, resp. rate and BP are reviewed. These are all vitals associated with determining the presence of severe sepsis and septic shock or affected by crystalloid fluid infusion.
- Question 177:** The note has to contain all the vital signs, and the time taken in the note doesn't matter?
- Answer 177:** Correct, all four vital signs must be referenced in a single physician note. The time those vital signs were taken can vary.
- Question 178:** What do you consider the difference between a single note and larger note for vital signs?



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- Answer 178:** The size of the note doesn't matter. What is important is that the note includes reference to all four vital signs and the value for those four vital signs.
- Question 179:** If the physician references 'pulse is normal,' is this sufficient or does it need to specify the location of the pulse?
- Answer 179:** If this is in reference to the *Peripheral Pulse Evaluation Performed* data element, "pulse is normal" is not sufficient. The documentation must make reference to peripheral pulses or state the location of the pulse, so it can be confirmed as a peripheral pulse.
- Question 180:** What if the vital signs are being brought into a note but the vital signs were taken before the IV fluids began even though the note/review is done after fluids began?
- Answer 180:** The vital signs pulled into the note should be taken after the crystalloid fluids have been started. Vital signs prior to this do not represent a repeat volume status and tissue perfusion assessment, which would occur after fluid administration.
- Question 181:** For vital signs exam, what if one of the elements, such as temperature, just says "not chart," but it is in the list of vitals reviewed?
- Answer 181:** This is not acceptable. The *Vital Signs Review Performed* data element specifically indicates a value must be included in the note.
- Question 182:** At 0700 patient presents with SIRS and shock per SBP. First provider documentation is 0900, and septic shock is documented. Provider documentation is preferred, however, criteria was present on arrival. Which times are the severe sepsis and septic shock start times?
- Answer 182:** It appears you may be referencing version 5.0 of the Specifications Manual. The manual has been updated twice and the reference to provider documentation being preferred was removed from the first revision. Please be sure to refer to the most recent version of the manual posted on *QualityNet*. You will use the time associated with the earlier of either when the last of the clinical criteria are met, OR physician, APN, or PA documentation. If clinical criteria were met before physician documentation, you will use the clinical criteria met time. If the physician documentation occurred prior to clinical criteria being met, you will use the time of physician documentation.
- Question 183:** If the only documentation is "sepsis" and have all criteria for severe sepsis and septic shock, will they be in sample?



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**Answer 183:** Patients will be in the initial patient population based on the presence of an ICD-10 code for sepsis, severe sepsis, or septic shock. Your sample population will be a randomly selected subset of this based upon the total number in the initial patient population. If the clinical criteria are met for severe sepsis and septic shock, you will need abstract the medical record.

### Vasopressor-Related

**Question 184:** We sometimes get patients that will agree to fluid administration, but refuse Vasopressins. Therefore, if the patient's BP does not respond to the fluids then we should be giving a Vasopressor, but if they refuse, we fail the measure. I don't think we should "fail" because they refuse that treatment. The current "refusal of treatment" looks like it is for blood draws and fluids only, how should we handle this?

**Answer 184:** There currently is not a way to exclude cases based on refusal of vasopressors. This is something that will be addressed in a future version of the manual.

**Question 185:** For administration contra to care, what if the patient and family refuse central venous access for pressors? This data element only lists refusal for blood draw, fluid administration, or antibiotic administration. Is vasopressors considered "fluid administration?"

**Answer 185:** There currently is not a way to exclude cases based on refusal of vasopressors. This is something that will be addressed in a future version of the manual.

**Question 186:** Does lactate over 4 means automatic initiation of Vasopressors?

**Answer 186:** No, vasopressors are ONLY given if persistent hypotension is present. Vasopressors are NOT given if septic shock is manifested only by a lactate  $\geq 4$ .

**Question 187:** What if vasopressor is not indicated, i.e., hypotension resolved or LA  $>4$  without hypotension?

**Answer 187:** If a vasopressor is not indicated, it should not be given. The measure only requires vasopressors if they are indicated (i.e., persistent hypotension following administration of 30 ml/kg of crystalloid fluids).

**Question 188:** The algorithm I've seen suggests we fail if vasopressors are started before they receive 30cc/kg. Is this true?

**Answer 188:** No, if you look closely at the calculations, there is not a calculation that determines whether or not a case fails based on the timing of the vasopressors in relation to administration of crystalloid fluids. The Vasopressor Time



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Calculation determines the time relationship of vasopressor administration and septic shock presentation. If the vasopressors are given greater than 360 minutes (6 hours) after septic shock presentation, the case will fail the measure. If the vasopressor time is less than or equal to 360 minutes, the case passes this part of the measure.

**Question 189:** What if the vasopressors are started before the 30 ml/kg is completed? How do you abstract whether persistent hypotension is present?

**Answer 189:** This is one of those situations that measure cannot totally account for. Persistent hypotension is present if there are two or more consecutive low blood pressures (defined in the *Persistent Hypotension* data element) within in the hour following conclusion of the crystalloid fluids. If after conclusion of the crystalloid fluids there are not two consecutive low blood pressures, then you would select "No" for *Persistent Hypotension*.

**Question 190:** Back to vasopressors: A patient is hypotensive and LA >4. By weight the patient needs 2400 ml and gets this in 2 hours. Persistent hypotension occurs and the patient is given fluid challenge 1 l over 30 minutes. Hypotension resolves. Still need vasopressor even it is not in the patient's best interest? If not given, the case would fail the measure?

**Answer 190:** We recognize there are cases where the recommended care in the guidelines and measure may not be in the patient's best interest, based on the physician's clinical judgment. In these cases, physician judgment should prevail. At the same time, to create a measure that tries to take into account every possible scenario makes the measure overly complex, very difficult to abstract, and virtually impossible to maintain. If the physician feels administering vasopressors is not advisable based on concern for the welfare of the patient, they should not be given. The case will not pass the measure, because this is not accounted for in the measure.

**Question 191:** If patient presents with septic shock but has BP improved with fluid bolus, do they still have to get vasopressors in order to avoid falling out of the core measure?

**Answer 191:** No, vasopressors are ONLY given if persistent hypotension is present.

**Question 192:** If the patient. has "persistent hypotension" (1 SBP <90 in the hour after the fluids) but then the following BP's are all >90, would you still require pressors?



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- Answer 192:** No, the recently released updated version of the Specs Manual has changed the requirement from "one single" blood pressure reading to "two consecutive" blood pressure readings in the hour following the conclusion of 30 ml/kg of crystalloid fluids.
- Question 193:** Is the expectation of the measure that a vasopressor be started for a single MAP <65 after fluid administration?
- Answer 193:** No, the recently released updated version of the specs manual has changed the requirement from "one single" blood pressure reading to "two consecutive" blood pressure readings in the hour following the conclusion of 30 ml/kg of crystalloid fluids.
- Question 194:** If the DR/PA/NP documents the reason for vasopressor not given even though MAP<65 or SBP<90, is that acceptable to exclude?
- Answer 194:** There is not an exclusion for vasopressors.
- Question 195:** If patient does not have persistent hypotension, must vasopressors be given?
- Answer 195:** No, vasopressors are ONLY given if persistent hypotension is present.
- Question 196:** If vasopressor was started by EMS prior to arrival, what start date and time should be used?
- Answer 196:** The *Vasopressor Administration Time* data element indicates to abstract the initiation time of the vasopressor that was infusing at the time of presentation of septic shock. An example similar to the scenario in your question is also provided within this data element.
- Question 197:** What if the vasopressor is given instead of or before fluid resuscitation?
- Answer 197:** This does not automatically result in a case passing or failing the measure. How the case progresses will depend on what happens to the blood pressure after the 30 ml/kg of crystalloid fluids are completed.
- Question 198:** How long after starting fluid administration does physician need to wait to order vasopressors?
- Answer 198:** The SEP-1 measure does not address this. When to start vasopressors is at the discretion of the physician. To pass the measure, if vasopressors are indicated, they need to be started within 6 hours of septic shock presentation time.



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**Question 199:** Why is the intraosseous infusion route not acceptable for vasopressor administration?

**Answer 199:** Intraosseous is not included as a route in the *International Guidelines for Management of Severe Sepsis and Septic Shock*. As such, they were not included in the measure. This is something we will look into for a future version of the manual.

### Abstraction Algorithm

**Question 200:** If multiple vital signs are taken within the hour following the initial fluid resuscitation, which one do you choose to determine persistent hypotension?

**Answer 200:** Based on the most recent version of the manual (5.0b), persistent hypotension is determined from two consecutive low blood pressure readings (as defined in the *Persistent Hypotension* data element) in the hour following the completion of the crystalloid fluids. If there are multiple readings, it doesn't matter which ones you use as long as there are two consecutive low BP readings. If there are not two consecutive low BP readings in that hour, the patient does not have persistent hypotension.

**Question 201:** Does comfort care include Do Not Resuscitate – Comfort Care Arrest (DNRCCA) also, or does it only include DNRCC?

