Inpatient Quality Reporting Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock
Part I: Severe Sepsis

Questions & Answers

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

Question 1: What is the definition for *broad spectrum*? Is it the antibiotic listed on table 5.0 and table 5.1?

Answer 1: Yes, the intent of the measure in terms of broad spectrum antibiotics would be the ones identified on table 5.1 and 5.0 by how the measure is designed. Those antibiotics are really only accounted for when we're looking at the broad spectrum or other antibiotic administration selection. So when you're abstracting broad spectrum antibiotic administration, you may also be looking at other antibiotics that are not on those two tables for identifying were they given a broad spectrum antibiotic and also for the date and times.

Question 2: Are patients excluded by transfer if the Severe Sepsis doesn't manifest and fill the days after the transfer?

Answer 2: Yes, any patient that is received in transfer from another facility regardless of when Severe Sepsis or Septic Shock manifests itself are excluded from the measure.

Question 3: Do both antibiotics from the combination antibiotic therapy row from column A, one from column B, need to be given within three hours in Severe Sepsis presentation or does only one need to be given within the three-hour, and why?"

Answer 3: So the answer to that is going to be that they both need to be started within that timeframe. They both do not need to be totally administered, however. The rationale for that is one of the things that is really important in treating Severe Sepsis is getting the broad spectrum antibiotic started early. So that is the rationale for that time window and why they would both need to be started within that time window.

Question 4: Can an order for IV fluid rate forward be considered already up in the rate as (its fact) as the site will allow?"

Answer 4: I would actually like to defer that one to our next presentation because we will be talking more about the crystalloid fluid administration and what constitutes the appropriate volume. We'll also be talking about the duration of administration of the crystalloid fluid, as well.

Question 5: What is the temperature that is being used for screening? Our DOH is using 38 Celsius. CMS has 38.3 C.

Answer 5: The CMS criteria are being used for the measure. It's the 38.3 C.

Question 6: For transfers, into a facility, the case is excluded. Is this for all transfers or only the ones that are known to have to Severe Sepsis or Septic Shock at the time of transfer?

Answer 6: So this would be any case that you are abstracting for this measure that is transferred in from another facility. You would exclude them regardless of whether they had Severe Sepsis or Septic Shock diagnosed at the other facility or the timing of when it was identified within your facility.

Question 7: Is this measure a requirement for Critical Access Hospitals?

Answer 7: The Critical Access Hospitals are not part of the IQR program. They are not required to submit the Sepsis measure. However, they do – they can submit it voluntarily, and we would encourage them to do that.

Question 8: For Severe Sepsis presentation, will there be a next step/involvement of clinical infection?

Answer 8: As you know right now, there is not a list of infections that are in there or how to identify if the condition a physician documents is an infection or not just based on what's in the data element right now. So we are working on some examples that will be in the next version of the manual. So there will be some examples in there and a little bit of guidance on what to do if a physician documents a condition that you're unsure of whether it's an infection or not. For the time being, pretty much what you're going to have to depend upon is what is documented. Now, for something that is obviously infection, such as pneumonia, you can select that. If it's something that may not be clear whether it's an infection or not, the word "infection" would need to be included in the documentation to confirm that it is an infection.

Question 9: How do abstract cases when a patient's chronic diagnosis will affect the lab, for example, a renal patient with the creatinine of 2.5 normally? Secondly, how could we give that patient 30 milliliters per kilogram if it could potentially be three to four liters? Or another example would be a patient with CHF and an EF of 20 percent. Are we still expected to be giving 30 milliliters per kilogram?

Answer 9: So the latter points in that question regarding crystalloid fluids, I would like to defer to the next presentation where we will be talking about those kinds of situations. The first question in regard to the lab values that may be abnormal due to a chronic condition or maybe even a medication being administered, the wording currently in the data element does not address that. It doesn't say to take those. It doesn't say not to take those.

The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal

lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 10: If a patient has a greater than 40 drop in systolic blood pressure after receiving propofol for intubation, is this systolic blood pressure reading to be allowed for sign of organ failure criteria of Severe Sepsis presence?

A**nswer 10:** That's a very interesting question and interesting scenario. The manual doesn't really address those types of situations. And I appreciate that being asked because it gives us an idea of maybe some things we need to look at for future revisions to the manual. The intent is that we are looking at drops in blood pressure that are greater than 40 that are related to Severe Sepsis or the infection, not necessarily that they are precipitated by some other events such as administration of propofol. I would have said to your point that the intent of the measure is to identify important components in the treatment of Sepsis. It is not to replace or substitute clinical judgment. So if there is an overwhelming impression to that that changes in the vital signs are a result of an iatrogenic process, then the clinician should act appropriately. How that impacts the data abstraction, as Bob said, is not yet clear. But we certainly want clinicians to react to conditions in the way they normally would.

Question 11: If the patient refuses a central line for vasopressors, is this an administrative reason? If it is not an antibiotic IV fluid or blood draw?

Answer 11: If a patient refuses to have an IV line put in, then it would not be possible to administer the IV fluids and IV antibiotics, and that would be acceptable. Refusal of a central line, however, is not an administrative reason. Central lines are not required for purposes of the measure. Medications given through a central line can also be given through peripheral IV access.

Question 12: What documentation as suspected as source of infection is allowed? Is it only MD, APN and PA documentation?

Answer 12: Currently, as worded, the data element does not state nursing documentation is acceptable. It also does not state that it is not acceptable. In the allowable sources for this documentation, it does indicate the entire ED record, which would include nurses' notes.

We recognize that a lot of facilities that have been working with Severe Sepsis and Septic Shock for a period of time do screening during the triage process in which nursing is identifying possible sources of infection. So, we are adding language to the data element for the Septic Shock presentation that will make it more clear that nursing documentation is acceptable.

Question 13: So, if the inception process element accepts this identification, can we infer from the results or does it have to be supported with documentation? For example, chest x-ray shows consolidation or density. May we infer pneumonia from that reading or do we have to wait for an extra MD documentation of pneumonia?

Answer 13: There does need to be documentation that an infection is suspected or present. There are different conditions that are non-infectious that could result in a consolidation on an x-ray. Now, if the x-ray report results were to state suspected pneumonia that would be sufficient because the x-rays are read by a physician. The majority of acute care of the septic patient involves working with many unknowns. Initially, the driving factor will be acute care of the patient – the vital signs and resuscitating the patient – and managing the suspected or likely etiologies in the most rational way possible. As the care of the patient continues and there's a clear diagnosis of – that comes forward, then we'll be able to identify a source. But there are many times where source is not identified. I think that the point to emphasize for clinicians is, again, document the medical decision making to diagnosis under consideration driving a suspicion of Severe Sepsis.

Question 14: Do I understand correctly that the transfer question should always be answered?

Answer 14: Yes.

Question 15: If the criteria for Severe Sepsis is met but the physician states patient doesn't have Severe Sepsis, how do we answer the Severe Sepsis present question "yes" or "no?"

Answer 15: You would answer "yes." The Introduction to the Data Dictionary reflects to take documentation that supports a positive response over documentation supporting a negative response, unless indicated otherwise in the data element. This data element does not indicate otherwise.

Question 16: Severe Sepsis Presentation Time and Date "Sepsis." Severe Sepsis Present does not include or exclude "Sepsis."

Answer 16: The term “Sepsis” alone is not sufficient because this may indicate the patient has uncomplicated Sepsis. The focus of the measure is on Severe Sepsis and Septic Shock. Documentation must indicate “Severe Sepsis.”

Question 17: Currently in the Sepsis algorithm there is no data element for "reason for not administering Crystalloid fluid." For example, if the patient has acute or chronic systolic heart failure, pulmonary hypertension or ESRD on dialysis, these would all be valid medical reasons why a physician or medical provider would not want to give crystalloid fluids to a patient. Currently abstractors can say “Yes” if the fluids are administered after presentation of Septic Shock or at time of presentation of Septic Shock and if the amount is 30 ml/kg (Option 1. Yes). However, even if crystalloid fluids are administered after presentation of Septic Shock or at time of presentation of Septic Shock, if the amount is less than 30 ml/kg or unable to determine we must answer “No” (Option 2. No). We must also abstract? No? If crystalloid fluids were altogether not given at any time. (Option 3. No).Currently in the algorithm, if abstractors answer Option 2, or Option 3, then the case will fall out. The fluids must be given and the amount must be 30 ml/kg. How come there is no reason or contraindication for not administering crystalloid fluids

Answer 17: This presentation covered Severe Sepsis and its data elements. We will defer this question until after the next presentation on Septic Shock, which will include information on crystalloid fluids.

Question 18: One of our ED physicians is stating that fluids are not necessary for Sepsis. Can you point me to some resources that show fluids are necessary?

Answer 18: This presentation covered Severe Sepsis and its data elements. We will defer this question until after the next presentation on Septic Shock, which will include information on crystalloid fluids.

Question 19: In order to exclude the patient using this data element is it necessary to have the refusal for all three (blood draw, antibiotics and fluid administration) or does one refusal from any of the three exclude the patient if documented by an MD/APN/PA?

Answer 19: Refusal of any one of the three is sufficient.

Question 20: Can we use MD documentation of Severe Sepsis as “time zero,” or do we have to look at the earliest of the last component?

Answer 20: If you have both physician documentation of Severe Sepsis and clinical criteria, “time zero” will be the earlier of the two. So, if the last of the clinical criteria is met before the physician documents Severe Sepsis, “time zero” is when the last of the clinical criteria are met. The converse is also true. If the physician documentation was before the last of the clinical criteria was met, then “time zero” is when the physician documented Severe Sepsis.

Question 21: Does this include transfers within one system?

Answer 21: Yes. The data element indicates this applies even if the two hospitals, EDs, or observation units are part of the same hospital system, have the same provider number, share a medical record, or are in close proximity.

Question 22: Are there any cases excluded because their co-morbidities exclude them from receiving care? ESRD, HF?

Answer 22: This presentation covered Severe Sepsis and its data elements. We will defer this question until after the next presentation on Septic Shock.

Question 23: Is it only the Principle Code or any code of Sepsis in the population?

Answer 23: The population includes patients admitted to the hospital for inpatient acute care with an ICD-10-CM Principal or Other Diagnosis Code for Sepsis, Severe Sepsis, or Septic Shock.

Question 24: What about oral antibiotics given for two days prior to hospitalization?

Answer 24: Oral antibiotics are not considered for the measure. Only IV antibiotics are taken into consideration for abstraction.

Question 25: How is the difference between Severe Sepsis and Septic Shock defined clinically?

Answer 25: Severe Sepsis is defined by the presence of three criteria (suspected infection, two or more SIRS criteria, and a sign of organ dysfunction). Septic Shock is defined by the presence of Severe Sepsis with hypoperfusion. The session in September will go into more detail on Septic Shock).

Question 26: What if [a patient] comes from a LTAC or SNF on antibiotics IV? Why is the comfort care so short? Three hours – many patients are still in ED. Why would it not be the first 12 or 24 hours?

Answer 26: There are a lot of unknowns in this first question, so I really cannot answer this. The response will depend on the timing of other antibiotics and the timing in relation to Severe Sepsis presentation time.

The Directive for Comfort Care, Severe Sepsis data element is specific to the Severe Sepsis portion of the measure. If comfort care is documented prior to Severe Sepsis presentation or within three hours of Severe Sepsis presentation, it could very well have resulted in the patient not receiving the required care elements for Severe Sepsis. To avoid a case failing the measure based upon this, these cases are excluded.

Question 27: If a patient refuses IV access, is this considered an Administrative Contraindication? Will the patient be excluded from this measure?

Answer 27: Refusal of IV access would not allow IV fluids or IV antibiotics to be administered. As such, this would constitute an Administrative Contraindication to Care.

Question 28: What constitutes a witness-signed consent? Can a nurse be the witness?

Answer 28: This would be a consent form that includes documentation indicating the patient is refusing to have blood drawn, or IV fluids administered, or IV antibiotics administered, and is signed by a witness. The data element indicates the refusal may be witnessed by physicians, APNs, PAs, or other hospital personnel. Yes, a nurse can be the witness.

Question 29: So, if the patient's family decides on day four that they no longer want treatment, the case would be excluded?

Answer 29: The treatment they no longer want must be specific to refusal of blood draws, or IV fluids administration, or IV antibiotics administration.

Question 30: Regarding administrative refusal, can a nurse be the witness on a signed form?

Answer 30: Yes, the data element indicates the refusal may be witnessed by physicians, APNs, PAs, or other hospital personnel.

Question 31: Does "other hospital" include LTACs?

Answer 31: The Transfer From Another Hospital or ASC data element indicates to select "yes" for transfers in from LTACs whether the LTAC is outside or inside your hospital.

Question 32: What is considered "time zero?" When does the clock start for the bundles?

Answer 32: "Time zero" is the earlier of either physician/APN/PA documentation of Severe Sepsis OR when the last of the clinical criteria is met. So if the last of the clinical criteria is met before the physician documents Severe Sepsis, "time zero" is when the last of the clinical criteria are met. The converse is also true. If the physician documentation was before the last of the clinical criteria was met, then "time zero" is when the physician documented Severe Sepsis.

Question 33: Does ED dx of UTI rule out count as one of three criteria for documentation of suspected infection?

Answer 33: This is acceptable as a suspected source of infection.

Question 34: Does the physician have to document UTI or go off when UTI UA is turned out as an infection?

Answer 34: The thing to keep in mind is while a confirmed infection is certainly acceptable; an infection does not need to be confirmed for purposes of the measure. You are looking for a possible or suspected infection. The condition documented must be an infection or the word “infection” must be included. A positive UA is not acceptable as documentation of a suspected infection. A UA can be positive without presence of an infection.

Question 35: Does coming from an urgent care center that is offsite count for being transferred from another hospital?

Answer 35: The Transfer From Another Hospital or ASC data element indicates you would select “No” for a transfer from an urgent care center.

Question 36: Does an urgent care center count as an outside facility relating to transfer, even if the patient/family drove the patient to our hospital?

Answer 36: The Transfer From Another Hospital or ASC data element indicates you would select “No” for a transfer from an urgent care center.

Question 37: Our senior behavioral health unit is physically attached to our hospital. Would that count as an "outside" facility?

Answer 37: The Transfer From Another Hospital or ASC data element indicates you would select “No” for a transfer from a psych or rehab unit inside your hospital.

Question 38: So would you include a patient from an ED in your system that you have access to the medical record?

Answer 38: The Transfer From Another Hospital or ASC data element indicates you would select “Yes” for a transfer from any ED outside your hospital even if that ED is a part of your hospital system, has a shared medical record or provider number, or is in close proximity.

Question 39: Why wasn't Transfer the first part of the algorithm before you have to search the entire chart for refusal of care?

Answer 39: I cannot speak to the specific rational for the sequencing of all of the data elements in the algorithm other than to say, in this case the Administrative Contraindication to Care will result in a case being excluded from the measure, so it was placed early in the flow of the algorithm.

