Inpatient Quality Reporting Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock Part III: Measure updates and Abstraction Guidance

Questions and Answers

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The answers contained in this document were answered using the Specifications Manual for National Hospital Inpatient Quality Measures*, Version 5.0b (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.

Abstraction Questions

Question 1: The data element, Administrative Contraindication to Care, is very labor intensive to abstract, but the Transfer from Another Hospital or ASC is not. Would it be possible for the algorithm to be changed so that the question Transfer from Another Hospital or ASC could be answered first eliminating the need to abstract Administrative Contraindication to Care, if the patient was transferred from another hospital? This would significantly decrease the burden of abstraction.

Answer 1: We recognize this is a concern and are in the process of re-evaluating the Administrative Contraindication to Care data element to tie it more closely to the presentation of severe sepsis and septic shock, rather than to any particular time during the hospital stay.

Question 2: Slide 110 of today's event, Persistent Hypotension: Things to look for, identified by two or more consecutive blood pressure readings of: systolic blood pressure (SBP) <90, etc. This conflicts with the Release Notes version 5.0a stating one single blood pressure reading is required to determine persistent hypotension present. Please clarify.

Answer 2: The release notes you are referencing are for version 5.0a. The change from one single to two consecutive readings is in version 5.0b.

Question 3: The specification makes it clear that septic shock is only present with severe sepsis and that we are only to abstract the first episode of severe sepsis or septic shock. Today's slides highlight that septic shock must only be abstracted within six hours of severe sepsis. In the event that patient initially has severe sepsis and develops another episode within six and a half hours or more of initial severe sepsis episode, and shock follows within a six hour window, is it right to assume that we still abstract for this episode of septic shock as it occurs within the defined time frame, just not within 6 hours of the first severe sepsis episode or do we not abstract at all?

Answer 3: You are only to abstract the first episode of severe sepsis or septic shock. If the first episode of septic shock is more than 6 hours after the first episode of severe sepsis, you will select "No" for Septic Shock Present and will not abstract the episode of septic shock.

Question 4: Can you please clarify how to abstract provider documentation: use note time or EMR file time?

Answer 4: If the physician documents the presence of a suspected infection, severe sepsis, or septic shock in an Emergency Department (ED) note, and there is a time within the note indicating when these conditions were identified, use that time. If there is not a time within the note, use the time the note was opened or started.

Question 5: The Patient (Pt) was in Observation (OBS) from 10/11 to 10/15, then on Inpatient (IP) order on 10/15. Pt met criteria for Severe Sepsis on 10/11, prior to IP order. No Criteria for severe sepsis or septic shock was met after order. Would the abstractor say "No" to severe sepsis, if no qualifying data could be abstracted after IP order?

Answer 5: If the clinical criteria are met for severe sepsis you would select "Yes" for Severe Sepsis Present. Criteria met in observation still qualify for the Severe Sepsis Present data element.

Question 6: In order for Severe Sepsis to be met, do all the three criteria have to occur in order? Does infection have to be confirmed, then the other two (SIRs + OD) within 6 hours of the infection diagnosis made?

Answer 6: No, all three criteria must be met within 6 hours of each other but they do not have to be in any particular order of occurrence.

Question 7: Using the order set, the physician documents, "Pt. doesn't meet the criteria for sepsis/septic shock." No further orders would be placed from sepsis order sets, correct?

Answer 7: It is unclear which data element this statement is referencing. As such, I am unable to respond.

Question 8: Imagine a sample set with a case with an International Classification of Diseases, Tenth Revision (ICD-10) code for sepsis that is then determined through abstraction to not have severe sepsis or septic shock. The case is then removed from the denominator. Is another case with true septic shock or severe sepsis needed for a full sample size for CMS submission? Same question for cases that are not fully abstracted because they were transferred in to the hospital. Same question for cases that received IV antibiotics 24 hours prior to presentation of severe sepsis.

Answer 8: Cases that are excluded through the course of abstraction are not replaced.

Question 9: If the MD documents sepsis likely secondary to colitis, is this acceptable as an infection, especially since he ordered antibiotics for this patient? I know colitis can be infectious and non-infectious, so am confused about using this documentation.

Answer 9: This is acceptable since your research of colitis indicates it can be an infectious process. Keep in mind the measure is not looking for a diagnosed infection, but for documentation of a suspected or possible infection.

Question 10: The link on *QualityNet* for Section 2.2 – Severe Sepsis and Septic Shock (SEP) (Updated 10/22/15) is bringing up Version 5.0a. How do you access Version 5.0b?

Answer 10: The links have been corrected.

Question 11: If the physician diagnosis is severe sepsis, but the patient does not have two or more Standardized Infection Ratio (SIR) criteria, elevated lactic acid (LA), or other evidence of organ dysfunction, should the abstractor select "does not meet sepsis criteria?"

Answer 11: Presence of severe sepsis is based upon the earlier of either when the last clinical criteria was met for severe sepsis or physician, Advanced Practice Nurse (APN), or Physician Advisor (PA) documentation of severe sepsis. It does not require both.

Question 12: In the inclusion guidelines for abstraction it states “severe sepsis, r/o severe sepsis, possible severe sepsis." If the Provider states septic without the word "severe," is it an inclusion or exclusion?

Answer 12: Septic without the word "severe" is not acceptable.

Question 13: Can a nurse’s suspected infection count even though no DX of an infection has been made and she is not referring to something diagnosed earlier?

Answer 13: Yes. Keep in mind the measure is not looking for a diagnosed infection, but for documentation of a suspected or possible infection.

Question 14: We have already abstracted the data elements. Do we have to revisit and update it with those new specifications for the abstraction?

Answer 14: The specification changes in version 5.0b are effective with discharges starting October 1, 2015.

Question 15: ED nurse performs severe sepsis screen with a general “is infection suspected” screen. Is this sufficient to respond “Yes” to “suspected infection?”

Answer 15: Yes. Keep in mind the measure is not looking for a diagnosed infection, but for documentation of a suspected or possible infection.

Question 16: If Physician documents severe sepsis would that alone suffice for following the SEP measure guidelines or do we need anything else?

Answer 16: Presence of severe sepsis is based upon the earlier of either when the last clinical criteria was met for severe sepsis or physician, APN or PA documentation of severe sepsis. It does not require both. However, you will also need to check the clinical criteria to determine whether the criteria were met prior to the physician documentation.

Question 17: One of our providers at our Critical Access Hospital (CAH) asked if we will be getting "dinged" on items that we don't offer on-site and if that lack of availability must be documented. For example, we can't perform in-house lactic acid.

Answer 17: The SEP-1 measure does not include exclusions from the measure elements based on this. Even if lactates cannot be performed in-house, they could be drawn within the 3 hour time frame.

Question 18: Updated guidelines state persistent hypotension definition was changed to require two or more consecutive readings rather than one single reading as before. Are we then required to have more than one blood pressure (BP) check in the hour after fluids to determine this, or does this just apply if there

is more than one? If there is only one BP reading, do we abstract no to persistent hypotension or unable to determine?

Answer 18: Two are required as opposed to one to help determine whether or not it truly represents **persistent** low blood pressure. If one is performed and it is adequate, there may not be a need for a second within the hour. If one is low, a second should be performed to determine whether or not it is a persistently low blood pressure. For the purposes of the measure, if only one low blood pressure is recorded in the hour following conclusion of the crystalloid fluids, it would not be considered persistent hypotension without the confirmation of a second blood pressure.

Question 19: When discussing data element Crystalloid Fluid Administration, can the speaker explain whether an order for fluids at 30ml/kg Bolus is abstractable? The order does not specify an actual rate or duration of infusion.

Answer 19: At this point in time, an order for a 30 ml/kg bolus is not acceptable because it does not include an infusion duration or rate.

Question 20: If a patient has been on IV antibiotics and on the day of severe sepsis a new antibiotic was added, how do we abstract antibiotic in this case? Do we take into consideration that the patient has been on antibiotics for more than 24 hours before new antibiotic are added?

Answer 20: When abstracting antibiotics, first look in the period 24 hours prior to presentation through 3 hours after presentation of severe sepsis. If antibiotics were only given in the 3 hours following presentation, you will disregard any antibiotics that may have been given more than 24 hours prior to presentation. If any antibiotics were given in the 24 hours prior to presentation, you will check to see if any of those were also given earlier than 24 hours prior to presentation. You will only take into consideration antibiotics given earlier than 24 hours prior to presentation, if a dose of that same antibiotic was also given within the time period 24 for hours prior to presentation. You will disregard any antibiotics given earlier than 24 hours prior to presentation, if a dose was also not given within 24 hours prior to presentation.

Question 21: If a patient is on vasopressors you will not have two or more hypotensive readings. How do you abstract this situation?

Answer 21: For purposes of the measure, if there are not two consecutive blood pressure readings reflecting hypotension in the hour following completion of the 30 ml/kg of crystalloid fluids, the patient is considered to not have persistent hypotension.

Question 22: Patient is in septic shock. However, documentation clearly states Medical Doctor (MD) does not suspect infection, rather, suspect's adrenal insufficiency. Is this patient included in the septic shock population based on

the MD documentation of septic shock? If so, they are expected to meet all indicators of treatment, correct?

Answer 22: If the physician documented the patient has septic shock, then for purposes of the measure they are considered to have septic shock and are expected to meet bundle requirements. We are looking into the issue of conflicting documentation to determine how this should be handled for a future version of the manual.

Question 23: Are there any allowances made to bundle compliance for a patient who goes to the OR during the bundle timeframe calculation period?

Answer 23: The time frame does not make allowances for patients going to surgery.

Question 24: In what measure subsets can non-advanced practice Registered Nurse (RN) documentation be used, specifically in the context of recognition?

Answer 24: Nursing documentation may be used based upon specifications within each data element. Where it states only physician/APN/PA documentation, nursing documentation is not acceptable.

Question 25: If a patient has congestive heart failure (CHF) with anuric End Stage Renal Disease (ESRD) and missed dialysis for six days and concomitant septic shock, would this patient be included in the septic shock measure?

Answer 25: If they meet the criteria for septic shock, they would be included.

Question 26: When are all these new notes for abstraction effective? Will a new version of the Severe Sepsis Measure Information Form (MIF) and data Dictionary be coming out?

Answer26: The changes are in version 5.0b of the specifications manual, which was posted on *QualityNet* on October 22, 2015 and are effective starting with October 1, 2015 discharges.

Question 27: What if a patient has hypotension the day prior to septic shock? Patient is treated with 30ml/kg of appropriate crystalloid fld. boluses. Do we abstract from when this bolus is completed even though it may be hours before meeting septic shock criteria?

Answer 27: Persistent hypotension is identified within the hour following completion of the 30 ml/kg of crystalloid fluids. Septic shock presentation time, if based upon presence of persistent hypotension, would therefore be within the hour following completion of the crystalloid fluids. If septic shock presentation is more than 6 hours after severe sepsis presentation, you should select "No" for Septic Shock Present.

Question 28: Is urosepsis an acceptable inclusion for abstraction?

Answer 28: Urosepsis is defined as sepsis caused by a urogenital tract infection. Because the definition includes a urogenital tract infection as the cause, it is acceptable to use as a suspected infection. However, it is not acceptable to use as documentation of severe sepsis.

Question 29: Initial lactate of >4, no infection documented or Standardized Infection Ratio (SIR) criteria. Because the patient does not meet severe sepsis criteria, does this exclude them from septic shock population?

Answer 29: Yes, if they do not meet the criteria for severe sepsis (clinical criteria not met and no provider documentation), you would select "No" for Severe Sepsis Present, and the case is excluded from further abstraction.

Question 30: If two or more readings are not consecutive, how will we abstract these?

Answer 30: For the purposes of the measure, persistent hypotension is defined by two or more consecutive readings of low blood pressure recorded in the hour following completion of the 30 ml/kg of crystalloid fluids. If the low blood pressure readings were not consecutive, this does not meet the criteria for Persistent Hypotension.

Question 31: If a patient's Respiratory Rate (RR) is set at 24 on a ventilator, could this be used as criteria for SIRs?

Answer 31: No, the SIRs criterion for respiratory rate is based upon patient spontaneous respiratory rate, not a mechanically supported respiratory rate.

Question 32: Updated guidelines deleted the statement "When determining organ dysfunction, any single BP or mean arterial pressure (MAP) reading in the first hour after presentation that is abnormal (per criteria listed) will satisfy the criteria for organ dysfunction." But it doesn't state that we have to have two or more like it does with persistent hypotension. Are we still able to use a single BP or MAP for this criteria or do we need two consecutive?

Answer 32: The Septic Shock Present data element's Notes for Abstraction include the following bullet point directing abstractors to the Persistent Hypotension data element for determining whether or not hypotension persists after crystalloid fluid administration. It is within the Persistent Hypotension data element that two or more consecutive readings are required. "For evaluation of blood pressure parameters to establish whether or not hypotension persists after crystalloid fluid administration, begin abstracting at the time that crystalloid fluid administration concludes (refer to the Persistent Hypotension data element); abstract for the time period that follows for the next hour only. Choose Value "1" if hypotension (systolic blood pressure < 90, or mean

arterial pressure < 65 or a decrease in systolic blood pressure by > 40 mmHg) was present in the hour after crystalloid fluid administration."

Question 33: When will the "information" descriptions be updated on the *Net*?

Answer 33: The changes are in version 5.0b of the Specifications Manual which was posted on *QualityNet* on October 22, 2015 and are effective starting with October 1, 2015 discharges.

Question 34: Are discharge summaries that state "Severe Sepsis point of admission" or "Septic Shock at point of admission" not acceptable? So, basically, we do not abstract from the Discharge Summary?

Answer 34: If the only documentation indicating the presence of severe sepsis or septic shock occurs after discharge time, you would not use it. As such you would select Value "2 (No)" for Severe Sepsis Present or Septic Shock Present.

Question 35: If the only documentation about infection occurs approximately every 24 hours (coinciding with times the physicians typically document), but the vital signs or lab values that meet criteria occur in between, the 6 hour window would not be met per the guidelines of documentation within 6 hours of each other. Would this abstract as a "Yes" (present) or "No" (not present)?

Answer 35: At this point it would abstract as a "No" because the specifications require documentation of the criteria occurring within 6 hours of each other. We recognize this will result in the exclusion of some cases and are looking further into potential criteria modifications to take this into account for a future version of the specifications.

Question 36: What time should be abstracted when there is documentation of acute respiratory failure, but there is no invasive or non-invasive mechanical ventilation? If there is documentation of respiratory deterioration, treatment initiated = BiPAP or bi-level positive airway pressure, is this sufficient as documentation of organ dysfunction?

Answer 36: The revised (v5.0b) Severe Sepsis Present data element specifies that acute respiratory failure as evidenced by a new need for invasive or non-invasive mechanical ventilation is acceptable. It also indicates that non-invasive may be referred to as BiPAP. Documentation of BiPAP being initiated is sufficient.

Question 37: If a provider documents "possible or probable" instead of "suspected," does that count for an actual diagnosis for abstraction?

Answer 37: Yes. Keep in mind that the measure is not looking for a diagnosed infection, but for documentation of a suspected or possible infection.

Question 38: Are the measures actually changing from what we previously had or just the way that it's abstracted?

Answer 38: The changes primarily represent abstraction clarification. However, there are a couple of changes that represent changes in the criteria of definitions within data elements.

Question 39: When will these measure update changes be reflected in Comet?

Answer 39: Please contact your abstraction software vendor to determine when these changes will be reflected in your abstraction tool.

Question 40: It seems like there have been multiple changes to the specifications made after the implementation date for the measure. Is it possible to suspend the measure until the specifications are fully defined? This is causing mass confusion among abstractors right now.

Answer 40: There is no discussions at this time for suspending the measure.

Question 41: Does clarification of "possible UTI" (urinary tract Infection) to "pyuria, chronic Foley catheter" remove the inclusion of a case?

Answer 41: No, because documentation of a possible infection is present. Keep in mind that there are three clinical criteria (suspected infection, two or more SIRs criteria, and a sign of organ dysfunction) or physician/APN/PA documentation of severe sepsis to be included.

Question 42: We initiate a "Sepsis Alert" at our facility when the patient meets all clinical criteria for severe sepsis. Can the "Sepsis Alert called" time be used for Severe Sepsis presentation date and time?

Answer 42: The specifications for Severe Sepsis Presentation data elements indicate presentation is the time the last of clinical criteria are met OR there is physician/APN/PA documentation of severe sepsis, whichever is earliest. As such "Sepsis Alert Called" time is not acceptable unless it coincides with the presentation time definitions in the specifications manual.

Question 43: Does subsequent positive fungal culture or viral culture remove a case?

Answer 43: Culture results are not sufficient, because they may not represent an actual infection. There must be documentation by a physician, APN, or PA noting the fungal or viral infection.

Question 44: Will the fourth quarter 2015 charts be validated for sepsis?

Answer 44: At this time, per the IPPS Final Rule, Sepsis will be validated.

Question 45: On what date are the addendum criteria active?

Answer 45: The changes are in version 5.0b of the specifications manual were posted on *QualityNet* on October 22, 2015 and became effective starting with October 1, 2015 discharges.

Question 46: If I have already abstracted sepsis charts operating under the knowledge of the Specification Manual prior to these addendums, do these charts have to be re-abstracted?