**Answer 201:** The *Directive for Comfort Care, Severe Sepsis and Septic Shock* data elements address "DNRCCA." This is an example of an inclusion term described as conditional and should be disregarded. If this is the only documentation present you should select "No."

**Question 202:** Are comfort measures and hospice the same?

**Answer 202:** Comfort measures and hospice are both on the *Inclusion Guidelines for Abstraction list in the Comfort Care, Severe Sepsis and Septic Shock* data elements.

**Question 203:** Does there have to be an order for Comfort Care, or can it be discussed in physician etc. charting?

**Answer 203:** The Notes for Abstraction in the *Directive for Comfort Care, Severe Sepsis and Septic Shock* data elements indicate physician documentation of a discussion is acceptable.



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- Question 204:** Can you please provide clarification on septic shock presentation? If a patient meets criteria for severe sepsis at 3 p.m., BP drops to 84/40 at 4 p.m. and fluids are completed with persistent hypotension at 7 p.m., is septic shock presentation time at 4 p.m. with the hypotension, or is it at 7 p.m. when fluids are completed with persistent hypotension?
- Answer 204:** *Septic Shock Presentation Time* (when based on persistent hypotension), is the time at which persistent hypotension is documented in the hour following the completion of the crystalloid fluids. In the example you provided, that would be 7 p.m.
- Question 205:** If 30 ml/kg fluids were administered prior to septic shock presentation time, does it still have to be administered at the time of presentation? If completed at shock presentation, is that sufficient?
- Answer 205:** The most recent version of the manual 5.0b clarifies the timing of *Crystalloid Fluid Administration* in relation to septic shock presentation time. Crystalloid fluids can be given prior to, at the time of, or after presentation of septic shock.
- Question 206:** To clarify: If crystalloid fluid is administered prior to, time of, and after septic shock presentation (within 3 hours of Septic Shock Presentation), would it suffice to answer "YES" to Crystalloid fluid administration? Please Elaborate.
- Answer 206:** Yes, provided the order for the crystalloid fluids is for 30 ml/kg and includes a time over which to infusion the fluids or an infusion rate.
- Question 207:** What about the septic shock presentation time >360 minutes after severe sepsis presentation time, will this result in a category D even though the algorithm does not allow the rest of the review to be completed?
- Answer 207:** This is addressed in version 5.0b of the Specifications Manual (released in October). If septic shock presentation is more than six hours after Severe Sepsis presentation, choose Value "2."
- Question 208:** Regarding the Focused Exam, would a reference to distal pulses be acceptable?
- Answer 208:** A reference to "distal pulses" is acceptable for the *Peripheral Pulse Evaluation Performed* data element, but that is the only Focused Exam element for which it is acceptable.
- Question 209:** Will HbO2% be acceptable for ScvO2?



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- Answer 209:** HbO<sub>2</sub>% is the percent of hemoglobin bound with oxygen and does not specify the location from where the sample came. For purposes of the measure, the measure must come from a central venous sample. Without documentation indicating the reading is from a central venous sample, it is not acceptable.
- Question 210:** Does an oxygen saturation from a venous blood gas (VBG) that is drawn from a peripherally inserted central catheter (PICC) line count as SvO<sub>2</sub>?
- Answer 210:** The documentation must be clear the SvO<sub>2</sub> results came from a central venous line. A PICC line is a peripherally inserted central catheter, and therefore a SvO<sub>2</sub> from a PICC line is acceptable.
- Question 211:** We use an arterial inserted Vigileo monitor. Will this count as the ScvO<sub>2</sub> reading?
- Answer 211:** ScvO<sub>2</sub> is central venous oxygen saturation and must come from a central venous line. Your question indicates the Vigileo monitor is used with an arterial line, which is not acceptable.
- Question 212:** If Central Venous Oxygen Measurement is measured via LiDCO, which utilizes BP and finger sensor to read it, if that is utilized without utilizing central line, would it suffice to answer "Yes" to CvO<sub>2</sub> measurement?
- Answer 212:** The central venous oxygen measurement must come from a central venous blood sample, which requires a central line. A reading based upon BP and finger sensor is not the same and is not acceptable.
- Question 213:** Is septic shock "Yes" or "No" in the following scenario? The first reading when patient was admitted to the ER is 88 at 19:13. All other MAP and SBP are >65 and >90. The patient weight for fluid is 2672. The patient received fluids at: 1000 started 20:40; 1000 started 21:42; 500 started 500. Severe sepsis was 07/26 01:00, no mention septic shock and lactate, and it never reached >3.5.
- Answer 213:** If the patient received 30 ml/kg of crystalloid fluids and they did not have hypotension in the hour following conclusion of the fluids, AND the lactate was < 4, AND there was not physician documentation of septic shock, the patient would not have septic shock. In this situation, you would answer, Value "2 (No)," for *Septic Shock Present*.
- Question 214:** A patient meets the severe sepsis diagnosis and develops hypotension w/SBP at 80. Their weight is 80kg, so they would need 2400 ml of NS per the guidelines. NS 1000 ml stat over one hour and again a second NS 1000 ml is



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given stat over one hr. At this point, the patient's SBP comes up to 95. The order is then given for NS 1000 ml over 6 hrs. My question is, do we still need to give more NS stat to meet the core measure guidelines, or since the SBP has improved, is the NS infusing over 6 hours acceptable to meet the measure?

- Answer 214:** The volume of crystalloid fluid that must be ordered and given is 30 ml/kg. Based on the patient's weight, they should receive 2400 ml. Even though the SBP increased to 95 after 2000 ml, at that point the patient had not received 30 ml/kg. The order for 1000 ml over 6 hours can be used to fulfill the target volume of 2400 ml, because it is being given at a rate greater than 125 ml/hour.
- Question 215:** Slide 21 states Decrease in SBP >40mmhg from last recorded SBP considered normal for patient. What if the patient comes into the ED in severe sepsis and their SBP~ 80? Obviously, this is probably not normal. Where are you supposed to look for that "normal" value?
- Answer 215:** If the patient arrives with a SBP < 90, determining what represents a decrease of >40 from normal is irrelevant, because the patient already has hypotension.
- Question 216:** Re: persistent hypotension: if you have both SBP and MAP and SBP <90 but MAP >65, which is the correct response?
- Answer 216:** If the patient is exhibiting one of the signs of persistent hypotension, you would select "Yes."
- Question 217:** In regard to crystalloid fluids: if 0.9NS is ordered at 30 ml/kg infused over 1H, about 40 minutes after the infusion is running, the patient's SBP is >90 and the patient is developing pulmonary edema so the fluids are stopped, would this still count as crystalloid administration?
- Answer 217:** For the *Crystalloid Fluid Administration* data element, the fluids need to be started and the order needs to be for 30 ml/kg. This data element does not take into consideration whether or not the volume is totally infused.
- Question 218:** Patient enters ED, Severe Sepsis and criteria are met, however, seven hours later the physician documents septic shock. Logic appears to take this case to W section, however you are not allowed to enter the criteria for septic shock so no counters are realized so ultimately you will fail the measure. Is this truly the intent?



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- Answer 218:** If septic shock presents more than 6 hours after the presentation of severe sepsis, you should select Value "2 (No)," as indicated in the *Septic Shock Present* Notes for Abstraction in version 5.0b of the manual.
- Question 219:** I am still confused about the reason behind the counters in the algorithm. Could you please elaborate?
- Answer 219:** The counters are the way the algorithm keeps track of whether or not an element was completed according to the specifications.
- Question 220:** Regarding the previous session on Severe Sepsis Present, we have trial abstracted some cases and found that it can literally take hours to answer just the Severe Sepsis Present question. The variables with 6 hours forward and backward are vast. When a patient develops severe sepsis during a lengthy encounter, we can have weeks or months of data to abstract for this one element. Has there been any discussion of the difficulty that hospitals will encounter with this data element and/or discussion of development of some type of software to enter all of the vital signs into in order to compare them all and assist if they fall within 6 hours of one another.
- Answer 220:** I am not aware of any tools for comparing vital signs.
- Question 221:** If a patient has both severe sepsis and septic shock, does the patient have two separate counters, one for severe sepsis and one for septic shock?
- Answer 221:** Yes.
- Question 222:** If you answer "no" to septic shock present if crystalloid fluids are not given, why is there a selection 3 to crystalloid fluids not given? Don't they contradict each other?
- Answer 222:** They do not contradict one another. If you select "no" to *Septic Shock Present* because fluids were not given, then selecting "3" indicating fluids were not given would be appropriate for *Crystalloid Fluid Administration*. As currently configured, however, if you select "no" for *Septic Shock Present*, the algorithm bypasses *Crystalloid Fluid Administration*.
- Question 223:** If the crystalloid fluid volume required determining persistent hypotension and thus shock is 30 ml/kg, that will have been administered before shock presentation and not at or after presentation. How should the fluid volume question be answered if the entire 30 ml/kg of crystalloid infused prior to shock presentation?



