Frequently Asked Questions
SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock

These frequently asked questions (FAQ) provide general and technical information for the Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1) chart-based measure used in the 2015 Hospital Inpatient Quality Reporting (IQR) Program. The specifications were first published in April 2015 as part of the *Specifications Manual for National Hospital Inpatient Quality Measures, Version 5.0*, for discharges beginning October 1, 2015, and the specifications were updated in the Version 5.1 addendum published on May 29, 2015.

The questions in this document address a range of topics, including the background of the measure and the data elements collected for the measure's calculations. This FAQ document is a living document and is intended to support the data collection for this measure and provide additional support to abstractors. The Centers for Medicare & Medicaid Services (CMS) and its contractors will update this FAQ periodically throughout implementation based on the needs of the stakeholders.

This FAQ is organized into the following chapters:

For questions about this measure, please use the Hospitals—Inpatient Questions & Answers tool.

Administrative Contraindication to Care

Q: Is there a time frame associated with documentation of the Administrative Contraindication to Care data element? Does documentation at any time during the encounter count?

A: Consider any documentation related to refusal of blood draw, fluid administration, or antibiotic administration that is present from time of arrival to ED or hospital:
- Refusal of blood draw would result in not having lactate levels or labs for determining the presence of severe sepsis.
- Refusal of fluid administration would result in crystalloid fluids not being administered.
- Refusal of antibiotic administration would result in antibiotics not being given.

Antibiotics

Q: The Broad Spectrum or Other Antibiotic Administration indicates that if an antibiotic on Table 5.0 in Appendix C was not given, to locate the name or names of antibiotics in Table 5.1. It references a left hand column (column A) and right hand column (column B) for pairing classes of antibiotics. Table 5.1 does not contain a column A and column B. What is this pairing referring to?

A: This is referencing the Combination Antibiotic Therapy Table located in the Broad Spectrum or Other Antibiotic Administration Selection data element, which has a Column A and Column B. This is not referencing columns on Table 5.1 in Appendix C.

If an antibiotic from Table 5.0 was not given, but an antibiotic from Table 5.1 was given, then note the antibiotic class (the dark shaded rows in the table above the list of antibiotics) from Table 5.1 and use that information in conjunction with the Combination Antibiotic Therapy Table located in the Broad Spectrum or Other Antibiotic Administration Selection data element. Two examples are provided below to illustrate the steps.

Example 1: Gentamicin was given (an Aminoglycoside per Table 5.1); look at the Combination Antibiotic Therapy Table located in the Broad Spectrum or Other Antibiotic Administration Selection data element. Aminoglycosides are in Column A. They must be given in combination with a drug from one of the classes in Column B. Look in the medical record to see if another antibiotic was given that is from one of the classes in Column B. In this case, Vancomycin (a Glycopeptide per Table 5.1) was also given. According to the Combination Antibiotic Therapy Table, this represents an appropriate combination, and selecting "Yes" for this data element is appropriate.

Example 2: Patient received Gentamicin (an Aminoglycoside) and Ciprofloxacin. Both are in Column A of the Combination Antibiotic Therapy Table. To select "Yes" there must be at least one from Column A and one from Column B. Since both are in Column A, "No" must be selected for this case.

Q: How would the antibiotics be abstracted for a case where two IV antibiotics were given within 24 hours of presentation of septic shock and the first dose of one of them was given two days before presentation of septic shock?
For example: Severe sepsis presentation 3/19/15 at 1330. Ancef 1st dose 3/16/15 at 1400 also had dose on 3/18/15 at 1400. Gentamicin 1st dose 3/18/15 at 1400.

A: In this case there was an appropriate antibiotic combination given in the time window within 24 hours prior to the presentation of severe sepsis. This patient was, however, on antibiotics for more than 24 hours prior to presentation of severe sepsis.

- Broad Spectrum or Other Antibiotic Administration: select Allowable Value "1 (Yes)" because IV antibiotics from Table 5.1 were given within 24 hours prior to presentation of severe sepsis.
- Broad Spectrum or Other Antibiotic Administration Date and Time: The Notes for Abstraction for these two data elements indicate that if an IV antibiotic was given within 24 hours prior to presentation of severe sepsis to abstract the earliest date and time that IV antibiotic was given. In this example, IV Ancef was given within 24 hours prior to severe sepsis presentation and the first dose was given 3/16/15 at 1400. Enter the date and time of the first dose of IV Ancef.