Answer 46: The specification changes in version 5.0b are effective with discharges starting October 1, 2015.

Question 47: How do you abstract when the ED provider note is after discharge from the ED and that is documentation of source?

Answer 47: You will need to use the time the note was opened or started. This may result in the criteria not being met within 6 hours of each other, which will result in the case being excluded.

Question 48: How will abstractors pull data when severe sepsis presents as inpatient and not initially in the ED?

Answer 48: This may very well depend on the medical record you are using. Since the measure is looking for the first episode of severe sepsis or septic shock, you should begin with the arrival and work back. Start by looking for criteria that are most easily identified or flagged in the medical record, such as abnormal labs or abnormal vital signs.

Question 49: If the physician documents severe sepsis or septic shock but the patient actually does not meet the criteria based upon their vitals/labs do we still abstract the chart?

Answer 49: Yes, presence of severe sepsis is based upon the earlier of either when the last of the clinical criteria was met for severe sepsis or physician, APN, or PA documentation of severe sepsis. It does not require both. So, if the criteria are not met, but the physician documents severe sepsis or septic shock, it would still count as being present.

Question 50: The criteria for Persistent Hypotension changed from one low BP reading to two low BP readings in the hour following fluid administration. But within the notes for septic shock, the first bullet point doesn't specify "persistent hypotension" or more than one low BP reading, and, the examples only list one BP reading following fluids. But, the second bullet point refers to the Persistent Hypotension data element. For Septic Shock, do we define "hypotension persists" as two low readings or one low reading in the hour after fluid administration?

Answer 50: The Septic Shock Present data element's Notes for Abstraction include the following bullet point directing abstractors to the Persistent Hypotension data element for determining whether or not hypotension persists after crystalloid fluid administration. It is within the Persistent Hypotension data element that two or more consecutive readings are required. "For evaluation of blood pressure parameters to establish whether or not hypotension persists after crystalloid fluid administration, begin abstracting at the time that crystalloid fluid administration concludes (refer to the Persistent Hypotension data element); abstract for the time period that follows for the next hour only. Choose Value "1" if hypotension (systolic blood pressure <90, or mean arterial pressure <65 or a decrease in systolic blood pressure by >40 mmHg) was present in the hour after crystalloid fluid administration."

Question 51: On the severe sepsis cases 1-5, what if the ED physician does not recognize sepsis in their note?

Answer 51: Presence of severe sepsis is based upon the earlier of either when the last of the clinical criteria was met for severe sepsis or physician, APN, or PA documentation of severe sepsis. It does not require both.

Question 52: How is the abstractor to determine whether the laboratory evidence of organ dysfunction is caused by the medication or a chronic condition? Must there be physician documentation of this association?

Answer 52: Physician documentation of the association is acceptable, but not required at this point. Two common examples (creatinine >2 for patients with end stage renal disease and an International Normalized Ratio (INR) >1.5 for patients on warfarin) are noted in the Severe Sepsis Present data element and would not require physician documentation.

Question 53: In example Case 4 the lactate was drawn at 10:20 and resulted at 10:50. In this example, he stated that the organ dysfunction result time was used as a sign of organ dysfunction. The specifications manual states that we use collection time, which would be 10:20.

Answer 53: The result time should be used when determining the presence of organ dysfunction, because presence of organ dysfunction cannot be determined without the results. At the time the lactate is drawn, you do not know whether or not it is elevated. For purposes of entering the date and time of Initial Lactate and Repeat lactate, you do use the time drawn.

Question 54: Can documentation of bowel perforation be a suspected source of infection?

Answer 54: A bowel perforation in itself is not an infection. It cannot be used as a suspected infection or suspected source of infection without documentation indicating it is an infection or causing an infection.

Question 55: There may be an antibiotic given in the ED due to diagnosis of an "other" infection and before Severe Sepsis criteria are met. This case would fail, is that correct?

Answer 55: It would not necessarily fail. Antibiotics given within 24 hours prior to presentation are acceptable.

Question 56: If an MD documents ruling out severe sepsis, and treats for something else (because the patient does not have severe sepsis) would they be expected to complete the sepsis treatment and be eligible for abstraction?

Answer 56: Because of the documentation in the medical record, the case would be eligible for abstraction. Physician clinical judgment should be used when determining the most appropriate course of treatment. If a physician's best clinical judgment indicates the patient does not actually have severe sepsis and providing that care is not appropriate, then they should not provide it.

Question 57: Where exactly in the Specifications Manual do we find the chart showing which antibiotics are in column A and which antibiotics are in column B?

Answer 57: The chart with the antibiotics is located in the Broad Spectrum or Other Antibiotic Administration Selection data element.

Question 58: According to the Specifications Manual, antibiotics are to be abstracted 24 hours prior to presentation to 3 hours after presentation. Why are you telling us to abstract antibiotics prior to the 24 hours before presentation? We are confused. This is not what the Specifications Manual says.

Answer 58: You only abstract antibiotics given more than 24 hours prior to presentation, if there was an antibiotic given in the 24 hours prior to presentation, and a dose of that same antibiotic was also given more than 24 hours prior to presentation. This is indicated in the first bullet point of the Broad Spectrum or Other Antibiotic Administration Time data element's Notes for Abstraction which states: "If any antibiotic was administered intravenously (IV) within 24 hours prior to Severe Sepsis Presentation Time, abstract the earliest time that a dose of the IV antibiotic was given. This may be the same time as the time of presentation, within 24 hours prior to presentation, or a time greater than 24 hours before presentation."

Question 59: With combination therapy, do both ABX have to be given within a 3 hour time window after presentation? What if they are given shortly before the presentation time?

Answer 59: The only time you compare the antibiotics given to the antibiotic tables is if the only antibiotics the patient received are in the 3 hours following presentation. In the question, the patient received an antibiotic prior to

presentation. Because of this, the Broad Spectrum or Other Antibiotic Administration Selection data element is not abstracted.

Question 60: Would we abstract antibiotics if the physician documents that the patient is on IV antibiotics at home, but the exact date and time of the administration is not known?

Answer 60: It depends on the timing of antibiotics given within the 24 hours prior to presentation. If a patient received the home IV antibiotics within the 24 hours prior to presentation, and the time it was started cannot be determined, you would need to enter UTD (unable to determine) for Broad Spectrum or Other Antibiotic Administration Time. If the home IV antibiotics were stopped before 24 hours prior to presentation, and the patient did not receive a dose of that same antibiotic in the 24 hours prior to presentation, you can disregard the home IV antibiotics.

Question 61: If lactate is >4 and no crystalloid fluids are administered, do you answer “Yes” or “No” for Septic Shock present?

Answer 61: The Septic Shock Present data element's Notes for Abstraction indicates that if crystalloid fluids were not administered after the presentation date and time of severe sepsis, to choose Value "2 (No)."

Question 62: For determining if the three severe sepsis criteria are met, do we only use the first time a source of possible infection is documented? If we are looking at Case 5 where the 6 hour criteria was not met, and the infection continues to be documented by every physician who sees the patient, do we continue to look for all three criteria being met with each physician documentation?

Answer 62: For the patient to be in your initial patient population, they have to have an ICD-10 code for sepsis, severe sepsis or septic shock. You will need to review the medical record from the point of arrival to discharge for either the severe sepsis clinical criteria being met or physician/APN/PA documentation of severe sepsis. You will use the first episode of severe sepsis. If your review of the medical record demonstrates criteria were never all met within 6 hours of each other and there was never physician/APN/PA documentation of severe sepsis, you would select "No" for Severe Sepsis Present.

Question 63: What if septic shock diagnosis (present) is taken from MD documentation, crystalloid fluids were not given, and the patient was put directly on vasopressors. Do you still abstract "Yes" for septic shock present?

Answer 64: If the physician documented that septic shock was present, then you would select "Yes" for Septic Shock Present.

Question 65: Our facility, implementing evidence-based antimicrobial stewardship, put a "cap" for fluid boluses. The purpose of this cap is to prevent, for example, a

10,000cc bolus being administered on an obese individual. Our policy is to administer 3l and evaluate the patient. How do you address this safe "cap" for data abstraction?

Answer 66: For patients who weigh less than 220 pounds (100 kg), this is not an issue because the target volume is 3000 ml. For patients weighing more than 220 pounds, 3000 ml could be ordered. Once infused, evaluate the patient, then order to provide a balance of the target volume, assuming this is acceptable per your hospital policy.

Question 67: To abstract crystalloid fluids given "prior to" presentation of septic shock, how far back may we look? Six hours? Please clarify.

Answer 67: Currently there is not a time frame for how far to look back for crystalloid fluids given prior to presentation. The Crystalloid Fluid Administration data element's Notes for Abstraction includes a bullet to only abstract crystalloid fluids given for the presence of severe sepsis with hypotension or for the presence of severe sepsis with a lactate ≥ 4 mmol/L.

Question 68: Since Septic shock can't exist without severe sepsis. We are instructed to abstract the first episode of severe sepsis. We are also instructed to abstract the first episode of septic shock. Does this mean that we are to abstract the first episode of severe sepsis and abstract for septic shock at that time? I'm thinking of a patient having severe sepsis for the first episode but not septic shock, but 5 hours later develops criteria for septic shock. Which episode of septic shock do we abstract?

Answer 68: Septic shock cannot exist without severe sepsis, but severe sepsis can easily occur without septic shock. You will abstract the first episode of severe sepsis, which may occur before or at the same time septic shock is present, and the first episode of septic shock. Note, however, that the Septic Shock Present data element's Notes for Abstraction indicate that if Septic Shock presentation is more than six hours after Severe Sepsis presentation to choose Value "2 (No)."

Question 69: Can IV infusion rate be used to determine "Duration?"

Answer 69: The infusion duration or rate must be specified in the order.

Question 70: Why do you need to do this calculation to determine if the target volume is met when clearly it was ordered over the target? It seems like over kill; too much abstractor time for what value?

Answer 70: If you know the volume ordered and given is clearly over the target, you may not need to perform the calculation to determine the target volume. Performing the calculation is recommended to ensure your abstraction is accurate. If the volume given is significantly over the target volume, this may

result in mis-ascertaining when the infusion was completed. This may impact the beginning and end of the one hour following the completion of infusion for determining the presence of persistent hypotension.

Question 71: So, the abstractor calculates when the infusion should end, rather than when it actually ends and that is what the measure is based on?

Answer 71: If the time the infusion actually ended is documented it should be used. Calculating when the infusion should end is used to estimate when the hour for determining the presence of persistent hypotension starts.

Question 72: How about those patients coming in as cardiac arrest from the field? Most of them have LA >4.

Answer 72: Presence of septic shock requires either provider documentation of septic shock or the presence of severe sepsis (suspected infection, two or more SIRs criteria, and a sign of organ dysfunction) plus a sign of hypoperfusion (persistent hypotension or lactate ≥4). A patient coming in with cardiac arrest will likely not have documentation of an infection or meet SIRs criteria.

Question 73: How do we abstract a chart if a lactate level is elevated due to documented rhabdomyolysis and not sepsis?

Answer 73: The Severe Sepsis Present data element indicates to not use evidence of organ dysfunction that is considered to be due to a chronic condition or medication. If documentation indicates the lactate is elevated due to rhabdomyolysis, do not use it as a sign of organ dysfunction. Keep in mind that if the patient does not meet the criteria for septic shock, whether by having provider documentation of septic shock or by meeting the clinical criteria (suspected infection, two or more SIRs criteria, and a sign of organ dysfunction), you would select "No" for Septic Shock Present. If the elevated lactate is the only sign of organ dysfunction, you would not use it and the patient does not have severe sepsis. If the patient does meet severe sepsis criteria with another source of organ dysfunction, then you would enter the appropriate allowable value for Initial Lactate Level Result based on the lactate level. Given that it is an elevated drawing, a repeat level is warranted.

Question 74: If vasopressors were given during crystalloid fluid administration, and there was not persistent hypotension in the hour after the fluids were administered, do we still abstract “No” for persistent hypotension, even though it may be due to vasopressors and not just the fluids?

Answer 74: Yes.

Question 75: In case #4, IV Fluids and Septic Shock, there was no specific order for 30ml/kg; but, if you multiply it, the volume does meet the 30ml/kg

requirement. So, does the order have to say 30ml/kg or can you do the math to see if the 30 ml/kg volume was met?

Answer 75: The order does not have to specifically state 30 ml/kg but the total volume ordered must be 30 ml/kg. If there is more than one order, you can add up the volume of each order to determine whether or not it totals 30 ml/kg.

Question 76: Will the case on slide number 117 fail the measure given that the targeted volume was not ordered?

Answer 76: Yes.

Question 77: Version 5.0a is coming up via the link, when will this be corrected?

Answer 77: The links have been corrected.

Question 78: For facility's that use the CMS Abstraction & Reporting Tool (CART) tool for data abstraction, how are you abstracting for the fourth quarter while the tool is down?

Answer 78: Until the CART tool is available for the fourth quarter 2015 sepsis abstractions, a Universal Sepsis Paper Tool is available on *QualityNet*.

Question 79: What is the plan to address the abstraction burden when the patient fails out of the SEP-1 bundle during severe sepsis (i.e., initial lactate level not met). Why are we required to continue with abstraction when we know the patient fails at this point and it's an all or none bundle?

Answer 79: We recognize this is a concern and are in the process of developing a resolution to this.

Question 80: If the patient presents with severe sepsis and greater than 6 hours later has septic shock, then the septic shock is not abstracted. Is that correct?

Answer 80: Correct. You would select "No" for Septic Shock Present.

Question 81: Does a patient have to meet the criteria via bundle (i.e., time frame), in order to code, or is the bundle a separate entity?

Answer 81: The measure bundle and coding are completely separate. Coding should be based upon ICD-10 official coding guidelines and not the SEP-1 measure. ICD-10 codes (sepsis, severe sepsis, and septic shock) are used to identify the SEP-1 initial patient population.

Question 82: If we select crystalloid fluids were not administered after the presentation date/time of Severe Sepsis and select allowable Value “2 (No),” does it fail the measure or is it excluded?

Answer 82: The septic shock portion of the measure is bypassed, and the case is evaluated for compliance only with the severe sepsis bundle element.

Question 83: If a patient does not meet any of the severe sepsis criteria and the physician/PA/APN documentation of severe sepsis is only in the discharge summary, would you select Value “2 (No)” for severe sepsis present?

Answer 83: If the only documentation indicating the presence of severe sepsis or septic shock occurs after discharge time, you would not use it. As such, you would select Value "2 (No)" for Severe Sepsis Present or Septic Shock Present.

Question 84: With regards to patient refusal of treatment, in the septic shock population, does refusal of vasopressors fall into the patient refusal category?

Answer 84: Not currently. We recognize that this does happen and are addressing this issue for the next version of the manual.

Question 85: There is a lot of confusion right now, and I do not believe that a valid measurement is possible. Is there any chance that this measure can be suspended until all definitions are simplified?

Answer 85: There are no discussions at this time for suspending the measure.

Question 86: Where can we find the "why" for these specific requirements? It's so much easier to teach this measure with sound reasoning, rather than just times and rules.

Answer 86: SEP-1 is primarily based upon the International Guidelines for Management of Severe Sepsis and Septic Shock: 2012. As such, much of the rationale for the measure comes from these guidelines. Keep in mind however that other studies, such as the Protocolised Care for Early Septic Shock (ProCESS), the Australian Resuscitation in Sepsis Evaluation (ARISE), and the Protocolised Management in Sepsis (ProMISE) trials, have also shaped the measure.

Question 87: For Septic Shock 5, it doesn't mean we can't say the patient doesn't have septic shock. The patient does have Septic Shock. He or she didn't receive the correct amount of fluids. So, the fluid portion would fail, correct?

Answer 87: The criteria for identifying septic shock indicate septic shock is present if "hypotension persists in the hour after the conclusion of the 30 ml/kg Crystalloid Fluid Administration." So, the Persistent Hypotension data element requires 30 ml/kg be given to identify whether or not persistent hypotension is present. Therefore, if 30 ml/kg were not given, persistent hypotension cannot be established and septic shock (based on hypotension) is not present for purposes of the measure.

Question 88: Would antibiotics prior to arrival be abstracted? For example, IV antibiotics are given in a nursing home, and we have the MAR from the facility.

Answer 88: It will depend upon the when the antibiotics were given in relation to severe sepsis presentation time. If they were given within 24 hours prior to arrival, you would abstract the earliest dose given, which could be more than 24 hours prior to presentation. If they were not given within 24 hours prior to presentation, you can disregard them.

Question 89: If being a transfer from another facility excludes the case from the measure, why isn't that question addressed first in the algorithm, instead of having to review a chart for administrative contraindication to care when it will be excluded based on being a transfer?

Answer 89: We recognize this is a concern and are in the process of re-evaluating the Administrative Contraindication to Care data element to tie it more closely to the presentation of severe sepsis and septic shock rather than at any time during the hospital stay.

Antibiotics Questions

Question 90: Do both required antibiotics (column A and column B) have to be started before the 3 hours?

Answer 90: Yes, if the only antibiotics the patient received were within the 3 hours following presentation and they received combination therapy, both must be started within the 3 hour period.

Question 91: If a patient is given an antibiotic (not a monotherapy) at 10:00, and severe sepsis presents at 11:00, and Cefepime (Monotherapy) is given at 12:00, the time for Broad Spectrum Antibiotic would be the 10:00 dose, correct? If so, would it be because the Monotherapy was administered within the 3 hour time frame, making the appropriate selection Value “1 (Yes)?”