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- Answer 223:** You would select "1 (Yes)" for *Crystalloid Fluid Administration*. Version 5.0b of the manual clarifies that fluids may be given prior to, at the time of, or after presentation of septic shock.
- Question 224:** Could you please clarify regarding allowable value 3 for crystalloid fluid administration, specifically when fluids are given PRIOR to septic shock or severe sepsis?
- Answer 224:** Version 5.0b of the manual clarifies that fluids may be given prior to, at the time of, or after presentation of septic shock. Value "3" would be selected if no crystalloid fluids were given prior to, at the time of, or after presentation of septic shock.
- Question 225:** For shock present, referring to example #2 of crystalloid fluids, if this amount given was used to determine septic shock present (less than 30 ml/kg), would you answer "No" to sepsis shock present?
- Answer 225:** If the amount of fluid given was less than 30 ml/kg and the patient still had hypotension, you would select "No" for *Septic Shock Present*. This is because *Septic Shock Present* requires that 30 ml/kg be given and then hypotension is still present to select "Yes."
- Question 226:** Would an order for 0.9NS 30 ml/kg given per pressure bag be adequate to answer "Yes" to the crystalloid fluid administration, since in essence, an administration per pressure bag is basically saying administer this as fast as possible?
- Answer 226:** No, the order must include an infusion duration or rate.
- Question 227:** Please clarify: to answer "Yes" to crystalloids, the fluids can be started and administered prior to or after the time of presentation of septic shock, as long as the fluids are still being given at the time of, or after presentation?
- Answer 227:** To answer "Yes" for *Crystalloid Fluid Administration*, there must be an order for 30 ml/kg of crystalloid fluids with an infusion duration or rate, and the crystalloid fluids must have been started prior to at the time of or after presentation of septic shock. The total volume could have been infused prior to presentation of septic shock, and that is still acceptable.
- Question 228:** If the physician starts the Pressors while the initial Crystalloid infusion of 30 ml/kg, will this meet the measure?
- Answer 228:** As long as the vasopressors were started within 6 hours following the presentation of septic shock, it is acceptable. There may be cases where



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hypotension is so profound and the initial response to fluids is so low the physician may start vasopressors while the crystalloid fluids are still infusing.

**Question 229:** If a patient meets severe sepsis criteria and the initial lactate is  $>4.0$  and NO crystalloid fluids were given, does this abstract to "Yes" or "No" for septic shock present element?

**Answer 229:** In this case, you would select "Yes" for *Septic Shock Present*. When the lactate is  $\geq 4$  the presence of septic shock is based upon the lactate, not a response to crystalloid fluids. Crystalloid fluids are required for treatment, however, if the lactate is  $\geq 4$ .

**Question 230:** In the case where severe sepsis or septic shock is diagnosed in the ED, and the ED has scribes, and you have three times documented in the chart, i.e., the "Time seen by Provider," the time the chart is signed off by the ED physician, and the time the scribe documents their notes, which time do we abstract for shock presentation?

**Answer 230:** Whichever time you use needs to be associated with documentation indicating septic shock is present or suspected. For example, if "time seen by provider" does not include documentation that the physician suspected septic shock, it should not be used. If there are multiple times with documentation indicating the provided suspected severe sepsis or septic shock, you should use the earliest time.

**Question 231:** In regards to ED Triage Time: in an FAQ published 8/4/15 it says that severe sepsis or septic shock is usually identified during triage through a sepsis screening process. Does this screen have to be positive in order to use the triage time? What if it's negative but the patient meets the criteria during the ED visit?

**Answer 231:** Triage time is only used if all clinical criteria are met prior to or during triage. If clinical criteria are met after triage time, use the time the last of the criteria are met for severe sepsis or septic shock presentation time.

**Question 232:** In the ED physician's note under clinical impression, it says sepsis due to unspecified organism. In searching for severe sepsis criteria, would this count as suspected source of infection?

**Answer 232:** This would not count because sepsis is not an acceptable term.



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- Question 233:** If the patient in example 2 had already gotten a 500 cc bolus for severe sepsis before the septic shock time, would it extract as Y since the patient has had the 30 ml/kg bolus, but it started before the septic shock time?
- Answer 233:** Yes.
- Question 234:** If a patient is Do Not Resuscitate (DNR)/Do Not Intubate (DNI), by not doing adequate bolus to avoid intubation, will measure still pass?
- Answer 234:** This is difficult to answer without knowing whether septic shock was identified by a lactate  $\geq 4$  or by persistent hypotension. If identified by a lactate  $\geq 4$  and 30 ml/kg were not given, the case will fail the measure. If identified by persistent hypotension and 30 ml/kg were not given, you will need to select "No" for *Septic Shock Present*. This is because the *Septic Shock Present* data element requires that 30 ml/kg be given to identify the presence of persistent hypotension. If 30 ml/kg were not given, one cannot say persistent hypotension was present.
- Question 235:** If fluid total equals 30 ml/kg but ordered in separate boluses would this equal allowable value 1?
- Answer 235:** Yes.
- Question 236:** Is the term "bolus" considered a time frame?
- Answer 236:** No.
- Question 237:** If the order was 30 ml/kg NS bolus with no duration indicated, how do we determine what time the fluids ended?
- Answer 237:** If the time the infusion was completed is documented, this could be used. If this is not documented and a duration or rate is not included in the order, you will not be able to determine when the infusion was complete. Note: if there is not an infusion duration or rate in the order, you will need to select "2" for *Crystalloid Fluid Administration*.
- Question 238:** If an order is given for a "bolus" normal saline 30 m/kg, will this pass the measure?
- Answer 238:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 239:** If there is an order for saline "bolus," can "bolus" be accepted as the rate?



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- Answer 239:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 240:** Can we accept an order with a rate of "bolus" if no specific cc/hour or time ordered?
- Answer 240:** No, the order needs to specify a time frame over which to infuse or a rate. "Bolus" is not specific enough and does not allow for determination of when the fluids were completed.
- Question 241:** How do you handle orders that state Bolus 1000cc with no order over time period?
- Answer 241:** If there is not an infusion duration or rate in the order, you will need to select "2" for *Crystalloid Fluid Administration*.
- Question 242:** If NS or LR is ordered STAT or "give bolus" without a period of time volume should be given (i.e., 30 minutes), can the order still be used with the assumption that it should be one hour or less?
- Answer 242:** If there is not an infusion duration or rate in the order, you will need to select "2" for *Crystalloid Fluid Administration*.
- Question 243:** Does the MD order have to include either a rate or time period? The reason we ask is our orders just say "30 ml/kg bolus," that's it, no rate, no time period.
- Answer 243:** If there is not an infusion duration or rate in the order, you will need to select "2" for *Crystalloid Fluid Administration*.
- Question 244:** What if the vasopressors that are started before the 30 ml/kg is completed? How do you abstract whether persistent hypotension is present?
- Answer 244:** For purposes of the measure, regardless of whether vasopressors were started prior to or after 30 ml/kg of crystalloids were given, if hypotension persists in the hour after the 30 ml/kg of crystalloids were given, you would select "Yes" for *Persistent Hypotension*. If hypotension does not persist, you would select "No."
- Question 245:** Do fluids given by EMS prior to arrival count in the total fluids given for septic shock? Our MDs do not want to overload the patient and said they are going to document total given by EMS and then subtract that from the 30



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ml/kg, and give the rest of the fluids needed. Will this pass if they document "given 2 L by EMS then given 1 L more if total 30 ml/kg=3 l?"

**Answer 245:** Yes.

**Question 246:** We have to send out our lactic acids. If the physician documents they are unable to get results, will it clear the measure?

**Answer 246:** No.

**Question 247:** If a patient does not clinically meet septic shock but on day after arrival to hospital a physician documents "Septic shock present on arrival," how would this be abstracted?

**Answer 247:** In this situation, you would take the physician documentation, and the septic shock presentation time would be triage time (assuming they came in through the ED).

**Question 248:** What is your estimate of the time it will take to abstract one record?

**Answer 248:** This may vary from case to case and be dependent upon the type of medical record you are working with.

**Question 249:** Have you estimated what the average time for abstraction of this measure will be?

**Answer 249:** This may vary from case to case and be dependent upon the type of medical record you are working with.

**Question 250:** What if patient doesn't develop septic shock until >6 hours past severe sepsis presentation, i.e., 24 hours later. Should they be excluded from the septic shock population? Right now, our vendor's software is counting them as complete fallout because all the septic shock elements are past the 6 hour time frame.

**Answer 250:** The recently released version 5.0b of the specifications manual addresses this in the *Septic Shock Present* data element. This data element includes a bullet point that indicates if septic shock presentation is more than six hours after severe sepsis presentation, choose Value "2."

**Question 251:** By including "sepsis" in the denominator, it seems that hospitals are penalized for successfully treating sepsis and preventing the onset of "severe sepsis" and "septic shock."