Question 40: If a patient was on a vasopressor like Levophed after administration of the crystalloid fluid, they might not have an SBP below 90 or a mean arterial pressure (MAP) below 65. This definition for Persistent Hypotension currently

does not take into account administration of vasopressors. Without administration of Levophed, the patient would most likely meet criteria for persistent hypotension and abstractor can say "Option 1. Yes." Thus, the case abstraction would be complete. Would you please clarify the persistent hypotension data element with vasopressor administration after crystalloid fluid administration in mind?

Answer 40: This presentation covered Severe Sepsis and its data elements. We will defer this question until after the next presentation on Septic Shock, which will include information on crystalloid fluids.

Question 41: Slide # 24 indicates that nursing documentation is an acceptable source of clinical infection for the data element Severe Sepsis Present. Please verify that this is accurate, as this does not seem to be reflected in the data Abstraction Manual for this data element. Thank you.

Answer 41: Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 42: Do we look at each abstraction as if the patient has Severe Sepsis? Ex. There is no physician documentation of Severe Sepsis, so do I go ahead and look for the three criteria at all charts?

Answer 42: Yes, the patient is in the initial population because they had a code for Sepsis, Severe Sepsis, or Septic Shock. The determination of the coding is based upon documentation in the medical record. For the purposes of the measure, Severe Sepsis is the earlier of either physician/APN/PA documentation of Severe Sepsis OR when the last of the clinical criteria is met. So if there is no physician documentation, you will need to review the record for the clinical criteria.

Question 43: I do not see where the Spec Manual states that the documentation of Refusal for Blood Draw, Fluids, or Antibiotics can occur at any time during hospital stay. Can you reference where you found this?

Answer 43: This can be found in the Alphabetical Data Dictionary under the Inclusions Guidelines for abstraction for *Administrative Contraindication to Care* data element (page 1–16 of version 5.0a).

Question 44: For the Infection Process, Element of Sepsis identification, can we infer from the result, or does it have to be supported with documentation? E.g. CXR= airspace dose, or consolidation, or densities, or consolidation. May we infer Pneumonia from that reading or do we have to wait for an actual MD documentation of Pneumonia?

Answer 44: You cannot infer presence of a possible infection based upon results of a test or procedure. There must be documented reference to an infection being present,

suspected, or possible. This could be documentation of a condition known to be an infection or use of the word “infection.”

Question 45: In regards to exclusion of patient’s being transferred to the hospital, does this include patients transferred to our facility from a nursing home, LTAC, or outside urgent care/medical office?

Answer 45: The Transfer From Another Hospital or ASC indicates to select “Yes” for LTAC (inside or outside your hospital). It indicates to select “No” for urgent care and skilled nursing facilities.

Question 46: If the ED physician documents the infection in his note but there is no other documentation of infection, do we take the time the note was started or do we have to take the time the note was signed.

Answer 46: Take the time the note is started.

Question 47: Am I clear on understanding that documentation of Administrative Contraindication to Care occurring any time during the EOC will exclude the patient, even though the refusal may occur after the Severe Sepsis initial phase when we are held to timelines?

Answer 47: Yes, you are correct. We are looking into making some changes to this to better align with the time periods associated with determining presence of and treatment of Severe Sepsis and Septic Shock.

Question 48: If the provider documents Severe Sepsis in a dictation that shows on the chart at a later point in time (the next day) and it does not have a time included in the note, what is considered “time zero” to begin the three hour bundle?

Answer 48: If you are basing the presence of Severe Sepsis upon physician documentation, it is the time the note is documented, unless there is an earlier time referenced within the note.

Question 49: Are differential diagnoses considered as "Possible" type diagnoses? Sometimes physicians cast a very broad net for differential diagnoses.

Answer 49: For purposes of the SEP-1 measure, yes.

Question 50: MD dictates at the end of the care. Will this be the time of documented source of infection?

Answer 50: If you are basing the source of infection on physician documentation, you will use the time the note is documented, unless there is an earlier time referenced within the note.

Question 51: Does use of Severe Sepsis order set by ED MD count as suspect of infection?

Answer 51: The use of a Severe Sepsis order set can be used as physician, APN or PA documentation of Severe Sepsis if it is clear the order set is being used to treat Severe Sepsis, and it is signed by a physician, APN or PA. It cannot be used as documentation of a suspected source of infection unless there is, somewhere on the order set, the provider is documenting or indicated a suspected source of infection.

Question 52: If the patient was dx with Sepsis in the ED, is that a suspected infection?

Answer 52: No, documentation of Sepsis is not sufficient as a suspected source of infection.

Question 53: I have ED MD's documenting "infection from unknown source." Would this be included?

Answer 53: Yes, documentation of "unknown source of infection" is acceptable. For many cases of Severe Sepsis, the source may not initially be known. Suspecting an infection is what is required for purposes of the measure.

Question 54: Language in the Severe Sepsis data element referring to Physician/APN/PA documentation of infection should be removed if you're allowing nursing documentation.

Answer 54: Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 55: Can you advise as to why Sepsis dx or Shock or Severe Sepsis dx is not accepted as infection criteria?

Answer 55: Sepsis is not an infection. It is the body's response to an infection. As such, it does not clearly identify the suspected presence of an infection. Shock alone is not acceptable because there are many causes of shock that are not related to infection or Severe Sepsis. Severe Sepsis is not acceptable as a source of infection because it is documentation of Severe Sepsis, and that meets the criteria for Severe Sepsis Presentation.

Question 56: What time do you use for a suspected infection documented in a note that was dictated hours after the infection was noted? That is if the only time on the document is the dictation time and transcription time.

Answer 56: You would use the earliest time reflecting the presence of a suspected infection.

Question 57: How do you account for chronic conditions where signs of organ failure are already present (renal failure) – Heme/Onc patients with preexisting low platelets?

Answer 57: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are

associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 58: Per the Specifications Manual, on the Organ Dysfunction Criteria, it doesn't include 'respiratory' dysfunction e.g. O2Sats <93% on RA, PCO2 < 32mmHg on an ABG, mechanical ventilation, etc. Do we not credit Respiratory Dysfunction to help identify Severe Sepsis?

Answer 58: The Surviving Sepsis Campaign International guidelines do include “arterial hypoxemia” as a sign of organ dysfunction. This has been noted as an oversight to the criteria in the measure. As currently worded, these cases would be excluded from the measure (which does not count against a facility). We are adding “respiratory failure” as a sign of organ dysfunction so these cases will be included in the future.

Question 59: Our ED physician note is narrative; the note begins with the initial encounter, so the earliest time of documented Severe Sepsis may not be accurate. Should the record be abstracted via criteria because the initial encounter time may be hours before the actual presentation?

Answer 59: You will need to abstract for both physician documentation and clinical criteria. The date and time you will enter is the earlier of either the physician documentation OR the time the last of the clinical criteria are met. Regarding your specific issue with the ED narrative note, if there is a time within the note associated with when Severe Sepsis was identified, you can use that for the physician documentation of Severe Sepsis. If not, you would use the time the note was started. The next set of revisions to the data element will reflect this.

Question 60: The term "infection" is excluded for the Severe Sepsis documented source of infection. In your example, the slide states that the nurse documentation of "In ED earlier today diagnosed with UTI" would not appear to be acceptable, and yet your slide indicates it is acceptable nursing documentation. Please reconcile this discrepancy.

Answer 60: The term “infection” is not excluded as a source of infection. If there is documentation referencing an infection is possible or suspected, it is acceptable as a suspected source of infection. The Severe Sepsis Present data element currently does not explicitly specify that nursing documentation is acceptable, and it does not specify that it is not acceptable. The “entire ED record” is an acceptable data source. Nursing documentation is in the ED record and many facilities are using Severe Sepsis and Septic Shock screening tools used by nurses in which they often do document a suspected source of infection. This is being clarified in the next version of the manual.

Question 61: Slide 24: Can you reference where the known or suspected infection can be noted by nurse? The Spec Manual states progress notes, consult notes, or similar physician/ APN/PA documentation.

Answer 61: Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the *Severe Sepsis Present* data element.

Question 62: Can differential diagnosis be used as documentation of suspected infection?

Answer 62: Yes, this is acceptable.

Question 63: Traditional SIRS criteria for temperature is > 38 NOT 38.3. - 38.3 is for Sepsis criteria. Why is it higher for the measure?

Answer 63: The Surviving Sepsis Campaign International guidelines published in 2012 upon which the SEP-1 measure is based use 38.3 as a criteria.

Question 64: Are there any guidelines for lab criteria for patients with contributory chronic conditions (cirrhosis, dialysis, etc.)?

Answer 64: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of manual to indicate that if abnormal lab values are due to a chronic condition or a medication to not use them as a sign of organ dysfunction.

Question 65: So if our hospital has a satellite ED at another location, and a patient is transferred to our facility, we should answer "yes" for Transfer from another ED/ASC?

Answer 65: Yes, this is correct.

Question 66: What physician documentation is needed to document that Sepsis was present on arrival? ED physicians do not generally document that Severe Sepsis was "present on arrival," only that it is present.

Answer 66: If a physician documents that Severe Sepsis was "present on arrival," that is acceptable. An example might be that in the ED notes it appears Severe Sepsis was present later in the ED stay, but in an admission note or H&P the physician documents "patient arrived to the ED with Severe Sepsis." In this case, you would use triage time for Severe Sepsis presentation date and time.

Question 67: If the mean arterial pressure is not documented should the abstractor calculate one?

Answer 67: There is no expectation at this point for the abstractor to calculate mean arterial pressure.

Question 68: Re: Administrative Contraindication to Care – If there is no documentation of treatment refusal from the ED and 24 hours later there is a documentation from the admitting physician, does that count? Thanks.

Answer 68: Yes, documentation of an Administrative Contraindication to Care at any point during the hospital stay is acceptable.

Question 69: If a patient is screened positive for Sepsis in the ED, however when lactate and other labs come back they are abnormal indicating hypoperfusion of organs and Severe Sepsis, is the presentation time at triage or when the lab results come back?

Answer 69: Presentation date and time of Severe Sepsis based upon clinical criteria is the date and time the last of the criteria are met. If all clinical criteria for Severe Sepsis are identified during triage, you will use triage time. If some criteria are identified during triage and lab value results come back later (such as in your question), you would use the date and time the lab results were reported, assuming they represent the last of the clinical criteria.

Question 70: If the patient was intubated/vented for airway protection, may we use that for an organ dysfunction? E.g. repeat Head CT revealed worsening subdural hematoma, so the MD decides to intubate the patient for airway protection. The patient had been started on an empiric antibiotic with HR=110 & RR=24 (Simple Sepsis). All criteria met within six hours of each other; does this now qualify the patient for the Severe Sepsis criteria?

Answer 70: Being intubated for airway protection is not reflective of respiratory failure or organ dysfunction and would not quality a patient as having Severe Sepsis. The Surviving Sepsis Campaign International guidelines do include “arterial hypoxemia” as a sign of organ dysfunction. This has been noted as an oversight to the criteria in the measure. As currently worded, these cases would be excluded from the measure (which does not count against a facility). We are adding “respiratory failure” as a sign of organ dysfunction so these cases will be included in the future.

Question 71: For Severe Sepsis Present time – is it the time of the last criterion being met, which is on page 176 of spec manual?

Answer 71: Page 176 of the Specs Manual is the Home Management Plan of Care Document Addresses Environmental Control and Control of Other Triggers data element. Severe Sepsis Presentation time is the earlier of either when the last of the clinical criteria are met OR physician/APN/PA documentation of Severe Sepsis. This is on pages 337 and 338 of the Specs Manual.

Question 72: Where does it say nursing documentation is acceptable for suspected source of infection?

Answer 72: Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 73: Does an order for a test, i.e., KUB with a comment by the MD of suspected infection count as one of the criteria for suspected infection or MRSA isolation documented within the six hours of other criteria?

Answer 73: There is not a restriction on where physician/APN/PA documentation of suspected infection must be. The suggested data sources state "Any physician/APN/PA documentation." Your first example of "KUB with a comment by the MD of "suspected infection" is acceptable. Being in MRSA isolation will depend on how it is documented. There must be documentation indicating a MRSA infection is suspected, possible, or present.

Question 74: When looking at signs of organ dysfunction, why aren't there any respiratory variables?

Answer 74: The Surviving Sepsis Campaign International guidelines do include "arterial hypoxemia" as a sign of organ dysfunction. This has been noted as an oversight to the criteria in the measure. As currently worded, these cases would be excluded from the measure (which does not count against a facility). We are adding "respiratory failure" as a sign of organ dysfunction so these cases will be included in the future.

Question 75: On slide 26 it discusses lactates >2. It was our understanding that this had been clarified by CMS to be four?

Answer 75: For determining a sign of organ dysfunction, the requirement in the Surviving Sepsis Campaign International guidelines and the SEP-1 measure is an elevated lactate. While what is considered elevated may vary depending on your lab references, it is most commonly 1.8 to 2.2. To take into account these variations but provide consistency for the measure, 2 was chosen as "elevated." This is also consistent with the Surviving Sepsis Campaign data collection and information. A lactate level >= 4 along with Severe Sepsis qualifies the patient as having Septic Shock.

Question 76: Infection: For Cultures (blood, urine, sputum, etc.), may we use the preliminary results or does it have to be the final results to credit it for infection?

Answer 76: Results of cultures are not sufficient as documentation of suspected infection. Results can be positive without an infection being present.

Question 77: Is a MAP <65mmHg considered organ dysfunction?

Answer 77: Yes.

Question 78: When a physician documents 'dx: Severe Sepsis,' do we use the note time or filed time for “Time Zero” purposes?

Answer 78: If there is more than one time associated with the documentation of "Severe Sepsis," use the earliest time.

Question 79: If our lactate results differ from these, how do we handle that? For example, our IP lactate "normal results" are .5-2.2. So, a lactate of 2.2 is actually normal at our facility. How do we handle this?

Answer 79: For determining a sign of organ dysfunction, the requirement in the Surviving Sepsis Campaign International guidelines and the SEP-1 measure is an elevated lactate. While what is considered abnormal may vary depending on your lab references, it is most commonly 1.8 to 2.2. Hyperlactatemia is defined as lactate levels greater than 2.0 mmol/L and is associated with increased mortality. This is also consistent with the Surviving Sepsis Campaign data collection and information. For measure purposes an elevated lactate is 2.0.

Question 80: Slide # 26 indicates that a decrease in SBP more than 40 from last previously recorded SBP "normal" for that patient. The data Abstraction Manual for the Severe Sepsis Present Organ Dysfunction only reads a decrease of 40. There is no reference to "normal" values. Why is there a difference between the presentation and the Abstraction Manual? Thank you.

Answer 80: It appears you may be using an older version of the Specifications Manual (v5.0). There was a revision published in late May on *QualityNet* as v5.0a that includes this wording.