Answer 91: If the patient receives an antibiotic within the 24 hours prior to severe sepsis presentation, you will select "Yes" for Broad Spectrum or Other Antibiotic Administration, and you will not need to respond to Broad Spectrum or Other Antibiotic Administration Selection.

Question 92: The antibiotic selection is still very confusing. Do they have to give a monotherapy from table 5.0 or one from two different categories or does any antibiotic given meet the measure?

Answer 92: This will depend on the timing of the antibiotic. If the patient received an antibiotic within 24 hours prior to presentation, you will not need to determine whether or not the antibiotic(s) meet(s) the Broad Spectrum or Other Antibiotic Administration Selection data element. The only time you will

need to determine whether or not the antibiotic(s) given meet(s) the Broad Spectrum or Other Antibiotic Administration Selection data element, is if the only antibiotics the patient receives are in the 3 hours following presentation. If this is the case, selecting "Yes" for the Broad Spectrum or Other Antibiotic Administration Selection data element is acceptable, if the patient received an antibiotic from the monotherapy table, or two antibiotics from the appropriate classes for combination therapy.

Question 93: Does fluid from antibiotics count in the 30 ml/kg of fluid? Vancomycin adds significant fluid, for example.

Answer 93: No.

Question 94: Can we use a pharmacist's note regarding Vancomycin dosage for possible pneumonia for suspected infection?

Answer 94: No, documentation of a suspected infection is limited to physician, APN, PA, and nursing documentation.

Question 95: Can we consider the use of antibiotics alone as one criterion for infection, if there are no clinical symptoms or documented source of infection?

Answer 95: No, there must be documentation of a suspected, possible, or confirmed infection. Documentation of the word "infection" or a condition that is an infection is acceptable.

Question 96: If the physician orders an antibiotic and included on that order is an indication that lists pneumonia (or whatever the suspected infection being treated is), can we use that date and time for infection criteria?

Answer 96: Yes.

Question 97: If the patient was administered IV antibiotics, for example, by a home healthcare provider more than 24 hours prior to arrival to the hospital and presentation of severe sepsis, would this exclude the patient?

Answer 97: Not necessarily. Patients are only excluded based on antibiotics if they received an antibiotic in the 24 hours prior to presentation and also received a dose of the same antibiotic more than 24 hours prior to presentation of severe sepsis.

Question 98: Cipro and Flagyl are often chosen for bowel infections. Flagyl is not on the list anywhere. Will that be considered at some point?

Answer 98: There is a note in the Broad Spectrum or Other Antibiotic Administration Selection regarding Flagyl that states "Metronidazole (Flagyl) is not represented on any table because it is not approved for monotherapy and if

given, must be given with two other combination antibiotic therapy drugs." I am not aware that there is consideration for giving Flagyl in combination with a single combination therapy antibiotic.

Question 99: What if antibiotics were given prior to hospitalization and the time cannot be determined from the record, but only from the patient/family report? What time is used to determine the time of first dose?

Answer 99: If you cannot identify the specific time an antibiotic was given (i.e., it is not documented) then you will need to enter "UTD."

Question 100: Why would I look prior to 24 hours before presentation for antibiotics if the question is "within 24 hours before or 3 hours after?"

Answer 100: The first bullet point in the Broad Spectrum or Other Antibiotic Administration Time data's element Notes for Abstraction indicates that if any antibiotic was administered intravenously (IV) within 24 hours prior to Severe Sepsis Presentation Time, abstract the earliest time that a dose of the IV antibiotic was given. This may be the same time as the time of presentation, within 24 hours prior to presentation, or a time greater than 24 hours before presentation.

Question 101: To be clear, prior to presentation, ABX must be IV?

Answer 101: Yes.

Question 102: Does this also apply to Septic Shock cases, if the patient has already been on antibiotics before 24 hours?

Answer 102: Antibiotic administration timing is based upon Severe Sepsis Presentation Time only, not Septic Shock Presentation Time**.**

Question 103: Please verify that we are looking at any IV antibiotic, not specifically a broad spectrum.

Answer 103: If the patient received an antibiotic within the 24 hours prior to presentation any antibiotic will suffice. It is only when the sole antibiotics given were within the 3 hours following presentation that determining whether or not they meet the Broad Spectrum or Other Antibiotic Administration Selection is necessary.

Question 104: Do I understand correctly that for Antibiotic Timing Case #3, ABX G is not the first dose documented? Is it because G is not a Broad Spectrum ABX? If the patient was given G and it is IV, but not a broad spectrum, that would not be abstracted as the earliest ABX given, correct?

Answer 104: Antibiotic G is not used because a dose of it was not given in the 24 hours prior to presentation. You should always first start by looking in the time period of 24 hours prior through 3 hours following presentation of severe sepsis. If one or more IV antibiotics were given in the 24 hours prior to presentation, you will look for the earliest dose(s) given. Given that, you may need to look earlier than 24 hours prior to presentation, the only time you will use the date and time of an antibiotic that was given earlier than 24 hours prior to presentation is if a dose of that same antibiotic was given in the 24 hours prior to presentation.

Question 105: If only one antibiotic is given for the combo drugs (Table 5.1), and that is the only antibiotic given, do you answer Value “2 (No)?”

Answer 105: That depends on what data element you are asking about and when that antibiotic was given. For the Broad Spectrum or Other Antibiotic Administration data element, it does not matter. As long as an IV antibiotic was given within 24 hours prior to presentation or within 3 hours following presentation, you will select Value "1 (Yes)." You will only answer the Broad Spectrum or Other Antibiotic Administration Selection data element if the only antibiotic(s) received were within the 3 hours following presentation. If this is the case, and only one combo antibiotic was given, you will select Value "2 (No)" for Broad Spectrum or Other Antibiotic Administration Selection.

Question 106: If you don't enter the antibiotic given >24 hours (for one that is also given during the specified time frame), then how does the algorithm exclude the case?

Answer 106: The algorithm will exclude a case if the Broad Spectrum or Other Antibiotic Administration Date and Time entered are greater than 24 hours prior to presentation.

Question 107: What if a patient has antibiotics listed as home meds?

Answer 107: You will need to identify whether or not the antibiotics listed as home meds were given within 24 hours prior to presentation. Please note that they must be IV antibiotics. If they were given within 24 hours prior to presentation and also earlier than 24 hours prior to presentation, you will need to enter the date and time of the earliest known dose. If that is unknown, you will need to enter UTD.

Question 108: In the ABX timing examples, were the ABX's representing the "recommended" ABX or any ABX at all IV?

Answer 108: The antibiotic timing examples were for any IV antibiotic. The letters were used to designate whether or not a dose was of the same antibiotic or a different one.

Question 109: An antibiotic timing question: what if the doses of IVAB in the 24 hours prior to presentation (or more than 24 hours prior to presentation) were given at a private Nursing Home that did not provide the exact times of the dosage administration, and will not provide the details? What if all we know is that the patient has been on IVAB for endocarditis since 09/18/15. Many patients are in Nursing Homes only because they need long term IVAB therapy for conditions such as osteomyelitis.

Answer 109: If you do not know the time of antibiotic administration, you will need to enter UTD.

Question 110: How do you determine the time of ABX given in 24 hour time frame prior to presentation if the patient and or family is not able to state exactly if or when the patient took the ABX before presenting for TX?

Answer 110: Please note the antibiotic must be an IV antibiotic. Doses of oral antibiotics should be disregarded. If the time is unknown, you will need to enter UTD.

Question 111: If a patient arrives in ED and ABX that are not broad spectrum are started prior to the final criteria for Severe Sepsis met, then the case passes even though there was no broad spectrum ABX given, correct?

Answer 111: Correct.

Question 112: If the patient receives only Zosyn in the first 3 hours, will this pass the measure?

Answer 112: Yes, Zosyn is on Table 5.0 Antibiotic Monotherapy for Sepsis.

Question 113: Just to clarify: both doses of the combination therapy need to be started in the 3 hours prior window to pass the measure, right?

Answer 113: Correct.

Question 114: Regarding combination therapy, what time do we take if column A is given an hour prior to column B? What time do we abstract for the antibiotic administration?

Answer 114: The Broad Spectrum or Other Antibiotic Administration Time data element's Notes for Abstraction indicate that if one or more than one IV antibiotic was given only after the presentation of severe sepsis, and the patient was not receiving an IV antibiotic in the 24 hours before severe sepsis presentation, abstract the dose given closest to the time of presentation of severe sepsis.

Question 115: Do both of the combination therapy antibiotics have to be complete within the 3 hour window or can you have one complete and one started, but not completed, within the 3 hour window?

Answer 115: Both must be started, but both do not need to be completed within the 3 hour window.

Question 116: For how many days should the antibiotics be entered into the data base, 24 hours, 48 hours?

Answer 116: If an antibiotic was given within 24 hours of severe sepsis presentation time, the Broad Spectrum or Other Antibiotic Administration Time data element's Notes for Abstraction indicate to abstract the earliest time that a dose of the IV antibiotic was given. This may be the same time as the time of presentation, within 24 hours prior to presentation, or a time greater than 24 hours before presentation. Based on this you would enter the earliest known/documented date and time the antibiotic was administered.

Question 117: If the patient received ABX only in the 24 hours prior to severe sepsis presentation, then we do not answer the selection question, correct?

Answer 117: Correct.

Question 118: Will the antibiotic requirement take into account national antibiotic shortages at the time of patient presentation?

Answer 118: There are sufficient antibiotic options to provide coverage for most antibiotic shortages.

Question 119: If a patient was given a monotherapy 30 minutes prior to the presentation of severe sepsis, is the expectation that the patient be given another dose of a monotherapy after presentation?

Answer 119: Administration of subsequent doses in this scenario should be based upon the dosing schedule for that antibiotic. The measure does not require antibiotics be given both within 24 hours prior to and 3 hours following severe sepsis presentation. It only requires antibiotics be given within 24 hours prior to or within 3 hours following presentation.

Question 120: Can you please address the rationale behind excluding monotherapy with metronidazole? There are instances of patients presenting with diarrhea and have a *Clostridium difficile* infection due to a polymerase chain reaction, which results fairly quickly.

Answer 120: Metronidazole does not provide sufficient coverage for broad spectrum monotherapy.

Question 121: Can you please clarify what you meant when said broad spectrum or other ABX administration selection is limited to the cases where the only antibiotics were given or started within 3 hours following presentation?

Answer 121: If an antibiotic was given within 24 hours prior to severe sepsis, the algorithm bypasses the Broad Spectrum or Other Antibiotic Administration Selection data element. The algorithm only requires the Broad Spectrum or Other Antibiotic Administration Selection if the Broad Spectrum or Other Antibiotic Administration Time is within 3 hours following severe sepsis presentation.

Question 122: I can't find the ABX Table with columns A and B in Data Element for Broad Spectrum ABX. Can you please post the page in specifications manual where this can be found?

Answer 122: The Combination Antibiotic Therapy Table is located on the second page of the Broad Spectrum or Other Antibiotic Administration Selection data element on page 1-66 of version 5.0b of the specifications manual.

Question 123: If the severe sepsis presentation time was 1330 and the two antibiotics were given 3 hours after severe sepsis presentation were Flagyl and Cipro and then Vanco 6 hours after, the case fails right? Flagyl is not a monotherapy, so I have to consider Cipro and Vanco, right?

Answer 123: Correct.

Question 124: Do the antibiotics given for Broad Spectrum or Other Antibiotic Administration have to be on 5.0 and 5.1?

Answer 124: That is the case if the only antibiotics that were given were in the 3 hours following presentation of severe sepsis. If any antibiotic was given in the 24 hours prior to presentation (even if an antibiotic was also given in the 3 hours following presentation), the antibiotic does not need to be on Table 5.0 or 5.1.

Question 125: Do the antibiotics given before presentation need to be IV to be counted?

Answer 125: Yes, only IV antibiotics are taken into consideration.

Question 126: If ABX was given in the 24 hours prior to presentation and the same ABX was also given a week before, would that still exclude the case?

Answer 126: Yes, based upon how the Broad Spectrum or Other Antibiotic Administration Time is specified in the manual, you would exclude this case.

Question 127: Does the antibiotic given 24 hours prior have to be IV if the patient received it in the physician's office or at home?

Answer 127: All antibiotics must be IV. IV is the only acceptable route. Antibiotics given via other routes should not be taken into consideration.

Question 128: What happens to the measure when you don't know the time of the antibiotic given within 24 hours prior to presentation? You select “No,” then does that exclude the case?

Answer 128: If you know an antibiotic was given within the 24 hours prior to presentation, but do not know the exact time is was given, you would select "Yes" for Broad Spectrum or Other Antibiotic Administration and enter "UTD for Broad Spectrum or Other Antibiotic Administration Time. The case will not be excluded, it will fail the measure.

IV Fluid Questions

Question 129: Is this example correct? If a patient should receive 1871 ml (30 mL/kg) of crystalloid fluids and the physician has ordered a rate or time over which to infuse, then you can determine a conclusion time, right?

Answer 129: Correct.

Question 130: If crystalloid fluids were administered at the volume of 30 ml/kg and persistent hypotension was present within one hour of conclusion of fluid administration then Choose Allowable Value “1 (Yes),” correct?

Answer 130: The question does not specify which data element it is regarding. Based on specifications for the Septic Shock Present and Persistent Hypotension data elements this would be correct.

Question 131: If a patient needs 1800 ml of fluid, and they get a liter at 10:00, a liter at 11:00 and a liter at 12:00, each over an hour, would we start looking for hypotension at 12:00 (after 2 liters are in) or at 13:00 (after entire infusion is in)?

Answer 131: The hour timeframe to look for persistent hypotension begins when the 30 ml/kg have been completely infused.

Question 132: Example 6 on slide 27: How can you answer value "1" if there is only one BP recording after the fluids are completed? The other BP is prior.

Answer 132: Example 6 does not specify whether one or multiple blood pressures were taken following the crystalloid fluid infusion. The underlying assumption is that the systolic blood pressure after the crystalloid fluids remained below 90. We will look into making this clearer in the next version of the manual.

Question 133: On page 107, are they saying the amount of crystalloid fluid can be over 8 hours to meet the ml/kg requirement, if the hypotension is still present after the first hour?

Answer 133: This is specifying that the rate of administration must be greater than 125 ml/hour, which is equivalent to 1000 ml over 8 hours. If persistent

hypotension (and therefore septic shock presentation) is more than 6 hours after severe sepsis presentation, you should select Value "2 (No)" for Septic Shock Present.

Question 134: Do we have any updates on the Crystalloid Fluid element of SEP-1 in CHF patients with low ejection fractions?

Answer 134: Nothing has changed with regard to the volume of crystalloid fluids required to meet the measure. There are no exceptions or exclusions for CHF patients.

Question 135: If our septic Shock time starts at 5 p.m. (1700), then does the administration of 30ml/kg of fluid have to be complete by 8 p.m. (20:00), which is 3 hours after the start time?

Answer 135: The 30 ml/kg of crystalloid fluids needs to be started, not completed, within 3 hours of Septic Shock Presentation Time.

Question 136: Are we allowed to use fluids administered by Emergency Medical Services (EMS) in route to our facility?

Answer 136: Yes, depending on the rate at which they are administered and whether or not there is an order or protocol that serves as an order. Fluids must be given at a rate greater than 125 ml/hour (equivalent to 1000 ml over 8 hours) to be considered in the total volume. There must also be an order and the order must include the duration over which to infuse, or an infusion rate.

Question 137: Is there a time frame for the crystalloid fluid administration? How do I know what time to use for the persistent hypotension? If it takes 6 hours to get all the fluids, is that acceptable?

Answer 137: There is not a specific time frame within which the crystalloid fluids must be infused. The time frame for totally infusing the 30 ml/kg will depend on a number of factors, including the total volume. The volume must be given at a rate greater than 125 ml/hour (equivalent to 1000 ml over 8 hours). Below this rate represents maintenance fluids and not fluids for resuscitation. The time to start looking for persistent hypotension corresponds to when the 30 ml/kg crystalloid infusion is completed. Note however, the Septic Shock Present data element's Notes for Abstraction indicate that if Septic Shock presentation is more than 6 hours after Severe Sepsis presentation, choose Value “2.”

Question 138: What if fluid is ordered as "bolus" as rate?

Answer 138: The order must include a duration over which to infuse the crystalloid fluids or an infusion rate. Bolus does not specify a duration or rate and is therefore not acceptable. You will need to select Value "2 (No)" for Crystalloid Fluid Administration.

Question 139: What if the physician orders fluid bolus with a rate of "wide open"? What would we use as the completion time? Can we assume that when another bolus is documented that the first has concluded?

Answer 139: The order must include a duration over which to infuse the crystalloid fluids or an infusion rate. Bolus and wide open do not specify a duration or rate and are therefore not acceptable. You will need to select Value "2 (No)" for Crystalloid Fluid Administration.

Question 140: Are you saying that there are no rate/time frame requirements for the crystalloid infusion?

Answer 140: The Crystalloid Fluid Administration data element does not set a time frame over which the fluids must be infused. It does specify that fluids given at a maintenance rate or to keep vein open, which is defined as 1000 ml over 8 hours (equivalent to 125 ml/hour) are not acceptable. If the only fluids were given at a rate of ≤ 125 ml/hour you would select Value "2 (No)" for Crystalloid Fluid Administration.

