



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.5a Measure Updates and v5.0b Through v5.2b Analysis Results

Questions and Answers

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The following document provides actual questions from audience participants. Webinar attendees submitted the following questions and subject-matter experts provided the responses during the live webinar. The questions and answers (Q&As) have been edited for grammar.

Question 1: **When do the changes for version (v) 5.5a become effective?**

The Specifications Manual for National Hospital Inpatient Quality Measures, Version 5.5a is effective for discharges from January 1, 2019 through June 30, 2019.

Question 2: **Slides 21 and 23. Please clarify the statement on slide 23, “The target ordered volume is NOT required to be completely infused within the specified time frame.” If the target volume is not infused within the specified time frame, will we still pass the bundle?**

The target ordered volume must be started within the specified time frame defined in the *Crystalloid Fluid Administration* data element. There must be documentation of a rate, duration, or end time to identify that the target ordered volume was completely infused, but it does not need to be completely infused within the specified time frame. As long as the target ordered volume is started during the specified time frame and documentation supports it was completely infused, the case will meet the measure requirements.

Question 3: **Slide 25. If the physician documents patient is obese and no other ideal body weight (IBW) is documented, can we abstract obese as greater than 30 body mass index (BMI)?**

To use the IBW to determine the target ordered volume, you would need to have clear physician documentation that they are using the IBW to determine a target ordered volume and that the patient is obese or has a BMI greater than 30.

If the physician only documents the patient is obese and does not include any documentation that the IBW is being used to determine the target ordered volume, then the weight documented would be used to determine the target ordered volume.



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Question 4: Slide 28. With the *Documentation of Septic Shock* data element being removed, does that mean physician documentation of septic shock has been removed?

Documentation of septic shock is still acceptable for the *Septic Shock Present* data element. The *Documentation of Septic Shock* data element was a triggering event for *Crystalloid Fluid Administration* in v5.4 of the specifications manual. With the algorithm changes to v5.5a, that data element is no longer needed as a trigger for *Crystalloid Fluid Administration*. If there is documentation that septic shock is present and that is the earliest presentation time for septic shock, you would still use the documentation of septic shock to select Value “1” (Yes) for the *Septic Shock Present* data element.

Question 5: Slides 31 and 32. Do we use the second of the two required hypotensive blood pressure (BP) readings for our “initial hypotensive time”?

Yes, for *Initial Hypotension*, the date and time of the second hypotensive BP reading would be abstracted for the *Initial Hypotension Date* and *Time*.

Question 6: Slide 35. Would readings less than 80/50 be used for *Initial Hypotension*?

Yes, based on the example in the slide, systolic blood pressure (SBP) readings less than 80 would be used for *Initial Hypotension*. An SBP less than 90 is considered hypotensive. The example on slide 35 indicates the patient’s low SBP of 80 is due to a medication.

The new guidance referenced in the slide states that all instances of less severe values should not be used. In this example, SBP values that are greater than 80 but still less than 90 are less severe hypotensive SBP readings, and can be disregarded. More severe low SBP readings, anything less than 80, should be used.

Question 7: Slide 42. If the emergency room (ER) nurse’s notes state lactate was drawn at 1300, and the lab report says lactate was collected at 1305, which time would we use?

In this scenario, based on the priority order given in the new guidance, you would use the laboratory documentation indicating when the lactate



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level was drawn. In this case, the *Initial Lactate Level Time* would be abstracted as 1305.

Question 8: Slide 44. Will “sepsis exam done” suffice to meet the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element? Do our providers need to document all the sepsis parameters, or is this element an either-or statement?

If the physician documented “sepsis exam done” and that documentation was within the specified time frame, that would suffice for selecting Value “1” (Yes) for the data element. They would not need to also document five of the now eight parameters.

Question 9: If a physician’s history and physical (H&P) that falls in the appropriate time frame states a review of systems completed, does this meet the criteria for reassessment?

Yes, for the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element, if there is physician documentation within that specified time frame stating they performed a review of systems or review of systems completed, then Value “1” (Yes) could be selected for that data element.

Question 10: How is the SEP-1 measure bundle compliance calculated? Is it simply a numerator/denominator calculation reported as a percentage with the numerator being the number of patients who met all of the measure elements and the denominator being all of the patients who have a diagnosis of severe sepsis/septic shock?

Bundle performance rates are calculated based upon dividing the number of eligible patients who meet all requirements for a bundle (numerator) by the number of patients who are eligible for the bundle of data elements (denominator). To be eligible for any given bundle, the patient must meet all requirements previous to the point in the algorithm where the respective bundle starts and not meet any exclusion criteria prior to or within that given bundle. The overall SEP-1 performance rate is based upon all dividing the number of patients who meet all measure requirements for which they are eligible by the number of patients eligible for the measure.



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Question 11: Slide 75. When it states that quarter one (Q1) 2018 is at 71.5 percent for the septic shock three-hour bundle, does that mean the patient first passed severe sepsis three-hour, plus severe sepsis six-hour? For example, is each step in the breakdown meaning they passed all prior levels, or does it mean 71.5 percent received 30 milliliters per kilogram (mL/kg), which is the only bundle item in septic shock three-hour bundle?

Yes, to be eligible for a bundle, the patient would need to have passed all previous bundles that they were eligible for and not be excluded prior to or within the bundle. In the example noted in this question, to be included in the 71.5 percent of patients who met the septic shock three-hour bundle, the patient would need to have passed the severe sepsis three-hour bundle and the severe sepsis six-hour bundle (assuming they were eligible for it).

Question 12: Do you have a link to the benchmark report?

The Benchmarks of Care reports, that were referenced in this presentation, are available on [QualityNet](https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier2&cid=1228768205297) at <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier2&cid=1228768205297>.

Question 13: When I ran a *Hospital Compare* preview report, the top 10 percent rate was not 80 percent. Please clarify.

The [Benchmarks of Care](#) reports that are posted on [QualityNet](#) use a different formula for determining a benchmark performance rate than is used for the Hospital Compare preview reports. The results are therefore not directly comparable. The Benchmarks of Care report uses a formula that looks at the average of the top 10 percent performing hospitals and applies a factor to adjust for facilities with lower volumes. The benchmark on the Hospital Compare preview report uses a formula that calculates the average performance rate of the top 10 percent performing hospitals but does not adjust that rate for lower volume hospitals.



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Subject-matter experts researched and answered the following questions after the live webinar. This content may have been edited.

Blood Culture Collection Acceptable Delay

Question 14: Slide 18. The second bullet point states, “if antibiotic was started within 24 hours prior to severe sepsis.” Does this also apply if the antibiotic was started greater than 24 hours before and the patient received the antibiotic within 24 hours?

Cases where the patient received the intravenous (IV) antibiotic within 24 hours prior to severe sepsis and also received a dose of the same IV antibiotic more than 24 hours prior to severe sepsis would be excluded at the Broad Spectrum Antibiotic Timing calculation in the algorithm prior to reaching the *Blood Culture Collection Acceptable Delay* data element.

Question 15: Slide 18. The wording could mean that if the patient received an IV antibiotic at 11:00 and blood cultures were drawn at 11:03, and the patient didn’t meet the severe sepsis criteria until 12:00, then we could say “Yes” to *Blood Culture Acceptable Delay*, as it was within 24 hours pre-presentation of severe sepsis. Is that correct?

Yes, that is correct. If the antibiotic was started for an infection within 24 hours before severe sepsis was identified, and a blood culture was drawn sometime after the antibiotic dose was started, Value “1” (Yes) would be selected for the *Blood Culture Collection Acceptable Delay* data element.

Question 16: Slide 18. Just to clarify, the blood culture still has to be drawn within the appropriate time window (i.e., latest time is still three hours after severe sepsis)? My understanding is the acceptable delay is just for circumstances where the blood culture is done after antibiotics were given, but the blood culture still must be done in the appropriate time window.

Yes, the *Blood Culture Collection* is required to occur within the specified time frame provided in the *Blood Culture Collection* data element. The *Blood Culture Collection Acceptable Delay* data element is only abstracted if the antibiotics are started before the blood cultures are drawn, but both must occur with the specified time frame for the respective data element.



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Question 17: **Slide 19. This only includes IV antibiotics, or does it include both oral and IV antibiotics?**

The references to antibiotics in the *Blood Culture Collection Acceptable Delay* data element are only to IV, intramuscular, or intraosseous (IO) antibiotics. The Exclusion Guidelines for Abstraction in the *Blood Culture Collection Acceptable Delay* data element for v5.5a of the specifications manual exclude oral (PO) antibiotics.

Question 18: **Is there a time frame for the blood culture collection?**

Yes, the *Blood Culture Collection* data element provides the specified time frame for *Blood Culture Collection* based on the *Severe Sepsis Presentation Time* and IV antibiotic administration time.

Per the specifications manual:

- If a patient **does not** receive an IV or IO antibiotic within the 24 hours before the presentation of severe sepsis, the appropriate time window is:
 - 24 hours prior to Severe Sepsis Presentation Date and Time through 3 hours following Severe Sepsis Presentation Date and Time.
- If a patient **does** receive an IV or IO antibiotic within the 24 hours before the presentation of severe sepsis, the appropriate time window is:
 - 24 hours prior to the administration of the antibiotic through 3 hours following *Severe Sepsis Presentation Date and Time*.

Question 19: **Would having only one set of blood cultures drawn prior to the antibiotic still be considered as a fallout, or does it meet the blood culture requirement?**

As long as one blood culture was collected within the specified time frame, Value "1" (Yes) would be selected for the *Blood Culture Collection* data element.



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Documentation of Septic Shock

Question 20: Slide 28. Do we count physician documentation of septic shock to say “Yes” to *Septic Shock Present* if the patient does not meet the septic shock criteria, as we did in the past?

Yes, physician/advanced practice nurse (APN)/physician assistant (PA) documentation of septic shock is acceptable justification to select Value “1” (Yes) for the *Septic Shock Present* data element.

Question 21: Slide 28. What is the rationale for removing the *Documentation of Septic Shock* data element?

The *Documentation of Septic Shock* data element was a triggering event for *Crystalloid Fluid Administration* in v5.4 of the specifications manual. With the algorithm changes to v5.5a, the *Documentation of Septic Shock* data element is no longer needed as a trigger for *Crystalloid Fluid Administration*.

Crystalloid Fluid Administration

Question 22: Slide 20. The physician documented sepsis and severe anemia and that they will use blood for the fluid resuscitation. Is that acceptable, as I do not see that listed on the inclusion list?

For purposes of SEP-1, blood and blood products are not acceptable solutions to use toward the target ordered volume of crystalloid fluids.

Question 23: Slide 20. If the antibiotic was started prior to hospital arrival, do we need documentation of the actual administration (e.g., the actual dose and time)?

Yes, documentation of actual administration, including the name, route, date, and time, is required.



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Question 24: Slide 21. What are some other synonyms for a ventricular assist device (VAD)?

The *Crystalloid Fluid Administration* only includes an implanted VAD as acceptable for selecting Value “4” (No). No other synonyms or devices are included as acceptable per the data element.

Question 25: Slides 21 and 23. If the patient needs 3200 ml of fluid based on 30 mL/kg, and it was started in the specified time frame, can we answer Value “1” even if the entire 3200 ml will not be completely infused within the specified time frame? For example, *Initial Hypotension* triggering event at 0600; 3200 ml fluid needed based on 30 mL/kg order to infuse over three hours started at 0800.

The target ordered volume must be ordered and initiated within the specified time frame, but it is not required to be completely infused within the specified time frame. For the example, if the 30 mL/kg ordered volume was started within the specified time frame, and there is a rate, duration, or end time documented, but the infusion is completed after the specified time frame, selecting Value “1” (Yes) would be acceptable.

Question 26: Slide 22. Does this mean we are no longer using lactic acid greater than 4 to determine septic shock?

No, slide 22 references the use of the *Initial Hypotension Date and Time* or *Septic Shock Presentation Date and Time* to determine the specified time frame for the abstraction of crystalloid fluids. An *Initial Lactate Level Result* greater than or equal to 4 continues to be a criterion for meeting the *Septic Shock Present* data element.

Question 27: Slide 23. Could you explain what you mean by documentation of target ordered volume completely infused? Can we no longer use the order of crystalloid fluids to be administered in 20 minutes as infused unless there is documentation that it was discontinued? Does there have to be documentation that it was completely infused?

To determine if the target ordered volume was completely infused, one of the following must be documented along with the infusion start time.



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If one of the following is not documented, do not use the fluids toward the target ordered volume:

- An infusion rate
- Infusion duration or time over which to infuse
- Infusion end or completion time

If there is a start time documented for the crystalloid fluid infusion, then the ordered duration would be acceptable to determine that the crystalloid fluids were completely infused. With an infusion start time and rate, duration, or end time documented, no further documentation stating the infusion was completely infused is required.