Question 81: Severe Sepsis present does not indicate NURSING documentation as an acceptable source, yet this presentation adds nursing documentation as an acceptable source. Please advise.

Answer 81: Nurses’ notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 82: Can you answer specifically if we do or do not take into consideration chronic illness for organ dysfunction? (For example, a patient with ESRD with a baseline Creatinine of >2 or on Coumadin and a therapeutic INR of 2.) Thanks

Answer 82: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on language that will be published in the next version of the manual to indicate not to use abnormal lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 83: What about the patient whose baseline SBP is 90s. According to the guideline, a decrease of >40 would bring this population to a SBP in the 50s. What is your recommendation?

Answer 83: Keep in mind that identification of Severe Sepsis is not based on any single parameter. It requires a suspected infection, two or more SIRS criteria, and the sign of organ dysfunction. If a patient had a suspected infection, had two or more SIRS criteria, and regardless of their baseline SBP, if it dropped below 90 or down to 50, they would by definition have Severe Sepsis according to the Surviving Sepsis International Guidelines and the SEP-1 measure.

Question 84: Example one, third bullet doesn't make sense. How is the BP less than 90?

Answer 84: The example considers 128 the last "normal" systolic blood pressure because it is the last of three consistent readings. A drop of > 40 means the SBP would need to drop to 87 to be considered a drop of > 40. The patient's SBP in this example would also be < 90, so they already meet criteria based on the SBP being < 90.

Question 85: Slide 28: The manual does not reflect a 40 point change from "normal." Can you reference where this is documented in the Spec Manual?

Answer 85: It appears you may be using an older version of the Specifications Manual (v5.0). There was a revision published in late May on *QualityNet* as v5.0a that includes this wording.

Question 86: Please clarify – Did you say an abnormal lab due to a chronic condition or medication should not be used as an indication of organ dysfunction?

Answer 86: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 87: Slide 23 stated to use the earliest time of A, B, or C. However, the Specs Manual states to use the time of the latest criteria met? Please clarify.

Answer 87: You are correct, when determining the presence of Severe Sepsis based only on the three criteria, you use the time the last of the three criteria (a, b, or c) are met. Many times there will be documentation of Severe Sepsis based on the criteria and physician/APN/PA documentation. The slide is referencing to use the "Earliest of either" the three criteria (all within six hours of each other), **OR** physician, APN or PA documentation of Severe Sepsis or suspected/possible Severe Sepsis to determine when Severe Sepsis is present.

Question 88: Slide #32 indicates, "If criteria not met, and there is no physician/APN/PA documentation of Severe Sepsis, BUT there is physician/APN/PA documentation of Septic Shock, this is acceptable." Why is this directive not found in the data Abstraction Manual for the data element Severe Sepsis Present?

Answer 88: It appears you may be using an older version of the Specifications Manual (v5.0). There was a revision published in late May on *QualityNet* as v5.0a that includes this wording.

Question 89: I missed the answer to “Is an abnormal lab value due to a chronic condition appropriate." Was it “yes” or “no?”

Answer 89: An abnormal lab value due to a chronic condition or medication should not be used as a sign of organ dysfunction. Revisions are in process to address this in the next version of the manual.

Question 90: Please confirm regarding chronic condition and organ dysfunction. ESRD with Creat >2 then do not use the Creat as the organ dysfunction?

Answer 90: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual to indicate that if abnormal lab values are due to a chronic condition or a medication to not use them as a sign of organ dysfunction.

Question 91: I'm currently reviewing Sepsis charts using the Severe Sepsis and Septic Shock. One patient had three SIRS criteria but no organ dysfunction, so Severe Sepsis was “no.” Two days into a five day stay, a hospitalist who picked-up the patient on that day documented “the patient had Severe Sepsis." Is that documentation sufficient to constitute an episode of Severe Sepsis starting on that date?

Answer 91: If clinical criteria were not met prior to this, and there is no prior documentation of Severe Sepsis by a physician/APN/PA, then this is sufficient.

Question 92: We have an alert that fires when two or more SIRS criteria for the provider to question if end organ dysfunction or suspected infection. Can that be used as a starting point?

Answer 92: Yes, this would certainly be an acceptable starting point from which to start reviewing the record for the remaining criteria for Severe Sepsis.

Question 93: Unless Septic Shock is documented, the 2.3 Lactic Acid does not capture the Severe Sepsis for HIM Coding.

Answer 93: If the patient is has an ICD-10 code for Sepsis, Severe Sepsis, or Septic Shock as defined in Appendix A Table 4.01, they are in the initial patient population and are eligible for sampling and abstraction. If one of these codes is not assigned, they are not in the initial patient population of the measure.

Question 94: How does this affect critical access hospitals? Is this going to be a PQRS measure and Meaningful Use? How many Sepsis patients does a facility need to have to report this measure?

Answer 94: Critical Access Hospitals are not part of the IQR program and are not required to submit SEP-1. They can voluntarily submit, and we encourage them to do so.

Question 95: Does this measure only apply to patients arriving through the ED, or would patients already in the hospital fall into this measure?

Answer 95: This applies to patients who have Severe Sepsis or Septic Shock, regardless of whether it is identified in the ED or as an inpatient.

Question 96: Can we use WBC greater than normal, such as WBC >15K? Can this be used as criteria of suspected infection rather waiting for MD to document 'pneumonia'?

Answer 96: No, an infection cannot be assumed based on lab values or diagnostic test results. There are conditions other than infections that can cause an elevated WBC. For a suspected infection, there must be documentation of a condition that is an infection or documentation including the word “infection” indicating an infection is present, suspected, or possible.

Question 97: What time would you consider for physician documentation with EMR, the time that the progress note is started or signed off? If signed off, then by attending or resident?

Answer 97: Since the goal is to use the earliest documentation indicating Severe Sepsis is present, use the time the note is started. There is a revision under development to address this in the next version of the manual.

Question 98: Where is the documentation for organ dysfunction?

Answer 98: This is indicated in v5.0a of the IQR Specifications Manual in the Severe Sepsis Present data element on page 337.

Question 99: In abstracting the data elements, Organ dysfunction and Persistent Hypotension, if the patients "normal" systolic BP is 90–100, in these patients a drop into the 80s systolic does not necessarily indicate shock or persistent hypotension.

Answer 99: Taken into consideration along with a suspected source of infection and two or more SIRS criteria, it would still be considered a sign of organ dysfunction.

Question 100: Our Sepsis Team states that the Lactate of more than two and respirations/HR increased could also be signs of dehydration or heat; put that with a mild UTI and we may be aggressively treating someone for Severe Sepsis when they are dehydrated or are overheated with a UTI. Please address this situation.

Answer 100: In this case, I would suspect this patient would not have been assigned a Sepsis, Severe Sepsis, or Septic Shock ICD-10 code and would not be in the initial patient population. They would therefore not be eligible for the SEP-1 measure.

Question 101: Where does ED triage time fit into all this? I understand that ED triage time should be used for patients who present through the ED, regardless of when the other criteria are met or when MD documentation states Severe Sepsis.

Answer 101: Triage time is ONLY used if the patient arrives to the ED with Severe Sepsis OR if Severe Sepsis is identified during triage. For Severe Sepsis to be considered identified during triage, ALL three clinical criteria must be met during triage. After triage (even if the patient is still in the ED), you would use the earlier of when the last of the three clinical criteria are met OR physician/APN/PA documentation of Severe Sepsis. If some but not all of the criteria are met during triage, do not use triage time. If the remaining criteria are met after triage, use the time the last of the clinical criteria are met.

Question 102: Is the use of Severe Sepsis order set considered acceptable?

Answer 102: The use of a Severe Sepsis order set can be used as physician, APN or PA as documentation of Severe Sepsis if it is clear the order set is being used to treat Severe Sepsis, and it is signed by a physician, APN or PA. It cannot be used as documentation of a suspected source of infection, unless the provider documented or indicated a suspected source of infection on the order set.

Question 103: What time would I use for this example: Nurse obtains vitals at 0800 but documents the vitals at 1200. Would I use the 0800 or 1200 time?

Answer 103: You would use the time documented that the vitals were obtained.

Question 104: In example two, why wouldn't we have gone backwards from 0800 when the first SIRS criteria were met before we looked "forward?"

Answer 104: You can. In the example, the assumption was the abstractor was using a lab report to flag abnormal lab values as the starting point. You can start from arrival and review all documentation if you wish.

Question 105: For lab consideration, is the time used the result reported time or the blood draw time?

Answer 105: For the Severe Sepsis Presentation Date and Time data elements, use the lab result reported time for any labs used to determine the clinical criteria for

Severe Sepsis. For the Blood Culture Date and Time, Initial Lactate, and Repeat Lactate Date and Time, the time the blood culture or lactate is drawn should be used.

Question 106: Can I use the SBP documentation a week prior to admission when the patient came for pre-testing assessment, but the patient was admitted earlier than scheduled surgery with an infection? The first SBP was more than 40mmHg since patient was getting septic. Most of the patient's SBPs were elevated.

Answer 106: This would be acceptable if the SBP documentation from a week prior is part of the current medical record and establishes a "normal" SBP for that patient.

Question 107: Patient did not meet criteria for Severe Sepsis; however, in the Discharge Summary, physician documents Septic Shock syndrome. So would the Discharge Summary be the presentation date and time since Severe Sepsis was mentioned in the Discharge Summary?

Answer 107: If the only documentation is in the discharge summary, the date and time of the discharge summary should be used. There is a revision that will be included in the next version of the manual to indicate that if the only documentation of Severe Sepsis occurs after discharge to select Value "2 (No)."

Question 108: Please clarify acceptance of nursing documentation of possible infection. Page 1-337 of guidelines indicates that only physician/APN/PA documentation can be used per the first bullet.

Answer 108: Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 109: Are there two separate clocks if patient has Severe Sepsis and Septic Shock; one for the bundle elements for Severe Sepsis; and one for the Septic Shock bundle elements?

Answer 109: Yes, this is correct.

Question 110: The physician documents Severe Sepsis in the discharge summary but criteria is not met during the admission time and this is the only documentation of Severe Sepsis. How would this be abstracted?

Answer 110: If the only documentation is in the discharge summary, the date and time of the discharge summary should be used. There is a revision that will be included in the next version of the manual to indicate that if the only documentation of Severe Sepsis occurs after discharge to select Value "2 (No)."

Question 111: What if elements of organ dysfunction are not new to patient and are chronic, for example, chronic creatinine elevation or elevated INR due to home med warfarin?

Answer 111: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal lab values as a sign of organ dysfunction if they due to a chronic condition or a medication.

Question 112: Severe Sepsis present - Notes for abstraction section "a" Source of infection, indicates to look for physician/PA/APN documentation, but Bob states nursing documentation for source of infection is acceptable. Please clarify.

Answer 112: Currently, as worded, the data element does not state nursing documentation is acceptable. It also does not state that it is not acceptable. In the allowable sources for this documentation, it does indicate the entire ED record which would include nurses' notes. In facilities where nurses routinely screen for Severe Sepsis and Septic Shock, nurses do document when an infection is suspected as part of the screening process. Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 113: So, with Severe Sepsis, if the lactate level was used as the criteria for organ dysfunction, we use the time the lactate level was drawn if that was the last criteria; so it would be "Yes" for the three hour time frame since that starts our time?

Answer 113: The time the lactate was drawn does not represent the time the determination of Severe Sepsis is made. It simply represents the time the lactate was drawn. The time Severe Sepsis is identified is when the results are reported for the lactate. If the lactate level is the last of the three Severe Sepsis criteria, you would use the time the results were reported as the time of Severe Sepsis presentation.

Question 114: Will all the 'possible' verbiage is from the CMS Table 2.6 Qualifiers & Modifiers table?

Answer 114: Table 2.6 Qualifiers and Modifiers Table in Appendix H does not apply to SEP-1. Please see the note under the table that states "These guidelines apply only to those data elements that refer to them in their Guidelines for Abstraction Exclusion list(s)." There are only a very limited number of data elements for which this table applies.

Question 115: "Palliative Care" documentation is also acceptable terminology?

Answer 115: Currently, palliative care is not acceptable for comfort measures. This is under consideration for a future version of the manual.

Question 116: Re: slide 29 – What if criteria were met prior to arrival (e.g., recorded by EMS or collected at a nursing home)?

Answer 116: This would mean the patient arrived to the ED with Severe Sepsis, and you would use triage time for Severe Sepsis Present Time data element.

Question 117: Our ED note doesn't have a dictated time. We have a Scribe authentication time, decision to admit time, and disposition time. When the source of infection is documented in the ED note, what time would I use for that criteria?

Answer 117: You would use the earliest time associated with the note reflecting the presence of a suspected infection.

Question 118: Can you give an example of using triage time in the ED and an example of an ED patient diagnosed after triage time but still in the ED?

Answer 118: Triage time would be used in a situation where nurses are conducting a Severe Sepsis/Septic Shock screening during triage and the nurse identified a patient with all three clinical criteria present during triage. Triage time would not be used if some, but not all criteria, were met during triage and the remaining criteria were met after triage. Triage time would also not be used for a patient where none of the clinical criteria were met in triage, but all three criteria were met after triage time. In the latter two cases, the time the last of the three clinical criteria were met would be used as Severe Sepsis Presentation time.

Question 119: Can you give an example where triage time would be used as the Severe Sepsis presentation time please?

Answer 119: Triage time would be used in a situation where nurses are conducting a Severe Sepsis/Septic Shock screening during triage and the nurse identified a patient with all three clinical criteria present during triage. Triage time would not be used if some but not all criteria were met during triage and the remaining criteria were met after triage. Triage time would also not be used for a patient where none of the clinical criteria were met in triage, but all three criteria were met after triage time. In the latter two cases, the time the last of the three clinical criteria were met would be used as Severe Sepsis Presentation time.

Question 120: So we would typically always be a “yes” since the lactate level starts our three hour time frame?

Answer 120: This question appears to be incomplete and cannot be answered based on the information provided.

Question 121: For the Directive for Comfort Care data element, are we looking for documentation three hours before and/or three hours after presentation of Severe Sepsis?

Answer 121: For the Directive for Comfort Care, Severe Sepsis data element, specifications indicate documentation prior to or within three hours following Severe Sepsis

presentation. Documentation at any time prior to presentation through three hours after presentation is acceptable.

Question 122: For SBP > 40 for organ failure, how can you determine if the patient's SBP is all over the place?

Answer 122: In this event there will likely be other signs of organ dysfunction. If not, there must be the ability to establish some type of baseline as "normal" from which to identify a > 40 mmHg drop. If this cannot be easily established, then you cannot use it as a criteria.

Question 123: Severe Sepsis identified at triage – how does this occur since RN is at triage?

Answer 123: Triage time would be used in a situation where nurses are conducting a Severe Sepsis/Septic Shock screening during triage and the nurse identified a patient with all three clinical criteria present during triage.

Question 124: We also have a time when the ED MD electronically signs the scribes note, but that may be a day or two after patient was in the ED.