Question 141: What if a patient received the appropriate volume of crystalloids, but was discharged before a blood pressure was rechecked within the time frame to check for persistent hypotension?

Answer 141: You would select Value "3 (No) or UTD" for Persistent Hypotension.

Question: 142: I thought BP <90 or lactate >4 were septic shock signs and the crystalloids were given then and vasopressors were given for persistent low BP. Why would you give an intravenous fluid (IVF) bolus if the BP is normal (as could be in severe sepsis).

Answer 142: For the purposes of the SEP-1 measure, the only time you would give an IV fluid bolus is when the patient had a SBP >90 or MAP >65, the SBP had not decreased by more than 40, and if the Lactate were ≥4.

Question 143: In the septic shock present question where it states hypoperfusion one hour after crystalloid fluid administration, does that have to be the 30 ml/kg specified in the crystalloid administration question?

Answer 143: Yes, this is clarified in version 5.0b of the manual posted to *QualityNet* on October 22, 2015.

Question 144: On slide 103, the Specifications Manual says: “If there has not been crystalloid administration, select “No” for septic shock. Patients with initial lactate >4 and severe sepsis present have septic shock without the administration of crystalloids.” Is this being addressed in the manual page 1-332?

Answer 144: For purposes of the SEP-1 measure, if crystalloid fluids were not given following presentation of severe sepsis, you should select "No" for Septic Shock Present. This allows the case to be excluded from the crystalloid fluid data elements. The case would fail if crystalloid fluids were not given. This does not mean the patient does not clinically have septic shock.

Question 145: If initial lactate is >4, but no crystalloid fluids are given during the 6 hours after severe sepsis, do we answer "No" to septic shock?

Answer 145: Not necessarily. You would select "No" for Septic Shock Present if no crystalloid fluids were given at all after presentation of severe sepsis. There is no time frame after severe sepsis presentation associated with this. If fluids were not given within 6 hours following presentation of severe sepsis but were given after 6 hours, then you would select "Yes." This is an all-or-none point for crystalloid fluids.

Question 146: There isn't an order for 30 ml/kg and the full amount wasn't administered. Can we use clinical knowledge to make the determination that the fluid is being administered at a rate of 30ml/kg by looking at the amount given and the rate it is being infused?

Answer 146: No. There must be an order for a fluid volume that is equivalent to 30 mL/kg. The order must include a duration for infusing or an infusion rate. Without the order you will need to select Value "2 (No)" for Crystalloid Fluid Administration.

Question 147: The nursing documentation for infection is no longer limited to the ER documentation, but can it be nursing inpatient documentation?

Answer 147: Yes.

Question 148: If the physician documents septic shock, but fluids are not given, and no other septic shock criteria are present is "septic shock" present, value 1 or value 2?

Answer 148: If no fluids were given after the presentation of severe sepsis, you would select "No" for Septic Shock Present, regardless of physician documentation or clinical criteria.

Question 149: Are EMS and OR fluid amounts allowable for crystalloid fluids administered, as most records will not have a rate or time to infuse, just the volume that was administered?

Answer 149: Yes, depending on the rate at which they are administered and whether or not there is an order or protocol that serves as an order. Fluids must be given at a rate greater than 125 ml/hour (equivalent to 1000 ml over 8 hours) to be considered in the total volume. There must also be an order and the order must include duration over which to infuse, or an infusion rate.

Question 150: Our documentation does include the ending time of the fluid administration. May we use this to calculate the correct fluids that are needed?

Answer 150: The volume of fluids the patient should receive is based upon the patient's weight.

Question 151: If not specified, how do we determine if the 30cc/kg crystalloids were given specifically for severe sepsis with hypotension, if it is not documented or the order does not indicate a reason?

Answer 151: This bullet point is to emphasize that crystalloid fluids for other purposes are not acceptable. If the patient has severe sepsis with hypotension, or severe sepsis with a lactate ≤4, or the physician documented septic shock, then fluids that were not given for other purposes (e.g., flushing lines, administering medications, or other purposes that are not related to hypotension, Lactate ≥4, or septic shock) would be given for severe sepsis.

Question 152: If using the ED Report by ED MD, do we use the Start Time of the whole report, which can be the Bedded Time?

Answer 152: If a sign of infection or severe sepsis is documented within the ED provider note (note the ED provider report), and there is a specific time within the note associated with the sign of infection or severe sepsis documentation, use that time. If there is not a specific time within the note, use the time the note was started or opened, which should be early in the course of the ED stay.

Question 153: What if Septic Shock is document right before surgery, can fluids given during surgery be used even though there are no orders?

Answer 153: The Crystalloid Fluid Administration data element indicates there must be an order for 30 ml/kg of crystalloid fluids and the order must include an infusion duration or infusion rate. If there is not an order, the fluids cannot be used.

Question 154: If a patient has evidence of fluid overload (i.e., positive fluid balance as documented by intake and output (I&O) or documentation from a MD/PA/APN) is the patient excluded from crystalloid fluid administration requirement?

Answer 154: There are no exclusions from the 30 ml/kg crystalloid fluid administration.

Question 155: If the MD orders a normal saline (NS) bolus order of 1000 ml/hour, but he puts those orders in on three separate time frames, without one order that states 30 ml/hour, will this pass the measure? Wouldn't it pass given that the patient does receive the minimum amount of fluids, despite the fact that the MD order does not explicitly state 30 ml/hour?

Answer 155: The order does not need to specifically state "30 ml/kg." The volume ordered must be equivalent to 30 ml/kg and can be in a single order or series of orders.

Question 156: For determining septic shock present, what if the crystalloid fluids given are less than 30 ml/kg and the patient is hypotensive, is septic shock present, “Yes” or “No?”

Answer 156: No, the Septic Shock Present data element criteria states "Hypotension persists in the hour after the conclusion of the 30 ml/kg Crystalloid Fluid Administration." For the purposes of the measure, if the correct amount of fluid (30 ml/kg) is not given, the presence of septic shock cannot be determined.

Question 157: Based on documentation in the note which indicates, "Septic Shock" (is time zero as no other criteria present to support earlier time) as the reason patient already on pressors, MAP>65, not hypotensive, lactate <4, so why would the patient require a 30cc/kg bolus?

Answer 157: If the MAP is >65 and SBP is >90 and the lactate is <4, the 30 ml/kg bolus is not indicated. However if the physician documented septic shock, then it might be indicated. According to your question, the patient is on vasopressors, which may indicate crystalloid fluids were already given. If so, then crystalloid fluids given prior to presentation of septic shock should be taken into consideration. If no crystalloid fluids were given after presentation time of severe sepsis, the Septic Shock Present data element's Notes for Abstraction indicate to select Value "2 (No)." There is not enough information in the question to comment further.

Question 158: What if the patient's initial lactate level is greater than 4? Is septic shock present time the same as the severe sepsis present in this case if fluids have not yet been administered?

Answer 158: Septic shock presentation time is based upon when the last of the clinical criteria indicating the presence of septic shock occurs. If an initial lactate result of 4 is documented before severe sepsis criteria are met, you could not use the time of the lactate result as septic shock presentation time, because septic shock requires the presence of severe sepsis. It would not be until the clinical criteria for severe sepsis was also met. Determination of septic shock based upon a lactate ≥4 does not require crystalloid fluid administration to determine the presence of septic shock. In the scenario described in the question, the septic shock presentation time could be the same time as or after severe sepsis presentation time, depending on the time each of the various criteria were met.

Question 159: If no crystalloid fluids were administered, the answer to septic shock present is no even if the physician documents septic shock?

Answer 159: Correct.

Question 160: Does the crystalloid fluid have to a bolus or can it be continuous IV? If it is continuous, how do you know when it ends?

Answer 160: There must be an order for the equivalent of 30 ml/kg, and the order must include an infusion duration or infusion rate. The total fluid given must be equivalent to 30 ml/kg. The fluid can be given very rapidly or over a longer period of time. It must be given at greater than 125 ml/hour (equivalent to 1000 ml over 8 hours) to count toward the Crystalloid Fluid Administration data element. Determining when the 30 ml/kg infusion ends can be based on documentation indicating when it ended or by calculating an estimated end time, if you know the start time and the rate of infusion.

Question 161: If there is MD documentation of "possible septic shock" but no crystalloid fluids were administered or were not administered at 30 ml/kg, would I answer the "Septic Shock Present" data element as a “No?”

Answer 161: If no fluids were given after the presentation of severe sepsis, you would select "No" for Septic Shock Present, regardless of physician documentation or clinical criteria. If fluids were given but not 30 ml/kg, you would select "Yes" for Septic Shock Present because of the physician documentation of possible septic shock.

Question 162: Is crystalloid fluid administration criteria "prior to septic shock" a change?

Answer 162: It is a clarification. Crystalloid fluids given prior to septic shock presentation have always been acceptable; it was not clearly stated in the prior version of the manual.

Question 163: Would you please clarify slide 103: If crystalloid fluids were not administered after the presentation date and time of Severe Sepsis, select Allowable Value "2 (No)," does this mean any crystalloid fluid or does this only apply if 30ml/kg was not given?

Answer 163: This means any crystalloid fluid.

Question 164: Is Wide Open without a time frame considered an acceptable rate if the amount of fluids given was adequate?

Answer 164: The order must include duration over which to infuse the crystalloid fluids or an infusion rate. Wide open does not specify duration or rate and is therefore not acceptable. You will need to select Value "2 (No)" for Crystalloid Fluid Administration.

Question 165: For Crystalloid fluid administered: if volume is not ordered but there is a rate on the MAR for 150 ml/hour continuous, can "Yes" be selected?

Answer 165: No, Allowable Value "1 (Yes)" states "… the volume ordered was 30 ml/kg," which means there must be an order. The Notes for Abstraction also reference that the order must include a time over which the fluids are to be given.

Question 166: IF volume calculates out to 1830 cc and the patient gets 1800 does mean we choose allowable value 2?

Answer 166: Yes, currently the measure does not allow for variations such as this.

Question 167: Persistent Hypotension start time: How is an end time determined for crystalloid fluids when a physician orders the crystalloid fluids to run 125 ml/hour? Would it be 8 hours or is it when the calculated amount (30 ml/kg) has infused?

Answer 167: Determining the end time can be based on the volume ordered and rate of administration noted in the order, and would be when the 30 ml/kg has been infused. Please note in the question, the crystalloid fluids are run at a rate of 125 ml/hour. If this is the case, you would need to select Value "2 (No)" for Crystalloid Fluid Administration because the Notes for Abstraction indicate that if crystalloid fluids are administered at a usual rate, which is 1000 ml over 8 hours, or at a "Keep Vein Open" (KVO) rate, choose Value "2." Because 1000 ml over 8 hours is equivalent to 125 ml/hour, this would be considered a "usual" or maintenance rate?

Question 168: If crystalloid was started before the severe sepsis or septic shock presentation, how far back can we abstract? For example, if crystalloid fluid was given at 12 noon but severe sepsis time zero is at 3 p.m., can I use 12 noon as the start time of crystalloid?

Answer 168: Yes, as long as the crystalloid fluids were running at a rate greater than 125 ml/hr (equivalent to 1000 ml over 8 hours) as identified in the Crystalloid Fluid Administration data element.

Question 169: **On s**lide 107, please clarify the total volume that needs to be infused.

Answer 169: When answering the Crystalloid Fluid Administration data element, you are only looking for an order for the equivalent of 30 ml/kg and that it was started prior to, at the time of or after the presentation of septic shock. Crystalloid Fluid Administration does not evaluate whether or not the full volume was actually infused. Whether or not the full 30 ml/kg volume was actually infused is evaluated in the Persistent Hypotension data element.

Question 170: **On** slide 107, are crystalloid fluids given via ambulance appropriate to use towards calculating appropriate fluid volume given?

Answer 170: Yes, depending on the rate at which they are administered and whether or not there is an order or protocol that serves as an order. Fluids must be given at a

rate greater than 125 ml/hour (equivalent to 1000 ml over 8 hours) to be considered in the total volume. There must also be an order and the order must include a duration over which to infuse or an infusion rate.

Question 171: If 30 ml/kg is 6000 ml, is it an expectation that all of this fluid be given?

Answer 171: For purpose of the measure, yes. The physician, however, should use their clinical expertise and judgment to monitor the patient and ensure the volume can be given safely. If the total volume, in the clinical judgment of the physician, will be detrimental to the patient they should exercise that clinical judgment and not give the fluids just to meet the measure.

Question 172: If the patient has severe sepsis and an initial lactate of 4.5 but does not receive any crystalloid fluids, would it still be "No" to Septic Shock Present due to not having any crystalloids given?

Answer 172: Correct.

Question 173: Previous webinars have stated fluids should be given rapidly, has this changed?

Answer 173: Crystalloid fluids should be given rapidly. However the rate at which they are administered and how long it takes to totally infuse the volume will vary based on several factors, including but not limited to, the total volume to be infused and the patient's condition and response. As such, the measure does not specify at what rate they must be administered but rather defines a lower limit based on the infusion being for maintenance (125 ml/hour or less) versus non-maintenance (greater than 125 ml/hour).

Question 174: Do we accept 125 ml an hour? The slide says “must be greater than 1000 ml over 8 hours which is 125 ml/hr.

Answer 174: No, the rate must be greater than 125 ml/hour.

Question 175: On slide #107, what is meant by "Total volume does not need to be completely infused?" Is this referring to a certain time frame?

Answer 175: When answering the Crystalloid Fluid Administration data element, you are only looking for an order for the equivalent of 30 ml/kg and that it was started prior to, at the time of or after the presentation of septic shock. Crystalloid Fluid Administration does not evaluate whether or not the full volume was actually infused. Whether or not the full 30 ml/kg volume was actually infused is evaluated in the Persistent Hypotension data element.

Question 176: If the physician states septic shock in their notes but no crystalloid fluids were administered, do we select “Yes” or “No” for septic shock?

Answer 176: If no crystalloid fluids were given after presentation of severe sepsis, you would select "No" for Septic Shock Present, regardless of how septic shock is identified.

Question 177: For crystalloid fluid administration, how many hours prior to the presentation of septic shock allow to abstract?

Answer 177: There is no time frame specified in the manual for this because it will depend on the total volume being infused and the rate at which it is being infused.

Question 178: So is 125 ml hour of fluid accepted as a bolus or not?

Answer 178: If the infusion rate is ≤125 ml/hour, you need to select Value "2" for Crystalloid Fluid Administration.

Question 179: If the right amount of fluid is not given can you still say “Yes” to Septic Shock if you have severe sepsis and a Lactate level of >4?

Answer 179: Yes, in this case the determination of the presence of septic shock is based upon severe sepsis with a lactate ≥4, not hypotension that does not respond to crystalloid fluids.

Question 180: What is the time frame for the two or more consecutive readings, knowing the first one must be within the hour after conclusion of the fluids? Can the second BP be 2 hours later if that is the next recorded BP?

Answer 180: Both blood pressure readings must be within the hour following conclusion of the fluids. If only one is recorded in the hour and it does not reflect hypotension, you would select Allowable Value "2 (No)" indicating persistent hypotension was not present because there is no indication of hypotension. If only one is recorded in the hour and it does demonstrate hypotension, you would select Allowable Value "3 (No) or UTD." Based upon only one reading of hypotension, you cannot determine whether or not the hypotension is persistent.

Question 181: So I see on Slide 103 that if Crystalloid Fluids were not administered after presentation date or time of Severe Sepsis, then there is no Septic Shock Present. If the patient was started on vasopressors once IVF were started, not necessarily a bolus ordered because the patient was obviously in a shock state, then can value "1" be chosen?

Answer 181: This will depend on other information in the medical record and how that information fits in with the specifications for the Septic Shock Present data element. For example, what criteria are you using to determine whether or not septic shock is present? The bullet point that states, “If crystalloid fluids were not administered after the presentation date and time of severe sepsis, choose Value ‘2’” makes an assumption that either clinical criteria were met or there

is physician documentation of septic shock. If neither are present, for purposes of the measure, the patient does not have septic shock.

Question 182: How would an abstractor proceed if a patient's initial lactate level was <2.0 but the repeat lactate level was >4.0? At the time of the repeat lactate level returning within 6 hours at a level greater than 4.0 (in the absence of hypotension <90), is the 30 cc/kg fluid bolus required or is the 30 cc/kg fluid bolus only required on the initial lactate level if it is greater than 4.0?

Answer 182: For purposes of the SEP-1 measure, the initial lactate level result value is what is used. Assuming the patient does not have hypotension, if the initial lactate level result is < 4 the patient does not have septic shock. If it is ≥4 the patient does have septic shock. The measure does not require abstraction of the repeat lactate result level, only the time the repeat lactate was drawn. Clinically this would still represent septic shock and the patient should be treated accordingly.

Question 183: If there is only one blood pressure reading in the hour following the completion of the crystalloid infusion but it meets the criteria for hypotension, is this considered persistent hypotension?

Answer 183: The two blood pressure readings demonstrating hypotension must be within the hour following conclusion of the fluids. If only one is recorded in the hour and it does demonstrate hypotension, you would select Allowable Value "3 (No) or UTD." Based upon only one reading of hypotension, you cannot determine whether or not the hypotension is persistent.