As illustrated in the algorithm on the bottom of page SEP-1-11 of the SEP-1 Measure Information Form, this case will be excluded because the first dose of Ancef was before the 24-hour window prior to severe sepsis presentation.

Q: In reviewing the recommended antibiotic tables for severe sepsis they do not appear to be based on treatment for a presumptive source of infection. This means if the source of infection is known, to meet the measure requires we give antibiotics that are not necessarily consistent with recommendations for the specific infection.

A: The antibiotic options for the measure are for broad spectrum coverage to minimize the risk of not covering the causative organism(s). Keep in mind these are options for initial antibiotic selection. Severe sepsis guidelines recommend initial treatment with broad spectrum coverage. After cultures come back and the causative organism is positively identified antibiotic treatment can be adjusted accordingly.

Crystalloid Fluid Administration

Q: If the crystalloid fluids are ordered and given over a series of boluses does this count for Crystalloid Fluid Administration?

A: Yes, if the total volume is at least 30 mL/kg and the last bolus is ordered and started within three hours of the presentation of septic shock.

For example: Presentation of septic shock was documented at 13:00. If the patient weighs 165 pounds (75 kg) the target volume (30 mL/kg) would be 2,250 mL. If the physician ordered 1,000 mL over 30 minutes at 12:00, and after that was completed, ordered another 1,000 mL over 30 minutes at 13:00, and after that was completed, ordered another 1,000 mL over 30 minutes at 14:00, this would be a total 3,000 mL ordered and administered, which is greater than the target volume. Since

the last bolus was ordered and started within three hours of presentation of septic shock, selecting Allowable Value "1 (Yes)" for the Crystalloid Fluid Administration data element is appropriate.

If however, the last bolus is not ordered or not started until 16:15, it would be more than three hours after the presentation of septic shock. Because only 2,000 mL (not the target volume of 2,250 mL) was ordered and started within three hours after presentation of septic shock, select Allowable Value "2 (No)" in this situation.

Q: The Crystalloid Fluid Administration data element includes a couple of examples where crystalloid fluids are administered over two hours (2400 mLs normal saline over the next two hours) and four hours (1000 mL Lactated Ringers over the next four hours). It also notes if crystalloid fluids are administered at a usual rate, which is 1000 mL over eight hours, or at a "Keep Vein Open" (KVO) rate, to choose Value "2." It does not specify a time frame over which the crystalloid fluids must be administered to be included in the 30 mL/kg volume. What rate is considered appropriate for determining infusion of the 30 mL/kg volume?

A: There is not a specific rate or time frame over which the crystalloid fluids must be administered, because this may vary depending on factors including the total volume to be delivered, the patient response, and the individual patient's condition. The goal is rapid infusion of the 30 mL/kg volume at a rate or over a time frame that represents a "bolus" and not at a rate or over a time frame that is reflective of IV fluids for maintenance of an IV line.

For example, a 110 pound patient requires a total volume of 1500 mL (110 divided by 2.2 = 50 kg x 30 mL/kg). This could be infused over a shorter period of time than the total volume for a 352 pound patient who requires a total volume of about 4800 mL (352 divided by 2.2 = 150). The physician may order the 1500 mL be given over 1.5 hours (rate of 1000 mL/hour) and may order the 4800 mL be given over 4 hours (rate of 1200 mL/hour). Both represent a rate or time frame greater than that for maintaining an IV line but both are different durations and different rates. By contrast the example of 1000 mL over eight hours as a usual rate or a Keep Vein Open Rate is a rate of 125 mL/hour.

Q: If there is documentation of actual fluid administration, does there need to be a corresponding order to consider the fluid as part of the "crystalloid fluids administered"? Can the documentation of fluid administration within the nurse's notes be used to determine if the appropriate amount of crystalloid fluids were administered?

A: The Crystalloid Fluid Administration data element's Notes for Abstraction indicate the measure is considering clear documentation in the medical record as evidence the crystalloid fluids were actually administered. This would include the volume given, date, and time of administration.

For example, 30 mL/kg for a particular patient is 3000 cc and "the time of presentation of septic shock" is 1/1/20xx 01:00. The nurse's note dated/timed 1/1/20xx 05:00 states, "3L 0.9% normal saline IV bolus given at 01:30 for hypotension." However, there is no corresponding order and therefore no documentation within the MAR. Since the nurse's note includes a date and time, and states normal saline was given as IV bolus, and the amount is equivalent to 30 mL/kg, this documentation would be acceptable for selecting "Yes" for this data element.