Answer 124: For physician notes that have more than one time associated with them and there is not a specific time in the note indicating when the physician identified a suspected infection or Severe Sepsis, use the time the note was opened or started. If there are multiple times, the goal is to use the earliest time associated with the documentation.

Question 125: What is considered an "elevated lactic acid" level?

Answer 125: For purposes of the SEP-1 measure, an elevated lactate level is 2 mmol/L.

Question 126: Question about SIRS criteria: In the second example, SIRS Criteria #1 was met at 0800SIRS. Criteria #2 was met at 1200Do. Do these two criteria need to occur simultaneously, or is it acceptable to have two positive criterions within the six hour window, even if they aren't simultaneous? For example, let's say the WBC at 0800 went down to 10 at 0900. Would SIRS criteria still have been met at 1200 when the temp was documented at 38.4, or would the 38.4 degree temperature now become the first SIRS criteria?

Answer 126: The SIRS criteria do not need to be met simultaneously. They must be within six hours of all the clinical criteria.

Question 127: Please explain again what the counters are and what happens when it says to "add a counter?"

Answer 127: The counters keep track of the number of interventions related to the Severe Sepsis and Septic Shock "bundle" data elements that are completed according to the specifications and within the correct time frame. When "one is added" to a

counter, that means that element was completed appropriately and within the correct time frame.

Question 128: Why do lactate levels six hours prior to Severe Sepsis count?

Answer 128: For determining presence of Severe Sepsis based upon clinical criteria, all clinical criteria must be met within six hours of each other. The time the last of the clinical criteria is met is considered the Severe Sepsis presentation time. This means the oldest lactate level that could be used for determining presence of Severe Sepsis would be six hours prior to Severe Sepsis presentation.

Question 129: Slide 40 indicates that UB-04 forms are not allowed for establishing discharge information. This information is contradictory to the Specification Manual in which the Suggested Data Sources in the Specification Manual list that as a Suggested Data Source. This is specifically educated in the measure that the claim information should only be used when chart review fails to provide the information. Please advise on this clear discrepancy.

Answer 129: The Discharge Disposition data element specifically lists "Coding documents" and "UB-04" as Excluded Data Sources, meaning they cannot be used for this data element.

Question 130: Our Sepsis marker is Procalcitonin. We do not have the capability of doing a lactate level. Procalcitonin is a valid marker of Sepsis. Will we be noncompliant if we use Procalcitonin instead of lactate?

Answer 130: The Surviving Sepsis Campaign International guidelines, published in 2012, upon which the SEP-1 measure is based, do not recommend the use of procalcitonin or other biomarkers to discriminate the acute inflammatory pattern of Sepsis from other causes of generalized inflammation. If a lactate is not drawn within three hours of Severe Sepsis presentation, the case will not pass the measure.

Question 131: What if the patient has Severe Sepsis and the provider does not order a lactate?

Answer 131: The case will not pass the measure.

Question 132: Contraindication to Care: Can a documentation of limited treatment in Advance Directives be part of this answer (i.e., DNR with limited treatment)?

Answer 132: For the Administrative Contraindication to Care data element, this documentation would have to be specific to refusal of blood draws, fluid administration, and antibiotic administration.

Question 133: Do I use those times or the time the SBP dropped to 80 on day three?

Answer 133: This question appears to be incomplete and cannot be answered based on the information provided.

Question 134: Where can we download a copy of SEP-1 Abstraction blank tool?

Answer 134: An abstraction tool for SEP-1 is under development but not yet available. A notification will be sent out when it is available.

Question 135: Re: Administrative Contraindication to Care – Does this apply to care provided up to and during the six hour counter or the entire hospital stay?

Answer 135: The Administrative Contraindication to Care data element applies throughout the entire hospital stay.

Question 136: Slide 51/52: The Spec Manual has the word "and" and not "or" for broad spectrum ABX. Does this mean that they would need both, 24 hours prior to and three hours after to meet the measure?

Answer 136: Feedback has indicated the word "and" leads people to believe the patient must receive an antibiotic both within 24 hours prior to Severe Sepsis presentation "and" within three hours following presentation. This is not the case. I used the word "or" in the presentation to help dispel that misinterpretation. The wording is being revised to replace the word "and" with "or" in the Specifications Manual.

Question 137: RE: slide 49 – The first bullet says > -360. Isn't that greater than six hours prior to presentation?

Answer 137: This is the result of a calculation, Initial Lactate Date and Time "minus" Severe Sepsis Presentation Date and Time. If Initial Lactate Date and Time is before Severe Sepsis Presentation Date and Time the result will be a "negative number." Please note the "negative" sign in front of 360. This is indicating >= "negative" 360 minutes. Greater than a negative number would be any negative number between that number and zero, as well as any positive number. In this case it is identifying the low end of a range "negative" 360 minutes (which is equivalent to six hours before Severe Sepsis presentation).

Question 138: How is hourly urine output calculated if it is not documented hourly? Do we average the output by hour?

Answer 138: If it is not documented hourly such that you are not able to determine whether or not the urine output is < 0.5 mL/kg/hour for two hours, do not use this as one of the criteria because it would be unknown.

Question 139: Does the antibiotic have to be started or completed in the time frame? Do you abstract the start time as the dose time?

Answer 139: You will abstract the start time as the dose time. Both need to be started within the time frame but neither has to be completely infused.

Question 140: If a patient was on an ABX prior to arrival to the hospital, would you use the time of the last dose at home for the administration date and time for a broad spectrum ABX, if it is the correct medication?

Answer 140: If the date and time of that IV antibiotic is known and documented in the medical record, it should be used.

Question 141: Why do you go back more than 24 hours and abstract that dose?

Answer 141: If the same antibiotic that was given within 24 hours of Severe Sepsis presentation was also given earlier than 24 hours prior to presentation, the case is excluded. The only way to determine this is to review the medical record and abstract a dose that was also given more than 24 hours prior to presentation.

Question 142: Slide 51: What if you have an Initial Lactate Level that was normal seven hours prior to Sepsis presentation, and then the patient showed signs of deteriorating. A second Lactate level was drawn within the window (say one hour after Sepsis presentation). How do you abstract that?

Answer 142: The time window within which the lactate must be drawn to count in the SEP-1 measure is “six hours prior” to “through three hours following” Severe Sepsis presentation. The Initial Lactate Level Collection data element indicates that if there are multiple lactate levels, only abstract the level drawn closest to the time of presentation of Severe Sepsis. This lactate level is considered the initial lactate for purposes of the measure.

Question 143: On slide 54 – Does doses given before arrival to your facility?

Answer 143: This question appears to be incomplete and cannot be answered based on the information provided.

Question 144: Dose time for IV antibiotic is start/hang time or finish time?

Answer 144: You will abstract the start time as the dose time.

Question 145: Antibiotics: Can you please send us the examples in writing? It was hard to follow verbally.

Answer 145: The October session will go into much more detail on some of the more complex data elements, such as this. I will be sure to include more written examples and graph displays.

Question 146: Can you please review the antibiotic date and time again. I am confused. If a patient has several ABXABX, how do you know which is for Severe Sepsis?

Answer 146: If antibiotics are given in the 24 hours prior to presentation, it doesn't matter whether or not they are for Severe Sepsis. What is important is that they received antibiotics. You will check to determine the earliest date and time of each antibiotic given in the 24 hours prior to presentation. You will enter the date and time of the earliest dose from all the antibiotics given in the 24 hours prior to presentation.

Question 147: If a patient has multiple antibiotics given within 24 hours prior to Severe Sepsis presentation, do you trace each antibiotic back to see if any dose was given before 24 hours prior to presentation of Severe Sepsis?

Answer 147: Yes, if any antibiotics were given in the 24 hours prior to presentation and the same antibiotics were also given earlier, the case will be excluded from the measure. Cases excluded from the measure do not count against a facility.

Question 148: Was a broad spectrum or other antibiotic administered intravenously in the time window 24 hours prior to and three hours following the presentation of Severe Sepsis? (Broad Spectrum or Other Antibiotic Administration) 1? Yes, Aztreonam 05/19 01:00 Vanco 05/18 22:30 2? No, or Unable to Determine (UTD) To choose Value 1? There must be a least one dose of the antibiotic given in the 24 hours preceding or three hours after the Severe Sepsis presentation time If antibiotics were administered in the prescribed time window both before and after Severe Sepsis presentation, abstract only the dose closest to and proceeding the time of presentation of Severe Sepsis. Aztreonam 05/17 10:00 enter this time? Vanco 05/17 08:05 enter this time?

Answer 148: If Aztreonam and Vancomycin were both given within the 24 hours prior to presentation and also both given earlier than 24 hours prior to presentation you will select “1 (Yes)" for Broad Spectrum or Other Antibiotic Administration. Since it appears they were also both given earlier than 24 hours prior to presentation, you will enter the date and time of the earliest dose for the Broad Spectrum or Other Antibiotic Administration Date and Time.

Question 149: I thought antibiotics for more than 24 hours before presentation was an exclusion. Does a change in antibiotics invalidate this?

Answer 149: Per the specifications in the manual and the algorithm, antibiotics that are given both within 24 hours prior to presentation and prior to that result in a case being excluded. If the antibiotic was only given within 24 hours prior but not earlier, the case is not excluded. Cases are also not excluded if the patient was on a different antibiotic more than 24 hours prior to presentation.

Question 150: If a patient received a dose of IV antibiotic at another facility, ED, or Urgent Care and states it was clearly within 24 hours but there is no actual documentation for this, can the patient’s statement be considered for abstraction?

Answer 150: No, you will need a specific date and time documented in the medical record that the antibiotic was actually given.

Question 151: For SIRS and Organ Dysfunction in determining Severe Sepsis, do we use collection times or reported times for labs?

Answer 151: For determining the presence of Severe Sepsis you need to use the reported times. The collection times only reflect when the lab was drawn. The results allow for the determination of whether or not Severe Sepsis is present. As such, Severe Sepsis presentation is known when the abnormal results are known.

Question 152: Does given equal time antibiotic hung and infusion started or when dose is complete?

Answer 152: You will abstract the start time as the dose time.

Question 153: Would I answer the 05/17 time not the 05/19 and is excluded from the case?

Answer 153: This question appears to be incomplete and cannot be answered based on the information provided.

Question 154: So if the presentation time was 0100, you would look for any antibiotics given within 24 hours prior to SSP and then look for the time it was first given, even if it was given three days prior, and abstract that date and time?

Answer 154: Correct.

Question 155: Slide 57: If the patient was on an ABX for > 24 hours to presentation time, and this was not a broad spectrum ABX, would it still be excluded? (Ex: Vancomycin monotherapy for two days prior to presentation)

Answer 155: If the patient was on IV Vancomycin for two days prior to presentation and also received a dose of IV vancomycin within 24 hours prior to presentation, you would enter the date and time of the earliest dose given (two days prior) and the case will be excluded. If the patient was on IV Vancomycin for two days prior to presentation and DID NOT receive a dose of IV vancomycin within 24 hours prior to presentation, then you ignore the vancomycin doses given two days prior to presentation.

Question 156: The Surviving Sepsis Campaign SIRS criteria was updated in 2001 and then republished again in 2012. Why do you follow the old criteria for this measure that considers only four indicators, when the updated Surviving Sepsis Campaign criteria considers the following 12 indicators

Answer 156: We recognize the list of SIRS criteria and some organ dysfunction criteria in the SEP-1 measure may be different from the 2012 guidelines, and what particular hospitals are using to screen or qualify for Severe Sepsis and Septic Shock.

Originally the idea behind defining SIRS was to define a clinical response to a non-specific injury of either infectious or non-infectious origin. The decision to list the four primary SIRS criteria only and not other variables, such as elevated glucose or altered mental status, is based on the fact that these latter criteria were only added on and are less specific that the initial criteria included. Although inclusion of these expanded variables might allow you to detect more cases of Sepsis, they may also broaden criteria so that screening becomes overly difficult and not particularly specific for the condition. It is perfectly acceptable to use the broader criteria for screening and identification purposes in your hospital. Cases identified based on the broader criteria will be excluded from the SEP-1 measure. This exclusion does not count against the hospital.

Question 157: If the first antibiotic given was not from the monotherapy or dual therapy lists

Answer 157: This question appears to be incomplete and cannot be answered based on the information provided.

Question 158: Do we list all ABX if there are more than one type of ABX (i.e., Levaquin and Zosyn) were given within the required time (24hrs prior to or three hours after Severe Sepsis presentation)?

Answer 158: The measure does not require entry of any antibiotic names.
You select "Yes" for Broad Spectrum or Other Antibiotic Administration if ANY antibiotic is given in the time frame from 24 hours prior to through three hours after Severe Sepsis presentation. Out of all the antibiotics given, you enter the date and time of the earliest dose given. The ONLY time the measure evaluates what antibiotics were given is if the patient ONLY received antibiotics in the three hours following Severe Sepsis presentation. You select "Yes" or "No" for Broad Spectrum or Other Antibiotic Administration Selection based on whether or not the antibiotic(s) given within three hours after presentation were on Tables 5.0 and 5.1.

Question 159: The beta-lactam antibiotics are listed (i.e. amoxicillin/Clavulanate to piperacillin/tazobactam). For some reason carbapenems, which are also a beta-lactams, (i.e. meropenem) are not listed in the table 5.0. Meropenem is considered very broad spectrum coverage. Table 5.1 is also interesting since it lists some agents that are no longer available (FDA removed telithromycin from the market) and teicoplanin that is available only in Europe. So, that being said, there is a lot of concerns regarding these two tables. Is it possible for someone to address our concerns/questions either electronically and/or have a conversation with our Clinical Pharmacist who oversees our Antibiotic Stewardship program?

Answer 159: Carbapenems are listed and include Doripenem, Eratepenem, Imipenem and Meropenem. If you have recommendations for what you feel should be included

as broad spectrum antibiotics please submit those as an inquiry via the QualityNet Q&A tool (https://cms-ip.custhelp.com/).

Question 160: Where can we find table 5.0 and table 5.1?

Answer 160: Tables 5.0 and 5.1 can be found in the Appendix C of the manual.

Question 161: Please clarify when using triage time is appropriate?

Answer 161: Triage time is ONLY used if the patient arrives to the ED with Severe Sepsis OR if Severe Sepsis is identified during triage. For Severe Sepsis to be considered identified during triage, ALL three clinical criteria must be met during triage. After triage (even if the patient is still in the ED) you would use the earlier of either when the last of the three clinical criteria are met OR physician/APN/PA documentation of Severe Sepsis. If some but not all of the criteria are met during triage, do not use triage time. If the remaining criteria are met after triage, use the time the last of the clinical criteria are met.

Question 162: Please tell us where to find the Combination Class Table?

Answer 162: The combination table can be found under the Notes for Abstraction of the *Broad Spectrum or Other Antibiotic Administration Selection* data element in the Alphabetical Data Dictionary in Manual v5.0a.