Question 28:

Slide 23. What constitutes documentation of target ordered volume completely infused? Is the estimation of a bolus end time no longer acceptable? For example, 2000 ml over two hours started at 1100.

To determine if the target ordered volume was completely infused, one of the following must be documented along with the infusion start time. If one of the following is not documented, do not use the fluids toward the target ordered volume:

- An infusion rate
- Infusion duration or time over which to infuse
- Infusion end or completion time

The example in the question provides sufficient information to determine the target ordered volume was completely infused. There is a start time (1100) and an infusion duration (over two hours).

Question 29:

Slide 23. Does the order now need to be time stamped during the specified time frame?

Yes, the target ordered volume must be ordered and initiated within the specified time frame of six hours prior through three hours after the *Initial Hypotension Date and Time* or *Septic Shock Presentation Date and Time*.

Question 30:

Slide 23. Can you provide examples regarding the infusion not required to meet time?

Slide 23 provides the guidance specifying the target ordered volume must be ordered and initiated within the specified time frame, as well as



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documented as completely infused. However, the guidance on slide 23 goes on to state, “The target ordered volume is not required to be completely infused within the specified time frame.” Therefore, as long as the crystalloid fluid infusion is ordered and started within the specified time frame and the documentation includes a rate, duration, or end time, if the infusion is completed after the specified time frame, it would still be acceptable.

Question 31: **Slide 24. Does a weight have to be specifically documented with the fluid order?**

No, the patient’s weight is not required to be included in the order for crystalloid fluids.

Question 32: **Slide 25. If the provider simply documents a BMI of 32, would that suffice for obesity documentation?**

Yes, physician/APN/PA documentation stating the patient is obese or has a BMI greater than 30 is acceptable.

Question 33: **Slide 25. It was stated that the same documentation is needed as per slide 24. If “dosing weight” is used, does it require physician/APN/PA documentation that the dosing weight is being used? In our electronic health record (EHR), this is automatically calculated every time an actual weight is entered.**

Yes, to use the IBW, adjusted body weight, predicted weight, or dosing weight, physician/APN/PA documentation that the patient is obese or has a BMI greater than 30 and the IBW, adjusted body weight, predicted weight, or dosing weight is being used to determine target ordered volume is required. The physician/APN/PA does not need to document the value for the IBW, adjusted body weight, predicted weight, or dosing weight, but the value for that weight must be included in the medical record.

Question 34: **Slide 25. If a patient has a known history of heart failure with a low ejection fraction, approximately 20 percent, and it is documented, can an albumin administration be given rather than crystalloids? Or can a reduced amount be accepted?**



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Albumin is not a crystalloid fluid or balanced crystalloid solution. Therefore, for purposes of SEP-1, albumin is not an acceptable alternative for crystalloid fluids or balanced crystalloid solutions. SEP-1 does not provide an exception for administering a lesser volume based on heart failure as a comorbidity.

Question 35: **Slide 25. If the order for 30 mL/kg crystalloid fluid includes the statement “ideal body weight used for patient obesity,” does this satisfy the first two bullet points? In other words, does this one statement sufficiently document that the patient is obese and that IBW is used to determine target ordered volume?**

Yes, this physician/APN/PA documentation is acceptable, as it includes the patient is obese and the IBW is being used to determine the target ordered volume.

Question 36: **Slide 25. Does the physician need to indicate the IBW in their notes, or can this be in the medical record from other sources?**

The physician/APN/PA documentation is not required to include the IBW value.

Question 37: **Is IBW to be used only for a BMI greater than 30, or can the physician use it for other reasons?**

The IBW is only acceptable to use when there is physician/APN/PA documentation stating the patient is obese or has a BMI greater than 30.

Question 38: **Is there ever going to be any exclusion for the crystalloid fluids if a physician documented a reason, such as renal failure or congestive heart failure?**

At this time, there are no plans for excluding cases from receiving the target ordered volume based on these comorbidities. The Centers for Medicare & Medicaid Services (CMS), the measure stewards, and the measure writers continue to weigh recommendations from recent literature and feedback from providers in consideration of future revisions.



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Question 39: Do you still require fluids for a lactate level greater than 4? That is still considered septic shock, correct?

While an *Initial Lactate Level Result* greater than or equal to 4 continues to suffice *Septic Shock Present* clinical criteria, the updates to v5.5a of the specifications manual base acceptable *Crystalloid Fluid Administration* on the *Septic Shock Presentation Date and Time*.

Question 40: Our electronic medication administration record (eMAR) documents IV end time with the dose or volume in the order. Is this enough to answer “Yes” for completely infused if the full volume is shown as given on the eMAR?

As long as there is a documented start time, documentation of the infusion/volume end time would be acceptable to consider the infusion completely infused.

Question 41: Is it acceptable to use an order without a stop time? For example, “infuse over 60 minutes.” The start time is 1400 without a stop time. Would it be acceptable if the medication label indicated a stop time?

Yes, as long as an infusion start time and rate, duration, or end time is documented, it would be acceptable.

Question 42: There is great confusion with what the “specified time frame” means. Does this mean the fluids have to be infused within the three-hour bundle?

The specified time frame for abstraction of crystalloid fluids is defined within the *Crystalloid Fluid Administration* data element as:

- The specified time frame for abstraction of crystalloid fluids is within 6 hours prior through 3 hours after either of the following trigger events. If both are present the specified time frame is determined by the earliest trigger.
 - Initial Hypotension Date and Time
 - Septic Shock Presentation Date and Time

The crystalloid fluids must be started within this time frame but do not need to be completely infused within this time frame.



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Question 43: Can fluids given in the ambulance prior to arrival be counted as part of the ordered fluids?

Yes, documentation of crystalloid fluids administered prior to arrival to the hospital (e.g., ambulance, nursing home) that is part of the medical record is acceptable if the documentation of fluid administration contains the type, volume, start time, and either a rate, duration, or end time of the fluid infusion. A physician/APN/PA order for fluids administered prior to arrival is not required.

Question 44: If the *Initial Hypotension Time* is before *Severe Sepsis Present*, would crystalloid fluids still be initiated between six hours prior to three hours after hypotension? For example, hypotension is at 9:00; severe sepsis criteria met at 11:00. Would crystalloid fluids still need to be initiated by 12:00?

Yes, the acceptable time frame for the abstraction of crystalloid fluids would be based on the *Initial Hypotension Date* and *Time* in this scenario. Therefore, if the *Initial Hypotension Date* and *Time* is 0900, crystalloid fluids ordered and initiated between 0300 through 1200 would be acceptable to abstract.

Question 45: If we need to look back at prior clinic visits for a weight, how far back are we expected to look?

If weight is not documented in the crystalloid fluid order, the weight closest to and prior to the crystalloid fluid order would be used. The *Crystalloid Fluid Administration* data element does not provide a specified time frame prior to the crystalloid fluid order.

Question 46: For IBW, can we use our EHR-calculated BMI, or must the provider document obesity?

Physician/APN/PA documentation indicating the patient is obese or has a BMI greater than 30 is required.



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- Question 47:** I have a case where normal saline (NS) is ordered at 1000 milliliters per hour (mL/hr). It was documented as being started at 16:00, but the end time was also listed as 16:00. Should we abstract 16:00 as the end time?
- If a rate or duration to infuse fluids contained within the order is different from the rate or duration the fluids that were actually administered, use the rate or duration over which the fluids were actually administered.
- Question 48:** If a patient has NS ordered at 150 mL/hr, but no amount is specified (e.g., it's a continuous order and not limited to one or two liters), can we use that for our crystalloid fluids?
- If the type of fluid, volume of fluid, rate, or infusion duration is missing, do not use the order toward the target ordered volume. Since this crystalloid fluid order does not contain a volume, the fluids would not be used in abstraction toward the target ordered volume.
- Question 49:** If the physician documents the use of IBW for crystalloid fluid amount, and the IBW is present in the record, but the physician/APN/PA doesn't specifically document that the patient is obese, but the record does include the BMI is greater than 30 in a flow sheet, is this acceptable?
- No, physician/APN/PA documentation indicating the patient is obese or has a BMI greater than 30 is required.
- Question 50:** For the completeness of the targeted volume administration, is the 10 percent leeway removed?
- No, crystalloid fluid volumes ordered that are equivalent to 30 mL/kg or within 10 percent less than 30 mL/kg are considered the target ordered volume.
- Question 51:** Our electronic medical record (EMR) allows providers to order weight-based fluids via IBW as long as a height and weight are documented. Does the provider need to document in their note what the IBW is?



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There must be physician/APN/PA documentation that the patient is obese or has a BMI greater than 30 and the IBW is being used to determine the target ordered volume. The IBW value must be present in the medical record but is not required to be documented by the physician/APN/PA.

Question 52: **When will transcatheter aortic valve replacement (TAVR) patients be excluded, as they are similar to VAD patients who are part of the excluded criteria?**

At this time, there are no plans for excluding patients who have received a TAVR from receiving the target ordered volume. CMS, the measure stewards, and the measure writers continue to weigh recommendations from recent literature and feedback from providers in consideration of future revisions.

Question 53: **Is there a minimum rate for fluid resuscitation?**

Only those crystalloid fluids given at a rate greater than 125 mL/hr would be used toward the target ordered volume. Do not use crystalloid fluids given at 125 mL/hr or less toward the target ordered volume.

Question 54: **Can the *Initial Hypotension* clock start ticking before the patient even meets criteria for the measure? For example, *Initial Hypotension* time is 1200, *Severe Sepsis Presentation Time* is 1530. Can the fluid component be met if the fluid is not started until 1530 when the patient meets clinical criteria?**

Yes, the specified time frame for abstraction of crystalloid fluids is within six hours prior through three hours after *Initial Hypotension Date and Time*. The specified time frame for the abstraction of crystalloid fluids is not based on the *Severe Sepsis Presentation Date and Time*.

Question 55: **If the 30 mL/kg bolus is administered in more than one infusion, would initiation of crystalloid fluids be the start date and time of the infusion that completes the target volume?**

If a single order is written for the target ordered volume and the infusion is given over multiple infusions, use the start date of the first crystalloid fluid infusion.



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Question 56: Do you anticipate seeing a decrease in the crystalloid fluid bolus component based on the v5.5a change requiring the fluid bolus to be completely infused within the specified time frame?

No, the target ordered volume of crystalloid fluids must be started within the specified time frame but does not need to be completely infused within a specified time. The fluid infusion can be completed after the specified time frame.

Question 57: Is it expected that a fluid reassessment would be performed prior to the completion of the target ordered IV fluids since the fluids are not required to be completed within the specified time frame?

The *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element must be completed within the time frame specified in that data element, which is from the *Crystalloid Fluid Administration Date and Time* through six hours after the presentation of *Septic Shock Date and Time*. The completion time of the target ordered volume does not affect the time frame for the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element.

Initial Lactate Level Collection

Question 58: Slide 41. *Severe Sepsis Presentation Time* is 1800. Which time would we use if the initial lactate was 2.5 and was resulted four hours prior to severe sepsis time at 1400, and the repeat lactate result was 3.8 resulted at 1900, which is one hour after *Severe Sepsis Presentation Time*?

The specified time frame within which an initial lactate must be drawn is within six hours prior through three hours following *Severe Sepsis Present*. If multiple lactate levels are drawn within the specified time frame, use the lactate drawn **prior** to the *Severe Sepsis Presentation Time* with the **highest** level. Based on the documentation provided, the *Initial Lactate Level Collection Time* would be 1400, and the *Repeat Lactate Level Collection Time* would be 1900.



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Question 59: **Slide 41. Can you provide some guidance or tips on how to abstract the second bullet point? It appears that it would be difficult to abstract and/or validate, especially if the patient has improving lactate levels.**

In this case, if multiple lactate levels are only drawn in the three hours after the *Severe Sepsis Presentation Time*, the *Initial Lactate Level Collection Date and Time* would be the lactate collection with the highest lactate level result within the three hours after the *Severe Sepsis Presentation Time*.

Question 60: **Slide 41. The *Severe Sepsis Presentation Time* is 12:00. There is a lactate drawn at 07:00 with a result of 2.1, another lactate is drawn at 11:00 with a result of 2.4, another lactate drawn at 13:00 with a result of 2.6, and another lactate drawn at 14:45 with a result of 2.7. In this scenario, which lactate draw time would you use, as there are multiple draws within six hours prior to *Severe Sepsis Presentation Time* and multiple draws within three hours after *Severe Sepsis Presentation Time*?**

The specified time frame within which an initial lactate must be drawn is within six hours prior through three hours following *Severe Sepsis Present*. If multiple lactate levels are drawn within the specified time frame, use the lactate drawn **prior** to the *Severe Sepsis Presentation Time* with the **highest** level. Based on the documentation provided, your initial lactate would be the lactate drawn at 1100 with a result of 2.4 mmol/L.