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- Answer 251:** Patients with ICD-10 codes for uncomplicated "sepsis" are included because of inaccuracies associated with coding. This is not an intent to penalize facilities. If a patient does not meet specifications for severe sepsis or septic shock, regardless if they had an ICD-10 code for sepsis, severe sepsis or septic shock, they will be excluded from the measure.
- Question 252:** How long do you anticipate an abstractor to complete one chart?
- Answer 252:** This may vary from case to case and be dependent upon the type of medical record you are working with.
- Question 253:** Where in the algorithm is the patient excluded who is on IV antibiotics 24 hours prior to presentation?
- Answer 253:** This is identified by the date and time entered for *Broad Spectrum or Other Antibiotic Administration* and the Broad Spectrum Antibiotic Time Calculation in the algorithm on page SEP-1-11.
- Question 254:** If we have D or E, will that require another case to be audited?
- Answer 254:** No.
- Question 255:** Slide 29, Calculation using Severe Sepsis Presentation Date and Time: coders may use Acute Respiratory Failure with Pneumonia as one of the criteria for Severe Sepsis. If other criteria are not present, would this be abstracted as Severe Sepsis Present = "No" even though primary diagnosis may be Severe Sepsis?
- Answer 255:** The coding is only used to identify patients for the initial patient population. For purposes of the measure, determining presence of severe sepsis depends on the documentation in the medical record. For example, if clinical criteria are not met and the physician documents severe sepsis, then you would select "Yes" for *Severe Sepsis Present*. If clinical criteria are not met and there is no physician documentation of suspected or possible severe sepsis, you will select "No" regardless of coding.
- Question 256:** Do we want to achieve a small numerator?
- Answer 256:** A small numerator would reflect you had few cases that met the measure. A larger numerator would reflect you had more cases that met the measure. As such, a larger numerator reflects high compliance with the measure specifications.



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**Question 257:** What can we use for infection? Does it have to say infection or can we go by a known infection such as PN? Can we take from the Active Problem List?

**Answer 257:** Either the word infection is used or the name of a condition that is an infection is documented. The active problem list is acceptable as long as it is current and up to date.

**Question 258:** Population=Sepsis, but the measure only applies to Severe Sepsis. When cases abstracted are only Sepsis, do they count for the population sample? What if only a few Sepsis sampled cases are actually Severe Sepsis?

**Answer 258:** If cases are excluded from the sample because documentation does not support presence of severe sepsis or septic shock, regardless of how they are coded, they are excluded from the denominator. You do not replace them in you sample population. However, it will result in a smaller denominator for the measure.

**Question 259:** What's time zero, when the words are written or when the criteria are in the chart, or time of triage?

**Answer 259:** Time zero (severe sepsis or septic shock presentation time) will depend on the documentation in the medical record. If all of the clinical criteria are met prior to or during triage, then use triage time. If clinical criteria are met after triage, use the time the last of the clinical criteria are met. If provider documentation of severe sepsis or septic shock is present and clinical criteria are not present, use provider documentation time. If both clinical criteria are met and there is also provider documentation of severe sepsis or septic shock, use the earlier of either when the last of the clinical criteria are met, OR physician, APN, or PA documentation.

**Question 260:** Slide 20: In this scenario, would the presentation time of severe sepsis be the same as the presentation time of septic shock?

**Answer 260:** Yes.

**Question 261:** If patient is presented with septic shock parameters and then six hours later goes into a rapid septic shock, since severe sepsis must be present for septic shock, can we still use this as septic shock, even though we have already counted one severe sepsis?

**Answer 261:** Yes. Please note, the specs manual was recently updated as version 5.0b, in which it indicates if the Septic Shock Presentation Time is more than 6 hours



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after the Severe Sepsis Presentation Time select "2 (No)" for *Septic Shock Present*.

**Question 262:** The MD usually orders as a bolus and not over an hour. How do would we calculate end time?

**Answer 262:** If the order is as a bolus and there is not any documentation indicating when the infusion ended, you will not be able to determine completion time.

**Question 263:** According to the FAQ, QNet directed us to subtract one minute to equal the end of fluids, i.e., order 1:00 over one hour, completion time is 1:59. This presentation states conclusion time is 2:00. Please clarify.

**Answer 263:** If the order includes an infusion duration (e.g., 2 hours), adding that to the time the infusion is started (e.g., 07:00) can be used to determine the infusion end time (09:00).

**Question 264:** We had a case where the patient didn't make criteria but the dictated note did say septic shock. What exactly is the time? The time the note was dictated?

**Answer 264:** If there is a time within the note indicating when septic shock was identified, that should be used. If a time within the note is not present, use the time the noted was dictated.

**Question 265:** Is differential diagnosis acceptable? *QualityNet* stated that since these are "working diagnosis" they should not be counted.

**Answer 265:** I am not sure which specific question on *QualityNet* is referenced in this question. There is a question on *QualityNet* that asks about using a problem or working diagnosis from a problem list. The response does not indicate it cannot be used. The response indicates there must be a date and time associated with the documentation, indicating it is current or still present to be sufficient. Problem lists are not always up to date, so the presence of an infection in a problem list should be reflective if the infection is still present. The measure does not require the diagnosis of an infection, rather that one is suspected or possible. As such, as long as there is a date and time associated with the differential diagnosis it is acceptable.

**Question 266:** If the patient becomes septic days into the admission, would the time the sepsis is identified be our start time for data collection or is this only on admission for these patients?

**Answer 266:** Data collection, depending on the data element, is associated with the time of severe sepsis presentation. Some data elements, such as Directive for Comfort



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Measures, may include documentation that occurred prior to severe sepsis presentation.

- Question 267:** IV fluids: I understood it was to abstract what was given, NOT what was ordered?
- Answer 267:** Crystalloid fluids includes two parts. The *Crystalloid Fluid Administration* data element requires an order for 30 ml/kg with an infusion duration or rate and that the fluids are started prior to at the time of or following septic shock presentation. The *Persistent Hypotension* data element requires that 30 ml/kg of crystalloid fluid were actually given.
- Question 268:** What if the total fluid required was 2508 ml but 2500 ml was given? Would we have to select value 2 because we were 8 ml below target total volume?
- Answer 268:** Yes, this is something we are looking further into as there may be some cases where a volume is given based on an estimated weight that is not documented, and the actual weight after fluids administration may result is higher target.
- Question 269:** If we have a fluid completion time, may we use that to determine persistent hypotension within one hour of fluid conclusion OR do we have to use the estimated examples based upon the duration of the order?
- Answer 269:** Persistent Hypotension is determined in the hour following conclusion of the crystalloid fluids. In order to determine when this hour starts, you need to determine when the fluid infusion was completed.
- Question 270:** How would you answer if BP >90 but MAP is <65?
- Answer 270:** If the patient is exhibiting one of the signs of persistent hypotension, you would select "Yes."
- Question 271:** Would you mind telling us again for clarification, what is the definition of "time of presentation" of severe sepsis and septic shock for the bundle sets to start?
- Answer 271:** Time of presentation of severe sepsis and septic shock is the earlier of either when the last of the clinical criteria are met, OR physician, APN, or PA documentation of severe sepsis or septic shock.
- Question 272:** When using clinical data to determine presence of severe sepsis will you pull from multiple vital sign assessments to meet "two pieces of SIRS criteria?"



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- Answer 272:** Yes, this may happen for some cases. For example, a patient may have an elevated temperature first, and then as they progress, develop an increased RR or HR. Keep in mind that all elements of clinical criteria must be met within 6 hours of each other.
- Question 273:** One of the inclusions in the Specs Manual is skin turgor. This does not include a color. Will this still pass?
- Answer 273:** While skin turgor is an inclusion term, the *Skin Examination Performed* requires skin color be documented. Without a color documented, you will need to select "No."
- Question 274:** Just to be clear, is the septic shock time the time of the first hypotension or the time of the persistent hypotension?
- Answer 274:** If based upon hypotension, *Septic Shock Presentation Time* is when persistent hypotension is noted.
- Question 275:** If a passive leg raise and a fluid challenge were performed, would this pass for the "Any Two" group part of the Sep-1 measure?
- Answer 275:** No, passive leg raise and fluid challenge are two different methods to assess the same thing (cardiovascular response to an increased vascular volume).
- Question 276:** For central venous measurement, does this have to be continuous or can it be a single lab draw?
- Answer 276:** Either is acceptable.
- Question 277:** Can we take the diagnosis from a medication order?
- Answer 277:** Yes.
- Question 278:** Can infiltrates on a chest X-ray be used for an infection?
- Answer 278:** No, because infiltrates are non-specific.
- Question 279:** Does the admitting diagnosis of "rule out severe sepsis" along with other non-related questionable diagnoses place this case into the severe sepsis category to determine if criteria are met?
- Answer 279:** Rule out severe sepsis is sufficient for physician documentation of severe sepsis. You will still need to check for clinical criteria, because the



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presentation time will be the earlier of either when the last of the clinical criteria are met, OR physician, APN, or PA documentation.

**Question 280:** Does intubation count as organ failure for septic shock?

**Answer 280:** Intubation does not count as organ failure for septic shock. If the patient is subsequently placed on mechanical ventilation, then it can count as organ dysfunction.