Question 163: If using a combination therapy, do both antibiotics have to be started in the time frame or just one?

Answer 163: Both need to be started within the time frame but neither has to be completely infused.

Question 164: What about antibiotics given interosseous, does it meet compliance? Since these were the first time the antibiotic given?

Answer 164: Interosseous is not currently identified as an acceptable route and is not mentioned in the Surviving Sepsis International guidelines. We will forward this to the measure stewards and writers for future consideration.

Question 165: Column B of the combination antibiotic therapy table has cephalosporins first and second generation - are 3rd and 4th generation included or are 1st and 2nd only required?

Answer 165: Third and fourth generation cephalosporins are listed in Table 5.0 Antibiotic Monotherapy, Sepsis.

Question 166: Where do we find the Combination Antibiotic Therapy Table?

Answer 166: The combination table can be found under the Notes for Abstraction of the Broad Spectrum or Other Antibiotic Administration Selection data element in the Alphabetical Data Dictionary in Manual v5.0a.

Question 167: Please explain the difference between data elements, Broad Spectrum or Other Antibiotic Administration and Broad Spectrum or Other Antibiotic Administration Selection, in regard to using Tables 5.0 and 5.1 and when not having to use table 5.0 and 5.1.

Answer 167: Broad Spectrum or Other Antibiotic Administration is simply identifying whether or not the patient received any IV antibiotic in the 24 hours prior to through hours following Severe Sepsis presentation. While it does include reference to Table 5.0 and Table 5.1 for antibiotics given in the three hours following presentation, this is being removed based on abstractor feedback reflecting it is confusing.

Broad Spectrum or Other Antibiotic Administration Selection is only abstracted if the only antibiotics received were given in the three hours following Severe Sepsis presentation. This is the only data element where Table 5.0 and Table 5.1 are really relevant.

Question 168: So based on the information on slide 62, the Initial antibiotic date and time recorded is not reflective of the antibiotic selection as long as the appropriate antibiotic is given within the appropriate time frame?

Answer 168: Correct. The initial antibiotic date and time is the earliest time an IV antibiotic was given.

Question 169: Please clarify the columns A and B on table 5.1.

Answer 169: If an antibiotic from Table 5.0 Antibiotic Monotherapy, Sepsis was not given, review to see if any antibiotics from Table 5.1 Antibiotic Generic/Trade Name Crosswalk, Sepsis. For every antibiotic given that is on Table 5.1, make note of the class it belongs to designated by the shaded row immediately above the antibiotic name. Next, refer to the Combination Antibiotic Therapy Table in Broad Spectrum or Other Antibiotic Administration Selection data element. If there was at least one antibiotic from a class in Column A and at least one from a class in Column B, the case meets the intent of the Broad Spectrum or Other Antibiotic Administration Selection data element. There is not a Column A and Column B actually in Table 5.1. Also note that the Sepsis antibiotic tables 5.0 and 5.1 are ONLY used for the Broad Spectrum or Other Antibiotic Administration Selection data element, which is evaluated when antibiotics are ONLY given in the three hours following Severe Sepsis presentation.

Question 170: Can you speak briefly on the "Time Clock" regarding transfers from one facility to another?

Answer 170: If a patient transfers in from another hospital, they are excluded from the measure. If they transfer in from another facility that does not result in an exclusion (e.g., skilled nursing facility) and Severe Sepsis was identified at the skilled nursing facility, they would have Severe Sepsis on arrival and triage time would be used.

Question 171: Do both antibiotics from Column A and Column B have to be given within the three hour time frame?

Answer 171: Both need to be started within the time frame but neither has to be completely infused.

Question 172: In the antibiotic therapy, if there was a class A and class B antibiotic ordered, is it necessary for both to be given within three hours from "time zero" or one from the column will be enough to start with?

Answer 172: Both need to be started within the time frame but neither has to be completely infused.

Question 173: How were the combinations listed in column A and B derived?

Answer 173: This information was provided by the measure stewards and combines narrow spectrum antibiotics to ensure broad spectrum coverage is provided.

Question 174: Do you have to have the 48 hours and within three hours?

Answer 174: This question appears to be incomplete and cannot be answered based on the information provided.

Question 175: Do you have to have two sets of blood cultures to meet the measure?

Answer 175: No, if more than one blood culture is drawn, you will abstract the earliest one drawn in the time frame.

Question 176: Re: Antibiotics Selection – Can we cover patients with multiple antibiotics allergies?

Answer 176: The antibiotics listed in the Tables should provide sufficient options for most patients with antibiotic allergies.

Question 177: Scenario: 0800 temp 102, P 110. 1100–MD documents pneumonia. 1500– lactic acid increases to 3.0. 2200– MD documents Severe Sepsis. Do I use the 2200 as presentation time even though patient clearly met Severe Sepsis several hours prior?

Answer 177: Based on the scenario in your question, the clinical criteria were not meet within six hours of each and cannot be used for determining presence of Severe Sepsis.

The physician documentation of Severe Sepsis at 2200 would therefore be Severe Sepsis presentation time.

Question 178: What happens when only one culture was drawn not two? How does that count?

Answer 178: Only one blood culture is required for the measure. If more than one blood culture is drawn, you will abstract the earliest one drawn in the time frame.

Question 179: Can you get information for initial antibiotics from a previous encounter?

Answer 179: This may in part depend on whether or not you are using an electronic health record (EHR). The Introduction to the Data Dictionary indicates that Data element information should be retrieved from the current medical record, covering the admission and discharge date being abstracted. Information ascertainable from previous testing or previous history AND determined to be part of the current medical record may be used in abstraction. As electronic data are available at all times during the hospitalization, it is acceptable to use this data for abstraction purposes.

Question 180: If IV ABX was given greater than 24 hours prior to presentation (i.e., 28 hrs. prior), will the case be excluded from the measure? You would still have to answer "no" to blood cultures if not done prior to ABX given?

Answer 180: If an IV antibiotic was given within 24 hours prior to Severe Sepsis presentation and an earlier dose of that same antibiotic was given more than 24 hours prior to presentation, the case is excluded from the measure and you do not collect blood culture information.

Question 181: Do both of the ATB have to be started in the three hour period?

Answer 181: Both need to be started within the time frame but neither has to be completely infused.

Question 182: What if a patient comes to the ER and a blood culture is drawn but the patient is sent home with oral antibiotics? The next day they come back and have developed Severe Sepsis. Because there is only mention in the current medical record and the exact time of the blood culture was done on a separate account number, does the case fail because you don't have a specific time in the current record of when that blood culture was drawn?

Answer 182: This may, in part, depend on whether or not you are using an electronic health record (EHR). The Introduction to the Data Dictionary indicates that Data element information should be retrieved from the current medical record, covering the admission and discharge date being abstracted. Information ascertainable from previous testing or previous history AND determined to be part of the current medical record may be used in abstraction. As electronic data

are available at all times during the hospitalization, it is acceptable to use this data for abstraction purposes.

Question 183: Considering that the American Burn association has different parameters for Sepsis in the burn patient, is exclusion of a burn patient being considered?

Answer 183: At this point in time burn patients are not excluded. Your comment will be taken into consideration for future versions of the manual.

Question 184: If the antibiotic was started in a SNF or at Home as IV therapy, does nursing home documentation count towards the data collection?

Answer 184: If that documentation is considered part of the current hospital medical record it is acceptable.

Question 185: Is this blood culture time 24hours prior to the administration to any antibiotic or just any broad spectrum antibiotic IV?

Answer 185: The 24 hours is not in relation to antibiotics from Table 5.0 or Table 5.1. If the patient was on IV antibiotics within 24 hours before presentation of Severe Sepsis, begin abstraction of a blood culture 24 hours before the first antibiotic dose was given. If the patient was not on antibiotics at the time of presentation of Severe Sepsis, begin abstracting 24 hours prior to the time of presentation of Severe Sepsis.

Question 186: Our blood gas machine includes lactate level in every ABG drawn. I have reviewed a Sepsis record and the blood gases were drawn hourly. It is going to be a fall out if the repeat lactate level will be drawn before the three hour period from Severe Sepsis presentation date and time. Can I abstract a repeat lactate level drawn after the three hour counter if there is one drawn, even if it was not the lactate level drawn following the initial lactate level? Should the repeat lactate level be the first lactate level drawn after the initial lactate level?

Answer 186: A repeat lactate level is defined as the next lactate level drawn after the initial lactate level. It is not dependent on or part of the three hour bundle (completed within three hours of Severe Sepsis presentation). The repeat lactate level must be drawn in the time period of six hours after the date and time of Severe Sepsis presentation (drawn within six hours of Severe Sepsis presentation).

Question 187: Will these rules replace the Sepsis reporting requirement for NYS DOH?

Answer 187: I am unable to answer this question. That will be a determination made by the NYS DOH.

Question 188: The blood culture collection is confusing. On slide 68, the question is whether a blood culture was collected 48 hours prior to and three hours following Severe

Sepsis. Why would we only look back 24 hours if the ABX were given exactly at time of presentation of Severe Sepsis?

Answer 188: The Blood Culture data elements specify that if the patient was started on antibiotics within 24 hours before presentation of Severe Sepsis, begin abstraction of a blood culture 24 hours before the first antibiotic dose was given. If the antibiotic was started at the same time as or within three hours after Severe Sepsis presentation, to begin blood culture abstraction 24 hours before Severe Sepsis presentation. The ONLY time you would actually start abstraction of the blood culture at 48 hours prior to Severe Sepsis presentation is if the antibiotic was given exactly at 24 hours prior to Severe Sepsis presentation. Because the blood culture abstraction starts at 24 hours prior to antibiotic administration, this would be 48 hours prior to Severe Sepsis presentation.

Question 189: Please clarify when you state "Severe Sepsis presentation" you mean the Severe Sepsis present date and time? Is this correct?

Answer 189: Yes, that is correct.

Question 190: What about drug allergies? I happen to be allergic to all aminoglycosides, quinolones, and azactam. Would I be excluded or would I fall out?

Answer 190: The antibiotics listed in the Tables should provide sufficient options for most patients with antibiotic allergies.

Question 191: If only receiving antibiotics from Table 5.1 do both antibiotics have to be given after presentation within three hours of Severe Sepsis?

Answer 191: Both need to be started within the time frame but neither has to be completely infused.

Question 192: If there are 2 sets of blood cultures ordered and first set was drawn prior to antibiotic but the second set was drawn after the antibiotic, do you count the first set drawn?

Answer 192: The Blood Culture Collection Date and Time data elements indicate that if multiple blood cultures were drawn, abstract the earliest blood culture drawn in the time window 48 hours prior to or three hours following the presentation of Severe Sepsis. In the example provided, you can count the first set drawn.

Question 193: On slide 49, are the </> signs before the 360 minutes backwards? Shouldn't the first one be <=360 minutes, and the second one be >360 minutes?

Answer 193: The slide is correct. Please note the "negative" sign in front of 360. This is indicating >= "negative" 360 minutes. Greater than a negative number would be any negative number between that number and zero as well as any positive

number. So in this case it is identifying the low end of a range "negative" 360 minutes (which is equivalent to six hours before Severe Sepsis presentation). This is the result of a calculation Initial Lactate Date and Time "minus" Severe Sepsis Presentation Date and Time. If Initial Lactate Date and Time is before Severe Sepsis Presentation Date and Time the result will be a "negative number."

Question 194: Slide 57 indicates antibiotic given earlier than 24hrs will assign the case to category B; however, slide 51 indicates that this would require allowable value of "No," which actually bypasses the opportunity for category B placement and goes straight to "W" (the last page of the algorithm). The data element for administration and the algorithm do not align. Please clarify.

Answer 194: The Broad Spectrum or Other Antibiotic Administration data element only identifies whether or not an antibiotic was given in the time period 24 hours prior to presentation through three hours after presentation. Allowable Value "2 (No)" would be selected if the patient did not receive any antibiotics in this time period. Patients who received a dose of the same antibiotic earlier than 24 hours are not excluded with this data element. The exclusion occurs after calculating the broad spectrum antibiotic time (the difference between the earliest does of IV antibiotic and Severe Sepsis presentation time). Those cases where the patient received an antibiotic within 24 hours prior to presentation and also received a dose of the same antibiotic more than 24 hours prior to Severe Sepsis presentation will be excluded.

Question 195: Can an MD exclude a patient with decompensated heart failure as evidenced by clinical exam, crackles, edema...?

Answer 195: No, the measure does not contain provisions for exclusions such as this.

Question 196: Are you referring to a venous or arterial lactate? Please specify.

Answer 196: Venous and arterial lactate are both acceptable and the ranges in the measure apply to both.

Question 197: The lactate manufacturers are listing a normal lactate up to 2.2. Why is Severe Sepsis listed as > 2?

Answer 197: For determining a sign of organ dysfunction, the requirement in the Surviving Sepsis Campaign International guidelines and the SEP-1 measure is an elevated lactate. While what is considered abnormal may vary depending on your lab references, it is most commonly 1.8 to 2.2. Hyperlactatemia is defined as lactate levels greater than 2.0 mmol/L and is associated with increased mortality. This is also consistent with the Surviving Sepsis Campaign data collection and information. For measure purposes an elevated lactate is 2.0.

Question 198: Our entities use Lactic Acid tests instead of Lactate Level. Is the Lactic Acid Test equal to Lactate Level?

Answer 198: Yes.

Question 199: If a patient received an antibiotic more than 24 hours prior to presentation of Severe Sepsis, then it looks like you answer “No” to the antibiotic question and then you skip down and don't even enter the antibiotic. But if the patient is on antibiotics more than 24 hours prior to presentation of Severe Sepsis, then they are excluded, but how does the algorithm know the patient had ABX more than 24 hours prior if you don't even enter them in?

Answer 199: If a patient received an antibiotic within the time window of 24 hours prior to presentation through three hours following presentation you would select "Yes" to Broad Spectrum or Other Antibiotic Administration, regardless of whether they also received a dose of the same antibiotic more than 24 hours prior to presentation. You only select "No" if the patient did not receive any antibiotic in the time window of 24 hours prior to presentation through three hours following presentation. You enter the date and time of the earliest dose of antibiotic given in the time window 24 hours prior to presentation through three hours following presentation. If the same antibiotic was given more than 24 hours prior to presentation that is the date and time you enter. The exclusion is based on the date and time you enter for the earliest dose of antibiotic.

Question 200: Can we count repeat lactate done even if it is only one hour apart?

Answer 200: A repeat lactate level is defined as the next lactate level drawn after the initial lactate level. If must be in the time period of six hours after the date and time of Severe Sepsis presentation.

Question 201: What if ABX are given prior to cultures drawn, for example, if cultures couldn't be obtained, but IV access is established so IV ABX can be administered?

Answer 201: The case will not pass the measure if IV antibiotics are given prior to blood cultures. Note however, if there is documentation indicating there was an unsuccessful attempt to draw the blood cultures, this can count as a "Yes" for Blood Culture Collection if it is documented. In this case, the date and time of the unsuccessful attempt would be used.