Question 61: **Slide 41. With the new *Initial Lactate Level Collection* guideline, how should we abstract if the lactic acid is documented as elevated due to a non-infectious process?**

Lactate values are not disregarded in the *Initial Lactate Level Collection* data element. If the *Initial Lactate Level Result* is greater than 2.0 millimoles per liter (mmol/L), then the following guidance may apply: if there is physician/APN/PA documentation prior to or within 24 hours after the initial lactate level result that indicates the initial lactate value is due to a condition that is not an infection, or is due to a medication, select Value "1" (Yes) for the *Initial Lactate Level Result* data element.



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Question 62:

If we now take the highest level for *Initial Lactate Level Collection*, would we just take the earliest lactate in the time frame after that highest for *Repeat Lactate Level Time*? The guidelines say that the repeat lactate is the next lactate after initial lactate but also states it should be after *Severe Sepsis Presentation Date and Time*. We could have a severe sepsis time of 10:00, lactate of 6 at 8:00, and lactate of 4 at 9:30. Would we take the 9:30 for the repeat lactate, or do we have to look after *Severe Sepsis Presentation Date and Time*?

The *Repeat Lactate Level Collection* is the next lactate level drawn after the *Initial Lactate Level Collection*, if the initial lactate is elevated (greater than 2.0 mmol/L). The *Repeat Lactate Level Collection* must be drawn in the time window beginning at *Severe Sepsis Presentation Date and Time* and ending six hours thereafter to choose Value “1” (Yes). For the example in this question, the lactate at 0930 could not be used for the repeat lactate because it was drawn prior to *Severe Sepsis Presentation Date and Time*. You would need to look for a lactate after *Sepsis Presentation Date and Time*. If a *Repeat Lactate Level Collection* was not drawn in the time window beginning at *Severe Sepsis Presentation Date and Time* and ending six hours thereafter, choose Value “2” (No).

Question 63:

If I obtain a lactate and the result is 3, fluids are given, and then a repeat lactate level is 5, which lactate do I use?

The specified time frame within which the *Initial Lactate Level Collection* must be drawn is within six hours prior through three hours following *Severe Sepsis Presentation*. If multiple lactate levels are drawn within the specified time frame, use the lactate drawn **prior** to the *Severe Sepsis Presentation Time* with the **highest** level. If multiple lactate levels are drawn **only** in the three hours after the *Severe Sepsis Presentation Time*, use the lactate drawn with the **highest** level within this time frame. Based on the documentation provided in the question, more information, such as the *Severe Sepsis Presentation Time*, would be needed to provide an accurate response.

Question 64:

Are we now supposed to use the collection time for the lactate instead of the result time?

For the *Initial Lactate Level Collection* data element, the date and time of the lactate collection would be used.



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Question 65: Why do you still call the data element “*Initial Lactate Level*” when it’s no longer necessarily the initial?

The *Initial Lactate Level Collection* is referring to the first of two lactate level collections required for the measure. The *Initial Lactate Level Collection* is the first, the *Repeat Lactate Level Collection* is the second lactate required.

Question 66: How would I abstract the following example case for both *Initial Lactate Level Collection* with date and time and the *Repeat Lactate Level Collection* with that date and time based on the new initial lactate level guidelines?

1000: HR 110 (criteria b)

1000: respiratory rate 24 (criteria b)

1000: BP 85/55 (criteria c)

1100: urinalysis shows urinary tract infection (criteria a)

1100: *Severe Sepsis Presentation Time*

1005: lactate drawn with result of 2.1

1050: fluids completed and second lactate drawn with result of 2.5

Per the new specifications, the lactate of 2.5 would be the “initial lactate.” Would this case fail because there is no third lactate?

In this scenario, the *Initial Lactate Level Collection Time* would be 1050 because the lactate of 2.5 mmol/L was recorded in the six hours prior to the *Severe Sepsis Presentation Date and Time*. In this scenario, if another lactate level was not collected between the *Severe Sepsis Presentation Date and Time* through six hours after the *Severe Sepsis Presentation Date and Time*, then Value “2” (No) would be selected for the *Repeat Lactate Level Collection* data element.



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Initial Lactate Level Date and Time

Question 67: If a lab is resulted under the “Lab” section of the EMR, and the provider open note time is dated and timed earlier than lab result in the “Lab” section of the EMR, and the note pulls in the lab without the lab result time, do we still have to use the open note time because it is earlier than the actual lab result time in a different section of the EMR?

Based on this updated guidance, if more than one date or time of documentation for the *Initial Lactate Level Collection*, follow the priority order to determine which *Initial Lactate Level Collection Time* to abstract within the specified time frame:

1. Laboratory documentation indicating date and time lactate was drawn.
2. Date and time the lactate is documented as drawn in a non-narrative location (e.g., sepsis flow sheet, checklist, screening).
3. Narrative note indicating lactate is drawn with an associated date and time.

Question 68: Slide 42. Can a handwritten lactate level, with date and time of draw, be abstracted if there is no lab documentation indicating the same lactate level result?

Yes, narrative documentation indicating the lactate was drawn with an associated date and time would be acceptable if no other documentation of the lactate collection was available.

Question 69: Slide 42. We use Epic at our organization. We have had issues with there being a delay in the way the lab is documenting the draw time for lactates and blood cultures. We have instructed our nurses to document in a narrative note when the labs were drawn. Per this specifications update, we now will not be using the earliest documentation, but following this order. The lab draws the labs, then scans them. Often times, in trying to get antibiotics administered, the nurses want to manually document to capture the earliest time of collection. Is there a rationale for this change?

The priority order was established based on concerns raised from abstractors that clinicians often pull lab results into their notes without the draw time. The note opened time was then used, which was typically much



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earlier and not an accurate reflection of when the lactate was drawn. If the lab did not document a date and time for the lactate collection, then other documentation reflecting lactate collection would be used.

Initial Hypotension

Question 70: **If I identify hypotension within the time frame, six hours prior to six hours after severe sepsis, but it was after the 30 mL/kg crystalloid fluids was completed, would I say “No” to *Initial Hypotension*?**

Correct. If the second hypotensive reading, within the specified time frame, was documented after the completion of the target ordered volume of crystalloid fluids, Value “2” (No) would be selected for *Initial Hypotension*.

Question 71: **If one hypotensive reading is before *Severe Sepsis Presentation Date* and *Time* and one after, but they are within three hours of each other, can you say *Initial Hypotension*, or do both readings have to be before, or do both have to be after?**

As long as the hypotensive readings are within the specified time frame, Value “1” (Yes) would be selected.

Question 72: **If the physician documents hypotension, but the vital sign reviews do not demonstrate any SBP less than 90 or mean arterial pressure (MAP) less than 65, do we use the physician documentation of hypotension? And, if so, what time do we use for *Initial Hypotension*?**

Physician documentation of the term “hypotension” would not be used to meet the criteria of the *Initial Hypotension* data element. The data element requires SBP readings less than 90 or MAP readings less than 65 to meet the criteria.

Question 73: **We have six hours post *Severe Sepsis Presentation Time* to collect BPs for determining *Initial Hypotension*, but we only have three hours post *Severe Sepsis Presentation Time* to get fluids in based off of the *Initial Hypotension*. How do we pass this measure if the second hypotension reading wasn’t present until after the three-hour fluid window?**



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The specified time frame for identification of *Initial Hypotension* is six hours prior through six hours after the *Severe Sepsis Presentation Date and Time*. The time frame within which crystalloid fluids must be started is not based on the *Severe Sepsis Presentation Date and Time*. If *Initial Hypotension* is present, the time frame for abstracting crystalloid fluids is within six hours prior through three hours after *Initial Hypotension Date and Time*.

Question 74: **For *Initial Hypotension*, can you have one SBP less than 90 and one MAP less than 65 to count, or do they need to be from the same measurement to count toward *Initial Hypotension*? For example, do you have to have two SBPs less than 90?**

An SBP less than 90 and MAP less than 65 would be acceptable for *Initial Hypotension* as long as the two readings are from different BP measurements. If the hypotensive systolic and MAP reading were from the same BP measure, it would only be used as one of the two readings needed for *Initial Hypotension*.

Question 75: **Are two BP readings less than 90 systolic, taken on different arms and timed at one minute apart, considered *Initial Hypotension*?**

Yes, these two readings would be acceptable, as they are two different measurements obtained at two different times.

Question 76: **Would you consider values that are obviously in error? For example, would you use a BP of 112/7 and MAP of 49?**

The BP of 112/7 and MAP of 49 would not be considered an obvious error. These values would be taken at face value and abstracted as documented in the medical record.

Question 77: **Can you please clarify the definition of an acute condition related to *Initial Hypotension*? Why is gastrointestinal (GI) bleed considered to be an acute condition and excludes the hypotension but dehydration should not be used? Neither is infectious.**

The example on slide 34 refers to physician/APN/PA documentation indicating hypotension is due to an acute condition, which is blood loss, in this case. Per the guidance on slide 34, to not use the hypotensive readings,



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the acute condition (i.e., blood loss) must be documented as due to a non-infectious source or process. Therefore, the example provides further physician/APN/PA documentation indicating the patient's blood loss is due to a GI bleed. In this example, GI bleed is the non-infectious source of the acute condition.

Question 78: **In regard to the two low BP readings or 40-point decline within three hours, does a 40-point BP drop need a provider link to an infectious cause?**

Yes, physician/APN/PA documentation must be present in the medical record indicating a greater than 40 millimeters of mercury (mmHg) decrease in SBP has occurred and is related to infection or severe sepsis and not related to other causes.

Additionally, the decrease in SBP of greater than 40 mmHg must occur within the specified time frame of six hours prior to or within six hours following *Severe Sepsis Presentation Date and Time* to meet the *Initial Hypotension* criteria.

Question 79: **Does the drop of a BP of greater than 40 points still need provider documentation that it was related to sepsis? Also, does this drop also need to be within the three-hour time frame (during the six hours prior to the six hours after presentation)?**

Yes, physician/APN/PA documentation must be present in the medical record indicating a greater than 40 mmHg decrease in SBP has occurred and is related to infection or severe sepsis and not related to other causes.

Additionally, the decrease in SBP of greater than 40 mmHg must occur within the specified time frame of six hours prior to or within six hours following *Severe Sepsis Presentation Date and Time* to meet the *Initial Hypotension* criteria.

Question 80: **If the provider documents hypotension during the specified time frame, and it may be in reference to an already hypotensive BP documented, but is not necessarily stated, would the patient meet *Initial Hypotension*?**



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Provider documentation of the term “hypotension” would not be used to meet the criteria of the *Initial Hypotension* data element. The data element requires SBP readings less than 90 or MAP readings less than 65 to meet the criteria.

Question 81: **The patient has severe sepsis and a target volume of fluid was initiated and completed. Then, within six hours after severe sepsis, the patient has two low BPs. Do you say “Yes” or “No” to *Initial Hypotension* if the fluids were already completely infused? The data dictionary states only to use BPs before target volume of fluid has been initiated and completed. Also, if those low blood pressures are not within one hour of the completed fluid administration time, do you select “No” to septic shock?**

If the target ordered volume of crystalloid fluids completed prior to the second hypotensive BP reading, which would identify *Initial Hypotension*, then Value “2” (No) would be selected for *Initial Hypotension*.

To determine the appropriate value to select for the *Septic Shock Present* data element based on *Persistent Hypotension*, only the BPs documented in the hour following the completion of the target ordered volume of crystalloid fluids would be used. BPs documented outside of the hour to assess for *Persistent Hypotension* would not be used.

Question 82: **If *Initial Hypotension* is noted prior to meeting severe sepsis criteria, but the BP increases prior to meeting criteria, does a fluid bolus still have to be administered?**

Yes, if Value “1” (Yes) is selected for *Initial Hypotension*, *Crystalloid Fluid Administration* is required.

Question 83: **Has there been any consideration requiring two low BPs (SBP less than 90 or MAP less than 65) for organ dysfunction instead of just one? We are using two BPs for *Initial Hypotension*.**

No, evidence of organ dysfunction for meeting the *Severe Sepsis Present* data element will remain one hypotensive reading within six hours of the other clinical criteria.



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Initial and Persistent Hypotension

Question 84: **Slide 34. Atrial fibrillation (A-fib) with rapid ventricular response (RVR) is non-infectious, but later it is said it should be used. Can you elaborate?**

Slide 34 provides guidance for cases where the physician/APN/PA has documented hypotension is due to an acute condition, and the acute condition is further documented as due to a non-infectious source or process.