**Question 281:** Regarding severe sepsis present, if abscess tooth is on active problem list but patient is here for abdominal pain and doctor says possible small bowel obstruction (SBO) vs. infection, would we use the tooth abscess?

**Answer 281:** In order to use an infection that is on the active problem list, there needs to be some documentation indicating it is still present. If abscess tooth is still present, and there is documentation of SBO vs. infection, either one can be used.

**Question 282:** Does physician documentation of septic shock take precedence over the clinical indicators? In other words, if there is physician documentation, can you go to the next step, or do you still have to check for the clinical indicators?

**Answer 282:** You need to check for both because the presentation time will be whichever is earliest of either the time the last of clinical criteria was met OR physician documentation.

**Question 283:** If we have an appropriate amount of fluid given (@30 ml/kg) but the order does not state a duration, BUT we can find in the medical record a fluid end time (infusion end time) indicating that the fluid volume met the criteria, will that pass the measure?

**Answer 283:** No, if there is not an infusion duration or rate in the order, you will need to select "2" for *Crystalloid Fluid Administration*.

**Question 284:** So, if the case is excluded does this mean that you stop abstracting the case?

**Answer 284:** Yes.

### General

**Question 285:** When will Version 5.0b be published?



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- Answer 285:** Version 5.0b was posted on *QualityNet* on 11/12/2015. It is effective with discharges starting 10/1/2015.  
<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228774725171>
- Question 286:** When will specs manual 5.0b be released and will it impact abstraction that begins on 10/01/2015?
- Answer 286:** Version 5.0b was posted on *QualityNet* on 11/12/2015. It is effective with discharges starting 10/1/2015.  
<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228774725171>
- Question 287:** Where can we find Appendix A, Table 4.01? Where can we access most current reference manual for measure?
- Answer 287:** Version 5.0b was posted on *QualityNet* on 11/12/2015. It is effective with discharges starting 10/1/2015.  
<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228774725171>
- Question 288:** Our facility uses Lactic Acid which is measured in mg/dL. Will a cross walk be provided from mmol/L to mg/dL in the Specs Manual?
- Answer 288:** To convert from mmol/L to mg/dL take the value in mmol/L x 9.  
Conversely, to convert from mg/dL to mmol/L take the value in mg/dL ÷ 9.
- Question 289:** Are Critical Access Hospitals (CAHs) required to report on the sepsis measure?
- Answer 289:** CAHs are encouraged to but not required to report on SEP-1.
- Question 290:** Is an acute rehabilitation setting considered an acute care center?
- Answer 290:** According to the *Transfer From Another Hospital or ASC* Notes for Abstraction, you would select "Yes" if the patient was transferred in from an acute rehab facility.
- Question 291:** I've heard that there is consideration being given to postponing implementation until 1/1/2016. Is that true?
- Answer 291:** I am not aware of plans for postponing implementation.



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- Question 292:** Is there any indication when *QualityNet* Q&A will post answers to questions in their queue?
- Answer 292:** Q&As are currently available on *QualityNet* for SEP-1.
- Question 293:** Regarding slide 103, the fact sheet on the *QualityNet* website includes an error under the measure information description on page 2. The last sentence indicates that repeat lactate measurement is expected to occur within six hours of presentation of septic shock. This is not accurate. I notified *QualityNet* of this several weeks ago and this has still not been updated.
- Answer 293:** Thank you for pointing this out.
- Question 294:** What is the definition of "persistent?"
- Answer 294:** Still present. Persistent hypotension is hypotension that is still present after 30 ml/kg crystalloid fluids are given.
- Question 295:** What is the definition of best practice nurse?
- Answer 295:** The SEP-1 measure and data elements do not make reference to "best practice nurse." They do make reference to "advanced practice nurses."
- Question 296:** Is Non-Invasive Blood Pressure (NIBP) mean the same thing as Mean Arterial Pressure (MAP)?
- Answer 296:** MAP can be from a NIBP, but an NIBP is not necessarily a MAP. NIBP is the method for obtaining a blood pressure whereas MAP is a specific blood pressure reading.
- Question 297:** Will CART update to allow for sepsis abstraction?
- Answer 297:** Yes.
- Question 298:** "Normal" blood pressure is very vague. This needs to be defined more
- Answer 298:** This is in the process of being addressed.
- Question 299:** When will the update to CART be available as well as the date abstraction tool?
- Answer 299:** I have heard estimates of February.



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**Question 300:** So, if Focused Exam is greater than 6 hours after presentation, then we have to do CVP Measure?

**Answer 300:** The repeat volume status and tissue perfusion assessment must be completed within 6 hours of septic shock presentation, regardless of whether a focused exam is performed or two of the other four (CVP, ScvO<sub>2</sub>, cardiovascular ultrasound, passive leg raise/fluid challenge) are completed.

**Question 301:** I have Providers interested in commenting on the sepsis core measure content for future consideration/changes in specifications. What is the best way to do this?

**Answer 301:** Submit questions and comments via *QualityNet*.

### Clock

**Question 302:** If a patient presents to triage on arrival to ED, has advanced triage protocols initiated, including lactate, CBC, has a systolic BP of 89, hour is 110, change in mental status, and 4 hours later, the physician documents suspicion of severe sepsis, when does the clock start, in triage or when the physician documents suspicion of severe sepsis?

**Answer 302:** The severe sepsis clock starts with the earlier of either when the last of the clinical criteria is met OR physician, APN, or PA documentation of severe sepsis. If this occurs prior to or during triage, you use triage time. If it occurs after triage, you use the time of last clinical criteria or the time of physician, APN, or PA documentation. In the scenario you describe, there is not a sign of suspected infection noted with the advanced triage protocol. As such, the clinical criteria are not met during triage. You would use the time of physician documentation.

**Question 303:** If you aren't hypotensive until more than 1 hour after hypotension, then do you start over with meeting all the criteria again? For example, you meet clinical criteria for Severe sepsis, then you are hypotensive and get 30cc/kg of IVF and your BP is stable after that for 3 hours. Then, the patient becomes hypotensive 6 hours later. Do you restart the severe sepsis and shock clock- or is the patient excluded from further reporting?

**Answer 303:** Persistent hypotension must occur within the 1 hour following conclusion of 30 ml/kg of crystalloid fluids. If hypotension presents more than 1 hour after conclusion of the 30 ml/kg of fluids, you would select "No" for *Persistent Hypotension*. While clinically the patient would have septic shock, for purposes of the measure, you would select "No" for *Septic Shock Present*.



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- Question 304:** In example 3, septic shock presentation time equals 0900. Don't we have 6 hours after septic shock presentation?
- Answer 304:** Crystalloid fluids must be started within 3 hours of septic shock presentation to pass.
- Question 305:** What is septic shock presentation time related to tissue hypoperfusion from hypotension; is it severe sepsis plus hypotension (initial BP drop) or severe sepsis plus persistent hypotension? Example 1 for the data element septic shock presentation time, in the Specs Manual state severe sepsis, was present at 2200 and at 0130. The BP was noted to be 74/40. Septic shock presentation time is 0130. This example leads me to think that severe sepsis presentation time is when the patient has severe sepsis plus hypotension (not persistent hypotension). Please explain?
- Answer 305:** Septic shock is defined per the *Septic Shock Present* data element as:  
Severe Sepsis with an initial lactate  $\geq 4$   
OR  
Severe Sepsis with persistent hypotension after 30 ml/kg of crystalloid fluids were given.
- Question 306:** I do not understand the term "add one to septic shock presentation counter." Add one what?
- Answer 306:** The counters are the way the algorithm keeps track of whether or not an element was completed according to the specifications.
- Question 307:** Can you please define time Zero and when does it start?
- Answer 307:** Time zero (severe sepsis or septic shock presentation time) will depend on the documentation in the medical record. If all of the clinical criteria are met prior to or during triage, then use triage time. If clinical criteria are met after triage, use the time the last of the clinical criteria are met. If provider documentation of severe sepsis or septic shock is present and clinical criteria are not present, use provider documentation time. If both clinical criteria are met and there is also provider documentation of severe sepsis or septic shock, use whichever occurs earlier.

### Lactate

- Question 308:** If initial lactate is  $>4$ , and all other severe sepsis criteria are met, does the patient automatically fall into the septic shock population? Would you use the same time zero for severe sepsis and septic shock at this time?