Q: On the algorithm on page SEP-1-14, the top diamond is Septic Shock Present. On page SEP-1-15, the top diamond is Crystalloid Fluid Administration. Can you confirm this is the correct order of the data elements?

A: For purposes of the algorithm and associated calculations to determine the timing of the crystalloid fluids, this is correct. Note, however, that it does not necessarily represent a sequential order in which crystalloid fluid administration may occur for every case of septic shock. In many cases the crystalloid fluids may have already been started or the infusion completed when the determination of septic shock is actually made. The volume of crystalloid fluids to meet the intent of the measure is 30 mL/kg and this applies to all references to crystalloid fluid administration except the Fluid Challenge Performed.

Q: The Crystalloid Fluid Administration, Septic Shock Present, Persistent Hypotension data elements and the Numerator Statement appear to contradict one another. To indicate Septic Shock is present the crystalloid fluids must be given before septic shock presentation. To indicate crystalloid fluids were given, the documentation must indicate they were given after presentation of septic shock or at the time of presentation. To indicate Hypotension is persistent, the hypotension must be present after administration of crystalloid fluids. If crystalloid fluids (30 mL/kg) are given prior to presentation of septic shock, which allowable value should be selected for the Crystalloid Fluid Administration data element?

A: The wording in the specifications does not clearly address crystalloid fluid administration started and completed before presentation of septic shock. The Crystalloid Fluid Administration Time data element does reference that in some cases, the infusion may have started prior to presentation of septic shock; if this is the case, the time it is started (even if prior to presentation time of septic shock) should be used.

By definition, septic shock is severe sepsis with hypotension or lactate >= 4 not responding to administration of crystalloid fluids (30 mL/kg). The 30 mL/kg of crystalloid fluids are only required to be administered if hypotension (or lactate >= 4) is actually present. Patients may present in a variety of ways at the point the fluids should be given and this may or may not reflect shock. Once the fluids are given, the determination of whether or not the patient actually has septic shock by strict definition can be made. Building all of the different scenarios into the measure and algorithm becomes prohibitive due to the complexity this creates.

Crystalloid fluids started and completed (30 mL/kg) before the determination of septic shock should be considered if the patient is still receiving the same crystalloid fluid (does not need to be at the same rate) at the time septic shock is identified as present. The algorithm allows for fluids administered prior to the presentation time of septic shock to pass this part of the measure.

Q: Is the crystalloid fluid volume of 30 mL/kg based on the patient's actual weight or ideal weight.

A: The volume of crystalloid fluids (30 mL/kg) is based on actual body weight.

Focused Exam

Q: Does the skin assessment need to be completed by a physician or can an RN do it?

A: Based on information in the Skin Examination Performed data element it must be a physician, APN, or PA. It cannot be performed by an RN.

Q: Why specifically must a physician, APN, or PA perform the following: Capillary Refill, Skin Exam, and Passive Leg Raise? Staff RNs, especially in critical care, perform and document these findings, so why not include/accept their documentation for these measures?

A: In the clinical trials that reference the elements of the focused exam in the "usual care" arms, patients received a high level of monitoring in the first six hours. The minimum standard those studies establish is a single reevaluation by a licensed independent practitioner who could actually immediately initiate orders to alter management based on their findings.

Lactate Level

Q: How do we determine whether or not a repeat lactate is indicated?

A: The decision flow of the algorithm determines whether or not a repeat lactate is indicated based on the value of the Initial Lactate Level Result.

The Numerator Statement on page SEP-1-8 of the SEP-1 Measure Information Form indicates to repeat the lactate level measurement within six hours of severe sepsis presentation only if the initial lactate level is elevated. The algorithm on the top of page SEP-1-13 shows that if the Initial Lactate Level Result = Allowable Value "2" or" "3", a Repeat Lactate Level should be collected. Based on this, if the lactate is > 2 a repeat lactate should be drawn.

Q: For data collection purposes, what are the allowable sample sources for initial and follow-up lactate level collection? Is this limited to serum samples only, or does it also apply to arterial blood gas samples (ABG)?

A: The most important factor regarding obtaining lactate levels is quick turnaround time. According to information from the Surviving Sepsis Campaign, either venous or arterial sources are acceptable. The source should be consistent for the initial lactate and the follow-up lactate.

Persistent Hypotension

Q: How is the Persistent Hypotension data element abstracted if the medical record does not specify at what time the crystalloid fluids end? For example the electronic health record (EHR) shows the total volume of fluids infused at the end of each hour but does not show when an infusion actually ended.