The documentation of “atrial fibrillation (A-fib) with rapid ventricular response (RVR)” considers the increased heart rate (HR) to be due to A-fib. If there is physician/APN/PA documentation that A-fib is a chronic condition for the patient, the HRs (RVR) due to the chronic condition would not be used. However, if A-fib is an acute condition, and there is no further documentation that the acute condition is due to a non-infectious source or process, then the elevated HRs would be used.

Question 85: **Slide 34. Can a BP other than 80 be used? For example, could you use a BP of 78/50?**

Yes, the example on slide 34 considers the BP of 85/50 to be due to an acute condition with further documentation of a non-infectious source. In this case, “more severe” hypotensive BPs or any SBPs less than 85 would be used.

Question 86: **Slide 35. Is there a typo in the example? Shouldn't it be less than or equal to?**

The bullet point is referring to not using hypotensive readings that are “less severe” than the hypotensive value that is documented as due to the medication. In the example, the BP of 80/50 is documented as due to the medication. Therefore, “less severe” values would be SBPs greater than or equal to 80. In this example, SBPs 80 or above would not be used.



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- Question 87:** **Slide 35. Does the physician have to state the value of the BP?**
- To not use a hypotensive BP reading, the BP value or a term defining or representing the abnormal value must be documented by the physician/APN/PA as normal for the patient or due to a chronic condition, medication, or acute condition with a non-infectious source.
- Question 88:** **Slide 35. If the physician/APN/PA simply documents “hypotension secondary to Lasix[®]” and doesn’t reference a specific value, would all hypotensive readings be disregarded?**
- Yes, with documentation of the term defining the abnormal BP readings, all hypotensive readings would not be used.
- Question 89:** **Slide 35. Is the new BP parameter 80/50 and not less than 90/60?**
- No, to meet criteria, SBPs less than 90 or MAP readings less than 65 are acceptable. The BP of 80/50 on slide 35 is providing an example of physician/APN/PA documentation of a hypotensive reading that is due to a medication.
- Question 90:** **Slide 36. Why would we use a BP that is due to dehydration or congestive heart failure (CHF), if documented, since these are non-infectious sources?**
- Hypotension documented as due to an acute condition, such as dehydration or an acute on chronic condition, would be used, as the cause of the acute condition is possibly the infection or severe sepsis. Hypotension documented as due to a chronic condition alone, such as CHF, would not be used.
- Question 91:** **Slide 37. Do we accept documentation of hypotension without actual MAP or SBP parameters, or not? Can we use the documentation of hypotension alone to meet criteria?**
- Physician/APN/PA documentation that includes the abnormal BP value or a term defining or representing the abnormal value (“hypotension”) that is documented as normal for the patient or due to a chronic condition,



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medication, or an acute condition with a non-infectious source or process would be acceptable to not use the hypotensive reading(s).

Question 92:

Slide 39. If the latest piece of documentation within 24 hours states, “Antihypertensive medications discontinued due to hypotension,” then the patient’s hypotensive readings should not be used as clinical criteria for *Severe Sepsis Present*, correct?

Yes, if there was conflicting documentation in two or more separate pieces of physician/APN/PA documentation, and this is the latest documentation within the time frame, the hypotensive readings would not be used.

Question 93:

Slide 39. The time to start looking at the hypotensive readings would be 1600, correct?

No, the hypotensive readings documented within the time frame specified for either the *Initial Hypotension* or *Persistent Hypotension* data element would be used to determine which hypotensive values would be used. The guidance on slide 39 refers to determining if hypotensive readings would be used if there is conflicting physician/APN/PA documentation. In the example, the documentation at 1600, which is the latest piece of documentation, determines that the hypotension is due to the infection. Therefore, the hypotensive readings documented within the specified time frames of either data element would be used.

Question 94:

Please clarify the use of the term “hypotension” and how this will impact the existing guidance for *Initial Hypotension* and *Persistent Hypotension*. For example:

- 1) **For *Initial Hypotension*, does a term negate needing a second value?**
- 2) **For *Persistent Hypotension*, what if we have a normal BP, a high BP, and a term? Are we still supposed to look at the last two BPs within the hour?**
- 3) **For *Persistent Hypotension*, if we have a term, does that change the meaning of consecutive? Or does the time the term is documented considered the time associated with a value?**
- 4) **For *Persistent Hypotension*, how does a term change the application of answers two and three above?**



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The term “hypotension” would not be used to meet the criteria for either the *Initial Hypotension* or *Persistent Hypotension* data elements. Both data elements require SBP readings less than 90 or MAP readings less than 65 to meet the criteria.

Regarding the examples:

- 1) No, a second hypotensive reading is required (SBP less than 90 or MAP less than 65).
- 2) You must still look at the last two documented readings within the hour. The term “hypotension” is not acceptable in place of a low value.
- 3) Documentation of the term “hypotension” should be disregarded for purposes of determining the presence of *Persistent Hypotension*. Only the documented numeric values would be used. Two values with a term documented in between is considered two consecutive values.

Physician/APN/PA documentation of the term “hypotension” is acceptable when used to represent the abnormal value to disregard it as criteria. For example, physician/APN/PA documentation that “hypotension” is normal for the patient or due to a chronic condition, medication, or acute condition with a non-infectious source or process is acceptable to disregard the low BP values.

Question 95: **Will the time window for *Persistent Hypotension* expand since it is moving up in the algorithm? For example, if Value “3” is selected, it may open the window for further time options to capture accurate data?**

No, the specified time frame for the abstraction of *Persistent Hypotension* remains the hour following the completion of the target ordered volume of crystalloid fluids.

Question 96: **Should *Persistent Hypotension* be selected if the patient is on Levophed® or vasopressors for hypotension?**

The allowable value selected for *Persistent Hypotension* is dependent upon the BP readings documented in the hour to assess for *Persistent Hypotension*. The administration of a vasopressor during the hour to assess for *Persistent Hypotension* would not impact the allowable value selected for *Persistent Hypotension*.



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Question 97: When determining the time for *Persistent Hypotension*, would you select the second time of the hypotensive value?

Yes, if the *Septic Shock Presentation Date and Time* is based on the time *Persistent Hypotension* is identified, the date and time of the second consecutive hypotensive reading would be used.

Question 98: On occasion, in the hour after crystalloids are infused, the SBP stays in the upper 80s while the MAP is above 65 and into the low 70s. The provider holds off on vasopressors, as they are using the MAP to guide the decision for vasopressors. The guidelines require us to indicate that the patient has *Persistent Hypotension* because of the low SBP, and the case fails because a vasopressor is not started. Can use of the MAP, and exclusion of the SBP, apply in this situation?

At this time, no. If there are two consecutive SBPs, and Value “1” (Yes) is selected for *Persistent Hypotension*, the case will proceed to *Vasopressor Administration*.

Question 99: In determining crystalloid fluid end times for *Initial Hypotension* and *Persistent Hypotension*, I have the following question:

A one liter NS bolus is ordered. There is a start time on the MAR of 2350, but there is no end time. Instead, there is documentation in the Intake and Output in hourly increments (for example, 2300–2359 NS 1000 mL). Am I able to use this fluid toward the target volume and, if so, would I use an end time of 2359, or do I have to do calculations to determine the end time?

If a fluid bolus end/completed time is not documented, the fluids would not be used toward the target ordered volume of crystalloid fluids.

Question 100: If a physician documented hypotension, but the vital signs do not show hypotensive values, how do we abstract this?

Only SBP values less than 90 or MAP readings less than 65 would be abstracted to meet the criteria of the *Initial Hypotension* or *Persistent Hypotension* data elements. Therefore, if “hypotension” is documented alone, this documentation would not be abstracted.



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Question 101: Are there any plans to change how *Persistent Hypotension* is abstracted? The system seems to punish those who take multiple BPs in the hour after the fluid bolus is completed. If the last BP is hypotensive, but all the others are normal, the case fails. The rules do not address how to abstract on two readings with the first being normal and the last being hypotensive.

At this time, no further updates to this guidance are planned. However, the measure is continually being reviewed, which may result in an update in a future version of the manual. For cases in which there is a normal BP reading followed by a hypotensive reading at the end of the hour to assess for *Persistent Hypotension*, a follow-up BP in response to the last hypotensive reading is required. Otherwise, *Persistent Hypotension* is unable to be determined, as there is a single hypotensive reading at the end of the hour.

Question 102: If there is physician documentation of “chronic hypotension” within the appropriate time frame, is that sufficient to disregard any low BP readings, or must they reference the specific BP in order for us to disregard it?

Yes, the physician/APN/PA documentation that hypotension is due to chronic condition is acceptable to not use the hypotensive readings to meet criteria.

Question 103: For the MAP, please discuss whether or not the abstractor should calculate it, or only take the record at face value. Our EHR does not automatically calculate the MAP.

The abstractor should not calculate the MAP value. If a MAP reading is not available in your medical record, the MAP reading would not be used.

Question 104: If the fluids take, for example, eight hours to infuse, how do you assess for *Persistent Hypotension* in the hour after fluids are completed? The required vasopressors would be too late to pass the measure.

Persistent Hypotension would be assessed in the hour following the completion of the target ordered volume of crystalloid fluids. If the fluids are infused at slower rates and *Persistent Hypotension* is identified after



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the time frame to administer a vasopressor, then Value “2” (No) would be selected for *Vasopressor Administration*.

Question 105: **In determining hypotension, if the BP is within normal limits, but the MAP is less than 65, do you still have to call it hypotension requiring fluids?**

Yes, if either the SBP is less than 90 or the MAP is less than 65, the value(s) would be used.

Repeat Volume Status and Tissue Perfusion Assessment Performed

Question 106: **Slide 43. Does the title “Reassessment” in the body of the note, after the fluid bolus, meet the requirement?**

No, the title or heading of a section would not suffice for physician/APN/PA documentation attesting to performing an exam.

Question 107: **Slide 43. If a physician/APN/PA documents a physical exam under the heading “Physical Exam” within an EHR (which is then electronically signed), does this count as a *Repeat Volume Status and Tissue Perfusion Assessment Performed*? Or do they have to free text that a physical exam was performed?**

The findings of a physical exam documented in the History and Physical (H&P) under the “Physical Exam” section would not suffice for physician/APN/PA documentation attesting to performing or completing a physical examination, perfusion (re-perfusion) assessment, sepsis (severe sepsis or septic shock) focused exam, or systems review. The findings of a physical exam may be used to suffice five of the eight parameters provided in the data element as a second option for meeting the data element.

Question 108: **Slide 44. What is the definition of “shock index”? Please provide more information on what the shock index is and how it can be documented.**

Shock index (SI) is the HR divided by the SBP. The shock index can be documented in the medical record by the physician/APN/PA as shock index or SI.



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Question 109: **Slide 44. You stated that if the physician/APN/PA documented five of the eight parameters (with shock index being new), then Value “1” should be selected. However, aren’t there other elements within that question that need to be performed, for example, an echocardiogram, central venous pressure (CVP), etc.? Or, is it as long as they do five of the following eight, they can say “Yes” to the *Repeat Volume Status and Tissue Perfusion Assessment Performed?***

Only one of the three options/assessments provided in the data element is required to select Value “1” (Yes):

1. Physician/APN/PA documentation indicating or attesting to performing or completing a physical examination, perfusion (re-perfusion) assessment, sepsis (severe sepsis or septic shock) focused exam, or systems review.
2. Physician/APN/PA documentation indicating or attesting to performing or completing a review of at least five of the following eight parameters.
3. Documentation demonstrating one of the following was measured or performed: central venous pressure (CVP), central venous oxygen saturation (ScvO₂) or mixed venous oxygen saturation (SvO₂), echocardiogram, or fluid challenge or passive leg raise.

Question 110: **Slide 44. What are the eight parameters included with the January 1, 2019 discharges?**

The eight parameters are Arterial Oxygen Saturation, Capillary Refill, Cardiopulmonary Assessment, Peripheral Pulses, Shock Index, Skin Color or Condition, Urine Output, and Vital Signs.

Question 111: **Slide 44. Does the reassessment have to be from the same note?**

Physician/APN/PA documentation indicating or attesting to performing five of the eight parameters do not have to be in the same physician/APN/PA documentation.

Question 112: **Can we use “Review of Systems” or “Physical Exam” for the sepsis reevaluation? Or does this “Review of Systems” have to have specific systems reviewed?**



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Physician/APN/PA documentation attesting to performing a “Review of Systems” or “Physical Exam” would be acceptable. If documented by the physician/APN/PA this way, no further documentation of the specified systems reviewed is necessary.

Question 113: **Would “I have assessed (rather than reassessed) patient’s hemodynamic status” within the appropriate time frame be acceptable for *Repeat Volume Status and Tissue Perfusion Assessment Performed*?**

Yes, this physician/APN/PA documentation within the specified time frame would be acceptable.