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- Answer 308:** If criteria for severe sepsis are present, and this includes an initial lactate  $\geq 4$ , then severe sepsis and septic shock presentation are the same time.
- Question 309:** To determine septic shock presentation, do we use any lactate  $\geq 4$  or only the initial lactate  $\geq 4$ ? The specifications don't say, but I've seen several interpretations using initial lactate  $\geq 4$  only.
- Answer 309:** Use Initial lactate level. This is specified in version 5.0b of the manual.
- Question 310:** So just to clarify, should our ED staff draw a repeat lactate if the initial lactate is 2? I ask because I have seen both lactate levels of 2 and 4 mentioned. Please clarify what initial lactate level requires a redraw within 3 hours.
- Answer 310:** A repeat lactate is warranted if the initial lactate level is elevated. The algorithm reflects an elevated lactate level is  $> 2$ . If the initial lactate level is  $> 2$ , then a repeat lactate needs to be drawn within 6 hours of severe sepsis presentation.
- Question 311:** If the Initial lactate is  $> 4$  but the repeat lactate is  $< 2$ , is a tissue perfusion assessment still required since the repeat lactate is no longer showing septic shock?
- Answer 311:** Yes, it is still required. The repeat volume status and tissue perfusion assessment is based on the presence of septic shock, not on the repeated lactate level.
- Question 312:** If your initial lactate level is  $> 4$ , should septic shock be present at this time?
- Answer 312:** Yes, if other criteria for severe sepsis are also present this would represent septic shock.
- Question 313:** What happens if an initial lactate level is not associated with septic shock i.e., admission lab, but two days later has septic shock with another lactic acid level done?
- Answer 313:** In this scenario, septic shock manifests clinical more than 6 hours after severe sepsis presentation so you would select "No" for *Septic Shock Present*.
- Question 314:** Slide 23 states septic shock is present if tissue hypoperfusion is demonstrated by a lactate level  $\geq 4$ , initial lactate level results. Going back to the severe sepsis specs, it was my understanding if lactate was  $> 2$  we were to repeat the lactate. Which lactate result are we to refer to?



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- Answer 314:** Septic shock is present if severe sepsis with an initial lactate  $\geq 4$  is present. This is independent of a repeat lactate. A repeat lactate should be drawn for an elevated initial lactate. The initial lactate is considered elevated if it is greater than 2. So for any initial lactate  $>2$ , a repeat needs to be drawn.
- Question 315:** If the first lactic acid at 10 a.m. is 3 mmol/L and severe sepsis diagnosis is met at 11 a.m. and a second lactic acid level is 4.5 at 1 p.m., then the patient meets septic shock diagnosis at 1:15, do we take the higher lactic acid or the first lactic acid?
- Answer 315:** In the most recent version of the manual (v5.0b), the *Septic Shock Present* data element indicates the initial lactate level is  $\geq 4$ . While this may clinically represent septic shock, for purposes of the measure, it is the initial lactate  $\geq 4$  with severe sepsis that identifies presence of septic shock.
- Question 316:** Looking at CMS' branching logic, can we take initial lactic acid drawn within 6 hours prior to severe sepsis up to 3 hours from severe sepsis?
- Answer 316:** You will need to enter the date and time of the lactate level that represents the initial lactate, as defined by the initial lactate level data elements. To pass the measure it must be within 6 hours prior to or within 3 hours following presentation of severe sepsis.
- Question 317:** If a patient has severe sepsis and has an initial lactate of 4, is the patient considered to have septic shock? Am I correct that the one hour timeframe after adequate fluid does not apply to that lactate value?
- Answer 317:** Yes, this is correct.
- Question 318:** What did you mean when you said "Be sure you are using the lactate level that is designated initial lactate"?
- Answer 318:** It is possible that several lactate levels may have been drawn. The *Initial Lactate Level Collection* data element's Notes for Abstraction provide guidance on how to determine which one is considered the initial lactate level.
- Question 319:** I did not fully understand the initial Lactic being greater than or equal to 4.0 means that septic shock is present. Please elaborate.
- Answer 319:** If severe sepsis is present and the initial lactate is  $\geq 4$ , the patient has septic shock.
- Question 320:** If the patient was not hypotensive but the lactate was  $>4$ , do we still need to give 30 ml/kg of fluids?



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- Answer 320:** Yes.
- Question 321:** Do patients with a lactate greater than 4 require intravenous fluids even if they are not hypotensive?
- Answer 321:** Yes.
- Question 322:** If a patient has Lactic above 2 and no hypotension, per definition is it considered severe sepsis as a diagnosis?
- Answer 322:** If there is documentation of a suspected infection, 2 or more SIRS criteria are present, and the lactate is  $>2$  (sign of organ dysfunction), the patient has severe sepsis. In this same scenario, if the lactate was  $\geq 4$  the patient would also have septic shock.
- Question 323:** How can you have septic shock when there is no hypotension present but the lactate is  $>4.0$ ?
- Answer 323:** By definition, septic shock is present if severe sepsis is present with tissue hypoperfusion as demonstrated with a lactate  $\geq 4$ .
- Question 324:** Unless lactate is used to identify septic shock, then it seems you will need two administrations of 30 ml/kg (one prior and one post shock presentation). Is that correct?
- Answer 324:** No, the 30 ml/kg of crystalloid fluids are only given once. In cases where septic shock is based upon hypotension, 30 ml/kg are given for patients with severe sepsis and hypotension. If they respond to the 30 ml/kg, they do not have septic shock. If they do not respond to the 30 ml/kg (this represents persistent hypotension), they have septic shock. More fluids are not required and vasopressors should be started.
- Question 325:** I often see a lactate and lactic acid drawn almost simultaneously, maybe two minutes apart. Would a result two minutes after the first result meet this data element or is there a minimum time (demonstrating a TRUE repeat)?
- Answer 325:** This will depend on the timing in reference to the presentation of severe sepsis.
- Question 326:** Regarding Lactic acid: is it more logical to use result time not collection time? Please clarify.
- Answer 326:** When determining the presence of severe sepsis or whether or not the lactate is elevated, you should be using result time, not collected time. This is



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because it is the result of  $>2$  or  $\geq 4$  that determines whether or not severe sepsis or septic shock is present, not the time the lactate is drawn. The only time you make use of lactate collection time is when determining when the lactate level was collected. This is used by the algorithm to determine if the lactate was drawn within 3 hours of severe sepsis presentation.

**Question 327:** If the last criterion is not the elevated lactate, but the lactate is greater than 4.1, what time stamp is used for septic shock?

**Answer 327:** The time when the last criterion was met.

**Question 328:** Surviving sepsis campaign doesn't use the term "septic shock" when the lactate is  $>4$ . These guidelines use the term severe sepsis. Is this a deviation? How does this work with ICD-10?

**Answer 328:** *The International Guidelines for Management of Severe Sepsis and Septic Shock: 2012* use the term "sepsis-induced tissue hypoperfusion" for patients with severe sepsis and lactate  $\geq 4$  mmol/L. In reference to lactate levels, they define severe sepsis with a lactate above upper limits laboratory normal, which is general understood to be a lactate  $>2$ . Once the lactate is  $\geq 4$ , the severe sepsis transitions to a state of hypoperfusion, which also defines septic shock. Septic shock is defined as severe sepsis where the lactate is  $\geq 4$  or where hypotension does not respond to 30 ml/kg of crystalloid fluids. If the lactate is  $<4$  or hypotension responds to crystalloid fluids, the patient has severe sepsis, not septic shock. ICD-10 coding is based upon clinical documentation, not definitions in guidelines.

### Exclusions

**Question 329:** Patients transferred in are exclusions. Is this true for the entire length of stay if the primary reason for transfer is not sepsis and they develop severe sepsis/shock during the admission?

**Answer 329:** All patients who meet the criteria established in the *Transfer From Another Hospital or ASC* are excluded from the measure.

**Question 330:** If a patient is not a candidate for fluid resuscitation of 30 ml/kg (acute Heart Failure, ARF, etc.), is there a plan to exclude that metric from the SEP Bundle or will those patients always automatically be in the denominator?

**Answer 330:** There are not exclusions to the crystalloid fluid volume. In those specific cases where in giving the full 30 ml/kg may be detrimental to the patient, based on the physician's best clinical judgment, physician judgment should



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prevail. It may result in the case failing the measure, but is in the best interest of the patient.

**Question 331:** Why is there no exclusion of crystalloids based on physician clinical judgment, i.e., CHF, Renal failure, Cor Pulmonale, etc.?

**Answer 331:** Most septic shock trials did not exclude patients with septic shock who also had these comorbidities. These patients all typically received the same amount of fluids and did not suffer deleterious side effects.

**Question 332:** Is there any allowance for heart failure or renal failure patients not getting the full 30 ml/kg bolus?

**Answer 332:** There are not exclusions to the crystalloid fluid volume. In those specific cases where in giving the full 30 ml/kg may be detrimental to the patient, based on the physician's best clinical judgment, physician judgment should prevail. It may result in the case failing the measure, but is in the best interest of the patient.

**Question 333:** If a patient is admitted and meets sepsis criteria and doesn't develop organ dysfunction for 8 hours after the initial presentation of sepsis, would the patient be part of the measure?

**Answer 333:** All of the criteria for severe sepsis must be met within 6 hours of each other. If they are not, you would select "No" for *Severe Sepsis Present*, and the case is excluded.

**Question 334:** For the exclusion, is there any IV antibiotics prior to severe sepsis?

**Answer 334:** No, the exclusion for patients who received antibiotics more than 24 hours prior to presentation is limited to those patients that received a dose of the same antibiotic both 24 hours prior to presentation AND within 24 hours prior to presentation.