Question 202: If repeat lactate level is not done, does that mean the patient fails the Severe Sepsis measure?

Answer 202: Yes, if the initial lactate is elevated (> 2 mmol/L) and a repeat lactate is not drawn, the case will fail the measure.

Question 203: Was a blood culture collected in the time window 48 hours prior to and three hours following the presentation of Severe Sepsis? 05/17 22:26 -05/20

01:26(Blood Culture Collection) 1 Yes 2 No or Unable to Determine if the patient was started on antibiotics within 24 hours before presentation of Severe Sepsis, begin abstraction of a blood culture 24 hours before the first antibiotic dose was given? If the patient received the first dose of antibiotics more than 24 hours prior to the time of presentation of Severe Sepsis, choose Value Severe Sepsis 05/19 22:26 more than 24 hours if anything given before 05/18 22:26 received dose Aztreonam 05/17 17:00Blood culture 05/17 03:05; 05/17 06:52; Aztreonam 05/17 10:00 enter this time? Vanco 05/17 08:55 enter this time? Blood Culture 05/18 00:43 05/19 00:50Aztreonam 05/19 01:00 Vanco 05/18 22:30.

Answer 203: If Aztreonam and Vancomycin were both given within the 24 hours prior to presentation and also both given earlier than 24 hours prior to presentation you will enter the date and time of the earliest dose for the Broad Spectrum or Other Antibiotic Administration Date and Time.

As identified in the Blood Culture Collection data element, if the patient received the first dose of antibiotics more than 24 hours prior to the time of presentation of Severe Sepsis, select Value “2 (No).” Because you will be selecting value "2" for this data element, you will not be required to enter a date and time for the blood culture.

Question 204: Who is responsible for documenting a failed lactate draw? Our lab does not document in the EHR.

Answer 204: The data elements do not specify who must document unsuccessful lactate lab attempts. As long as it is documented as an unsuccessful attempt, the documentation can be used.

Question 205: What does "Add 1 to Sepsis three hour counter" mean?

Answer 205: The counters keep track of the number of interventions related to the Severe Sepsis and Septic Shock "bundle" data elements that are completed according to the specifications and within the correct time frame. When "one is added" to a counter, that means that element was completed appropriately and within the correct time frame.

Question 206: I have a question about the algorithm for calculating initial lactate time and blood culture time. I don't understand why you would ever have a situation in which the calculated values for initial lactate would be <360 or >180 minutes since you would answer "no" to the question, “initial lactate level collection based upon no level between six hours prior to and three hours after Severe Sepsis,” which would skip the initial lactate level date and time collections. The blood culture calculations are the same if I answer "no" for the blood culture collection collected (not within 48 hours and three hours after.

Answer 206: That is currently how the algorithm is designed. We are looking further into the design to see if there are ways to decrease the abstraction burden based upon questions such as yours.

Question 207: Suppose a patient is admitted from the ED with a diagnosis of pneumonia, but then two days into the hospital stay develops Severe Sepsis. Should that patient be abstracted for SEP-1 since the Severe Sepsis was not diagnosed in the ED?

Answer 207: Yes, where Severe Sepsis or Septic Shock is identified does not matter.

Question 208: Also, the initial Lactic Acid result normal high range is 2.1 or 2.2 for some of our entities, which would not be considered abnormal. If the Lactic Acid was 2.2, which is not considered abnormal, would we still have to do a repeat since it is >2?

Answer 208: Yes, for determining a sign of organ dysfunction, the requirement in the Surviving Sepsis Campaign International guidelines and the SEP-1 measure is an elevated lactate. While what is considered abnormal may vary depending on your lab references, it is most commonly 1.8 to 2.2. Hyperlactatemia is defined as lactate levels greater than 2.0 mmol/L and is associated with increased mortality. This is also consistent with the Surviving Sepsis Campaign data collection and information. For measure purposes, an elevated lactate is 2.0.

Question 209: **S**o if Severe Sepsis is present on admit and two days later the patient refuses lab draws and or antibiotics, they are excluded from the measure all together?

Answer 209: Correct.

Question 210: Severe Sepsis present guidelines state suspected infection must be documented by an MD/PA/APN. It does not elaborate with suggesting nursing documentation can be taken. If nursing can be taken, then CMS needs to make this clarification ASAP. I cannot get an answer from *QualitNet* on this because they are so busy with questions. This is a crucial inter-presentation for answering the YES/NO for Severe Sepsis present.

Answer 210: Currently, as worded, the data element does not state nursing documentation is acceptable. It also does not state that it is not acceptable. In the allowable sources for this documentation, it does indicate the entire ED record which would include nurses' notes. In facilities where nurses routinely screen for Severe Sepsis and Septic Shock nurses do document when an infection is suspected as part of the screening process. Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 211: Do we need to do a repeat lactic acid draw if lactic acid >2?

Answer 211: Yes.

Question 212: Patient has Severe Sepsis. The BP dropped to 62/39 @ 1400, Dopamine started at 1430, and Levophed at 1443; NS 500 ml bolus given at 1753. What do I answer to Crystalloid Fluid administration? If MD aggressively starts the patient on vasopressor instead administering crystalloid fluids, would we answer crystalloid fluid not administered at/after presentation of Septic Shock?

Answer 212: Since the volume of normal saline in your question is less than 30 mL/kg you would need to select "No" for Crystalloid Fluid Administration.

Question 213: For broad spectrum antibiotic administered IV within 24 hours and three hours following, you said any antibiotic was acceptable. Why does the manual have bullet points referring to the Appendix 5.0 and 5.1 for selection?

Answer 213: Broad Spectrum or Other Antibiotic Administration is simply identifying whether or not the patient received any IV antibiotic in the 24 hours prior to through three hours following Severe Sepsis presentation. While it does include reference to Table 5.0 and Table 5.1 for antibiotics given in the thee hours following presentation, this is being removed based on abstractor feedback reflecting it is confusing. Broad Spectrum or Other Antibiotic Administration Selection is only abstracted if the only antibiotics received were given in the three hours following Severe Sepsis presentation. This is the only data element where Table 5.0 and Table 5.1 are really relevant.

Question 214: What specifically is required in the triage not to be counted as "time zero?"

Answer 214: Triage time would not be used if some, but not all criteria, were met during triage and the remaining criteria were met after triage. Triage time would also not be used for a patient where none of the clinical criteria were met in triage, but all three criteria were met after triage time. In these cases, the time the last of the three clinical criteria were met would be used as Severe Sepsis Presentation time.

Question 215: What happens if you have all of the criteria but the lactate level is only 1.7?

Answer 215: If all the criteria for Severe Sepsis are met, then the patient has Severe Sepsis and you need to continue abstracting. If the lactate is less than 2, a repeat lactate is not necessary.

Question 216: On Slide number 24 titled, “Severe Sepsis Present: Suspected Infection,” bullet four states "Nursing documentation acceptable." However, the newest Specification Manual (v5.0a) Severe Sepsis Present definition states “... or similar reference in progress notes, consult notes or similar Physician/APN/PA documentation.” It does not indicate that nursing documentation is acceptable. Version 5.0 did say Physician/APN/PA documentation preferably. Can you clarify that nursing documentation is acceptable?

Answer 216: Currently the worded data element does not state nursing documentation is acceptable. It also does not state that it is not acceptable. In the allowable sources for this documentation, it does indicate the entire ED record which would include nurses' notes. In facilities where nurses routinely screen for Severe Sepsis and Septic Shock nurses do document when an infection is suspected as part of the screening process. Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 217: If a patient with Severe Sepsis with no hypotension was given the three hour bundle and on the ninth hour will have hypotension, should the treatment of fluids and vasopressors on the ninth hour be reported because it will be past the protocol's time of six hours?

Answer 217: If Septic Shock presents more than six hours after Severe Sepsis presentation, submission of data and continued abstraction beyond Septic Shock date and time is not required.

Question 218: If antibiotic is given after an unsuccessful attempt to draw blood cultures, will the measure "blood cultures drawn before antibiotic given" pass the measure?

Answer 218: If the date and time of the unsuccessful attempts to draw the blood culture were made before the antibiotic was started, the case will pass this part of the measure.

Question 219: Will the "counters" ordinarily be done by our software vendor as part of the logic to determine if the patient had a variance?

Answer 219: Yes, the counters and calculations associated with them are done behind the scenes by the software into which you enter your data.

Question 220: **S**o we either pass the three hour measure or not. We do not pass if we miss one portion, such as the lactic acid drawn?

Answer 220: Correct. This is an all or none composite measure.

Question 221: Does coding as POA affect the presentation time determination?

Answer 221: Coding does not affect presentation time. Documentation of when the clinical criteria are met or when the physician/APN/PA documents Severe Sepsis will affect presentation time.

Question 222: Did you say that we should not use for Sepsis criteria of organ failure any results due to chronic conditions or medications say that impact lab such as Coumadin?

Answer 222: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 223: Will CAHs need to submit this data?

Answer 223: Critical Access Hospitals are not part of the IQR program and are not required to submit SEP-1. They can voluntarily submit, and we encourage them to do so.

Question 224: Are patients excluded if family has declined vasopressors?

Answer 224: Refusal of vasopressors is not currently an exclusion.

Question 225: How much time is required to abstract an average case?

Answer 225: I do not, at this point, have an average time for abstraction, as it may vary depending on the format of your medical record, complexity of the case, documentation, and a number of the other factors.

Question 226: If physician documents Sepsis, does this exclude the patient for the measure or is this only exclusion for possible infection?

Answer 226: Physician documentation of "Sepsis" does not result in the case being excluded if the clinical criteria are met. Documentation of "Sepsis" is not acceptable as a suspected source of infection and is not acceptable in place of "Severe Sepsis" or "Septic Shock."

Question 227: Blood cultures drawn before antibiotics?

Answer 227: This question appears to be incomplete and cannot be answered based on the information provided.

Question 228: Under the Spec Manual, I cannot open the appendix A, Table 4.01 to look at the diagnosis to be abstracted. Am I correct, you must have DX from this list to even begin abstraction?

Answer 228: Yes, your initial patent population will consist of all patients discharged during the reporting period with an ICD-10 code from this table. The table includes ICD-10 codes for Sepsis, Severe Sepsis, and Septic Shock. If a patient does not have a code from Table 4.01, they will not be in your initial patient population.

Question 229: Is there a tool to conduct a Sepsis study prior to the October 2015 date worksheet available to [use?]

Answer 229: A tool is under development and should be available prior to the go live date of the measure on October 1, 2015.

Question 230: Are there CE points available for this presentation?

Answer 230: Yes, this is discussed in slide 100–105.

Question 231: When do leg raises come into play?

Answer 231: This will be discussed in the second session, which explores Septic Shock and its data elements on September 21.

Question 232: Would you please clarify presentation of Severe Sepsis in the ED when not at triage? You said to use the time of "earlier" criteria, but isn't that only if it is the time of the last criteria met?

Answer 232: After triage (even if the patient is still in the ED), you would use the earlier of either when the last of the three clinical criteria are met OR physician/APN/PA documentation of Severe Sepsis. If some but not all of the criteria are met during triage, do not use triage time. If the remaining criteria are met after triage, use the time the last of the clinical criteria are met. For example, if a patient has two SIRS criteria at 0800, physician documents possible pneumonia at 0815 and there is a sign of organ dysfunction at 0830; clinical criteria are met at 0830. If the physician documents at 0900 possible Severe Sepsis, since the criteria was met "earlier" than the physician documentation of Severe Sepsis, then the Severe Sepsis Presentation time is 0830.

Question 233: Does a CMO order taken via telephone order written by RN qualify for exclusion?

Answer 233: As long as the order is co-signed by the ordering physician, this would be acceptable as an order from a physician and represent physician documentation.

Question 234: Does "Severe" have to be documented with Sepsis? Most of the physicians just document Sepsis.

Answer 234: Yes, “Sepsis” alone is not sufficient. If Severe Sepsis presentation is based upon physician documentation, it must reference "Severe Sepsis."

Question 235: Can the nurse document leg raises?

Answer 235: This will be discussed in the second session on September 21, which explores Septic Shock and its data elements.

Question 236: In order to establish the presence of Severe Sepsis, all the criteria (a, b, c) need to meet. This question is for organ dysfunction and SBP definition. The patient presented to the ED with a BP of 154/62 at 0837, 182/93, 174/71 then 97/76 at

1026. The definition says that an SBP decrease of more than 40 mmHg from the last previously recorded SBP considered normal for that specific patient will meet criteria. Would this scenario meet criteria? What is considered normal for each specific patient is a very broad and individualized. How are we going to define “considered normal?”

Answer 236: In the provided scenario, it is difficult to establish any kind of baseline that could be considered "normal." Defining "normal" may not be easy in every case, and is based on establishing a baseline from existing SBP readings. If a baseline cannot be established, then organ dysfunction based upon a SBP decrease > 40 mmHg cannot be determined.

Question 237: Can you explain what the letter codes on the algorithm stand for?

Answer 237: "B" indicates the measure is not in the measure population; it is excluded. "D" indicates the measure is in the measure population but the intent was not met and the case fails the measure. "X" indicates data is missing, the case is rejected and the missing data must be entered. "W" takes the case to the last page of the algorithm. "E" indicates the case is in the numerator population and passes the measure. All other letter codes connect the algorithm from one page to another page.

Question 238: If Septic Shock develops more than six hours after Severe Sepsis, does the Septic Shock need to be abstracted again?

Answer 238: If more than one episode of Severe Sepsis occurred, you abstract the earliest episode of each. The same is true for Septic Shock.

Question 239: Back to triage time, to use the triage time, do you need to have a screening tool as part of the ED program? If you don't have a screening tool do you then use the times when the criteria are all met?

Answer 239: To use triage time, the patient must either have Severe Sepsis on arrival OR must meet all three criteria during triage. If all three criteria are not met during triage, you will use the time the last of the three criteria are met.

Question 240: Can one SIRS criteria be considered if the second SIRS criteria is within five hours of the first? In other words, if the RR = 22 AT 1200 but the HR does not show elevation at 104 until 1700, is this considered SIRS?

Answer 240: Yes, the SIRS criteria do not need to be met simultaneously. All the clinical criteria must be met within six hours of each other.

Question 241: When the physician is having to recheck the patient at the six hour mark, is that the latest point, or do they have to hit that exact time frame?

Answer 241: The repeat volume status and tissue perfusion assessment must be completed within six hours (<= 360 minutes) after presentation of Septic Shock.

Question 242: For transfer from acute care facility for exclusions, does LTAC count?

Answer 242: According to the Transfer From Another Hospital or ASC data element, if a patient transfers from an Long term acute care (LTAC) you should select "Yes." The specific types of facilities for which you will select “yes” are identified in the Transfer From Another Hospital or ASC data element.

Question 243: If they go from observation to Inpatient, does the counter start during the observation period?