Question 114: **What is the rationale that determined an H&P is not an acceptable post fluid bolus assessment when five of the eight required measures are appropriately documented?**

It is acceptable if five of the eight parameters are documented by the physician/APN/PA in the H&P within the allowable time frame.

Question 115: **Will a registered nurse’s assessment for re-perfusion ever be acceptable?**

At this time, CMS is not planning to update the guidance to accept nursing documentation of a reassessment.

Question 116: **Will patients with severe sepsis and *Initial Hypotension* still require documentation of a reassessment/reevaluation if hypotension persists within the one hour following completion of fluid bolus, or has this been eliminated?**

Yes, cases with Value “1” (Yes) selected for *Persistent Hypotension* or Value “2” (No) selected for *Persistent Hypotension* with an *Initial Lactate Level Result* greater than or equal to 4 are required to complete the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element.

Question 117: **If there is timely documentation in the H&P that the patient is hemodynamically stable, would this suffice for the focused exam?**



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No, this would not suffice for physician/APN/PA documentation indicating or attesting to performing or completing a physical examination, perfusion (re-perfusion) assessment, sepsis (severe sepsis or septic shock) focused exam, or systems review.

Severe Sepsis Present

Question 118: **Slide 46. What time should be used when the patient goes from the emergency department (ED) to the operating room (OR), and then postoperative, goes to the floor? In this case, our event log states the patient is admitted to perioperative care and then transferred to the floor.**

The updated guidance on slide 46 indicates that if an infection or severe sepsis is documented as “present on admission,” the earliest time the patient arrives to the floor or unit for admission would be used. Therefore, unless there was earlier documentation of an infection or earlier *Severe Sepsis Presentation Time* available, the time the patient arrived to the floor for admission postoperative would be used in this scenario.

Question 119: **Slide 46. If an ED provider completed a “cut and paste” of a chest x-ray result, with a determination of pneumonia, that only has a date and time within the “cut and paste,” can this be used as an infection time when there is no other time listed? Or would the time the ED provider opened the note be used if they mentioned pneumonia as a diagnosis without a specific time?**

If the infection (pneumonia, in this case) is documented within the chest x-ray result that is copied into the physician’s note with a date and time included for this documentation, that date and time would be used as a specified time for the documented infection. If a specified date and time was not included in the physician’s note for the documentation of pneumonia, then the note opened time would be used.

Question 120: **Slide 46. If the documentation states a patient is being treated with an antibiotic for an infection, and that antibiotic is ordered, do we say “Yes” for infection? If so, what time would we take; the time the**



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patient received the antibiotics? Can those antibiotics be PO, or do they have to be IV?

A condition documented as an indication for an antibiotic would be acceptable for *Severe Sepsis Present* criteria a (infection). Per the guidance, the time of the original documentation of the condition as an indication for an antibiotic would be acceptable, or any time after the original documentation where a dose of that antibiotic was administered would be acceptable for *Severe Sepsis Present* criteria a (infection). In general, only conditions documented as an indication for IV antibiotics are acceptable since oral antibiotics are only acceptable when *Clostridium difficile* is identified by the physician/APN/PA.

Question 121:

Slide 46. For infection present on admission, does this include when the patient arrives to the ED, and the ED notes that the patient is being treated for infection? Do you use the time of arrival to the ED for the infection date and time?

If an infection is documented as “present on admission,” the earliest time of arrival to the floor or unit for admission would be used. For infections documented as “present on arrival,” the earliest date and time of arrival to the hospital/ED would be used for the time of the infection. If there is documentation of an infection in the ED notes, the specified time of this documentation would be used or the note opened time if a specified time was not available.

Question 122:

Slide 46. Does physician/APN/PA documentation of “patient admitted with urinary tract infection (UTI)” equate to UTI being present on admission? And, should the time the patient arrives to the floor or unit for admission be used for criteria a in determining if severe sepsis is present?

Yes, the documentation of “patient admitted with UTI” would reflect the infection was “present on admission.” Therefore, the earliest time of arrival to the floor or unit for admission would be used.

Question 123:

Slide 46. For the first bullet point, do we need documentation in the MAR that an antibiotic is being administered for an infection, or do we need additional nursing documentation? If so, where?



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The physician/APN/PA, nursing, or pharmacist documentation that the patient is being treated with an antibiotic for an infection is not required to be on the MAR. The documentation sufficing this bullet point must simply be physician/APN/PA, nursing, or pharmacist documentation within the medical record.

Question 124: **Slide 46. For the first bullet point, do we consider antibiotic dose given time or order time for SOI?**

Further information is needed to completely respond to the question, as the measure developers are not clear on the meaning of the abbreviation “SOI.” However, if there is physician/APN/PA, nursing, or pharmacist documentation that the patient is being treated with an antibiotic for an infection, the time of the documented infection or the date and time of a later administered dose of the antibiotic would be acceptable for criteria a. Which infection time is used will depend on which documentation is within six hours of *Severe Sepsis Present* criteria b and c.

Question 125: **Slide 46. There are times when the hospital is full and sepsis patient time zero is hours before the arrival to the floor, and the admit physician documents severe sepsis on admit. In this scenario, we are already well past time zero and treatment, and it does not make sense to time zero for that patient at arrival to the unit. Please comment.**

If severe sepsis is only met by physician/APN/PA documentation stating “severe sepsis present on admission,” then the arrival time to the floor or unit for admission would be used. However, if severe sepsis is documented as “present on admission,” and there is also an earlier *Severe Sepsis Presentation Time* available (e.g., severe sepsis clinical criteria met in ED), then the earliest *Severe Sepsis Presentation Time* would be abstracted. CMS appreciates your comment regarding this situation and will share this with the measure stewards.



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Question 126: **Slide 47. Do we only refer to physician/APN/PA documentation to determine if creatinine is above baseline, or can we reference the EHR from previous admissions?**

Only physician/APN/PA documentation of chronic kidney disease (CKD) and the baseline creatinine are acceptable.

Question 127: **Slide 48. Could you clarify the note for abstraction in regard to not using vital signs in the OR?**

For specifications manual v5.5a, systemic inflammatory response syndrome (SIRS) criteria or evidence of organ dysfunction documented in the OR should not be used. For example, if a BP of 87/54 was documented in the OR, this hypotensive BP value would not be used as evidence of organ dysfunction.

Question 128: **Slide 48. Can you define what is considered the OR? For example, preoperative versus post-anesthesia care or just the actual time in the OR itself.**

The bullet point in specifications manual v5.5a only refers to the “operating room.” Therefore, SIRS criteria or evidence of organ dysfunction documented in preoperative areas prior to entering the OR and in postoperative care areas after leaving the OR would still be used.

Question 129: **Slide 48. Are you able to use vital signs during other procedures? For example, interventional radiology or cardiac catheterization laboratory.**

Yes, SIRS criteria or evidence of organ dysfunction documented in other procedural areas would still be used.

Question 130: **Slide 48. Does the second bullet point include clinical documentation improvement/coding queries, which are answered within the patient stay or after the time of discharge?**

If the coding query is documented prior to discharge, the documentation would be acceptable to use. However, if documented after discharge, the documentation would not be used.



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Question 131: **Slide 48. Does the “documented after the time of discharge” apply to documentation clarifications that are made within 30 days post discharge?**

The bullet point specifically refers to not using documentation of SIRS criteria, organ dysfunction, an infection, severe sepsis, or septic shock after discharge. Therefore, if an addendum or late entry within 30 days after discharge is documenting SIRS criteria, organ dysfunction, an infection, severe sepsis, or septic shock, the documentation would not be used. Other documentation in an addendum or late entry within 30 days after discharge would be acceptable based upon the element being abstracted.

Question 132: **Slide 49. If the nurse’s notes state that there is a critical lactate of 5.3 at 1240, but the lactate report from the lab states the lactate was resulted at 1245, which time would we choose?**

Based on the priority order added to the *Severe Sepsis Present* data element in specifications manual v5.5a, the time of the result reported by the lab (1245) would be used.

Question 133: **Slide 49. Could you provide some examples for number 3: Laboratory test sample draw or collected time?**

If the laboratory test value result time is not on a lab report, not in a narrative note that specifies the result time, and the result time is not in a non-narrative location such as a flow sheet, then documentation indicating the time the lab test was drawn or collected would be acceptable. The drawn or collected time for a laboratory test value may be in any source reflecting the lab was drawn. For example, documentation by the lab of a drawn time or narrative documentation stating when the lab was collected.

Question 134: **Slide 49. For number 4, it says to use the time the note was opened. Many of our narrative notes are revised multiple times after being opened. These revisions have date/time stamps. At times, the revisions occur days after the care was provided. It seems it would be more accurate to use the note revision time and not the time the note was opened. Please comment.**



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If the “note revision time” is directly associated with the laboratory test value, the “note revision time” would be acceptable to use as the first supporting source in cases where a result time is not documented by the lab. If a result time is not documented by the lab, and the “note revision time” is not directly associated with the laboratory test value, one of the other supporting sources would be used.

Question 135:

Slide 49. Can you please provide further guidance for the infection and note opened time? There is a lot of confusion of when you have to use the note opened time and if there is specific documentation or time stamps in the note for discharge time.

If an infection is documented in a physician/APN/PA, nursing, or pharmacist note without a specific date and time, use the date and time the note was started or opened. In this scenario, if a specified time is not available for the documentation of an infection, the note opened time must be within six hours of *Severe Sepsis Present* criteria b and c in order to use the infection for criteria a. Disregard any documentation of an infection in a discharge note, discharge summary, or documented after the time of discharge.

Question 136:

Slide 49. Our physician notes do not contain an “open note time,” they only contain the dictation time. If this time (e.g., for infection, severe sepsis, etc.) is earlier than other documentation, such as an order, can we use the dictation time?

Per the guidance in the *Severe Sepsis Present* data element, unless the dictated time reflected the specified time for the documentation of an infection or severe sepsis, a note opened time would be used. If a note opened time was unavailable, the documentation of an infection would not be used, as a time would not be available to determine if the infection was documented within six hours of the other *Severe Sepsis Present* clinical criteria.

Question 137:

Slide 49. If the laboratory test value result time is present in the EHR, but the time is way off, and you also have a value earlier, for example, in the ED flow sheet, could you use the flow sheet value?



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No, if the laboratory test value result time from the lab is available, this time would be used, as this is the primary source for the abstraction of the lab result time.

Question 138:

Slide 49. In our EHR, the “resulted” time terminology is “verified.” Our lab slips have the collected time and verified time, which is the time the laboratory test value was resulted and released into the EHR and is available to the provider. Would this level be appropriate for the “resulted” time?

No, a “verified time” would not be used in place of a resulted time. If the resulted time from the lab is not available, one of the supporting sources would be used to determine the time of the laboratory test value.

Question 139:

Slide 49. If the lab notifies the nurse or physician of a critical value, can you take that as the result time rather than the lab result time?

The time of narrative documentation that is directly associated with the laboratory test value would only be used as the supporting source if the result time from the lab is not available.

Question 140:

Slide 51. Does this guidance supersede the guidance regarding elevated creatinine levels for patients with end-stage renal disease (ESRD) who are on dialysis?

No, the guidance on slide 51 would not supersede other guidance within the data element. The guidance on slide 51 requires physician/APN/PA documentation stating the SIRS criteria or sign of organ dysfunction is due to a chronic condition in order to not use the SIRS criteria or sign of organ dysfunction. For example, if the physician/APN/PA documented “creatinine 3.0 due to ESRD,” the elevated creatinine would not be used.

The guidance under criteria c, creatinine provides two other scenarios in which an elevated creatinine value may be disregarded. The first of those scenarios to not use an elevated creatinine refers to having physician/APN/PA documentation of ESRD, and the patient is on hemodialysis or peritoneal dialysis. The second scenario refers to physician/APN/PA documentation of CKD and a documented baseline creatinine, and only to use documented creatinine values greater than 0.5 above the documented baseline in this specific scenario. In both of these



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scenarios, further physician/APN/PA documentation that the creatinine is due to the chronic condition is not required.

Question 141:

Slide 52. Would only the creatinine of 3.0 be excluded, or would all creatinine results up to 3.0 be excluded? In addition, if there is no baseline creatinine for a patient with CKD documented, are all creatinine values excluded?

In the example on slide 52, the creatinine of 3.0 is due to CKD, a chronic condition. Per the updated guidance in the *Severe Sepsis Present* data element, “less severe” values would not be used. Therefore, creatinine values less than 3.0 would also not be used in this case, as values less than 3.0 are less severe.

This also applies in the case that a baseline creatinine is not documented. With the creatinine of 3.0 documented as due to CKD, the creatinine of 3.0, as well as “less severe” creatinine values, would not be used. Without a baseline creatinine documented, creatinine values greater than 3.0 would be used. If a baseline creatinine was included in this documentation, creatinine values greater than 0.5 above the documented baseline would be used as evidence of organ dysfunction.