Question 184: If the presentation of septic shock is 0900 and crystalloid fluids have not been started until after that presentation time, is it accurate to say that we now have 6 hours to get in the 30 ml/ kg crystalloid fluids and wait one hour and to document reassessment after that hour is finished, so only 6 hours to give fluids and do the repeat assessment an hour after the fluids?

Answer 184: The repeat volume status and tissue perfusion assessment must be completed within 6 hours following the presentation of septic shock to pass the measure. Crystalloid fluids should be given as rapidly as possible to treat hypoperfusion. The time window for the components of the repeat volume status and tissue perfusion assessment do not start with the conclusion of the crystalloid fluids. They start with the beginning of the crystalloid fluid infusion and end 6 hours following septic shock presentation.

Question 185: Are we allowed to count the amount of crystalloid fluids given per EMS if septic shock was present in the ED?

Answer 185: Yes, depending on the rate at which they are administered and whether or not there is an order or protocol that serves as an order. Fluids must be given at a rate greater than 125 ml/hour (equivalent to 1000 ml over 8 hours) to be

considered in the total volume. There must also be an order and the order must include a duration over which to infuse or an infusion rate.

Question 186: Slide 113: How can I select septic shock present at 9:00 if there have not been any crystalloid administration until 9:15? On slide 103 it was said to answer "No" to septic shock without the crystalloid administration.

Answer 186: In this example, septic shock presentation is identified by the lactate being ≥4.2, and the crystalloid fluids are administered to treat the hypoperfusion evidenced by the lactate level. The crystalloid fluids do not play a role in determining the presence of septic shock when it is based upon a lactate ≥4. If the presence of septic shock is based upon hypotension not responding to crystalloid fluids, the fluids must have been administered prior to the presentation of septic shock because the hypotension not responding to the fluids is what defines septic shock.

Question 187: Is Sodium Chloride considered an acceptable crystalloid fluid for this measure?

Answer 187: Sodium Chloride is not acceptable because it is not specific enough. There are different concentrations of sodium chloride solution and the only acceptable concentration is 0.9%, which is also referred to as "normal saline."

Question 188: Do the additional orders for crystalloid infusion have to be back-to-back with no lapse of time?

Answer 188: No.

Question 189: I thought you could not use flushes or maintenance fluids towards crystalloid fluid administration, is this correct? In the septic shock example number #4, it sounded different during presentation.

Answer 189: Correct, crystalloid fluids used for flushes and being given at a maintenance rate do not count toward the total volume. As soon as the rate of a maintenance IV is increased to greater than 125 ml/hour, it is no longer considered a maintenance IV, and any fluids administered at the rate greater than 125 ml/hour can be used. The volume of fluid infused prior to the rate being increase to greater than 125 ml/hour cannot be counted.

Question 190: How does the focused exam fit in with the changes on crystalloid fluids? Does the exam have to happen after the conclusion of the fluids or just after the start as the data dictionaries state?

Answer 190: The time window for the components of the focused exam do not start with the conclusion of the crystalloid fluids. They start with the beginning of the crystalloid fluid infusion and end 6 hours following septic shock presentation.

Question 191: Did I understand you to say if they do not deliver 30ml/kg we need to answer no to Septic Shock since we are unable to evaluate due to lack of adequate volume infused?

Answer 191: This will depend on how septic shock presents. If septic shock is based on a lactate ≥4, you will select "Yes" for Septic Shock Present, regardless of how much of the volume was infused, because septic shock presence is defined by the lactate ≥4. If septic shock is based on hypotension that does not response to 30 ml/kg of crystalloid fluids and 30 ml/kg of crystalloid fluids were not given, you will select "No" for Septic Shock Present. Septic Shock Present requires that 30 ml/kg of crystalloid fluids be given and the hypotension persists after that.

Question 192: For the Crystalloid Fluid Administration data element, if there is no order for rate/duration, do you select value "2?"

Answer 192: Correct. The Notes for Abstraction include a bullet point that indicates if a fluid volume is ordered but the order does not include a time over which the fluids should be given, to select Value "2 (No)."

Question 193: In one hour following administration of crystalloid fluids, two or more consecutive blood pressure readings of either – what are the "either" referred to here?

Answer 193: This is referring to the blood pressure parameters established in the Persistent Hypotension data element, which have not changed and were therefore, not repeated on the slide.

Question 194: Would an order of "wide open" for IVF count for IVF administration as long as the total volume is given within the 3 hours?

Answer 194: The order must include a duration over which to infuse the crystalloid fluids or an infusion rate. Wide open does not specify a duration or rate and is therefore not acceptable. You will need to select Value "2 (No)" for Crystalloid Fluid Administration.

Question 195: Are patients with renal failure/heart failure excluded from the crystalloid fluids administration?

Answer 195: No.

Question 196: Under "Crystalloid "Fluid Administration" #3 (No) selection, fluids were not administered prior to. Does this only refer to crystalloid fluids administration boluses or does this also include maintenance doses of crystalloid fluids?

Answer 196: The Crystalloid Fluid Administration data element is identifying whether or not a 30 ml/kg volume was ordered and started. It does not pertain to

maintenance fluids. If the crystalloid fluids were given a rate ≤ 125 ml/hour (equivalent to 1000 ml over 8 hours) the Notes for Abstraction reflect to select Value "2."

Laboratory and Examination Questions

Question 197: If a patient presents to ED with a heart rate of 113 and in an uncontrolled atrial fibrillation rhythm, with no history of atrial fibrillation, are we to accept the heart rate of 113 as one of the SIRs criteria for severe sepsis present?

Answer 197: Currently there is not wording in the Severe Sepsis Present data element to disregard the heart rate in this situation. Keep in mind that to be abstracting a case, the patient has to have an ICD-10 code for sepsis, severe sepsis, or septic shock. If one of these codes was not assigned the case, they will not be in your initial patient or sample population. Also keep in mind that all the criteria must be met (suspected infection, two or more SIRs criteria, and a sign of organ dysfunction) within 6 hours of each other to be considered severe sepsis.

Question 198: If a patient becomes hypotensive (SBP less than 90) during a hemodialysis treatment, which is common, should the SBP less than 90 during a hemodialysis session be disregarded for purposes of signs of organ dysfunction and signs of persistent hypotension?

Answer 198: Currently there is not wording in the Severe Sepsis Present data element to disregard the blood pressure in this situation. Keep in mind that to be abstracting a case the patient has to have an ICD-10 code for sepsis, severe sepsis, or septic shock. If one of these codes was not assigned the case they will not be in your initial patient or sample population. Also keep in mind that all the criteria must be met (suspected infection, 2 or more SIRs criteria, and a sign of organ dysfunction) within 6 hours of each other to be considered severe sepsis.

Question 199: When abstracting postop patients, it's not uncommon for some of the BPs to fall below 90, either in the OR or in PACU. I'm currently looking at a case with one BP in PACU of 89, although all of his others have been >90. It's also not uncommon for these patients to have an elevated HR and/or RR due to pain issues. It doesn't seem clinically appropriate to treat them for severe sepsis based on these vital signs, assuming surgery was for an infection-related process. Are there plans for any exclusions for these types of cases? If not, it would be helpful to know the rationale so we can educate our physicians.

Answer 199: Currently there is not wording in the Severe Sepsis Present data element to disregard the blood pressure, heart rate, or respiratory rate in this situation. Keep in mind that to be abstracting a case the patient has to have an ICD-10 code for sepsis, severe sepsis, or septic shock. If one of these codes was not assigned the case they will not be in your initial patient or sample population. Also keep in mind that all the criteria must be met (suspected infection, two or more SIRs criteria, and a sign of organ dysfunction) within 6 hours of each other to be considered severe sepsis. In regards to treating patients, if in the clinical judgment of the physician the patient does not have severe sepsis or septic shock, then that judgment should prevail and the patient should be treated accordingly.

Question 200: Do the vital signs need to be from the same time, or within 6 hours of each other to determine the two SIRs criteria?

Answer 200: No, the SIRs criteria may manifest at different times. All criteria must be met within 6 hours of each other.

Question 201: For the persistent hypotension element it now states two or more consecutive readings are required, but is that the same for determining septic shock? Is one reading of low BP in the hour after fluid administration enough to say "Yes" to septic shock?

Answer 201: Two consecutive blood pressures demonstrating hypotension following conclusion of 30 mL/kg of crystalloid fluids are required. This is referenced in the second bullet point where it states, "Refer to the Persistent Hypotension data element."

Question 202: So the times used for lab values should be the reported time, not collected time, with the exception of the blood culture collection time?

Answer 202: This depends on what data element you are working with. Anything that calls for lab results must come from a lab results report and therefore reflect reported time. Results are not known at the time the lab is drawn. They are only known at the time the results come back. For Severe Sepsis Present and Septic Shock Present, you must use the lab results, which can only come from the results report. For Initial Lactate Level Result, you must use results for the initial lactate, which are from the lab results. Any data element that calls for a collection time requires you use the time the lab is drawn or collected. For Initial Lactate Level Time, Repeat Lactate Level Time, and Blood Culture Collection Time, you need to use the time the lab was drawn or collected.

Question 203: Is the lactic acid result time what might trigger the start clock on severe sepsis and septic shock even though the draw time is used to meet the three/six hour requirements?

Answer 203: Yes, the clock cannot start until severe sepsis or septic shock presentation time is known. This is not determined based on when any lab is collected, because the results are not known when the lab is drawn. The results time must be used because that is the time when the results that can help determine the presence of severe sepsis or septic shock are known.

Question 204: If UTI is listed in the differential diagnosis, would this count as an infection for severe sepsis?

Answer 204: Yes.

Question 205: Can you take the same elevated SIRs s/s twice; for example, an elevated pulse at 1200 and 1215, as two criteria for SIRs?

Answer 205: No, the SIRs criteria require two or more of the criteria listed. Counting one twice does not constitute two or more from the list.

Question 206: If there is contradictory documentation of infection, i.e., if an ED nurse documents suspected infection in triage but the ED physician documents that no infection is present in his ED H&P, do we give preference to the physician/APN/PA documentation over nursing documentation?

Answer 206: Currently the manual does not give preference. In this situation, for purposes of the measure, a positive finding of suspected infection would be taken over a negative finding of no infection. This is something we will look further into for future revisions to the specifications.

Question 207: Are we required to do blood cultures x1 or blood cultures x2 to pass the SEP blood culture requirement?

Answer 207: No, the data element does not require that more than one blood culture be drawn for purposes of the measure.

Question 208: If a physician includes vital signs in his progress notes, is the time of the progress note the time for the vitals?

Answer 208: If this question is in reference to the Vital Signs Review Performed data elements, then the time of the progress note would be used as the Vital Signs Review Time.

Question 209: Shouldn't repeat lactate >4 be the definition of shock, not the initial, similar to how shock is not diagnosed until after fluid bolus administration?

Answer 209: While clinically a repeated or subsequent lactate ≥4 could signify the presence of septic shock, initial lactate is used for purposes of the measure to reduce the complexity in determining the presence of severe sepsis and septic shock. Please note, for purposes of the measure the initial lactate is not necessarily

always going to be the first lactate drawn. The first bullet point in the Initial Lactate Level Collection data element's Notes for Abstraction states, "If there are multiple lactate levels, only abstract the level drawn closest to the time of presentation of severe sepsis. That lactate level is the initial lactate level for purposes of this data element."

Question 210: Can you please clarify, for patients that are in the OR, do we use these vital signs to determine severe sepsis and septic shock?

Answer 210: That depends on the timing of other criteria for determination of the presence of severe sepsis.

Question 211: Septic Shock Present: On slide 26 it was added that the lactate level greater than 4 is related to the initial lactate. So if the repeat lactate to be done for the 6 hour window for severe sepsis is greater than 4 but the initial was only 2.1, does this qualify as septic shock of no hypotension is present?

Answer 211: For purposes of the measure, the repeat lactate level is not collected and not taken into consideration. The measure only looks at whether or not a repeat lactate was drawn and the time it was drawn. If the initial lactate is < 4 and the patient does not have persistent hypotension, the patient does not have septic shock for purposes of the measure.

Question 212: Can r/o pneumonia in the progress notes be accepted as suspected source of infection? Can r/o pneumonia in the orders for a CXR be accepted as suspected source of infection?

Answer 212: Yes.

Question 213: Sepsis presentation time is met and greater than 4. Is that the time that is also used for the septic shock Severe Sepsis met because 14:40 Lactated 6.0? Is this the septic shock time or do you look at the next lactate for that time?

Answer 213: If a lactate ≥4 is part of the clinical criteria for determining presence of severe sepsis, then the severe sepsis and septic shock presentation times would be the same.

Question 214: Our hospitalists have questioned the reasoning of repeating the lactate greater than 2. They said that literature shows severe sepsis is lactate greater than 4 and not 2. We have had a difficult time getting the lactate repeated. Do you have any info I could forward on to them?

Answer 214: The International Guidelines for Management of Severe Sepsis and Septic Shock define the lactate for severe sepsis as "Lactate above upper limits laboratory normal." While normal lab upper limits may vary from lab to lab, it is generally > 2 mmol/L. The lactate level for sepsis-induced hypoperfusion, which is septic shock, is defined as ≥4 mmol/L.

Question 215: How will we tell if labs are related to chronic organ dysfunction? Are we to assume?

Answer 215: If there is documentation indicating the abnormal lab is due to or may be due to a chronic condition or medication that is acceptable. The measure also provides two examples that are acceptable, creatinine >2 for a patient with end stage renal disease, and an INR > 1.5 for a patient on Warfarin.

Question 216: Can x-ray results diagnosing pneumonia be used as a source for identifying infection?

Answer 216: Yes.

Question 217: If on 7/27 at 11:29 a.m. a suspected infection was documented. Then on 7/27 at 8:30 a.m. lactic acid was 2.4; 7/27 at 8:01 = 2 abnormal vital signs, what is the time I will use for the last criteria of severe sepsis was met? Is it 8:01?

Answer 217: When based on the clinical criteria, severe sepsis presentation time is when the last of the criteria are met. The criteria do not need to be met in any specific order and must all be within 6 hours of one another. The question does not specify whether 7/27 8:01 is an a.m. or p.m. time. If it is an a.m. time, severe sepsis criteria based on the question would be 11:29 a.m. when the last criterion (suspected infection) was documented. If it is a p.m. time, for purposes of the measure, the patient would not have severe sepsis because the criteria were not met within 6 hours of each other.

Question 218: If you are using the fact that the initial lactate >4 as the only reason for Septic Shock Present, please verify that you would use the time the result was reported (as opposed to draw time).

Answer 218: You have to use the time reported for the lactate because that is when the results are known. At the time the lactate is drawn, the results are not known. Without the results, septic shock could not be confirmed.

Question 219: If doctor states in ED when ordering an X-ray, reason for the x-ray is Pneumonia, but the X-ray result does not support this so I interpret the X-ray reason is to r/o PN, does that count as an infection? What if the final DX in ED is UTI, doesn't that count as an infection?

Answer 219: Both could count as a suspected infection. Keep in mind the measure is not limiting the documentation of an infection to a confirmed diagnosis, rather it is looking for a suspected or possible infection.

Question 220: If we have an order for 3,000 cc NS now, can we use this volume in determining if we have given 30 ml/kg since the order does not have duration or rate?

Answer 220: You can determine whether or not this is 30 ml/kg if you also have a patient weight. Determining if 30 ml/kg was ordered is based on the total volume ordered and the patient weight. But because the order does not include an infusion duration or rate, you will need to select Value "2 (No)" for Crystalloid Fluid Administration. The last bullet point in the Notes for Abstraction indicates that if a fluid volume is ordered, but there is no order for the time over which the IV fluids are to be given, to choose Value "2."

Question 221: Is the time the labs are drawn/collected or the time the result is reported used in collection of the organ dysfunction criteria?

Answer 221: You have to use the time reported for the labs because that is when the results are known. At the time the labs are drawn, the results are not known. Without the results, organ dysfunction cannot be confirmed.

Question 222: Can we use an X-ray that the radiologist has read and states the patient has pneumonia, or if MD writes order for an X-ray with clinical indication r/o pneumonia?

Answer 222: Yes.

Question 223: Why Temp >100.9 instead of 100.4?

Answer 223: The International Guidelines for Management of Severe Sepsis and Septic Shock define fever as >38.3 degrees C. Converted to Fahrenheit, this is 100.94 degrees. The value is rounded to the nearest tenth.

Question 224: Do the two SIRs criteria need to be met at the same time? For example, if temp is elevated at 1100 vitals, then at 1200 RR is elevated, do you consider SIRs criteria met?

Answer 224: No, the SIRs criteria may manifest at different times. All criteria must be met within 6 hours of each other.

Question 225: Can vital signs taken while a patient is in OR be used in determination of Severe Sepsis or Septic Shock?

Answer 225: That depends on the timing of other criteria for determining the presence of severe sepsis.

Question 226: Does it matter the source of the temperature, as a rectal temp or core temp may be normally considered one degree higher than oral?

Answer 226: It does not matter, as the measure and current specifications do not specify the source.

Question 227: Temperature in the SIRs criteria does not specify a method of obtaining it. If the method is axillary, should the temperature be adjusted upward one degree, or should it be taken at face value? By the same token, should rectal temperatures be adjusted downward one degree?

Answer 227: The measure does not specify the source, so based on the current specifications, no adjustments need to be made.