Answer 243: The "time clock" starts from the time Severe Sepsis is identified, regardless of whether the patient's status is observation or inpatient.

Question 244: For the look back time frame for the blood culture, Severe Sepsis “time zero” is defined how? (first or last of the Severe Sepsis indicators)?

Answer 244: Severe Sepsis presentation (time zero) is defined in the Severe Sepsis Presentation data element, on page 337 of the Alphabetical Data Dictionary in the IQR Specification Manual v5.0a, as the earlier of either when the last of the three Severe Sepsis clinical criteria are met, OR physician/APN/PA documentation of Severe Sepsis.

Question 245: MD here. Do the physicians need to explicitly refer to organ dysfunction labs, SIRS, etc., or can this be extracted? Second, what if "correct" ABX administration isn't to use two ABX, i.e., respiratory FQ for pneumonia, or complicated skin infection is treated with clinda/vanco (appropriately), yet these two ABX aren't from Cat. A and B? Finally, why are only IV ABX considered as exclusions when the bioavailability of clinda and the FQs are considered similar IV or PO?

Answer 245: Physicians do not need to explicitly document the lab values for determining SIRS criteria and organ dysfunction. The Abstraction Manual specifies which labs are used for this and the values that are considered abnormal for purposes of the measure. The Surviving Sepsis International guidelines, upon which the SEP-1 measure is based, specifically reference the importance of using broad spectrum antibiotics until the causative organism is known. At which point, they should be adjusted to the specific organism(s) and sensitivities. The only time antibiotics are subject to the review with Table 5.0 and Table 5.1 is if the only antibiotic(s) are given only in the three hours following Severe Sepsis presentation. If a patient receives any antibiotics or combination in the 24 hours prior to presentation, they are acceptable and not subject to Table 5.0 or Table 5.1. Surviving Sepsis International guidelines specifically reference the administration of intravenous antibiotics.

Question 246: Can we watch this Webinar Presentation again? Is this going to be found in IPRO Sepsis Website?

Answer 246: A recording of the presentation will be posted for viewing. An email announcement should be coming out regarding that.

Question 247: Please explain why a case would continue through algorithm after one of the requirements is identified as missing or not done, such as Initial Lactate Level.

Answer 247: That is currently how the algorithm is designed. We are looking further into the design to see if there are ways to decrease the abstraction burden based upon questions such as yours.

Question 248: Regarding patients that "transfer in," does this include a separate "Subacute unit" that are admitted to the hospital?

Answer 248: According to the Transfer From Another Hospital or ASC data element, if a patient transfers from an outside hospital where they were an outpatient or an inpatient you should select "Yes." The specific types of facilities for which you will select yes are identified in the Transfer From Another Hospital or ASC data element.

Question 249: The Administrative Contraindication to Care is regarding refusal, not contraindication such as CHF, ESRD?

Answer 249: Correct. Administration Contraindication to Care is referring to a patient or surrogate care giver refusing blood draws, fluid administration, or antibiotic administration.

Question 250: If a patient comes in with SBP 180 and vacillates between 210 and 170, would you answer 'yes' to Organ Dysfunction if SBP drops to 130, even if the drop may be due to a BP lowering medication?

Answer 250: In the provided scenario, it is difficult to establish any kind of baseline that could be considered "normal." Defining "normal" may not be easy in every case and is based on establishing a baseline from existing SBP readings. If a baseline cannot be established, then organ dysfunction based upon a SBP decrease > 40 mmHg cannot be determined. Additionally in this situation, the drop is due to the BP lowering medication and not due to the infection or Severe Sepsis, so it does not truly represent organ dysfunction.

Question 251: If the physician only documents "Sepsis," would that be considered acceptable for Severe Sepsis?

Answer 251: No, "Sepsis" alone is not sufficient. If Severe Sepsis presentation is based upon physician documentation it must reference "Severe Sepsis."

Question 252: Is a point of care lactate okay to use?

Answer 252: Yes.

Question 253: Re: initial lactate level collection allowable value of 1 for attempted blood draw (slide 42): if never able to obtain lactic acid level, how do we answer initial lactate level result (slide 81)?

Answer 253: Slide 82 Initial Lactate Level Result (slide 3 of 3) states, "If the initial lactate level was drawn but there are not results, select Value "3."

Question 254: Why is the fluid bolus required for Severe Sepsis resuscitation not included in the Severe Sepsis measure?

Answer 254: All crystalloid fluids are included in the Septic Shock portion of the measure because they are related to either determination of Septic Shock or treatment of Septic Shock.

Question 255: Is it considered a fall out if the blood cultures are drawn after antibiotic administration but within three hours of presentation of Severe Sepsis?

Answer 255: If blood cultures were drawn after antibiotics were started, the case will fail the measure.

Question 256: Can you please review the antibiotic times further, specifically if the patient is on antibiotics prior to presentation, if they have doses of the same antibiotic before the 24 hour?

Answer 256: The October session will go into much more detail on some of the more complex data elements, such as this. I will be sure to include more examples and graph displays.

Question 257: Did I understand correctly that an RN cannot document patient refusal, that it has to be documented by a physician/APN?

Answer 257: For the Administrative Contraindication to Care data element, documentation indicating the patient refused blood draws, fluid administration or antibiotic administration must be from a physician, APN or PA to be acceptable. The exception is if patient refusal is in the form of witness-signed consent form; nurses can be the witness who signs the consent.

Question 258: When reading the spec, it says primary and all other diagnosis. Does this mean if DX is number 20 we will still need to abstract the cases?

Answer 258: Yes, cases are included in the initial patient population if they have an ICD-10-CM Principal or Other Diagnosis Code as defined in Appendix A, Table 4.01.

Question 259: Approximately how much time should each abstract time and the hospital burden?

Answer 259: I do not at this point have an average time for abstraction as it may vary depending on the format of your medical record, complexity of the case, documentation, and a number of the other factors.

Question 260: For those who have been practicing abstracting these cases, on average how long is it taking to go through it?

Answer 260: I do not at this point have an average time for abstraction as it may vary depending on the format of your medical record, complexity of the case, documentation, and a number of the other factors.

Question 261: Given the definition of Severe Sepsis "presentation," is that ED admission or admission to inpatient either as transfer or direct admission?

Answer 261: Severe Sepsis Presentation represents the time that Severe Sepsis was identified either by meeting the three clinical criteria OR by physician/APN/PA documentation. It is not necessarily associated with admission or arrival.

Question 262: Slide, page 88: "Add 1 to Sepsis Six Hour Counter:" One what?

Answer 262: The counters keep track of the number of interventions related to the Severe Sepsis and Septic Shock "bundle" data elements that are completed according to the specifications and within the correct time frame. When "one is added" to a counter that means that element was completed appropriately and within the correct time frame.

Question 263: IF a nurse does a screening at 1400 and puts possible suspected UTI but physician does not agree; and then at 2100 put UTI and documents Severe Sepsis, would we take the original nurses thought of suspected UTI or later, the physicians?

Answer 263: This may depend on when other clinical criteria are met. The goal is to abstract the earliest documentation indicating the presence of Severe Sepsis. If the nurse's documentation of "possible suspected UTI" combined with two or more SIRS criteria, and a sign of organ dysfunction occurs before the physician documentation at 2100, then the nurse's documentation could be used.

Question 264: Do you recommend clinicians abstract the Sepsis data for submission versus a coder who is a non-clinician?

Answer 264: This is really an issue that needs to be decided by your facility. In theory, if either is familiar with the measure and abstraction guidelines, either could abstract cases.

Question 265: How would you define Sepsis present on arrival? What documentation would be needed?

Answer 265: This could occur with physician documentation. For example, the physician documents patient arrived to ED with Severe Sepsis in a progress note. This could also occur based on clinical criteria. For example if a patient arrives by ambulance from home meeting all the criteria for Severe Sepsis, and this was communicated to the hospital prior to or on arrival.

Question 266: Blood culture collection: if the patient receives an antibiotic prior to the only blood culture collection, can “yes” still be answered if it was drawn in this time frame of 48 prior through three hours following?

Answer 266: No, determining whether to select "Yes" or "No" is also partly dependent on when the antibiotic was started. The Blood Culture Collection data element indicates that if the patient was on IV antibiotics within 24 hours before presentation of Severe Sepsis, begin abstraction of a blood culture 24 hours before the first antibiotic dose was given. If the patient was not on antibiotics at the time of presentation of Severe Sepsis, begin abstracting 24 hours prior to the time of presentation of Severe Sepsis.

Question 267: What is category W?

Answer 267: Category "W" takes the case to the last page of the algorithm.

Question 268: Will a drop-down window containing the list of broad spectrum antibiotics be available for the abstractor to select the antibiotic(s) used?

Answer 268: I am not able to speak on behalf of how vendors have built tools for data abstraction. Please note, there is no requirement for entering or submitting antibiotic names.

Question 269: Does comfort care count if it is mentioned in a progress note or does an order have to be in place, and if patient got ABX within 24 hours from presentation and patient got it from outpatient, can we take patient's word for it with time and type of ABX?

Answer 269: Comfort Care does not have to actually have been ordered or initiated. Documentation of it within the contexts specified in the Directive for Comfort Care, Severe Sepsis data element is sufficient. For purposes of the measure and abstraction, the date and time of the antibiotic must be documented in the medical record. Patient report time is fine as long as it is documented in the medical record.

Question 270: What are the minimum cases that need to be submitted monthly?

Answer 270: This will depend upon your initial patient population. Monthly sampling is included in the SEP-1 Measure Information Form.

Question 271: If patient is admitted from an urgent care center attached to the hospital, how does the timing of antibiotics or presentation differ? Do antibiotics received prior to admission count? If diagnosis made in UCC, does the clock start?

Answer 271: If documentation of the date and time the antibiotics were given is part of the medical record, it is acceptable. In the event Severe Sepsis was identified in the UCC, then the patient arrived to the ED with Severe Sepsis. In this case, ED triage time would be used for Severe Sepsis presentation time.

Question 272: When establishing "time zero," are you able to count a SIRS criteria if the value later goes back to normal? For example, a patient has a documented source of infection at 0800, organ dysfunction at 0830, HR of 110 at 0900 and then temp of 39 at 1000, but at 1000 the HR is back to normal.

Answer 272: Yes, this is acceptable.

Question 273: Can you please clarify the need for a repeat lactate? If the level is normal below 2, does a repeat lactate level need to be done?

Answer 273: A repeat lactate needs to be drawn if the "initial" lactate is greater than 2. If it is 2 or less, then it does not need to be repeated.

Question 274: If blood cultures were drawn more than 48 hours before Severe Sepsis presentation, do repeat blood cultures need to be drawn?

Answer 274: There is no requirement for repeat blood cultures. If the cultures are more than 48 hours prior to Severe Sepsis presentation, the case will not pass the measure. If cultures were drawn more than 48 hours prior to Severe Sepsis presentation, the only way to pass this part of the measure is for another culture to be drawn within 48 hours prior to presentation. Note however, the time frame for blood culture abstraction is in part based on when an IV antibiotic was given and 48 hours is just the maximum. The notes for abstraction indicate that if the patient was started on antibiotics within 24 hours before presentation of Severe Sepsis, begin abstraction of a blood culture 24 hours before the first antibiotic dose was given. So if a blood culture was drawn 46 hours prior to Severe Sepsis presentation and the antibiotic was given two hours to presentation, the blood culture was drawn 44 hours prior to the antibiotic.

Question 275: What determines presentation, physician documentation, SIRS plus organ dysfunction?

Answer 275: Severe Sepsis presentation is defined in the Severe Sepsis Presentation data element, on page 337 of the Alphabetical Data Dictionary in the IQR Specification Manual v5.0a, as the earlier of either when the last of the three

Severe Sepsis clinical criteria are met OR physician/APN/PA documentation of Severe Sepsis or suspected Severe Sepsis.

Question 276: If there is a mono therapy ATBX chosen and one from Column B, is that outside the guidelines for appropriate choice of Broad Spectrum ATBX?

Answer 276: No, it doesn't matter how many other antibiotics were given. As long as at least one antibiotic from the monotherapy table (Table 5.0) is given, the case will meet the intent of the Broad Spectrum or Other Antibiotic Administration Selection data element. Similarly for the combination therapy (if a monotherapy antibiotic was not given), it doesn't matter how many other antibiotics were given. As long as at least two (one from Column A and one from Column B) were given, the intent of the data element is satisfied.

Question 277: Can we use the volume of fluid from in route administration?

Answer 277: Yes, this is acceptable as long as it was being administered at a rate greater than that to maintain an IV line. This is defined in the Crystalloid Fluid Administration data element as greater than 1000 mL over eight hours, or 125 mL/hour.

Question 278: In an electronic medical record are we using the time that the note was opened or the time that it was actually filed when trying to assign a time to Severe Sepsis presentation?

Answer 278: The goal is to use the earliest time associated with documentation of Severe Sepsis. In this case, it is the time the note was opened or started. This is being addressed in the next version of the manual.

Question 279: What is the purpose of a repeated lactic acid?

Answer 279: While not specifically one of the measure outcomes, one of the goals is normalization of the lactate levels. This cannot be ascertained without a repeat lactate in the case where the initial lactate is elevated.

Question 280: If an ED nurse documents "physician notes possible UTI," is this acceptable possible infection?

Answer 280: Yes.

Question 281: Is there a reason for only one indicator with the Sepsis bundle?

Answer 281: Literature has demonstrated that when care is bundled into elements that are proven to improve outcomes, the outcomes are better when all elements of the bundle are performed together, as opposed to some being done but not all. The way the data is being collected and submitted will still allow for hospitals to

identify elements that are not being completed consistently for improvement opportunities.

Question 282: When do you anticipate the next volume will be published?

Answer 282: A release date is pending.

Question 283: Did I understand correctly that patients with a diagnosis of Sepsis, not just Severe Sepsis and Septic Shock, will need to be abstracted?

Answer 283: The initial patient population includes cases with ICD-10 codes for Sepsis, Severe Sepsis, and Septic Shock. Facilities will identify a sample population to abstract, though abstraction cases that do not meet the criteria established in the Severe Sepsis Present data element will be excluded from the measure. Your facilities' denominator population will be those cases in the sample that meet the criteria established in the Severe Sepsis Present data element.

Question 284: Can you clarify the comments made on organ dysfunction as it relates to chronic conditions and to organ dysfunction clearly due to another etiology?

Answer 284: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 285: Who is required to document unsuccessful lactic acid labs?

Answer 285: The data elements do not specify who must document unsuccessful lactate lab attempts. As long as it is documented as an unsuccessful attempt, the documentation can be used.

Question 286: The Sepsis protocol at my facility has the temperature listed as above 100.4. Your presentation lists 100.9. Is this a recent change or is based on facility?

Answer 286: Temperature criteria in the Surviving Sepsis Campaign International guidelines, upon which the SEP-1 measure is based, use > 39.3 or < 36 degrees C. This converts to > 100.9 and < 96.8 degrees F.