Question 142:

Slide 52. For “Hypotension after pain meds,” do we disregard all BP readings? What is the time period? Is it just that specific date or just for a certain time period after the medication was given?

With the term defining the abnormal BP readings (“hypotension”) documented as due to the medication, all hypotensive BP readings would not be used. If the documentation includes the statement “BP 85/60 due to pain meds,” only this specific BP and less severe SBP readings would not be used.

The guidance only provides a time frame in which this documentation must occur, which is prior to or within 24 hours after the *Severe Sepsis Presentation Date and Time*. A time frame for which hypotensive reading would not be used is not provided.



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Question 143: **Slide 54. The example states that we would exclude a high lactate if due to a seizure, but on slide 56, it says “Lactate 4.3 r/t seizure” should be used. Which one is correct?**

Slide 54 is providing examples for the bullet point provided on slide 53, which refers to not use SIRS criteria or a sign of organ dysfunction documented as due to an acute condition that has a non-infectious source. Therefore, the lactate is not used in the example on slide 54 because the lactate is documented as due to the seizure, and the seizure is further documented as due to a brain injury, which is the non-infectious source.

The lactate in the example on slide 56 is used because the lactate is only documented as due to an acute condition (seizure, in this case), and there is no further documentation that the acute condition has a non-infectious source.

Question 144: **Slide 54. If we have an elevated creatinine secondary to dehydration without the post diabetic ketoacidosis, we should take the creatinine, correct? Or, if we have a lactate of 4.3 related to a seizure without the post brain injury, we would use the creatinine?**

Correct. If the elevated creatinine or lactate is only documented as due to an acute condition without documentation of a non-infectious source, the elevated creatinine or lactate would be used.

Question 145: **Slide 55. Does the baseline creatinine not apply?**

The example on slide 55 does not provide a baseline creatinine. Therefore, a baseline creatinine would not apply in this scenario.

Question 146: **Slide 55. Please provide the rationale as to why the platelet counts of less than 75 or a creatinine greater than 2.8 would not be used.**

Based on the updated guidance, a particular value of SIRS criteria or sign of organ dysfunction would not be used; “less severe” values would also not be used. For example, if the platelet count of 75 was documented as due to a medication, “less severe” values or platelet counts between 75–100 would not be used, as they are “less severe” than 75.



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Similarly, if the creatinine of 2.8 is documented as due to a chronic condition, “less severe” creatinine values or creatinine values between 2.0–2.8 would also not be used, as those values are “less severe.”

Question 147:

Slide 55. If the physician documented thrombocytopenia related to chemotherapy (chemo), would we disregard all platelet counts? Additionally, if the physician documented thrombocytopenia related to chemo, does the physician also have to note the platelet count, or is the documentation of thrombocytopenia related to chemo sufficient?

With the term defining the abnormal platelet count (“thrombocytopenia”) documented as due to the medication, all low platelet counts would not be used. In this scenario, the specific low platelet count value would not need to be included in the physician/APN/PA documentation because the term “thrombocytopenia” defines the abnormal platelet count. If the documentation includes the statement “Platelets 75 due to chemo,” only this specific platelet count and platelet counts “less severe” than 75 would not be used.

Question 148:

Slide 55. In regard to the bullet “Cr 2.8, CKD”; if the patient has a creatinine value of 2.9, would we not consider this value because the specifications also say only to use creatinine values greater than 0.5 from the patient’s normal creatinine levels?

That is incorrect. Only in cases where the physician/APN/PA documents CKD and a baseline creatinine would values greater than 0.5 above baseline be used. In the example on slide 55, the specific creatinine of 2.8 is documented as due to CKD. A baseline creatinine is not included. Therefore, creatinine values greater than 2.8 would be used to meet organ dysfunction criteria.

Question 149:

Slide 55. Is there a typo in the first sub-bullet under the “Examples”? Should it state less than 75?

No, “less severe” platelet counts would be platelet counts greater than or equal to 75. For example, a platelet count of 85 is “less severe” than a platelet count of 75.



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Question 150: **Slide 56. “Acute” cholecystitis with no antibiotic ordered should not be used as documentation of infection, correct?**

Since cholecystitis is not listed under the Inclusion Guidelines for Abstraction for infections, a medical resource must be referenced to determine if the condition is infectious or caused by an infection. Since the condition may or may not be infectious or caused by an infection, supportive documentation would be needed to use this condition as an infection sufficing *Severe Sepsis Present* criteria a.

Question 151: **Slide 56. As the lactate related to seizure does not say it is due to a non-infectious source, it would be used, correct?**

Correct. Since the lactate is documented as due to an acute condition (seizure, in this case) without further documentation of a non-infectious source, the elevated lactate would be used.

Question 152: **Slide 56. If the lactate of 4.3 is documented as related to a seizure, why would this not be excluded?**

SIRS criteria or evidence of organ dysfunction (e.g., lactate) documented as due to an acute condition without further documentation of a non-infectious source would be used. Since the acute condition alone is potentially the result of the infection, severe sepsis, or septic shock, the SIRS criteria or evidence of organ dysfunction documented as due to an acute condition without a non-infectious source would be used.

Question 153: **Slide 56. Is there a typo in the first bullet? Should it read “should not be used”?**

No, this is not a typo. SIRS criteria or evidence of organ dysfunction (e.g., lactate) documented as due to an acute condition without further documentation of a non-infectious source would be used. Since the acute condition alone is potentially the result of the infection, severe sepsis, or septic shock, the SIRS criteria or evidence of organ dysfunction documented as due to an acute condition without a non-infectious source would be used.



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Question 154: **Slide 57. Does current A-fib with history of A-fib no longer exclude all tachycardic values greater than 90 beats per minute?**

If the elevated HR is documented as due to A-fib, and A-fib is a chronic condition for the patient, the elevated HR(s) would not be used. If the physician/APN/PA documentation does not consider the elevated HR to be due to chronic A-fib, then the HRs would be used.

Question 155: **Slide 57. Is this physician/APN/PA documentation only? Also, would the documentation of “acute kidney injury” be acceptable if the creatinine is less than or equal to 2.0?**

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication.

To suffice the criteria of the *Severe Sepsis Present* data element, the actual value(s) of the SIRS criteria or sign of organ dysfunction are required. A term that represents or defines SIRS criteria or sign of organ dysfunction would not be used to meet the clinical criteria of the *Severe Sepsis Present* data element.

Documentation of “acute kidney injury” would not be acceptable to use as evidence of organ dysfunction.

Question 156: **Slide 57. If the physician documents hypotension, would we use the note time for a hypotensive reading even if we have an SBP less than 90 during this time and none less than 90?**

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication.



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To suffice the criteria of the *Severe Sepsis Present* data element, the actual value(s) of the SIRS criteria or sign of organ dysfunction are required. A term that represents or defines SIRS criteria or sign of organ dysfunction would not be used to meet the clinical criteria of the *Severe Sepsis Present* data element.

The time the term “hypotension” is documented would not be used. The taken or obtained time of an actual hypotensive value would be used. If the taken or obtained time of a hypotensive value was not available, the documented time of the hypotensive reading would be used.

Question 157:

Slide 57. If the physician documents A-fib, would it also need a reference to tachycardia or RVR in order to disregard the HRs for SIRS criteria?

Yes, to not use the elevated HRs, physician/APN/PA documentation must include the HR value(s) or a term that represents or defines the elevated HR(s) (e.g., tachycardia) and the chronic condition.

Question 158:

Slide 57. Has the SIRS criteria for tachycardia changed to be an HR of greater than 100 rather than greater than 90?

No, HRs greater than 90 continues to meet criteria b (SIRS criteria) for the *Severe Sepsis Present* data element. The example on slide 57, “A-fib with tachycardia, A-fib with RVR, or tachycardia (Heart rate>100)” is in reference to if a physician/APN/PA documents “tachycardia due to something non-infectious” that the term “tachycardia” means HR greater than 100.

Question 159:

Slide 57. The time and date would then be when this was documented in a note?

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication. Yes, a time is required for this documentation to determine if the documentation was within the time frame, which is prior to or within 24 hours after the *Severe Sepsis Presentation Date and Time*.



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Question 160: **Slide 57. If the patient has a history of A-fib and the HR is over 100, can it be used as an organ failure?**

If the elevated HR is documented as due to A-fib, and A-fib is a chronic condition for the patient, the elevated HR(s) would not be used. If the physician/APN/PA documentation does not consider the elevated HR to be due to chronic A-fib, then the HRs would be used.

Question 161: **Slide 57. If the physician documents tachypnea secondary to a non-infectious etiology, would we disregard using a respiratory rate greater than 20 for SIRS criteria?**

No, in order to not use the elevated respiratory rate, the physician/APN/PA documentation must reflect tachypnea was normal for the patient, due to a chronic condition or medication, or do to an acute condition with a non-infectious source; then, the elevated respiratory rate would not be used.

Question 162: **Slide 57. The example includes A-fib with tachycardia, A-fib with RVR, or tachycardia. Are we allowed to take this now?**

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication.

Question 163: **Slide 57. Can we accept a narrative documentation of “tachypnea” as a SIRS criterion, or must there also be a respiratory rate of greater than 20 documented within the note or within a vital signs flow sheet?**

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication.

To suffice the criteria of the *Severe Sepsis Present* data element, the actual value(s) of the SIRS criteria or sign of organ dysfunction are required. A



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term that represents or defines SIRS criteria or sign of organ dysfunction would not be used to meet the clinical criteria of the *Severe Sepsis Present* data element. Therefore, the documentation of “tachypnea” alone would not be used for evidence of organ dysfunction. Documentation of an actual respiratory rate greater than 20 would be required.

Question 164: **Slide 57. Can you please clarify if this is only for determining if SIRS criteria or organ dysfunction should be excluded for meeting severe sepsis?**

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication.

To suffice the criteria of the *Severe Sepsis Present* data element, the actual value(s) of the SIRS criteria or sign of organ dysfunction are required. A term that represents or defines SIRS criteria or sign of organ dysfunction would not be used to meet the clinical criteria of the *Severe Sepsis Present* data element. For example, documentation of “acute kidney injury” would not be acceptable to use as evidence of organ dysfunction.

Question 165: **Slide 57. If a patient does not meet SIRS criteria, but the physician dictates leukocytosis, but the patient only has a white blood cell (WBC) count of 11.5, does this meet the SIRS criteria? If so, what do we use for the time? Would it be the time of the note?**

The guidance on slide 57 refers to documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication.

To suffice the criteria of the *Severe Sepsis Present* data element, the actual value(s) of the SIRS criteria or sign of organ dysfunction are required. A term that represents or defines SIRS criteria or sign of organ dysfunction would not be used to meet the clinical criteria of the *Severe Sepsis Present* data element. Therefore, documentation of “leukocytosis” would not be



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used to meet criteria. An actual WBC count meeting the criteria of the data element would be required to use the WBCs as SIRS criteria.

Question 166:

Slide 57. In the manual version 5.4, we were told to exclude documentation of A-fib with RVR. Now, we are told to use this documentation as SIRS criteria. Please provide the rationale for this change.

The documentation of “A-fib with RVR” has never been accepted as meeting the SIRS criterion of an HR greater than 90. In previous manuals and continuing in manual v5.5a, the physician/APN/PA documentation of “A-fib with RVR” is acceptable to disregard the elevated HRs when A-fib is a chronic condition for the patient, as the documentation of “A-fib with RVR” considers the elevated HRs to be due to the chronic condition.

Question 167:

Slide 57. In regard to the new guidance that a term can be used in place of an abnormal value, would this not cause possible inappropriate use of medication or care for the patient?

The actual value(s) of the SIRS criteria or sign of organ dysfunction are required to meet the clinical criteria for the *Severe Sepsis Present* data element. The terms noted on slide 57 or similar terms are not acceptable for determining the presence of severe sepsis and should not be used for the purpose of determining whether severe sepsis is present.

The guidance on slide 57 is specific to physician/APN/PA documentation indicating one of the SIRS criteria or sign of organ dysfunction was not present, due to it being normal for the patient, due to a chronic condition or medication, or an acute condition with a non-infectious source, and they used one of these terms that represents or defines a SIRS criterion or sign of organ dysfunction instead of stating the specific criteria.

Abstractor feedback has demonstrated that these terms in the bullet list on slide 57 are frequently used in this context by clinicians in narrative documentation. Because this update is to better capture how clinicians currently document narratively to reflect an abnormal value is due to something specific, it should not have an adverse impact on patient care.