Question 228: If there is documentation that the patient's normal SBP is <90, can septic shock present be answered "No?"

Answer 228: A normal SBP <90 would be considered a chronic condition. A chronic condition is defined as, "human health condition or disease that is persistent or otherwise long-lasting in its effects." It is not limited to only diseases. As such, a patient with a chronically low SBP would qualify as having a chronic condition, a chronically low SBP. If there are SBP readings recorded in the medical record of <90 and there is documentation in the medical record the patient normally has a low blood pressure or their SBP is normally <90, then you could exclude this as a sign of organ dysfunction for determining presence of severe sepsis. If the patient had another sign of organ dysfunction and was being assessed for septic shock, there are several factors that need to be taken into consideration to answer Septic Shock Present. If the patient did not receive 30 ml/kg of crystalloid fluids, you would select "No" regardless of SBP. If the patient did receive 30 ml/kg of crystalloid fluids and there were not two consecutive SBP readings <90 in the hour following presentation, you would select "No."

Question 229: If a physician documents after admission "severe sepsis or septic shock on admission" on a patient who does not meet the criteria for either, would we use the arrival time of the patient or when the doctor writes the admission order for presentation time?

Answer 229: If the physician documentation specifically states "on admission," then (assuming the patient came in through the ED) you would use triage time. The Severe Sepsis and Septic Shock Presentation Time data elements indicate if severe sepsis/septic shock is present on arrival to the ED, presentation time is the time the patient was triaged in the ED.

Question 230: If a patient has a low platelet or WBC, but has been receiving chemotherapy, would this be considered a chronic condition when determining severe sepsis?

Answer 230: The current specifications do not disregard SIRs criteria based on chronic conditions. We are working on this for a future version of the manual.

Question 231: For persistent hypotension, will there need to be at least two BP values within the hour post 30ml/kg of fluids in order to say it was assessed? If only one BP

is noted and it is normal, would that be enough to say they are not with Persistent hypotension?

Answer 231: If only one BP is noted in the hour following completion of the 30 ml/kg of crystalloid fluids and it is normal, this is sufficient to reflect the patient does not have persistent hypotension. Two consecutive BPs demonstrating hypotension are required only to indicate the patient has persistent hypotension.

Question 232: For Septic Shock Criteria B Hypotension persists, are we only looking for one blood pressure reading or do we follow the new persistent Hypotension guidelines of "two or more consecutive blood pressure readings?"

Answer 232: Two consecutive blood pressures demonstrating hypotension following conclusion of 30 ml/kg of crystalloid fluids are required. This is referenced in the second bullet point of the Septic Shock Present data element where it states, "Refer to the Persistent Hypotension data element."

Question 233: If the patient presents with Septic Shock, is there a reason for having to document severe sepsis presentation time, especially if Septic Shock cannot be present without severe sepsis.

Answer 233: If the patient presents with septic shock, the Septic Shock Presentation Time and Severe Sepsis Presentation Time would be the same.

Question 234: If patient has severe sepsis and hypotension but BP responds to <30 cc/kg fluid bolus, is this fallout?

Answer 234: In this situation you could not say the patient has septic shock because the definition in the Septic Shock Present data element requires that 30 ml/kg were given. Because less than 30 ml/kg were given, you would select "2 (No)" for Septic Shock Present.

Question 235: If a patient has a chronic condition that impacts their lab values, we should not use that. However, if the values are substantially off from the patient's normal, can we use those or do we need to use other criteria not impacted by their chronic condition?

Answer 235: For purposes of the measure, you will need to use other criteria not impacted by the chronic condition.

Question 236: If MD states "No clear source of infection" and orders cultures, lactic, and other labs, can we assume that that the entire patient is the source of infection because they met SIRs criteria and Organ dysfunction?

Answer 236: The physician documentation would imply that an infection is suspected, but the source is not clear or unknown. Using this as documentation of a suspected infection for the three clinical criteria is acceptable.

Question 237: I am confused regarding which times to use for lab values, the collected time or the time the value is reported by the lab.

Answer 237: For determining a sign of organ dysfunction or SIRs based on lab values, you must use the time the result is reported from the lab. This represents the earliest time the results are known and therefore can help with determining the presence of severe sepsis or septic shock. Drawn or Collected time cannot be used when determining the presence of severe sepsis or septic shock, because at that time the results are not known, you only know a lab was drawn.

Question 238: How do you determine a baseline or normal BP when looking at a 40 point drop? For example, we had a patient with renal calculus and pyelonephritis that was hypertensive (SBP 170s) and painful on admission. Post-op his pressure was >40 points lower but still normal at 129/70. This case was abstracted as septic shock present. Can you use the BP trend after the drop as the "normal/baseline?"

Answer 238: This will be based on documentation reflecting the decrease in SBP represents a drop of more than 40.

Question 239: Do you count vitals taken during a surgery?

Answer 239: That depends on the timing of other criteria for determination the presence of severe sepsis.

Question 240: Oncology patients have different lab values due to the manifestation of their particular cancer and effects of Radiation and Chemotherapy. Oncologists asked in Cancer Committee how they should respond when they get a Sepsis alert. Is Sepsis criteria different for Oncology?

Answer 240: No, for purposes of the measure, any lab values considered abnormal due to chemo or radiation therapy should not be discarded for determining presence of severe sepsis or septic shock. Clinically, the physician will have to make the determination based on the patient's presentation.

Question 241: How do we know the patient doesn't normally run a B/P of <90 at triage?

Answer 241: Assume they do not normally run a SBP <90, unless the patient states that they do.

Question 242: Are the signs of acute organ dysfunction on slide 49 the only ones we should be looking for?

Answer 242: The signs of acute organ dysfunction you should be looking for are identified and defined in the Severe Sepsis Present data element.

Question 243: Will we disregard the triage time if all three are met in the ED?

Answer 243: It depends on the timing of the criteria in the ED. If all three criteria are met prior to or during triage, you will use triage time. If any of the criteria are met after triage time, you will use the time the last of the criteria were met. If all three are met after triage, you will use the time the last of the criteria are met.

Question 244: All of the examples involve the ED, are cases of severe sepsis and shock presenting several days into admission included, e.g., post-op?

Answer 244: Yes.

Question 245: Patient was admitted but prior to admission had been on antibiotics. Patient went into the Severe Sepsis Measure 8 hours after admission. Physician documented, "lactic acid was normal, no blood cultures were drawn, patient was already started on clindamycin yesterday" (which was prior to admission to the hospital). Lactic acid was not repeated because the initial result was only 0.49. Since this patient's Sepsis three hour counter is equal to 2 is it failing this measure? (Only received Antibiotics and Lactic Acid Drawn.) Does the Physician have to draw Blood Cultures even if the result will be invalid or inaccurate in order to pass this measure?

Answer 245: To meet the measure, blood cultures must be drawn within three hours of severe sepsis presentation and prior to antibiotics. If blood cultures are drawn after the date and time entered for the Broad Spectrum or Other Antibiotic Administration Time, the case will fail the measure.

Question 246: In case #5, what if you had a chest X-ray result that says PNA?

Answer 246: This would be acceptable.

Question 247: If infection is documented but the SIRs/organ dysfunction criteria are met >6 hours after but within 6 hours of each other, is this answered severe sepsis "Yes" since infection has already been established?

Answer 247: Currently, you would select "No" because the documentation of the infection was not within 6 hours of the other criteria. We recognize in this situation the infection is still present and are looking at ways to address this in a future version of the manual.

Question 248: On Severe Sepsis case 5 you use when labs are drawn not resulted. Did I misunderstand this?

Answer 248: This was a typo in the slide. For determining the presence of severe sepsis, you need to use the result time, not the drawn time.

Question 249: Is there any consideration for the patient with end stage renal failure as far as the fluid resuscitation (volume, rate, etc.)?

Answer 249: There are not any exclusions from the 30 ml/kg crystalloid fluid administration.

Question 250: Please clarify contradiction in lab draw results in slides 59 and 60. Do you take the "drawn" or "reported" times? In case 4 you used the reported time for the organ dysfunction. In case 5 you used the drawn time.

Answer 250: This was a typo in the slide. For determining the presence of severe sepsis, you need to use the result time, not the drawn time.

Question 251: Is it true that for SIRs we can use Lab done up to 12 hours prior to screening, but those results might be more than 6 hours of presentation time so they cannot be used? Please clarify.

Answer 251: No, all criteria for determining the presence of septic shock must be within 6 hours of each other.

Question 252: Slide 60 is incorrect. The first bullet point should be the reported time not the draw time, correct? It should have read 0850 not 0830?

Answer 252: This was a typo in the slide. For determining the presence of severe sepsis, you need to use the result time, not the drawn time.

Question 253: Why is it that we can accept different times for the vital signs for establishing the presence of severe sepsis, but we cannot take different time entries from physicians with the vital sign re-evaluation in septic shock? Frequently with EMRs the vital signs can be automatically imported and they may not be taken all at the same time, hence different time intervals.

Answer 253: The Vital Signs Review Performed by the physician must contain all four vital signs and their values (Temp, RR, HR and BP) contained within a single note. The source of vital signs within that single note can be from different sources and different times. The fact your EMR automatically imports them will be advantageous for the physician.

Question 254: For Severe Sepsis Case 5, if also you had a Bilirubin lab reported @ 12:00 of 2.1, would you then use value "1?"

Answer 254: Yes, because then the criteria for severe sepsis would have all been met within 6 hours of each other.

Question 255: Abstraction asks for time lactate level drawn, not the time reported. Which are we abstracting?

Answer 255: For the Initial Lactate Level Time and Repeat Lactate Level Time data elements, you are abstracting time drawn because that is what the data elements specify. When you determining Severe Sepsis Presentation, you must use the results time. This is because without the results, you cannot determine whether or not severe sepsis is present.

Question 256: Your examples for determining Severe Sepsis presentation time referred to the time that lactate levels were reported. The instructions for Initial Lactate are to take the time the lactate was drawn or collected. Has this instruction for abstracting Initial Lactate time now been changed to taking the reported time?

Answer 256: Nothing has changed regarding this. For the Initial Lactate Level Time and Repeat Lactate Level Time data elements, you are abstracting time drawn because that is what the data elements specify. When you are trying to determining Severe Sepsis Presentation, you must use the results time. This is because without the results, you cannot determine whether or not severe sepsis is present.

Question 257: For Severe Sepsis Case 5, page 60, what if there is an additional Creatinine level drawn at 1600 and it is still elevated at 2.5, would you then answer "Yes" for Severe Sepsis and use the time of 1600 for the Presentation time?

Answer 257: Correct. In this case, the criteria would all have been met within 6 hours of each other with the last being at 1600.

Question 258: What if the patient is seen in ED 12 hours earlier and given IV ABX and was ultimately discharged, worsened at home and so returned with severe sepsis? Do we look at the two different visits for times of ABX?

Answer 258: You will need to identify the time of antibiotics given in the 24 hours prior to severe sepsis presentation. If that is not recorded in the current record and you are using an electronic health record, you can take the time from the previous ED visit.

Question 259: In the abstraction guidelines for “severe sepsis present" there is a bullet point that indicates that "laboratory values used in determining organ dysfunction must have been reported within the 6 hours preceding the onset of severe sepsis.” If we are using lab values to determine severe sepsis, how can we determine if the lab values were reported prior to onset of severe sepsis?

Answer 259: All of the criteria must be meet within 6 hours of each other. This bullet point is essentially indicating that any lab older than 6 hours prior to severe sepsis presentation cannot be used.

Question 260: I'm confused as to why triage time is acceptable in some cases since nurses cannot diagnose.

Answer 260: The measure does not require a diagnosis of an infection. It only requires documentation that one is suspected. This can be from a history in the nurse documents. It has been part of the clinical standard for identifying the possible presence of severe sepsis with the Surviving Sepsis Campaign for many years.

Question 261: For determining septic shock present, are we to only look at the initial lactate drawn? If the initial lactate is 2.5 but the follow-up lactate is 4.5, we would still abstract “No” to septic shock present if there is no persistent hypotension?

Answer 261: Correct. While clinically this would still represent septic shock and the patient should be treated accordingly. For purposes of the measure, this is not considered septic shock. The case would be excluded from this part of the measure. The measure ONLY calls for the level of the initial lactate. It does not require abstraction of the repeat lactate level.

Question 262: Initial lactate over >4 and severe sepsis is no longer criteria for Septic Shock after what you said on slide 103. What is the relevance of initial lactate of >4 then?

Answer 262: Clinically the patient still has septic shock and should be treated accordingly. They should have received 30 ml/kg of crystalloid fluids to treat the tissue hypoperfusion demonstrated by a lactate ≥4. For purposes of the measure only, if no crystalloid fluids were given, you would select "No" for Septic Shock Present.

Question 263: If only one BP is less than 90 systolic in a grouping of other BP results, is that one result sufficient to signify organ dysfunction or is it two or more consecutive readings?

Answer 263: Two consecutive blood pressure readings demonstrating hypotension in the hour following crystalloid fluid conclusion must be present. The Septic Shock Present data element includes a bullet point that states, "For evaluation of blood pressure parameters to establish whether or not hypotension persists after crystalloid fluid administration, begin abstracting at the time that crystalloid fluid administration concludes (refer to the Persistent Hypotension data element) ..."

Question 264: If a patient has severe sepsis, does not receive crystalloid fluids but has a Lactate of 4.2, would we say “Yes” to septic shock?

Answer 264: Clinically the patient still has septic shock and should be treated accordingly. They should have received 30 ml/kg of crystalloid fluids to treat the tissue hypoperfusion demonstrated by a lactate ≥4. For purposes of the measure

only, if no crystalloid fluids were given, you would select "No" for Septic Shock Present.

Question 265: Severe Sepsis Presentation: 10/12/15 1910 Initial lactate level >4; 10/12/15 1501 Repeat lactate level 2.5; 10/12/15 1923 Crystalloid fluids concluded; 10/12/15 1814 Map 10/12/15 58 10/12/15 1900. Would this be “Yes” to septic shock with an initial lactate level >4?

Answer 265: Correct, this would be septic shock because the patient has severe sepsis and an initial lactate level >4. Time of septic shock presentation would be 1901, because that is when the last of the criteria establishing the presence of septic shock occurred. It happens to coincide with severe sepsis presentation, because of how the severe sepsis and septic shock manifested.

Question 266: Just want to clarify, lactate level is reported time rather than drawn time, correct?

Answer 266: This depends on what you are abstracting. For the Initial Lactate Level Time and Repeat Lactate Level Time data elements, you are abstracting time drawn because that is what the data elements specify. When you are trying to determining Severe Sepsis Presentation, you must use the results time. This is because without the results you cannot determine whether or not severe sepsis is present.

Question 267: What about chronic conditions for elevated WBCs such as leukemia or other blood dyscrasias? Should they be excluded for SIRs criteria?

Answer 267: The current specifications do not disregard SIRs criteria based on chronic conditions. We are working on this for a future version of the manual.

Question 268: A patient is in ICU and on vasopressors which were titrated for the episode of hypotension. The patient was not given crystalloid fluids but the doctor documents septic shock. The lactate level was not greater than 4. Is septic shock present?

Answer 268: Based on the Notes for Abstraction in the Septic Shock Present data element, if crystalloid fluids were not administered after the presentation date and time of severe sepsis, you would choose Value “2 (No).”

Question 269: If the patient presents with Septic shock on admission, is the second lactate still required?

Answer 269: A lactate is required within 3 hours of severe sepsis presentation. If a patient presents with septic shock, the Severe Sepsis and Septic Shock Presentation Times are the same. A repeat lactate is required if the initial lactate is >2.

Question 270: Are Lactate and Lactic Acid results equivalent?

Answer 270: They are essentially the same test. However, the results may be reported using different units. If the results are reported as mg/dL, you can convert to mmol/L by dividing the mg/dL value by 9.

Question 271: Organ dysfunction is positive with a lactate >2?

Answer 271: Correct.

Question 272: What if we do not have a lactate level available in our hospital?

Answer 272: A lactate drawn within 3 hours of severe sepsis presentation is required to pass the measure.

Question 273: Can positive culture results be considered a source of infection?

Answer 273: No, positive culture results could represent colonization. There must be documentation including the word "infection" or including the name of a condition that is an infection or possible infection.

Question 274: Can the lactate greater than or equal to 4 be used for septic shock or do you need to have severe sepsis presentation with it?

Answer 274: There must be both severe sepsis present and an initial lactate ≥4.

Question 275: When does the blood culture need to be collected in regards to the time of first dose of antibiotic? For example, does the blood culture count if collected after an IV antibiotic given greater than 24 hours ago?

Answer 275: To pass the measure, the blood culture must be obtained prior to the antibiotic administration.

Question 276: If there is a lactate done at the bedside and a repeat lactate that was sent to the lab, two different methods, can they both be used?

Answer 276: Yes, they are both lactate levels.

Question 277: Please define the length of time we are allowed to determine triage time? Is this only defined by Vital Signs only or do we use if the patient has an Inpatient admission order?

Answer 277: There is no requirement for how long triage lasts or how long a patient should be in triage.

Documentation Questions

Question 278: Does source of infection by the provider have to be documented within 6 hours of other criteria for the patient to start the sepsis clock? For example,

the physician documents in a physician note that the patient has suspected source of infection but the two SIRs criteria and organ dysfunction does not present until 12 hours later. Can that physician documentation of suspected infection be used to meet the criteria of Severe Sepsis? Physician documentation may be completed daily in the evening, and labs may be drawn in the morning each day, separating criteria by 8–12 hours.