**Question 335:** If the patient doesn't meet criteria, but the patient got IV antibiotics (ABX) in treatment for possible infection, then the physician's dictated note is after this ABX time, is the case excluded because the patient met the criteria AFTER IV ABX were given?

**Answer 335:** The question indicates the patient did not meet criteria, and does not indicate the physician documented severe sepsis. If there is not an indication of severe sepsis (criteria not met and no physician documentation of severe sepsis), the case is excluded regardless of antibiotic timing.



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- Question 336:** Regarding previous IV antibiotics: if a patient had a dose of an antibiotic <24 hours prior to presentation of septic shock (example, patient goes to OR for surgery and receives intra-operative antibiotics and 4 hours post op presents with septic shock), is the patient to be excluded from the numerator, the denominator, or both? Does a single dose of IV antibiotics prior to presentation exclude the patient from the measure?
- Answer 336:** This will depend on the timing of the antibiotics and which antibiotics were given. The exclusion for patients who received antibiotics more than 24 hours prior to presentation is limited to those patients that received a dose of the same antibiotic both 24 hours prior to presentation AND within 24 hours prior to presentation.
- Question 337:** Is there any exclusion for septicemia and/or bacteremia?
- Answer 337:** Septicemia and bacteremia are not acceptable terms for identifying the presence of a suspected infection or for the presence of severe sepsis.
- Question 338:** Can note/consultation for palliative care account for comfort care measures? Please clarify.
- Answer 338:** Yes.
- Question 339:** Clarify statement on slide 25: if fluids not given, select 2, likely not in septic shock and will be excluded.
- Answer 339:** The *Septic Shock Present* data element's Notes for Abstraction include a bullet point that states "If crystalloid fluids were NOT administered after the presentation date and time of Severe Sepsis, select Allowable Value "2 (No)." This means if the patient meets criteria for septic shock or there is physician documentation of septic shock, but crystalloid fluids were NOT given after *Severe Sepsis Presentation Time* you would select Value "2 (No)" for *Septic Shock Present*.
- Question 340:** In a hypothetical situation where an initial lactic acid value is not drawn, and the 6 hour window passes, would this patient be excluded from the measure, even though they may still have septic shock clinically?
- Answer 340:** If the patient meets criteria for severe sepsis or septic shock and a lactate is not drawn, the case will fail the measure. A lactate is required within 3 hours of severe sepsis presentation to meet the measure.



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- Question 341:** What if a physician noted the patient has a normal SBP of 85 and does not treat an SBP of 85 as hypotension due to this? Can a detailed physician's note exclude this patient from septic shock abstraction?
- Answer 341:** There are not exclusions to the crystalloid fluid volume. In those specific cases where in giving the full 30 ml/kg may be detrimental to the patient, based on the physician's best clinical judgment, physician judgment should prevail. It may result in the case failing the measure, but is in the best interest of the patient.
- Question 342:** What if the patient met septic shock criteria by lactate level but was deemed inappropriate for fluids due to already present cardiopulmonary fluid overload on chest x-ray?
- Answer 342:** There are not exclusions to the crystalloid fluid volume. In those specific cases where in giving the full 30 ml/kg may be detrimental to the patient, based on the physician's best clinical judgment, physician judgment should prevail. It may result in the case failing the measure, but is in the best interest of the patient.
- Question 343:** If the patient has a DNR with no Pressors but has persistent hypotension, how do you take this patient out of the measure?
- Answer 343:** There currently is no exclusion for refusal of vasopressors. We recognize this does occur and are working to address this in the next version of the manual.
- Question 344:** A patient with extremely poor IV access, required central line. The patient met bundle after the central line was placed, bloodwork was drawn and resulted (WBC was 2nd qualifier). The patient did not meet 3 hour as triage time utilized. Would there be any consideration on removal of these types of events from numerator?
- Answer 344:** Cases such as this are not excluded.
- Question 345:** A patient with a chronic illness and known documented labs that are elevated presents, does that qualify them under the SIRS criteria (i.e., chronic renal failure, known thrombocytopenia, etc.)
- Answer 345:** In version 5.0b of the manual posted on *QualityNet* in mid-October, this is addressed with the following "Do not include evidence of organ dysfunction that is considered to be due to a chronic condition or medication (e.g., Creatinine >2 for a patient with end stage renal disease, INR >1.5 for a patient on Warfarin)."



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**Question 346:** The measure does not list exclusions for ESRD creat  $>2$ , INR  $>1.5$  or a PTT $>60$  and anticoagulated or bilirubin elevation in patients with liver pathology. Do you know if these will be added soon?

**Answer 346:** In version 5.0b of the manual posted on *QualityNet* in mid-October, this is addressed with the following "Do not include evidence of organ dysfunction that is considered to be due to a chronic condition or medication (e.g., Creatinine  $>2$  for a patient with end stage renal disease, INR  $>1.5$  for a patient on Warfarin)."

**Question 347:** If a physician documented a reason for not prescribing 30cc/kg fluid resuscitation, will this be excluded?

**Answer 347:** There are not exclusions to the crystalloid fluid volume. In those specific cases where in giving the full 30 ml/kg may be detrimental to the patient, based on the physician's best clinical judgment, physician judgment should prevail. It may result in the case failing the measure, but is in the best interest of the patient.

### Perfusion

**Question 348:** What processes have been utilized out there to meet the upcoming CORE-SEP-1's time sensitive 6-hour bundle element of "Tissue Perfusion Assessment" (Focused Exam and Hemodynamic Monitoring)? What are other facilities doing or planning on doing to be able to meet this 6-hour bundle metric?

**Answer 348:** There was a webinar on November 10 that featured the activities and interventions implemented at SSM Health System. The slide set and recording of the event are available on the *Quality Reporting Center* website at <http://www.qualityreportingcenter.com/inpatient/iqr/events/>.

**Question 349:** Please clarify if the Repeat Vol Status or Tissue Perfusion Assessment timing must be completed AFTER the CF has been given or can it be completed WHILE the CF is still infusing?

**Answer 349:** The repeat volume status and tissue perfusion assessment must be performed within 6 hours following the presentation of septic shock to pass this part of the measure. The acceptable time frame within which it must be performed starts with the Crystalloid Fluid Administration Date and Time and ends at 6 hours after Septic Shock Presentation Date and Time.



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#### Rationale

**Question 350:** Why does the core measure for sepsis base the diagnostic criteria on the old ([pre-2001) SIRS criteria and not the updated Sepsis criteria that was published by the Surviving Sepsis Campaign in 2001 and 2012? The old SIRS criteria only includes four elements, but the new criteria includes additional elements, such as altered mental status, hyperglycemia in the absence of diabetes, elevated lactate levels, elevated protein-C, elevated procalcitonin, and edema.

**Answer 350:** The measure stewards identified that the original SIRS criteria are what were used in most studies and have stronger evidence supporting their association with severe sepsis than the additional SIRS criteria. The expanded SIRS criteria can certainly be used in the clinical setting to help cast a wider net for identifying patients at risk for severe sepsis, if your facility chooses. For purposes of the measure, the expanded criteria are not currently being used. This will simply mean that patients identified using expanded criteria will be excluded from the SEP-1 measure. Elevated lactate levels are not considered a part of SIRS criteria in the guidelines, and are a sign of organ dysfunction and/or tissue hypoperfusion.

**Question 351:** It makes no sense to me that the 30 ml/kg need to be administered to the patient in order to determine if the patient is in the septic shock population. Yet, the 30 ml/kg is only required if the patient is already in the septic shock population. Please help me to understand.

**Answer 351:** The 30 ml/kg of crystalloid fluids is indicated for the following:

- **Severe sepsis with hypotension.** The 30 ml/kg of crystalloid fluids is given to treat the hypotension. If the hypotension persists in the hour following the infusion of the crystalloid fluids, the patient has septic shock. In this case, the fluids are given prior to presentation of septic shock to treat the hypotension and the lack of blood pressure response signifies the presence of septic shock. The 30 ml/kg is not repeated after presentation of septic shock.
- **Severe sepsis with a lactate  $\geq 4$ .** The 30 ml/kg of crystalloid fluids given to treat the lactate  $\geq 4$ . The fact the lactate is  $\geq 4$  is what signifies the presence of septic shock, not the administration of the fluids. In this case, the fluids are given after presentation of septic shock for treatment and do not contribute to determining the presence of septic shock. Again the 30 ml/kg is given only once.
- **Physician, APN, or PA documentation of septic shock.** The 30 ml/kg of crystalloid fluids may be given prior to, at the time of, or after



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presentation as signified by documentation depending on the timing of the documentation and when the fluids are started. Again the 30 ml/kg is given only once.

**Question 352:** In reference to slide 21, the Specifications Manual does not support the need for 30 ml/kg of fluids. Please ask the presenter to clarify this.

**Answer 352:** The *Septic Shock Present* data element does in fact support this as part of the determination of the presence of septic shock, and it is further clarified in version 5.0b of the manual posted on *QualityNet* in mid-October. Administering 30 ml/kg of crystalloid fluids is a recommendation in the *International Guidelines for Management of Severe Sepsis and Septic Shock* for patients presenting with severe sepsis and hypotension.