Some examples of how these terms may be found in narrative documentation include but are not limited to the following:



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Terms from slide 57:

- Tachypnea (Respiration > 20 per minutes)
- Tachycardia, RVR (Heart rate > 90)
- Leukopenia (White blood cell count < 4,000)
- Leukocytosis (White blood cell count > 12,000)
- Thrombocytopenia (Platelet count < 100,000)
- Hypotension (Systolic blood pressure < 90 mmHg)

Examples of above terms being used in clinician documentation:

- “Leukopenia due to chemotherapy.” Since leukopenia is defined by a WBC count less than 4,000, a WBC less than 4,000 should not be used as a sign of organ dysfunction.
- “Patient has chronic A-fib with RVR.” Since RVR is associated with a heart rate greater than 90, and the documentation indicates the RVR is due to chronic A-fib, a heart rate greater than 90 should not be used for SIRS criteria.
- “Leukocytosis likely associated with DVT.” Since leukocytosis is defined by a WBC count greater than 12,000, a WBC greater than 12,000 should not be used as a sign of organ dysfunction.

NOTE: DVT=deep vein thrombosis

Question 168:

Slide 57. Is pancytopenia acceptable for low platelets?

Yes. Pancytopenia is a medical condition in which there is a reduction in the number of red and white blood cells, as well as platelets. If there is physician/APN/PA documentation that “pancytopenia” is normal for the patient, due to a chronic condition or medication, or due to an acute condition with a non-infectious source, then platelets less than 100,000 and WBC less than 4,000 should not be used.



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Question 169: **Slide 59. Would that be sepsis time zero used for sepsis criteria based on the latest documentation?**

Conflicting documentation within two or more separate pieces of documentation must be within 24 hours after the *Severe Sepsis Presentation Date and Time*, which is sometimes referred to as “sepsis time zero.”

Question 170: **Slide 59. Would you use the respiratory rate only after 1500 time in the first example?**

No, with the respiratory rate documented as due to an infection in the latest piece of documentation within 24 hours after the *Severe Sepsis Presentation Date and Time*, all elevated respiratory rates would be acceptable.

Question 171: **Slide 60. Are there any examples of documentation with both positive and negative qualifiers for infection?**

Some examples of documentation containing a positive and negative qualifier would be, “severe sepsis possible, but unlikely,” or “concern for UTI, ruled out.”

Question 172: **Slide 60. How do we abstract if the physician/APN/PA documents a statement with a positive and negative qualifier for infection criteria that states, “Sepsis (or infection) must be considered; will treat as sepsis/infection with antibiotics”?**

The physician/APN/PA documentation provided in the question does not contain a negative qualifier. Based on the documentation provided in the question, “sepsis” or the infection would be used for *Severe Sepsis Present* criteria a.

Question 173: **Slide 60. If one physician documents a positive qualifier to meet severe sepsis, and then an hour later another physician documents a negative qualifier, do we use the positive qualifier to meet criteria, or do we not use the positive qualifier to meet criteria? Note: These are two separate documentations, not the same documentation containing both a positive and negative qualifier.**



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Documentation of severe sepsis with a positive qualifier would be used to select Value “1” (Yes) for *Severe Sepsis Present*, if this reflects the earliest *Severe Sepsis Presentation Date and Time*.

The positive and negative qualifiers provided on the table within the *Severe Sepsis Present* data element are used to determine if documentation of an infection, severe sepsis, or septic shock would be used to suffice the data element. The positive and negative qualifiers are not necessarily used to negate the presence of an infection, severe sepsis, or septic shock after one of these has already presented/been documented.

To negate an infection, severe sepsis, or septic shock after the presentation, further physician/APN/PA documentation indicating the infection is not present or indicating the patient does not have severe sepsis or septic shock is required.

Question 174:

Slide 60. How do you abstract if there is a question mark (“?”) in the medical record documentation? For example, the physician documents “?sepsis.” Does this mean likely sepsis or questionable sepsis? Is it a positive or negative qualifier?

The documentation of an infection, severe sepsis, or septic shock including a “?” reflects the condition is “questionable.” Since questionable is a negative qualifier per the table, this documentation would not be used as documentation of current or suspected infection, severe sepsis, or septic shock.

Question 175:

How do we abstract if there is documentation that the “patient was admitted with severe sepsis” (and admit time to unit is 1500), but clinical criteria were met at 1430? Which time is used?

The earliest *Severe Sepsis Presentation Date and Time* would be abstracted. In the example provided, 1430 would be abstracted for the *Severe Sepsis Presentation Date and Time*.



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Question 176: Can physician’s documentation of infection in a narrative note be used as infection? For example, the physician documents “concerning patient is becoming progressively septic with an infected kidney hydronephrosis.”

Yes, physician/APN/PA or nursing documentation of an infection or suspected infection in narrative documentation is acceptable.

Question 177: To confirm, the term “hypotension” would not meet the criteria for severe sepsis, correct?

Correct. Documentation of a term that represents or defines a SIRS criterion or sign of organ dysfunction would not be used to meet the clinical criteria for *Severe Sepsis Present*. A term that represents or defines a SIRS criterion or sign of organ dysfunction is only acceptable when there is physician/APN/PA documentation that the SIRS criterion or sign of organ dysfunction is normal for the patient or due to a chronic condition or medication. To suffice the criteria of the *Severe Sepsis Present* data element, the actual value(s) of the SIRS criteria or sign of organ dysfunction are required.

Question 178: Is the guidance in the following response, from the July 26, 2017 SEP-1 v5.2a and v 5.3 commonly asked questions webinar still correct?

Question 6: Can the pharmacy indication for an antibiotic, for example, Zosyn, ordered with an indication of “sepsis” or “abdominal infection” be used as a known or suspected infection? And, if so, would you use the order time or the time of the first dose given?

Response: Yes, per the *Severe Sepsis Present* data element, pharmacist documentation indicating a patient is being treated with an antibiotic for an infection that is within six hours of criteria b or c is acceptable as a suspected infection (e.g., Levaquin is documented in the MAR for pneumonia).

Yes, specifications manual v5.5a continues to provide the following guidance:



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Physician/APN/PA, nursing, or pharmacist documentation indicating a patient is being treated with an antibiotic for an infection and that antibiotic is documented as administered within 6 hours of criteria b or c is acceptable (e.g., Levaquin is documented in MAR for pneumonia and nursing documentation within 6 hours of criteria b and c that indicates a dose was given).

With the infection documented as an indication for an antibiotic, the order that includes the antibiotic indication or a time the antibiotic is documented as administered would be used for the time of criteria a. The earliest acceptable infection documentation time within six hours of criteria b and c would be used to determine the earliest *Severe Sepsis Presentation Date and Time*.

Question 179: **Can you provide the specific documentation required to exclude HRs for a patient with chronic A-fib? Based on conversations with abstractors from other facilities, everyone is including/excluding the HRs differently.**

If the elevated HR is documented as due to A-fib, and A-fib is a chronic condition for the patient, the elevated HR(s) would not be used. If the physician/APN/PA documentation does not consider the elevated HR to be due to chronic A-fib, then the HRs would be used. Often, A-fib is documented by the physician/APN/PA as “history of” or “chronic” and further documented as “A-fib with RVR” or “A-fib with tachycardia.”

Question 180: **If the physician does not use the term “severe sepsis” but only “sepsis” in a patient that meets severe sepsis criteria, can this be abstracted as “severe sepsis”?**

Yes, if all three *Severe Sepsis Present* clinical criteria were met within six hours of each other, Value “1” (Yes) would be abstracted.

Question 181: **Has the SIRS criteria of altered mental status and blood glucose greater than 140 been removed?**

The SEP-1 measure has never included altered mental status or blood glucose as acceptable SIRS criteria.



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Question 182: If the provider documents “tachycardia normal for patient” with no value documented in the note, would I exclude the HR values as SIRS criteria?

Yes, if the physician/APN/PA documents “tachycardia is normal for the patient,” the elevated HRs would not be used.

Question 183: If the physician documented that the patient had CKD with no mention of dialysis, and they had a creatinine greater than 2, should the creatinine level be used as organ dysfunction?

The elevated creatinine would be used unless the physician/APN/PA documented the creatinine was due to the chronic condition.

Question 184: In regard to severe sepsis presentation/septic shock, are there any types of circumstances that allow us to disregard documentation of “septic shock” because the patient was not clinically in septic shock?

If a physician/APN/PA documented septic shock as present, and there is additional physician/APN/PA documentation indicating septic shock is not present within six hours of the *Septic Shock Presentation Date and Time*, Value “2” (No) would be selected for *Septic Shock Present*.

Question 185: If the ED provider mentions an infection term but does not list a time, and an antibiotic is ordered with the infection term mentioned in the order, should the time of the ordered antibiotic be used for the infection time, or should the abstractor use the time the ED provider opened their note?

Since both documentation of an infection in an untimed narrative note and documentation of an infection in the antibiotic order are acceptable, the earliest acceptable infection time would be used. For example, if the note opened time is used for the infection documented in an untimed narrative note, and the note opened time was earlier than the antibiotic order time, the note opened time would be used if it was within six hours of criteria b and c.



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Question 186: **It seems that any abnormal value that could count toward organ dysfunction has to be used, unless they document that it is not due to an infection. For example, instead of documenting “elevated lactate due to seizure,” they would have to document “not due to an infection.” Is that correct?**

To not use a SIRS criterion or sign of organ dysfunction, the physician/APN/PA must document the SIRS criterion or sign of organ dysfunction is normal for the patient, due to a chronic condition or medication, or due to an acute condition with a non-infectious source.

For example, the physician/APN/PA documentation “elevated lactate due to seizure” considers the lactate to be due to an acute condition, and the elevated lactate would be used. However, if the physician/APN/PA documentation stated, “elevated lactate due to seizure” and “seizure due to brain injury,” then the elevated lactate would not be used as the acute condition (seizure) is further documented as due to a non-infectious source (brain injury).

Question 187: **If an MD documents “SIRS,” and there are not two indicators, can we use that as a “Yes” to SIRS when looking for severe sepsis?**

No, to suffice the *Severe Sepsis Present* clinical criteria, two abnormal values qualifying for the SIRS criteria provided in the data element are required. The physician/APN/PA documentation of “SIRS” alone would not be used.

Question 188: **The documentation requirements seem challenging regarding SIRS criteria that is due to a non-infectious source in regard to “less severe values.” Oncology patients with recent chemo may continue to demonstrate thrombocytopenia, but values will be related to when the patient had chemo. This seems like a challenge versus the documentation of just having thrombocytopenia due to chemo. Is my interpretation correct?**

The guidance on slide 55 to not use “less severe values” applies only to situations where the physician/APN/PA documentation references or states specific physiologic parameter or lab values are normal for the patient, due to a chronic condition or medication, or due to an acute condition with a non-infectious source. For example, if the physician documents “platelet



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count 75,000 due to chemo” then platelet counts of 75,000 to 100,000 should not be used as a sign of organ dysfunction.

In previous versions of the manual, because the documentation specifically indicates a platelet count of 75,000 is due to the chemo, only that value could be disregarded. Other subsequent low platelet values could not be disregarded without additional clinician documentation indicating they are also low due to chemo. This new guidance allows abstractors to disregard any platelet values that may be subsequently obtained that are also low but not less than 75,000 (75,000–100,000) without additional documentation by the clinician.

This is different from documentation where the clinician uses a term defined by a value range. For example, if the clinician documents “thrombocytopenia due to chemo,” they have not identified a specific value (e.g., 75,000) that is due to chemo; rather, they have identified platelet count values defined by the term. Since thrombocytopenia is defined as a platelet count less than 100,000, all platelet counts less than 100,000 should be disregarded.

Question 189:

If the patient has one organ failure of hypotension, they do not require resuscitation with fluid until we get a second low BP in three hours. If there is only one low BP, would the patient still qualify for severe sepsis?

Yes, only one hypotensive BP reading within six hours of criteria a and b is needed for evidence of organ dysfunction (criteria c).

Severe Sepsis Presentation Date and Time

Question 190:

Slide 61. The patient presents to the ED, the status is changed from ED to inpatient while the patient is still in the ED, and the patient is boarded or housed in the ED for a period of time after the status change. Would we still use the time that the patient arrived on the floor or the time that the status change occurred?

If severe sepsis was documented by the physician/APN/PA as “present on arrival,” the earliest documented arrival time to the ED would be used. If severe sepsis was documented by the physician/APN/PA as “present on



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admission,” the earliest arrival time to the inpatient floor or unit for admission would be used.

Question 191: **Slide 62. Can you further define pre-hospital records? Does this include what we can see in our EHR? For example, a patient is seen in the infusion center and is then sent to the ED. Do we abstract the infusion center vital signs? The infusion center data are not part of the ED encounter data, but we could print and include them if the record was selected for validation.**

Documentation in pre-hospital records (e.g., ambulance records, nursing home records, clinic records) that is considered part of the medical record is acceptable for determining presence of severe sepsis. Therefore, if the documentation from the infusion center is included in the medical record, it would be acceptable to be used in abstraction.