A: The order must include the total volume and a rate at which to infuse or a time frame over which to infuse it. The medical record must also include a date and time the infusion was started. Using this information, you can determine when the infusion should have been completed.

For example: Target volume (30 mL/kg) for a 165 pound (75 kg) person is 2,250 mL.

- Order is for 2,500 mL over two hours
- Infusion started at 12:00
- End of 1st hour (12:59) volume infused = 1500 mL
- End of 2nd hour (13:59) volume infused = 1000 mL

Even though more than the target volume of 2,250 mL was infused, this would indicate that the target volume was infused by 13:59. Use 13:59 as the time for end of infusion from which to determine the one hour time frame for identifying the presence of persistent hypotension.

Physician Documentation

Q: If Severe Sepsis and Septic Shock order sets are used by physicians, can the time this order set is initiated be used as the time of presentation?

A: The order set or supporting documentation must clearly indicate the order set is being used for severe sepsis or septic shock. If the order set intended for use with severe sepsis or septic shock is being used for another diagnosis or condition, it cannot be used for Severe Sepsis or Septic Shock presentation time.

Q: If a Problem (via Problem List) or working diagnosis is documented by the physician, would this qualify as an acceptable data source?

A: This could serve as a trigger point. There must be documentation substantiating it is current and there must be a date and time associated with it. This is because identification and treatment of severe sepsis and septic shock are very time sensitive. A condition on a problem list or a working diagnosis without a time and date associated with it are insufficient for determining the date and time severe sepsis or septic shock is present and whether or not treatment occurred within the appropriate time frame.

Presentation Criteria

Q: Would a clinical event created by a clinical decision support system (through SIRS criteria) qualify as an acceptable data source?

A: This could serve as a trigger point to start looking for criteria to establish severe sepsis or septic shock. It cannot necessarily be used to identify the presence of severe sepsis or septic shock. The source information that triggered the alert would need to be used. This is because the time frame within which the decision support triggers may or may not be consistent with the requirements for the Severe Sepsis Present data element. Additional information is required to meet the criteria for severe sepsis, and it is all very time sensitive.

Q: The Septic Shock Present data element indicates there must be documentation of severe sepsis present. How do we answer this data element if all of the clinical criteria for severe sepsis are not documented prior to documentation of septic shock by the physician and the physician does not document presence of severe sepsis? How would we answer the Severe Sepsis Present data element?

A: For septic shock to be present, severe sepsis must also be present. There is some variation in the presentation of the sequence of clinical criteria with severe sepsis or septic shock. It may occur so rapidly that septic shock manifests before severe sepsis is identified. If a physician, APN, or PA documents septic shock and there is no documentation prior to this of severe sepsis, or severe sepsis clinical criteria are not met prior to this, select Allowable Value "1 (Yes)" for both Severe Sepsis Present and Septic Shock Present. Enter the same date and time for both.

Q: How is severe sepsis determined without a physician/PA/APN diagnosis? The Severe Sepsis Present data element indicates the first step is to determine if there is a suspected source of clinical infection, then whether the case meets other criteria. Usually they cannot identify a source or even an infection of any sort until the criteria with vital signs and labs within the inclusion ranges are present.

A: The three criteria for determining severe sepsis (documentation of new suspected infection, two or more SIRS criteria met, and indication of organ dysfunction) do not necessarily present themselves as sequential and do not need to occur in the order listed in the Severe Sepsis Present data element. All criteria must be met within six hours of each other, but the order in which they are found does not matter.

Q: The Septic Shock Present data element indicates that septic shock is present if severe sepsis is present AND tissue hypoperfusion persists after crystalloid fluid administration. However, the measure algorithm does not evaluate for crystalloid fluid administration until after septic shock is determined. In order to meet the measure, are we required to administer 30 mL/kg of crystalloid fluids before evaluating the patient for septic shock?

A: The timing of crystalloid fluid administration is dependent upon the criteria used to determine septic shock. If you are using clinical criteria, crystalloid fluid administration followed by persistent tissue hypoperfusion would need to occur prior to or when septic shock is identified. If the presence of septic shock is based on physician documentation, septic shock could be documented prior to crystalloid fluid administration.