Answer 278: Currently, all criteria, including documentation of a suspected infection, must be met within 6 hours of each other. We recognize for patients who develop severe sepsis later in the hospital stay, the SIRs criteria and sign of organ dysfunction could easily be more than 6 hours after the documentation of the infection, but the infection is still present. We are considering options for addressing this in a future version of the manual. In the meantime, it will result in these cases being excluded from the measure.

Question 279: Please will you clarify if a "differential diagnosis" of an infection within a progress note counts as a source of infection? Also, is documentation by a pharmacist or nurse acceptable?

Answer 279: A differential diagnosis is acceptable. The measure does not require a confirmed infection or diagnosis. It is looking for a suspected or possible infection. Pharmacist documentation is not acceptable. Version 5.0b clarifies that nursing documentation of a suspected or possible infection is acceptable.

Question 280: It appears that viral and fungal infections are no longer an accepted source of infection. Does this exclusion also include documentation from physicians/APNs/PAs or is this exclusion only for nursing documentation?

Answer 280: Any documentation of a viral or fungal infection from a physician, APN, PA, or nurse should not be used.

Question 281: Please define what previously recorded SBP considered normal for a specific patient is? We do not document what the patient's normal blood pressure is; furthermore, a patient may not know what a normal blood pressure is for them. Presenting blood pressure may not be normal for the patient.

Answer281: If you do not know what is normal for that patient, you will not be able to determine whether or not a decrease is greater than 40 from the normal. Therefore, you cannot use this blood pressure criterion.

Question 282: Our question today is identifying the documentation of infection. If the patient is started on antibiotics does this count as probable infection?

Answer 282: No, there must be documentation of a suspected, possible, or present infection, including either the word infection or a condition that is an infection.

Question 283: If weight was not documented in ED, can we use the weight documented on the unit to calculate the required volume of fluid that was given in ED?

Answer 283: Yes.

Question 284: Is there a time constraint on administrative contraindication to care or must we review the entire record for a refusal?

Answer 284: There is not currently a time frame for the administrative contraindication to care. It could occur at any point during the patient's stay.

Question 285: Can septic shock be diagnosed without physician documentation, lactate >4, and without crystalloid fluid being administered below the 30 mg/kg?

Answer 285: The measure does not require a physician diagnosis of septic shock to determine septic shock is present. The measure is looking for the earliest documentation indicating septic shock is present. By definition, septic shock is present if severe sepsis with a lactate ≥4 is present. In this case, crystalloid fluids should be given to treat the patient, but are not required to determine the presence of septic shock. Physician documentation is not required to confirm the presence of septic shock. It is present based on the clinical criteria.

Question 286: How much time is allowed to credit prior lactate and blood culture draw from the actual documentation of severe sepsis or septic shock?

Answer 286: Based on the algorithm, if the lactate is more than 6 hours prior to or more than 3 hours after severe sepsis presentation, the case will fail the measure. If the blood culture is drawn more than 48 hours prior to or more than 3 hours after severe sepsis presentation, the case will fail the measure. Also note, the blood culture must be drawn prior to the antibiotic administration time to pass.

Question287: If physician documents patient has cough, fever, and was discharged last week with pneumonia, would this count as suspected infection?

Answer 287: The infection needs to be currently suspected. This documentation only states they were discharged last week with pneumonia. It does not reflect the physician suspects it is still present.

Question 288: Would cellulitis, appendicitis, colitis, pancreatitis, cystitis, or any other "itis" diagnosis be an acceptable documentation for a suspected source of clinical infection?

Answer 288: The suffix "itis" means inflammation and does not necessarily confer the condition is an infection. The condition itself must an infection or caused by an infection to be considered an infection.

Question 289: Updated guidelines state to only abstract fluids given for severe sepsis w/hypotension or severe sepsis w/lactate ≥4. I don't see where documentation of another reason for elevated lactate (e.g., severe dehydration) excludes the value from being considered an organ dysfunction criteria if other criteria are met. So even if they document another reason and then don't give the full fluid volume, it appears we will still fail the case?

Answer 289: Correct. Please keep in mind, to get this far in the measure, all three clinical criteria must be met for severe sepsis (suspected infection, two or more SIRs criteria, and a sign of organ dysfunction). If even one of the three criteria are not met, the case is excluded, regardless of the lactate level.

Question 290: If the doctor writes "consider Pneumonia," can I use this as documentation for "possible source of infection?

Answer 290: Yes.

Question 291: What if our documentation of the fluids does include the end time? May we use that to calculate the total volume of fluids given?

Answer 291: Yes.

Question 292: Can we use "differential diagnosis" as a documentation of suspected source of clinical infection? Also, if there is an infection documented in the differential dx but is not in the final diagnosis, can we use that differential diagnosis even though it did not make the final diagnosis?

Answer 292: Yes.

Question 293: If a patient cannot tolerate the 30mg/kl due to volume overload, renal failure, etc., is MD documentation sufficient or should the MD order the 30ml/kg and document why the patient will not receive all the crystalloid fluid?

Answer 293: There are not any exclusions to the 30 ml/kg of crystalloid fluids. However, if in the clinical judgment of the physician there are concerns that the full volume of 30 ml/kg may be detrimental to a specific patient, they should exercise their clinical judgment and treat that patient accordingly.

Question 294: If physician documents patient received 500ml NS bolus per EMS, may I use this amount toward total amount for fluid resuscitation?

Answer 294: It can be used if there is an order or protocol that includes a rate of administration or duration over which to infuse it.

Question 295: If the documentation by nursing states PEG tube could be infected, can this be accepted as suspected source of infection?

Answer 295: Yes, the measure is looking for a suspected infection, not necessarily a confirmed or diagnosed infection.

Question 296: Would the differential diagnosis of several different possible infections be counted to say “Yes” to infection? Does the nurse’s documentation have to indicate a source of infection?

Answer 296: Yes, the documentation does not need to include the word "source." It does need to include either the word infection or a condition that is an infection.

Question 297: Does acute on chronic respiratory failure count as documentation of organ dysfunction?

Answer 297: For the purposes of the measure, acute respiratory failure is evidenced by a new need for invasive or non-invasive mechanical ventilation. Invasive mechanical ventilation requires an endotracheal or tracheostomy tube. Non-invasive mechanical ventilation (may be referred to as BiPAP) uses a mask.

Question 298: May pharmacist documentation be used to abstract a source of infection?

Answer 298: Pharmacist documentation is not acceptable.

Question 299: Does the physician have to document linkage between the chronic condition and/or medication and the lab result in order for the abstractor to not include or just the documentation of the result and evidence in the record of the medication can the abstractor assume a link?

Answer 299: A linkage does not need to be documented for Creatinine >2 for a patient with end stage renal disease, and INR >1.5 for a patient on Warfarin, because those are included in the Severe Sepsis Present. For other conditions and medications, there should be documentation indicating the association.

Question 300: Does the Notes for Abstraction new bullet point 6 include date and time of discharge, including the patient discharge date and time of death? Documentation may occur after the patient has expired to clarify Sepsis. Is this your intent?

Answer 300: The new bullet point 6 for the Severe Sepsis Present data element's Notes for Abstraction states, “If the only documentation indicating presence of Severe Sepsis is after the discharge time, choose Value ‘2.’” This would not apply to a situation where there is documentation after discharge (or time of death) clarifying presence of severe sepsis or septic shock that was in the medical record prior to discharge or death.

Question 301: If the ED Physician documents severe sepsis, would triage time count for presentation of sepsis or triage time? Please clarify.

Answer 301: It depends on when the physician documented severe sepsis. The Severe Sepsis Presentation Time data element's Notes for Abstraction indicate that if severe sepsis is present on arrival to the Emergency Department or severe sepsis is identified in triage, the Severe Sepsis Presentation Time is the time the patient was triaged in the Emergency Department. So if the physician documentation was prior to triage, you would use triage time. If it is after triage, you use the time the physician documented severe sepsis.

Question 302: If indicators for severe sepsis are present but the primary physician documents "sepsis not present," does that override the indicators?

Answer 302: Currently, the physician documentation would not override the presence of the clinical criteria. We are looking into this further.

Question 303: Is RN documentation of infection acceptable? If so, will the Specification Manual be updated to reflect this?

Answer 303: Yes, it is. Version 5.0b of the manual was updated to reflect this and it was discussed during the webinar on slides 31 and 45.

Question 304: How do you determine time zero when a physician does not document in the record for 12 hours after seeing the patient, meet SIRs criteria on arrival and had source of infection, but no MD documentation of sepsis for 12 hours after arrival?

Answer 304: Presentation time does not require physician documentation. The Severe Sepsis Presentation Time data element's Notes for Abstraction indicate that if there are multiple times indicating the presence of severe sepsis to use the earliest time.

Question 305: Our hospital has a high population of elderly patients many who have CHF. Our physicians have concern about how to document a contraindication to the crystalloid fluid bolus of 30ml/kg,

Answer 305: There are not any exclusions to the 30 ml/kg of crystalloid fluids. However, if in the clinical judgment of the physician there are concerns that the full volume of 30 ml/kg may be detrimental to a specific patient, they should exercise their clinical judgment and treat that patient accordingly.

Question 306: Does there have to be both documentation of BiPap or mechanical ventilation along with respiratory failure or is just one of these acceptable? I am trying to figure out if I need both and what time I would use for time zero if the last criteria I am looking for is organ dysfunction. For example, if a patient has documentation of respiratory failure at 07:30 but no reference to BiPap or mechanical ventilation, then at 08:34 there is documentation of BiPap, is the time zero 07:30 or 08:34?

Answer 306: The Severe Sepsis Present data element indicates that acute respiratory failure is evidenced by a new need for invasive or non-invasive mechanical ventilation. As such, documentation of acute respiratory failure without documentation of invasive or non-invasive mechanical ventilation is not sufficient. Conversely, if documentation indicates that invasive or non-invasive mechanical ventilation was started, documentation of acute respiratory failure would also be required. Because confirmation of respiratory failure is based on mechanical ventilation, in the situation you describe, 0834 would be the time to use for sign of organ dysfunction.

Question 307: What if the three criteria are present but the documentation only says Sepsis, not severe sepsis?

Answer 307: If the three clinical criteria are met, physician documentation is not required. In this situation, since the three clinical criteria are met, you would select Value "1 (Yes)."

Question 308: What if there is documentation by the LIP that "Severe Sepsis is not present" but there are criteria to support that there is?

Answer 308: Currently the LIP documentation would not override the presence of the clinical criteria. We are looking into this further.

Question 308: What if the APN or PA or Physician documents that severe sepsis is ruled out but the patient has met the criteria?

Answer 308: Currently, the physician/APN/PA documentation would not override the presence of the clinical criteria. We are looking into this further.

Question 309: If criteria are met but there is no physician documentation of severe sepsis, do we use the time criteria met?

Answer 309: If the three clinical criteria are met, physician documentation is not required. In this situation, since the three clinical criteria are met, you would select Value "1 (Yes)."

Question 310: If the physician documents severe sepsis but all severe sepsis criteria are not met, do you then say the patient had severe sepsis or did not have severe sepsis?

Answer 310: If the physician documents severe sepsis, the three criteria are not required. In this situation, since the physician documented severe sepsis, you would select Value "1 (Yes)."

Question 311: Is the nursing documentation used only in ED record or any nursing documentation?

Answer 311: It is not limited to the ED.

Question 312: If there are two choices/check boxes for either severe sepsis or septic shock on the top of an order set and the physician/APN/PA checks one of these boxes on the order set, will this count as documentation that severe sepsis or septic shock is present? If so, can we use the date/time order set initialed as the start time?

Answer 312: As long as the physician signs the order set this will represent physician documentation.

Question 313: If the ED physician documents reference to the ambulance record and BP 70/40 and fluids given, can we count the low BP as Organ Dysfunction with time of OD being the ED physician note or the time actually written in the ambulance record if that ambulance record is available?

Answer 313: Yes.

Question 314: Does the MD have to tie the increased lab to the chronic condition? For example, does the physician need to document Creatinine 2.6 due chronic renal failure?

Answer 314: An association does not need to be documented for Creatinine >2 for a patient with end stage renal disease, and INR >1.5 for a patient on Warfarin, because those are included in the Severe Sepsis Present. For other conditions and medications, there should be documentation indicating the association.

Question 315: On slide 34 it says not to include evidence of organ dysfunction that is considered chronic. Is the documentation of ESRD in the patient's history enough or does the physician need to specifically link the two in his/her documentation?

Answer 315: An association does not need to be documented for Creatinine >2 for a patient with end stage renal disease, and INR >1.5 for a patient on Warfarin, because those are included in the Severe Sepsis Present. For other conditions and medications, there should be documentation indicating the association.

Question 316: Can you use documentation of a suspected or actual infection from either a pharmacist or radiologist?

Answer 316: Documentation from a pharmacist is not acceptable. Since a radiologist is a physician, this would be acceptable.

Question 317: Would the terminology Profound Shock be acceptable for documentation of sever sepsis

Answer 317: No, because it does not identify the shock as being associated with or caused by severe sepsis. Profound shock could be due to any number of other conditions.

Question 318: What about MD documentation of acute chronic renal failure. Patient's baseline creatinine is documented by the MD as 2.5 and creatinine is 3.5. MD states AKI. Would this still not be considered organ dysfunction for this patient?

Answer 318: Currently, the specifications do not account for conditions such as this, so it would not be considered organ dysfunction for purposes of the measure.

Question 319: If documentation indicates organ dysfunction is not related to an infection (i.e., AKI d/t dehydration, elevated lactate r/t hemorrhage, etc.), are we required to use these as organ dysfunction criteria to support the presence of severe sepsis? In other words, does the organ dysfunction have to be related to or linked to an infection or, if not specified, do we assume it is related to an infection?

Answer 319: If not specified, you will assume it is related to the infection and severe sepsis. This is something we are looking further into for a future version of the manual.

Question 320: If a physician documents severe sepsis but there is no clinical data to support this diagnosis, do we take the time for presentation of severe sepsis when the physician made the severe sepsis note?

Answer 320: If the physician documents severe sepsis, the three criteria are not required. In this situation, since the physician documented severe sepsis, you would use the time of the physician note as Severe Sepsis Presentation Time.

Question 321: In the ED, if criteria are not met for severe sepsis and Physician documents severe sepsis, can we utilize that documentation for severe sepsis present? Please discuss this scenario.

Answer 321: If the physician documents severe sepsis, the three criteria are not required. In this situation, since the physician documented severe sepsis, you would select Value "1 (Yes)."

Question 322: Scenario: Patient comes into ED and is diagnosed with a UTI and patient meets two SIRs criteria but not organ dysfunction. Four hours later, the patient deteriorates while still in the ED and now the patient is meeting the organ dysfunction criteria. Are you saying we must go back to the triage time as the start time? It would already be too late to meet all the elements. Please clarify.

Answer 322: The Severe Sepsis Present data element indicates that if severe sepsis is present on arrival or is identified in triage, you would use triage time. If it is identified after triage, you use the time the last of the three clinical criteria were met.

Question 323: In determining Sepsis, if the physician documents suspected Sepsis, would that be an inclusion for severe sepsis?

Answer 323: No, Sepsis is listed in the Exclusion Guidelines for Abstraction, indicating it is not an acceptable term for identifying severe sepsis.

Question 324: Our physicians continue to use the terms "sepsis" and "Bacteremia." If criteria are met in the form of elevated vitals and lactate levels yet the physician states, "possible sepsis of unknown origin," what do I select? It is clear that they are treating a suspected infection based on the fact that antibiotics are given. I don't want to exclude patients based on terminology if they should be included.

Answer 324: The Specifications Manual indicates the term sepsis is not acceptable and cannot be used. In this situation, unless the physician documents the word "infection" or "severe sepsis" instead of "sepsis," it is not acceptable.

Question 325: Sometimes a provider may document a diagnosis (i.e., severe sepsis) in error. If clinical criteria for severe sepsis have not been met, a provider documents rule out or actual severe sepsis and later documents "after further study, severe sepsis was ruled out" or "severe sepsis was documented in error," how should the abstractor proceed?

Answer 325: Based on the current specifications, the documentation indicating severe sepsis was suspected or possible would be used. We are looking further into situations like this and plan to address it in a future version of the manual.

Question 326: What if your patients all meet the severe sepsis criteria but the MD/ANP/PA only documents sepsis?

Answer 326: If the three clinical criteria are met, physician documentation is not required. In this situation, since the three clinical criteria are met, you would select Value "1 (Yes)."

Question 327: I've noticed that with my ED documentation, if I "audit it' I can see what time the entry was actually made. Let's say a note is documented at 1530, but if I audit it, I can see what time the note was actually documented, 1730. Would I date the 1530 or the 1730? Do I take the time that the physician states his note is for or the actual time he documents the note?

Answer 327: According to the Notes for Abstraction, you would take the time the note was documented.

Question 328: Severe Sepsis Organ Dysfunction criteria includes "urine output < 0.5 ml/kg/hour for two hours." If no urine output is documented on the I&O for a two hour time period, would this be counted or is this criteria based on a documented note rather than I&O documentation?

Answer 328: It can be based on a note or I&O documentation.