Question 287: is cellulitis considered an infection?

Answer 287: Cellulitis is a bacterial skin infection and is acceptable as a source of infection.

Question 288: Will the Sepsis/Septic Shock measure be subject to validation for IQR by CMS/CDAC? If yes, when?

Answer 288: Yes, based on the Final Rule this could be associated with when the measure starts, cases discharged starting October 1, 2015.

Question 289: What if the SIRS criteria are actually a result of the infection and not a systemic response, i.e., tachypnea and tachycardia?

Answer 289: Tachypnea (respiratory rate > 20) and tachycardia (heart rate > 90) due to an infection is SIRS criteria and indicative of Sepsis. If a sign of organ dysfunction is also present, the patient by definition has Severe Sepsis.

Question 290: Documentation of a suspected source of clinical infection: there may be reference to possible infection from xx, suspect infection from xx, or similar reference in progress notes, consult notes, or similar physician/APN/PA documentation

Answer 290: This question appears to be incomplete and cannot be answered based on the information provided.

Question 291: Can presence of infection be documented by an RN for example?

Answer 291: Currently, as worded, the data element does not state nursing documentation, is acceptable. It also does not state that it is not acceptable. And in the allowable sources for this documentation, it does indicate the entire ED record which would include nurses' notes. To clarify this, nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 292: So can documentation from a nurse can be used?

Answer 292: Nurses' notes will be included as a Suggested Data Source in the next version of the manual (version 5.0b) for the Severe Sepsis Present data element.

Question 293: For the Physician Documentation of infection Criterion, will a differential diagnosis count?

Answer 293: Yes.

Question 294: If the ED physician lists Sepsis and pneumonia in the impression, would we need to look for the three Severe Sepsis criteria since the physician did not document any Severe Sepsis terms?

Answer 294: Correct. Since the physician documented "pneumonia," this will qualify for the suspected infection criteria.

Question 295: Does a differential diagnosis of infection count? Does a differential of Sepsis count?

Answer 295: A differential diagnosis of an infection counts. Documentation of uncomplicated "Sepsis" is not acceptable as a suspected source of infection.

Question 296: Can you please clarify whether or not documentation of infection, two or more SIRS, and organ dysfunction must be met in order, as per the Specs Manual?

Answer 296: There is not a sequence associated with the three Severe Sepsis criteria. They can be met in any order.

Question 297: CMS has approved the use of the Esophageal Doppler Monitor for fluid volume. Can you include Stroke distance or Flow Time Corrected in the Septic Shock measure as an option?

Answer 297: At this point in time, Stroke distance and Flow Time Corrected are not acceptable. This data element is not looking for specific parameters, calculations, or results, but rather that the procedure was performed as part of an assessment of the patient's volume status and tissue perfusion assessment.

Question 298: My facility has a psych hospital on site. If they are moved from this facility, is this considered a transfer?

Answer 298: According to the Transfer From Another Hospital or ASC data element, if a patient transfers in from a psych unit in an outside hospital, free-standing psych hospital/facility/pavilion outside your hospital, OR psych hospital inside your hospital you should select "Yes." The specific types of facilities for which you will select yes are identified in the Transfer From Another Hospital or ASC data element.

Question 299: Does a nursing home or urgent care count as an outside facility, or only acute care hospitals?

Answer 299: The Transfer From Another Hospital or ASC data element indicates that if a patient transfers from an urgent care center or skilled nursing facility to select "No." The specific types of facilities for which you will select "Yes" are identified in the Transfer From Another Hospital or ASC data element.

Question 300: Why is bacteremia unaccepted? If patient cultures bacteria in her blood with a PICC and no other source is suspected, what should it be called?

Answer 300: Bacteremia itself may not indicate an infection. For purposes of the measure, an infection cannot be assumed in this case. There must be reference to a condition that is an infection or the word infection documented. Specific to the question, the following phrases would all be acceptable: "suspect CLABSI", "possible central line infection," "rule out PICC as source of infection," "infection source unclear possibly PICC."

Question 301: Regarding the Antibiotic Administration Selection: the definition states that ABX administered within three hours after the date and time of presentation of Severe Sepsis. Is the window 24 hours prior until three hours after the time of presentation, or just within the three hour window?

Answer 301: The Broad Spectrum or Other Antibiotic Administration Selection data element is ONLY relevant to and limited to antibiotics given in the three hours following presentation of Severe Sepsis.

Question 302: If patient had a CXR done that read as being pneumonia, would the X-ray report count as documentation for source of infection, or does a physician have to have specifically documented?

Answer 302: As long as the chest x-ray was read by a physician, the report was documented by a physician, and the report included reference to possible or suspected pneumonia, this would count as documentation of a suspected source of infection.

Question 303: What date and time would we abstract if they were on IV antibiotics at home?

Answer 303: If the date and time of administration is not in the medical record, you will need to enter UTD (unable to determine).

Question 304: If a patient is transferred in from a Critical Access Hospital, are they considered to be a transfer from an acute care facility?

Answer 304: According to the Transfer From Another Hospital or ASC data element, if a patient transfers in from an outside hospital you should select "Yes." The specific types of facilities for which you will select “Yes” are identified in the Transfer From Another Hospital or ASC data element.

Question 305: Can we use physician documentation of infection from an x-ray---radiologist states pneumonia or infiltrates in his interpretation?

Answer 305: Yes, this is acceptable as long as the documentation includes a condition that is an infection or the term “infection” is used.

Question 306: If the initial SBP is 158 and the next is 116, would that represent a drop of 40? How would we determine if the SPB of 158 is normal?

Answer 306: To establish a "normal" SBP you would need a series of consistent readings to establish a baseline.

Question 307: Slide 20 – do long term care transfers count?

Answer 307: According to the Transfer From Another Hospital or ASC data element, if a patient transfers from an Long term acute care (LTAC) you should select "Yes."

The specific types of facilities for which you will select "Yes" are identified in the Transfer From Another Hospital or ASC data element.

Question 308: When does the updated manual get released?

Answer 308: A release date is pending.

Question 309: What about elevated HR and RR related to asthma or nebulizer treatments?

Answer 309: For identification of Severe Sepsis, the SIRS criteria (which include HR > 90 and RR > 20) are not used independently. They are used in combination with a suspected infection and sign of organ dysfunction to determine presence of Severe Sepsis.

Question 310: In reference to the question regarding suspected source of infection, the answer provided includes the term "new suspected source of infection." The term "new" is not included in the data element or referenced before now. Does the source of infection documentation need to reference a "new suspected source of infection" as stated in this document?

Answer 310: While the term "new" is not included in the data element, the underlying assumption is the infection is currently present or suspected as being currently present. Documentation in a physician note of a previous infection that is not currently present or suspected as being currently present is not sufficient.

Question 311: Do critical access hospitals have to report on the Sepsis measure?

Answer 311: Critical Access Hospitals are not part of the IQR program and are not required to submit SEP-1. They can voluntarily submit, and we encourage them to do so.

Question 312: Regarding organ dysfunction, would you please repeat when it is not applicable not due to medication, but rather associated with the infection? Does organ dysfunction for the measure relate to lab values or does the patient need to demonstrate kidney, respiratory, liver, etc. failure?

Answer 312: The Surviving Sepsis Campaign International guidelines indicate that you should only use abnormal lab values for signs of organ dysfunction that are associated with the infection. We are working on some language that will be published in the next version of the manual that indicates not to use abnormal lab values as a sign of organ dysfunction if they are due to a chronic condition or a medication.

Question 313: Do AB w/i 48 hr. of Severe Sepsis presentation count if given IV PTA, e. g., SNF?

Answer 313: That depends of when the IV antibiotic was given and whether or not it is documented in the current medical record. If, for example, a patient received the

same IV antibiotic at 34 hours prior to presentation and at 22 hours prior presentation and those dates and times were documented in the patient's hospital medical record, the dose at 34 hours would be abstracted. If a patient received only one dose of an IV antibiotic more than 24 hours prior to presentation, then it would not be abstracted.

Question 314: How are those patients that start in the ED at one hospital and are sent to another going to be looked at? Coming from another facility excludes them?

Answer 314: The Transfer From Another Hospital or ASC data element indicates that if a patient transfers from an outside ED to select "Yes." The specific types of facilities for which you will select “Yes” are identified in the Transfer From Another Hospital or ASC data element.

Question 315: Will the language change to be able to exclude the patient with chronic renal or chronic liver failure in the next revision change and when will that occur?

Answer 315: I am not aware of any plans to exclude these patients from the measure.

Question 316: If we call it SIRS, shouldn’t two SIRS criteria occur together? i.e., if a patient becomes SOB from walking to the restroom, but five hours later patient develops an elevated heart rate but the RR is now back to normal, do we call this SIRS since both were elevated within a five hour window?

Answer 316: The SIRS criteria do not need to be met simultaneously. They must be within six hours of all the clinical criteria. For the purposes of identifying presence of Severe Sepsis clinically in real time, this would not be consistent with SIRS criteria for Severe Sepsis. For the purposes of the measure, keep in mind the abstractor is retrospectively reviewing the medical record. If the nurse records an elevated RR right after the patient returns from walking to the bathroom, the abstractor has no way of knowing if this is "abnormally" elevated or not. The documentation must be taken at face value.

Question 317: Does the route of temp matter, or is it strictly just a temperature?

Answer 317: The temperature is what matters, and the method used to obtain it is not relevant for purposes of the measure.

Question 318: Ex. 3 criteria: one is met at 1600; number two is met at 1730; and number three is met at 1800. What time would we use for out start time?

Answer 318: If the last of the criteria is met at 1800, then 1800 is the Severe Sepsis Presentation Time.

Question 319: Need clarification: So, a central line will not be required, but will be up to the physician to order a central line?

Answer 319: Correct. While the central line is an option for assessing volume status and tissue perfusion, it is not required. If the physician feels a central is appropriate, they can certainly order and put one in.

Question 320: Last year with CMS validation, they now have the ability to validate a record once a new measure is introduced. So Sepsis will be available for validation with 10/1/15 discharges. There are already too many data elements that need clarification to include Sepsis in validation. Any possibility of validation delay?

Answer 320: I am not able to answer this question. It is a question for CMS.

Question 321: I have heard the presenter mention that the next printing of the manual language would be changed. When is the next printing of the manual?

Answer 321: A release date is pending.

Question 322: Only one blood culture is required?

Answer 322: Only one blood culture is required for the measure. If more than one blood culture is drawn, you will abstract the earliest one drawn in the time frame.

Question 323: Aspiration PN included for infection?

Answer 323: Pneumonia is considered an infection. Aspiration represents the cause of the pneumonia. Since pneumonia is documented, this would be acceptable as an infection for SEP-1.

Question 324: Until these various revisions are made for the next version, should the abstractor just use the current data manual and not take into account the future changes?

Answer 324: Yes.

Question 325: Differential diagnosis in the ED record of a suspected infection is also considered, correct?

Answer 325: Yes, this is acceptable.

Question 326: Follow up to the chest x-ray result question: what about a urinalysis result that shows leukocytes, wbc, and bacteria? Can we infer that a UTI is possibly present or wait for MD documentation of UTI or possible UTI?

Answer 326: Presence of an infection cannot be inferred or implied by the abstractor based on signs, symptoms, lab or other diagnostic test results. There must be documentation clearly indicating an infection is present, suspected, or possible.

Question 327: If there is no documentation of Severe Sepsis but meet other criteria, the provider uses a Severe Sepsis order set. Is that enough documentation to support a suspected infection?

Answer 327: The use of a Severe Sepsis order set can be used as physician, APN, or PA documentation of Severe Sepsis, if it is clear the order set is being used to treat Severe Sepsis and it is signed by a physician, APN, or PA. It cannot be used as documentation of a suspected source of infection, unless the provider documented or indicated a suspected source of infection somewhere on the order set.

Question 328: Do you have to meet all the items in this measure to pass/ fail, or are they listed out by each to fail on its own, Lactic acid, Infection source, etc.?

Answer 328: This is an all or none composite measure. All elements must be completed per the specifications and within the designated time frames to pass the measure.

Question 329: What if your hospital's antibiogram does not align with the antibiotic choices?

Answer 329: Keep in mind the Broad Spectrum or Other Antibiotic Administration Selection data element and comparison to Tables 5.0 and Table 5.1 is ONLY relevant if the patient ONLY received antibiotics in the three hours following Severe Sepsis presentation. There are a number of options for monotherapy and combination therapy that should meet the needs of most every patient and facility. If there are not any antibiotic options in the tables that correspond with your antibiograms, consider submitting a question in the *QualityNet* Q&A tool (https://cms-ip.custhelp.com/) with recommendations for other broad spectrum antibiotics you would like included in the table.

Question 330: Does antibiotics selection matter for the Broad Spectrum or Other Antibiotics Administration Question?

Answer 330: No, Antibiotic select is ONLY relevant for Broad Spectrum or Other Antibiotic Administration Selection data element. While the Broad Spectrum or Other Antibiotic Administration data element includes reference to Table 5.0 and Table 5.1 for antibiotics given in the three hours following presentation, this is being removed based on abstractor feedback reflecting it is confusing.

Question 331: Can you only document shock after fluids have been administered?

Answer 331: This presentation covered Severe Sepsis and its data elements. We will defer this question until after the next presentation on Septic Shock, which will include information on crystalloid fluids.

Question 332: I would like to clarify the denominator-included cases. The denominator includes the diagnosis codes (in Appendix A, Table 4.01) only if they are

Severe Sepsis/Septic Shock? For example, will patients that have one of those diagnoses be excluded if Severe Sepsis criteria is not met?

Answer 332: The initial patient population includes cases with ICD-10 codes for Sepsis, Severe Sepsis, and Septic Shock. Facilities will identify a sample population to abstract. Through abstraction, cases that do not meet the criteria established in the Severe Sepsis Present data element will be excluded from the measure. Your facilities' denominator population will be those cases in the sample that meet the criteria established in the Severe Sepsis Present data element.

Question 333: If the provider documents that the patient does not have Severe Sepsis, does this end the abstraction, or do we still have to dig for all the other elements of the measure?

Answer 333: You will also need to review the medical record for the clinical criteria. It could be the patient did not initially present with Severe Sepsis and the physician documented "does not have Severe Sepsis," but later the patient developed Severe Sepsis and clinical criteria were present. In this case, the earlier documentation by the physician would not be valid for the patient's condition, as the patient met the clinical criteria later in the stay.

Question 334: Are you discouraging the use of four hour administration times for Zosyn in Severe Sepsis?

Answer 334: No, the measure does not require antibiotics be completed within three hours of presentation of Severe Sepsis. It requires they be started.

Question 335: Will there be any "exceptions" to the amount of crystalloid fluids, i.e., ht. failure patients, Dialysis patients, etc.?

Answer 335: This presentation covered Severe Sepsis and its data elements. We will defer this question until after the next presentation on Septic Shock, which will include information on crystalloid fluids.

END