The algorithm evaluates for Crystalloid Fluid Administration in reference to Septic Shock Presentation Time in a calculation called Crystalloid Fluid Admin Time on page SEP-1-15 of the SEP-1 Measure Information Form. If the crystalloid fluids are administered <= 180 minutes from Septic Shock Presentation Date and Time, the case will pass this part of the measure. This means crystalloid fluids given prior to, at the time of, or up to three hours after the presentation of septic shock will pass this part of the measure.

Q: Should signs of organ dysfunction be used if they are due to chronic conditions? For example if a patient with end stage renal disease (ERSD) has an elevated creatinine, would this be considered organ dysfunction for severe sepsis?

A: If the sign of organ dysfunction is due to a chronic condition, such as an elevated creatinine in a patient with ESRD, it should not be used for determining presence of organ dysfunction for severe sepsis.

Q: When using the three criteria to identify presence of severe sepsis, can physician documentation of "sepsis" be used for a suspected source of clinical infection.

A: Documentation of "sepsis" is not sufficient for a suspected infection. Sepsis is not an infection, rather it is the body's response to an infection. There must be actual documentation that there is a suspected infection to select Allowable Value "1 (Yes)."

Q: Does the source of infection need to be identified in the physician documentation or is "infection source unknown" acceptable?

A: Physician documentation of "infection source unknown" is acceptable. In some cases of severe sepsis the patient may exhibit all the signs and symptoms of an infection but the source may initially be unknown until a further workup can be completed. The physician may very well suspect an infection but not know the source yet.

Presentation Time

Q: The Specifications Manual states, "For patients who enter the ED with severe sepsis/septic shock, the Severe Sepsis/Septic Shock Presentation Time is the time they were triaged in the ED." Could you please clarify what is meant by "enter the ED with Severe Sepsis/Septic Shock"?

A: Some facilities include a sepsis screening tool as part of their ED triage process. If the patient meets clinical criteria for severe sepsis or septic shock based on the screening occurring at triage, triage time would be used for severe sepsis or septic shock presentation time. If there is documentation in the triage notes reflecting that severe sepsis criteria were met, this would also support using triage time as presentation time.

Q: Does the sepsis measure apply to cases present on admission only, or does the measure apply to all inpatient sepsis cases, including those recognized after admission to an inpatient setting?

A: The SEP-1 measure applies to all cases of severe sepsis and septic shock that are present on arrival to the ED, that develop in the ED after arrival, or that develop during the inpatient hospitalization.

Q: For patients who enter the facility via the ED and are found to meet either severe sepsis or septic shock presentation criteria while in the ED, are the severe sepsis and/or septic shock date and presentation time the ED triage time?

A: For patients who develop severe sepsis or septic shock after arrival to the ED (either while still in the ED or as an inpatient) the presentation time is the time clinical criteria are met or the time the physician documents severe sepsis or septic shock, whichever comes first. Triage time is only used for cases where severe sepsis or septic shock is identified as being present on arrival to the ED. This is usually identified during triage, either through a sepsis screening process performed during triage or when triage priority is assigned.

Q: The Severe Sepsis Present data element indicates that all three criteria must be met within six hours of each other. If there is no physician documentation of severe sepsis, at what point should the six-hour time frame for abstraction begin?

A: To determine the presence of and the date and time for severe sepsis, use the earliest time of either physician documentation OR clinical criteria met. If a physician documents severe sepsis and this is before the clinical criteria are met, this is sufficient for establishing presence and the date and time of severe sepsis presentation.

Starting the process may vary depending on the patient and the documentation. When looking for physician documentation for patients admitted through the ED, start with physician ED documentation. If physician, APN, or PA documentation are not present, then look for clinical criteria. All clinical criteria must be met. Lab values may be a good place to start. Abnormal lab values are often easier to identify than other elements because you can make use of lab reports. Vital signs can also be helpful because they may be displayed graphically depending on your documentation system. Once you have found one of the criteria, then look at the time period before that and after that, keeping in mind that all criteria must be met within six hours of each other. The six-hour window is more of a floating window with a start time that is dependent on when the clinical criteria are found.

For example: If there is a lactate > 2 at 12:00, look in the six hours preceding to see if other criteria are met. If a RR > 20 and an HR > 90 are documented with vitals at 11:00, then documentation of a suspected infection at any time from 06:00 (six hours before the lactate) to 17:00 (six hours after the vitals) will result in all criteria being met within six hours of each other.

The point at which the last criterion is met is when severe sepsis is present. As such, an abnormal lab value used as part of the criteria, or any of the other clinical criteria used to establish presence of severe sepsis, can never be after presentation of severe sepsis.