**Question 353:** If we need to review for skin "color," why is "turgor good" and "turgor absent" acceptable?

**Answer 353:** These are being removed in a future version of the manual.

**Question 354:** Can you explain using ED Triage Time as presentation time?

**Answer 354:** Triage time is only used if all clinical criteria are met prior to or during triage. If clinical criteria are met after triage time, use the time the last of the criteria are met for severe sepsis or septic shock presentation time.

**Question 355:** Doctors are concerned with two SIRS criteria primarily if HR >90 and RR >20. Using these two creates a large number of patients to be included. Are you hearing that others are concerned with only two criteria rather than three?

**Answer 355:** Patients are not included solely based upon two SIRS criteria. There must also be a suspected infection and a sign of organ dysfunction. These criteria have been used for many years to identify patients with severe sepsis and are included in the *International Guidelines for Management of Severe Sepsis and Septic Shock*.

**Question 356:** Why wasn't this measure divided into multiple measures?

**Answer 356:** Literature reflects that when all of the elements of a care bundle are implemented outcomes are better than if just some of the elements of a care bundle are performed. Therefore, measuring the bundle performance rate is desirable. A study by IMPReSS study published in 2015 demonstrated that while compliance with all the evidence-based bundle elements was low, when all components of the 3 hour and 6 hours bundles were completed the odds of dying in the hospital were reduced by 40% and 36%, respectively.



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(Rhodes A, Phillips G, Beale R, Cecconi M, Chiche JD, De Backer D, Divatia J, Du B, Evans L, Ferrer R, Girardis M, Koulenti D, Machado F, Simpson SQ, Tan CC, Wittebole X, Levy M. (2015) The Surviving Sepsis Campaign bundles and outcome: results from the International Multicentre Prevalence Study on Sepsis (the IMPReSS study). *Intensive Care Med.* 2015 Sep;41(9):1620-8.)

### Contraindication to Care

**Question 357:** On page 12 it lists Administrative contraindication to care. Can you describe what this would be?

**Answer 357:** What constitutes an Administrative Contraindication to Care is defined in the *Administrative Contraindication to Care* data element. It is documentation of the refusal of blood draw, fluid administration, or antibiotic administration. There are specific requirements associated with this, and I encourage you to review the data element specifications.

### Sampling Requirements

**Question 358:** Based on true sepsis records being excluded, how do we determine the appropriate records to pull to meet the appropriate records to abstract to meet the sampling requirements?

**Answer 358:** The initial patient population is identified based upon age 18 years or greater with an ICD-10-CM Principal or Other Diagnosis Code of sepsis, severe sepsis, or septic shock as defined in Appendix A, Table 4.01, and a length of stay 120 days or less. From that population, you randomly select patients for the month or quarter (depending on if you are doing monthly or quarterly sampling) until the appropriate sample size (see tables in SEP-1 MIF) has been reached based upon your monthly or quarterly initial patient population following the Population and Sampling Specifications. If a case is excluded, they still need to be submitted but you do not need to find a replacement to fill out your sample population.

**Question 359:** How much will the coding narrow down the population?

**Answer 359:** Coding is not used to narrow down the population. It is used to identify the initial patient population.

### Weight



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- Question 360:** We plan to use ideal body weight as we have many bariatric patients. Is that okay?
- Answer 360:** If there is a significant difference between the ideal and actual body weight, this may result in a smaller volume of crystalloid fluids being given. If that volume is less than 30 ml/kg, the case may fail the measure.
- Question 361:** What if there are several weights in the record?
- Answer 361:** If there are multiple weights recorded, use the weight prior to and closest to the crystalloid infusion order. If there are multiple weights recorded after the crystalloid infusion order but not before the time of the order, use the weight closest to the crystalloid infusion order.
- Question 362:** Current weight or ideal body weight? Can we take patient-reported weight?
- Answer 362:** The weight used needs to reflect the actual weight and not an ideal weight. It may not be feasible at the time of presentation to weigh the patient. As such, if there is a patient reported or estimated actual weight, it can be used.
- Question 363:** Actual weight, does that mean their first weight on admission?
- Answer 363:** Actual weight refers to what the patient actually weighs as opposed to an ideal weight which what a patient should weigh based on gender, age, and height.
- Question 364:** Do patients need to be weighed, or can abstractors use patient-reported or an estimated actual weight?
- Answer 364:** It may not be feasible at the time of presentation to weigh the patient. As such, if there is a patient reported or estimated actual weight, it can be used.
- Question 365:** Which do you use the heaviest or lightest?
- Answer 365:** If there are multiple weights recorded, use the weight prior to and closest to the crystalloid infusion order. If there are multiple weights recorded after the crystalloid infusion order but not before the time of the order, use the weight closest to the crystalloid infusion order.
- Question 366:** Are there any options for patients who may be severely obese in order to control the total amount of fluid to meet the 30 ml/kg?
- Answer 366:** There are not any exclusions or adjustments for severely obese patients.



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**Question 367:** I would like clarification for Slide #39 where it states “For purposes of the measure use actual weight or estimated weight documented closest to order.” Per the SEP-1 FAQs found on the *QualityNet* website, “the volume of crystalloid fluids (30 ml/kg) is based on actual body weight” (pg. 5). Moreover, during the Q&A part of Part I of the Clinician Perspective on Sepsis Care held on September 10th, in providing the rationale for requiring actual body weight, Dr. Townsend mentioned that while data is limited in terms of literature, “to date the standard has always been actual,” and that is applied here, as well. So, please clarify whether estimated (or stated) body weight can be used for the purpose of Crystalloid Fluid Administration abstraction calculation.

**Answer 367:** In many cases the patient's weight may not be known depending on the condition of the patient. If the patient has not been weighed, an estimated or stated body weight can be used but it must reflect "actual" weight and not "ideal" weight.

**Question 368:** If the only weight in the record is after admission but the crystalloids were ordered and administered in the ED, would I use that weight to calculate what 30 ml/kg would be?

**Answer 368:** Yes.

### Process

**Question 369:** With the septic shock focused reassessment, could the assessment be after the 30 ml/kg bolus is started or should it be after the bolus is completed?

**Answer 369:** Ideally, it should be after the 30 ml/kg infusion is completed. It can be after the infusion is started and before the infusion is completed and still pass the measure.

**Question 370:** Where must the tip of the PICC line be in order to meet the CVP measure?

**Answer 370:** In the superior vena cava near the junction with the heart.

**Question 371:** Is it acceptable for a Focused Exam to be done by the RN under the supervision of the e-physician?

**Answer 371:** As long as the evaluation is performed by the physician, there is nothing in the specifications that reflect nursing assistance is not acceptable. As currently worded, the nurse could not perform the exam and then report the results to the physician.



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- Question 372:** In reference to the SvO<sub>2</sub> measurement: we do not have the equipment to monitor this. However, we can have it drawn and run as a lab test. Will this pass the central venous oxygen measurement?
- Answer 372:** As long as the sample comes from a central venous catheter, this is acceptable. While continuous monitoring is ideal, it is not required.
- Question 373:** Is it acceptable for the elements of the Focused Exam to be completed by two different providers? Example, vitals and cardiopulmonary exam included in one provider's note and cap refill, peripheral pulses and skin exam in another provider's note?
- Answer 373:** Yes.
- Question 374:** We utilize a "distant" ICU service during the night. How can we meet the requirement that the physician/APN/PA have done the peripheral pulse evaluation when they are not physically present? They are evaluating the patient via a Skype-like camera system with assistance by the bedside nurse.
- Answer 374:** As long as the evaluation is performed by the physician, there is nothing in the specifications that reflect nursing assistance is not acceptable. As currently worded, the nurse could not perform the exam and then report the results to the physician.
- Question 375:** Do all elements of the Focused Exam have to be completed by the same physician?
- Answer 375:** No.
- Question 376:** Is there any consideration given to using the CHEETAH monitor from Nicom? It gives us a fluid responsiveness based on the Passive Leg Raise for fluid challenge?
- Answer 376:** The way you determine the effectiveness of fluid responsiveness to a passive leg raise or fluid challenge is not specified in the measure specifications. How you determine the responsiveness is based upon processes, policies, and procedures in your facility. The measure only indicates there must be documentation that a passive leg raise or fluid challenge was performed.
- Question 377:** Does the repeat assessment need to be performed by the same provider, and must that provider be a physician, NP, or PA? Does the same apply for the dynamic parameters?



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- Answer 377:** The Focused Exam currently must be performed by a physician, APN, or PA. It does not need to be performed by the same provider that ordered the fluids or other elements of care. The other parameters do not necessarily require a physician to perform them. Please refer to the data elements of each respective element of the repeat volume status and tissue perfusion assessment.
- Question 378:** If your facility has a policy defining the word STAT with a specific amount of time (e.g., 20 minutes), would the order for STAT only be allowed?
- Answer 378:** At this time the infusion duration must be specified in the order.