Question 329: Can documentation of the focused exam be done outside of the six hour timeframe as long as the documentation includes the time the exam was performed?

Answer 329: The note would need to specify when the exam was actually performed and meet all the criteria of each component of the focused exam.

Question 330: If at triage of 0800 the RN documents infection suspected and SIRs met but the MD doesn't document suspected infection until 0900, which is the Time Zero? Your examples 1 and 3 use examples of where there was already a diagnosis of infection. What if there wasn't a prior diagnosis but it is suspected by the RN at ED triage?

Answer 330: "Time zero" or presentation time (if based on the three clinical criteria) is when the last of the clinical criteria is met. The earliest clinical criteria within 6 hours of each other should be used. Based on the question, if the two notes indicating presence of a suspected infection constitute the last of the clinical criteria, use the earlier of the two

Question 331: Can we document an IV antibiotic that was given the day before admission? Patient was discharged and readmitted >24 hours.

Answer 331: If that documentation is in the current medical record and the antibiotic was given within 24 hours prior to presentation, it can be used.

Question 332: For severe sepsis case 5, if results for repeat labs at 1630 showed continued elevation of creatinine and/or lactate, then patient would meet criteria for severe sepsis, and presentation time would be 1630, correct?

Answer 332: Correct.

Question 333: For severe sepsis presentation time, if provider documentation of severe sepsis occurs prior to patient meeting criteria, which time do you take?

Answer 333: The Severe Sepsis Presentation Time data element's Notes for Abstraction indicate that if there are multiple times documented when the last clinical criterion was met or physician documentation, use earliest time. In the situation described in this question, you would use the provider documentation because it was prior to clinical criteria being met.

Question 334: We may know that an antibiotic was given prior to presentation but will never know the time, as this won't be documented in our Med Record. Please advise.

Answer 334: If you don't know the time the antibiotic was given, you will need to enter UTD.

Question 335: Is intentional hypotension as documented by a physician/PA/NP considered an exclusion for using SBP <90 as a source of organ dysfunction?

Answer 335: Current wording in the specifications would allow the organ dysfunction in the case to be disregarded if the hypotension was induced by a medication. "Do not include evidence of organ dysfunction that is considered to be due to a chronic condition or medication." If the intentional hypotension was not due to a medication, it cannot currently be disregarded. We are looking further into situations such as this to address in a future version of the manual.

Question 336: Can documentation of free air in abdomen be used as suspected source of infection?

Answer 336: Free air in the abdomen is referred to as pneumoperitoneum and may be caused by a bowel perforation, which may result in an infection. As such, it can be used as a suspected or possible infection.

Question 337: Can we accept nurse documentation of infection/suspected source of infection? Slide 56 referenced during triage, "patient currently on antibiotics for pneumonia."

Answer 337: Yes.

Question 338: Does documentation of risk for infection or risk for surgical site infection count as possible/suspected infection documentation?

Answer 338: The term "risk" does not reflect an infection is currently suspected and would not be acceptable.

Question 339: If there is a sepsis tool that is built into the electronic medical record and the questions is, "Is there a suspected infection?" and the nurse response "Yes," is that sufficient for suspected infection without a source?

Answer 339: Yes.

Question 340: How do you determine time zero when a physician does not document in the record for 12 hours after seeing the patient, "Meet SIRs criteria on arrival; lactate 2.9 at triage" but there is no MD documentation of infection for 12 hours after triage? Will this case be excluded?

Answer 340: This case will likely be excluded because all criteria must be met within 6 hours of each other. If another set of vitals or labs, closer to the time of the physician documentation of infection demonstrated SIRs and a sign of organ dysfunction, you could use those.

Question 341: Can we use nursing documentation to calculate the amount of crystalloid fluid administered?

Answer 341: Yes, to determine how much was given. The order must still include a volume equivalent to 30 ml/kg.

Question 342: If severe sepsis is present with an initial lactic acid of 3.5, and the repeat lactic acid is 4.0, do I answer "Yes" or "No" to Septic Shock Present?

Answer 342: For the purposes of the measure, only the initial lactate is used for determining presence of septic shock.

Question 343: If there is physician documentation of septic shock but no fluids were given, we answer "No" to septic shock present?

Answer 344: Correct.

Question 345: Does the physician documentation also have to be within 6 hours of the other severe sepsis criteria? For example: Patient arrived and all criteria for severe sepsis were evaluated within 6 hours. The patient had a source of infection and one SIR criteria. Therefore he was not treated for severe sepsis. Twelve hours later, a consultant documented severe sepsis in consult note. No other parameters on the patient had changed.

Answer 345: The only documentation from a physician that needs to be within 6 hours of the other clinical criteria (SIRs criteria and organ dysfunction) is the documentation of a suspected infection. Physician documentation of severe sepsis is totally independent of the three clinical criteria. In this situation, the time the consultant documented severe sepsis represents Severe Sepsis Presentation Time.

Question 346: Earlier you said if the physician/PA/APN documented that septic shock was present, we should check "Yes" for Septic Shock Present. Then in slide 103, you said if crystalloid fluids were not given after the Severe Sepsis presentation date/time, regardless of what the physician has documented, we check "No," that Septic shock is not present. These two statements seem to contraindicate each other.

Answer 346: They actually do not contradict one another. Septic shock is identified one of three ways: a) presence of severe sepsis with hypotension not responding to 30 ml/kg of crystalloid fluids; b) presence of severe sepsis with an initial lactate ≥4; or c) physician/APN/PA documentation of septic shock. The bullet

point you reference indicating if crystalloid fluids were not given to select Value "2 (No)" references all of these. It really could not apply to "a" because in order to determine presence of septic shock this way, crystalloid fluids have to be given. The presence of septic shock based on "b" or "c" does not require fluids be given. They should be given to treat the septic shock, but if crystalloid fluids were not given, this bullet point allows the abstractor to select "No," and the case is excluded from the septic shock portion of the measure.

Question 347: If there is only one value for SBP in the hour after completion of fluids, should we mark UTD for persistent hypotension?

Answer 347: If that value is normal, you could select Value "2 (No)," because hypotension is clearly not present. If the value is low, you would select Value "3 (No) or UTD," because two low BPs are required to confirm the presence of persistent hypotension. Either response will have the same effect for next steps with abstraction and the algorithm flow.

Question 348: If the ED physician documents EMS crystalloid IV fluid with the total volume infused on arrival and there is a start time documented on the EMS record, can these fluids be used as part of the fluid total?

Answer 348: They can, if there is an order or protocol for the fluids that includes the volume and an infusion rate or infusion duration.

Question 349: What if the patient meets the criteria for either Severe Sepsis and/or Septic Shock, and the physician documents it is not present?

Answer 349: Currently, the physician documentation would not override the presence of the clinical criteria. We are looking into this further.

Question 350: If the physician order for 30 ml/kg crystalloid fluids does not include a time over which the fluids are to be given but the nurse documents a start and stop time, is this acceptable to meet the crystalloid fluid administration data element?

Answer 350: No, the order must include an infusion duration or infusion rate.

Question 351: On Slide 114, what if only one BP was documented at 1805 for 88/32? Which option would you select for septic shock present? Would you select No?

Answer 351: In this situation, you would select "No" because the presence of septic shock for this case requires presence of persistent hypotension. Persistent Hypotension requires two consecutive low blood pressures within the hour following conclusion of the crystalloid fluids. The second bullet point in the Septic Shock Present data element's Notes for Abstraction refers abstractors to the Persistent Hypotension data element for evaluation of blood pressure

parameters to establish whether or not hypotension persists after crystalloid fluid administration.

Question 352: If there is a crystalloid fluid order for 30ml/kg with no duration ordered but there is documentation of the start and end time of the infusion which allows calculation of the duration, can the order and administration of the fluids be accepted as documentation of crystalloid fluid administration of 30ml/kg?

Answer 352: No, the order must include an infusion duration or infusion rate.

Question 353: Case input: 1) Patient weight of 600#, in shock, fluid volume is 8l. Only 2l ordered and concern with volume goal has been expressed. 2) Patient with septic shock presents from short dialysis run. Nephrologist does not want fluids because patient is already significantly above dry weight and has pulmonary edema. Currently there is no provider documentation exclusion, so it abstracts as a missed measure.

Answer 353: There are not any exclusions to the 30 ml/kg of crystalloid fluids. However, if in the clinical judgment of the physician there are concerns that the full volume of 30 ml/kg may be detrimental to a specific patient, they should exercise their clinical judgment and treat that patient accordingly.

Question 354: What if the MD/PA/NP documents severe sepsis or septic shock but you do not have a documentation time?

Answer 354: If there is no time associated with the documentation of severe sepsis or septic shock, you will need to enter UTD for the respective data element time.

Question 355: In reference to severe sepsis case #5, if severe sepsis or septic shock is documented by the intensivist in ICU, do you start the severe sepsis and shock timer at the time of that note?

Answer 355: Yes.

Question 356: How do we answer when there is no Crystalloid Fluid Administration for documented fluid overload?

Answer 356: There are no any exclusions to the 30 ml/kg of crystalloid fluids. However, if in the clinical judgment of the physician there are concerns that the full volume of 30 ml/kg may be detrimental to a specific patient, they should exercise their clinical judgment and treat that patient accordingly.

Question 357: To capture the date and time documented by the MD/APN/PA for documentation of severe sepsis, can we use the time that the MD/APN/PA opens the EHR to document H&P, progress note, or consult note like the ED open notes for severe sepsis for infection?

Answer 357: Yes.

Question 358: Is the documentation of "severe leukocytosis" sufficient for suspected/actual infection in regards to identifying severe sepsis?

Answer 358: Leukocytosis is an increase in the total number of WBCs due to any cause. If the WBCs are greater than 12,000, that is leukocytosis, which is one of the SIRs criteria. This would not be sufficient for a suspected infection.

Question 359: Can you please tell me, is it permissible for our Focused Exam Vital Signs documentation within our EMR to be pulled from nursing documentation into the Provider Repeat Focused Exam document?

Answer 359: Yes.

Question 360: What if you have contradictory documentation by MDs: one states not Septic shock and one documents septic shock?

Answer 360: Currently, you would take the positive documentation of septic shock present over the negative documentation of septic shock not present. We are looking further into how to address situations such as this for a future version of the manual.

Miscellaneous Questions

Question 361: Can R/O infection, r/o pneumonia be used as source of clinical infection?

Answer 361: Yes.

Question 362: Does Time Zero get any adjustment if the patient presents in a full arrest?

Answer 362: If the patient presents in full arrest, it will be difficult, if not impossible to apply the criteria for determining the presence of severe sepsis or septic shock.

Question 363: If the physician orders 30ml/kg fluid resuscitation at 150cc/hr., is this acceptable?

Answer 363: Yes.

Question 364: For organ dysfunction, can Acute Respiratory Failure be counted if the patient has an ETT Tube or Bipap Ventilation?

Answer 364: The patient must be receiving either invasive or non-invasive mechanical ventilation. Invasive ventilation requires the placement of an endotracheal tube or tracheostomy tube. Non-invasive uses a mask and is often referred to

as BiPAP. It is not enough to have an endotracheal tube in place. The patient must also be receiving mechanical ventilation.

Question 365: Altered Mental Status or Metabolic encephalopathy was also left out of the criteria for organ dysfunction. Do you intend to address these criteria?

Answer 365: This has been discussed with the measure steward, and there are not currently plans to add this.

Question 366: Is cellulitis considered an infection? Would Cholecystitis be considered an infection?

Answer 366: Cellulitis is defined as a skin infection caused by bacteria. This is an infection. Cholecystitis is a sudden swelling and irritation of the gallbladder that occurs when bile becomes trapped in the gallbladder most commonly due to a gallstone blocking the cystic duct. This is not an infection, unless noted by the physician, APN, or PA that there is an associated infection.

Question 367: Why is Meningitis listed when it can be viral or bacterial? So if the documentation states Viral Meningitis, would it not meet criteria for Infection?

Answer 367: The list of conditions is from Surviving Sepsis Campaign materials. Meningitis is included because when initially presenting, it is difficult to differentiate viral from bacterial. Standard practice is to treat it as bacterial until it is clearly identified as viral.

Question 368: If the DX is Sepsis with no other DX listed for source of infection, then it is excluded?

Answer 368: Correct.

Question 369: Referring back to the slide discussing organ failure related to respiratory failure, am I correct in reading that to say that organ failure is present if the patient is intubated?

Answer 369: They must be receiving either invasive or non-invasive mechanical ventilation. Invasive ventilation requires the placement of an endotracheal tube or tracheostomy tube. Non-invasive uses a mask and is often referred to as BiPAP. It is not enough to have an endotracheal tube in place. The patient must also be receiving mechanical ventilation.

Question 370: Is there any exclusion for septic patients that are brought to surgery?

Answer 370: No.

Question 371: If suspected infection is documented and it does not specify viral or bacterial, such as respiratory infection, do we assume bacterial unless the provider specifies viral?

Answer 371: Yes.

Question 372: Can you please define “chronic condition?”

Answer 372: A chronic condition is defined as “a human health condition or disease that is persistent or otherwise long-lasting in its effects.” It is not limited to only diseases.

Question 373: We have cases where the BP and the tachycardia are related to an acute cardiac event. We don't see recognition of this. The only exclusion that we would be able to use is if the physician documents "not an infectious process". Are you considering this in the future for exception?

Answer 373: We are looking into ways to address SIRs criteria that are related to other conditions and not related to the infection. Keep in mind, while they meet SIRs criteria based on this, in order to indicate the patient has severe sepsis, they must also have a sign of organ dysfunction and documentation of a suspected infection.

Question 374: Please clarify the use of SBP decrease of more than 40 points from normal for that patient. You said something about not recommending it.

Answer 374: In a previous webinar we discussed ways to try and estimate a normal or baseline SBP, which proved to be problematic. We clarified that there must be documentation reflecting there was a decrease of more than 40 from the patients normal blood pressure.

Question 375: Would a Level of Service (bed placement) order with a differential diagnosis of "Severe Sepsis/Septic Shock" which is signed by a physician count as documentation of septic shock?

Answer 375: As long as it represents physician documentation, it would be acceptable.

Question 376: Does language of "differential diagnosis" inclusive of infection count as suspected infection?

Answer 376: Yes.

Question 377: What examples do we have for patients who are on the floor? ED is pretty easy to figure out. It's the inpatients that are tricky.

Answer 377: The criteria for determining the presence of severe sepsis and septic shock are the same regardless of whether the patient is in the ED or an inpatient.

Question 378: If a patient's weight in kg is 72.56, would we round this up to 73kg?

Answer 378: The measure does not address rounding of the patient's weight. At this point, it is not recommended. We will look into this for a future version of the measure.

Question 379: Can an LIP clarify in a progress note what the time of presentation was for severe sepsis and/or Septic Shock, even if it was a few days prior to the note (i.e., 10/15/15 note: "pt. developed severe sepsis 10/12/15 at 2200)?

Answer 379: This would be acceptable.

Question 380: Weight is documented as 136 lbs. 10 oz. What weight do you use for calculation, 136 or 137?

Answer 380: The measure does not address rounding of the patient's weight. At this point, it is not recommended. We will look into this for a future version of the measure.

Question 381: Can you please clarify the time frame the 30ml/kg crystalloid fluid must go in over again (minimum amount of time)?

Answer 381: The infusion rate must be >125 ml/hour (equivalent to 1000 ml over 8 hours). Any rate ≤125 ml/hour is considered for IV maintenance, and the volume infused at that rate cannot be counted toward the 30 ml/kg total.

Question 382: What about patients with CHF or acute/chronic renal failure? Our providers are concerned about fluid overload with the 30 ml/kg requirement.

Answer 382: The measure does not contain any exclusions to the 30 ml/kg volume of crystalloid fluids. Physician clinical judgment should be used if there is concern that 30 ml/kg would be detrimental to a given patient.

Question 383: What are the ranges (parameters) that identify hypotension? Does age of patient make a difference?

Answer 383: No, SEP-1 is for patients that are 18 years of age or older.

Question 384: How is the infection time determined, if the provider lists suspected infection or infection on day 1 in the hospital, but the SIRs and organ dysfunction does not become evident until later in the stay? Does the provider have to list the infection again within the 6 hour window, or is the infection listed previously enough?

Answer 384: Currently, the documentation of the infection would need to occur within 6 hours of the other criteria (SIRs and organ dysfunction). We realize in

situations like this the infection is still present, and are considering changes to address this for a future version of the manual.

Question 385: What is the opinion of CMS on tele-ICU reviews in the record? Are there specific criteria that must appear in the AICU notes to qualify specifically for severe sepsis/septic shock?

Answer 385: This documentation is acceptable. There are not any special documentation requirements. For Focused Exam data elements that require they be performed by the physician, a notation indicating a physician performed with nursing assistance or something to that effect may be helpful.

Question 386: Would a patient be excluded if the only organ dysfunction was a chronic condition with the provider noting acute on chronic situation. For example, acute on chronic renal failure. Patient chronic renal failure creatinine is 1.8 and comes in with creatinine of 2.5.

Answer 386: Yes, if this was the only sign of organ dysfunction, you would disregard it.

Question 387: If a patient comes in and it is noted that the patient had a UTI four days prior but does not indicate it is still present, do we use that as a possible infection?

Answer 387: There would need to be documentation reflecting it is still present.

END