Question 192: **Slide 62. If there is no time of the patient being received to the floor, would we then take the earliest documentation that implies the patient is on the floor or the time the patient left the ED?**

Yes, documentation supporting the earliest time the patient arrived to floor or unit for admission would be used.

Question 193: **Would I use provider documentation of “testing for *Clostridium difficile*” as the infection time?**

Yes, the physician/APN/PA documentation would suffice for documentation of a suspected or possible infection.

Question 194: **If the crystalloid fluid order states, “For severe sepsis? Yes,” can this be used as the *Severe Sepsis Presentation Time*?**

If the documentation on the crystalloid fluid order referencing “severe sepsis” is the earliest presentation of severe sepsis, then it would be acceptable to abstract the date and time of this documentation for the *Severe Sepsis Presentation Date and Time*.



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Question 195: **Is the ED triage time no longer used at all when “severe sepsis present on admission” is documented?**

Correct. The ED triage time is no longer used. If severe sepsis is documented by the physician/APN/PA as “present on admission,” the earliest documented arrival time to the inpatient floor or unit for admission would be used.

Question 196: **If provider documents severe sepsis, but the patient did not meet SIRS criteria, do we follow the provider documentation for the *Severe Sepsis Presentation Date and Time*? How do we abstract if it was reversed, if there was no provider documentation of severe sepsis, but there was a positive SIRS criteria?**

Presence of severe sepsis may be identified based upon clinical criteria or physician/APN/PA documentation of severe sepsis. To establish severe sepsis by clinical criteria, all three clinical criteria (a, b, and c) must be met within six hours of each other.

If a physician/APN/PA documents severe sepsis, but all three clinical criteria were not met, the physician/APN/PA documentation of severe sepsis would be used to determine the *Severe Sepsis Presentation Date and Time*. If the abstraction was reversed, and there was no physician/APN/PA documentation of severe sepsis, but the patient met all three clinical criteria (a, b, and c) within six hours of each other, the *Severe Sepsis Presentation Date and Time* would be when all three clinical criteria were met.

Question 197: **For present on admission, we have had patients who come in through the ED that do not meet all of the criteria until several hours after they are still in the ED. Then, upon admission to inpatient status, they now meet the criteria. Therefore, sepsis is present on admission to the floor but not present on arrival to the ED? How would this be abstracted?**

If the patient met all three clinical criteria, the date and time at which all three clinical criteria were met would be abstracted for the *Severe Sepsis Presentation Date and Time*. The admission time (i.e., earliest time of arrival to the inpatient floor or unit for admission) is only used when severe sepsis clinical criteria met in pre-hospital records and patient is a direct admit, physician/APN/PA documentation of severe sepsis in pre-hospital records



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and patient is a direct admit, or when there is physician/APN/PA documentation that severe sepsis was present on admission.

Question 198: **If the ED physician documents “patient was hypotensive at nursing home prior to hospital arrival” or “patient tachycardic with emergency medical service (EMS),” does that mean we could use that documentation and would use the arrival time for the criteria time?**

No, the actual values and time of SIRS criteria or evidence of organ dysfunction must be documented to meet the *Severe Sepsis Present* clinical criteria.

Question 199: **If there is no pre-hospital record, but the ED nurse documents in the timeline that the EMS vital signs meet SIRS criteria, can I use the ED nurse documentation of EMS vital signs?**

No, the actual values and time of SIRS criteria or evidence of organ dysfunction must be documented to meet the *Severe Sepsis Present* clinical criteria.

Question 200: **Could you please address how to abstract when there are multiple sources of infection contained within the same document, and one of the sources has a time stamp?**

If multiple infections are documented and contained within the same document, each infection documented is potentially acceptable for criteria a. To be used for criteria a, the earliest infection documentation within six hours of criteria b and c would be used. The earliest documented infection is abstracted in an effort to determine the earliest *Severe Sepsis Presentation Date and Time*.

Question 201: **If a patient meets clinical criteria and the physician documents severe sepsis after that time, our physician wants to know if we can use his documentation of the diagnosis instead of the time when all the clinical criteria are met?**

No, the earliest *Severe Sepsis Presentation Date and Time* would be used, regardless of whether severe sepsis was met by clinical criteria or physician/APN/PA documentation first.



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Septic Shock

Question 202: For *Septic Shock Present*, why does the data element not include an option for physician documentation? It is only severe sepsis with *Persistent Hypotension* or severe sepsis with a lactate greater or equal to 4. It should also include an option for severe sepsis with documentation of septic shock.

The *Septic Shock Present* data element provides the following guidance, which includes documentation of septic shock as acceptable:

- Presence of Septic Shock may be identified based upon clinical criteria OR physician/APN/PA documentation of Septic Shock.
- If clinical criteria for Septic Shock are NOT met, but there is physician/APN/PA documentation of Septic Shock, choose Value “1” (Yes).

Question 203: If the patient does not meet triggers for septic shock, but the physician documents the next day “septic shock resolving,” would we no longer use this documentation as criteria for septic shock?

Documentation of “septic shock resolving” would not be sufficient documentation to establish septic shock is present or suspected.

Question 204: If a physician is queried and states that septic shock was present on admission, but criteria were present before this query, which time would be used?

The earliest *Septic Shock Presentation Date* and *Time* would be used. Therefore, if septic shock clinical criteria are met prior to the admission time, abstract the time the last clinical criterion was met for the *Septic Shock Presentation Time*.

Question 205: Does the definition of septic shock still include a lactate greater than 4?

Yes, severe sepsis and an *Initial Lactate Level Result* greater than or equal to 4 continue to meet the criteria for the *Septic Shock Present* data element.



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Other Data Element Abstraction Guidance

Question 206: Most of our sepsis patients who come from a skilled nursing facility have already received either oral or IV antibiotics. How do we abstract this data element?

Documentation of actual IV antibiotic administration in pre-hospital records that are considered part of the medical record would be acceptable. For the *Broad Spectrum or Other Antibiotic Administration* data element, PO antibiotics would not be acceptable. Documentation that demonstrates actual administration of the antibiotic includes the antibiotic name, route, date, and time of administration.

Question 207: In our EMR the radiology notes are pulled into the ED note. The time stamp on the radiology report is actually the order time, not the result time, but it does not reflect this fact. Do I use the radiology note time within an ED note, or the ED note opened time, or the actual radiology report with the actual time?

The earliest acceptable time available for the infection documentation would be used. If the radiology report is pulled into the ED physician's note, with a specified time associated with the radiology report, the specified time documented within the ED physician's note would be used if this was the earliest time for the infection documentation. Otherwise, the time of the radiology report containing the physician/APN/PA documentation of the infection would be used.

Question 208: If an antibiotic is administered in the GI lab, several hours prior to the ED admission, should we use this in abstraction? All medication administration is available for viewing in our EHR.

Documentation of actual IV antibiotic administration in pre-hospital records that are considered part of the medical record would be acceptable. Documentation that demonstrates actual administration of the antibiotic includes the antibiotic name, route, date, and time of administration.



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Question 209: Can we use any documentation after discharge, such as amended progress notes?

Unless specified within a data element, an addendum or late entry made up to 30 days after discharge may be used for abstraction. The Introduction to the Data Dictionary provides specific guidance related to addendums and late entries.

Question 210: Can you review or provide an example of how you would use the documentation of “consult palliative care”?

For the *Directive for Comfort Care or Palliative Care, Severe Sepsis*, and *Directive for Comfort Care or Palliative Care, Septic Shock* data elements, physician/APN/PA documentation of an inclusion term within specific contexts outlined in the notes for abstraction are acceptable. Because both “palliative care” and “palliative consult” are inclusion terms, this includes physician/APN/PA documentation of palliative care or palliative consult as a recommendation, an order, patient request, plan, or referral.

Question 211: Do patients who arrive as a direct admit from another hospital or ED without a completed bundle count against you, or are they excluded?

The SEP-1 measure excludes patients who have been transferred from another hospital, ED, or ambulatory surgery center.

Comments and Questions

Question 212: Our ED physicians constantly ask who is “making hospitals do this” when asked to document better for sepsis abstraction. Is there a specific website where they could actually submit their own thoughts and suggestions?

Questions and comments regarding the SEP-1 measure may be submitted via the online [Hospital Inpatient Q&A tool](#) found on [QualityNet](#).



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- Question 213:** **There were changes made to the approved monotherapy and crosswalk antibiotics; how were these changes decided upon, and who is on the decision-making team for this?**
- The updates to the medication tables are based on measure steward and measure writer review of the medications. Medications that have been discontinued for one year or more were removed from the medication tables.
- Question 214:** **Why do you give us 24 hours prior to or within 24 hours for clinical criteria, but they only give us six hours after *Severe Sepsis Presentation Date and Time* for the physician to document no severe sepsis? If the patient does not meet the clinical criteria based on physician documentation within 24 hours, then the same rule should apply for the 24 hours for the physician to state no severe sepsis.**
- The time frame for physician/APN/PA documentation indicating severe sepsis is not present being within six hours after the *Severe Sepsis Presentation Time* is based on the need to perform the three-hour and six-hour bundle elements within that time frame. Once the severe sepsis clinical criteria are met or severe sepsis is documented by the physician/APN/PA, severe sepsis should be evaluated at that point and determined not present by physician/APN/PA documentation.
- Question 215:** **What percentage of facilities/cases are being validated for abstraction accuracy?**
- The selection of facilities and cases for validation is not based on a percentage. For more information regarding validation selection and processes please refer to [QualityNet](https://www.qualitynet.org/dcs/ContentServer?cid=1228776288808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page) at <https://www.qualitynet.org/dcs/ContentServer?cid=1228776288808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page>.
- Question 216:** **Has there been discussion in updating the CMS guidelines to reflect the 2016 sepsis definition?**
- CMS, the measure stewards, and the measure writers continue to monitor the literature regarding validity and reliability of the Sepsis-3 definition for application in early identification of severe sepsis and septic shock. To date, the literature is inconclusive.



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Question 217: Do you have any information about how funding will be tied to the measure compliance?

A hospital's SEP-1 performance is not tied to payment under the Hospital Inpatient Quality Reporting (IQR) Program requirements. However, failure to submit SEP-1 measure data may result in a one-fourth annual payment update (APU) reduction.

Question 218: Some of our physicians feel that the quick Sequential Organ Failure Assessment (qSOFA) criteria should be used to screen for sepsis. Will the screening criteria be changed in the near future?

At this time, CMS is not planning to incorporate qSOFA scoring into the SEP-1 measure in place of SIRS and organ dysfunction-based criteria. CMS, the measure stewards, and the measure writers continue to monitor the literature regarding validity and reliability of qSOFA compared to SIRS and organ dysfunction criteria for application in early identification of severe sepsis and septic shock. To date, the literature is inconclusive.

Question 219: Instead of putting lipstick on this pig, why not retire this useless and burdensome bundle and focus on meaningful outcome measures?

Thank you for the comment. At this time, the SEP-1 measure has produced data that demonstrate significant improvement in the treatment of severe sepsis and septic shock. CMS does understand the SEP-1 measure is complex. However, CMS, the measure stewards, and the measure writers continue to focus on quality improvement within the Severe Sepsis and Septic Shock measure while continuing to work on decreasing abstraction burden.

Question 220: Why are obstetric patients not excluded from this measure?

The measure does not exclude patient populations based on the hospital department the patient is in nor the patient's comorbidity. However, within the measure's data elements, there is specific guidance related to obstetric patients.



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Question 221: Is the Surviving Sepsis Campaign criteria the same as the CMS criteria? And, which temperature is CMS using, greater than 100.9 or greater than 100.4?

The SEP-1 measure is closely aligned with the Surviving Sepsis Campaign. Per the *Severe Sepsis Present* data element, which provides the SIRS criterion temperature criteria, temperatures greater than 100.9 would be used.

Bundle Analysis

Question 222: Slide 65. For crystalloid fluids, it states it qualifies for the septic shock six-hour bundle if the fluids were completed within three hours of initial hypotension and/or septic shock; is that correct?

Yes, this is correct. *Initial Hypotension* and *Septic Shock* both serve as triggers for administering crystalloid fluids.

Question 223: Slide 65. The slide implies that *Initial Hypotension* meets the septic shock criteria. It has always been my understanding that *Persistent Hypotension* is needed for septic shock. Is this still true?

Yes, this is still true. *Initial Hypotension* is a trigger to administer crystalloid fluids. If the hypotension persists, the patient has septic shock. If septic shock is present based upon persistent hypotension, then the septic shock six-hour bundle has been met because the fluids were given prior to the presence of septic shock.

Question 224: Slide 65. For the three-hour bundle and the initial antibiotic started, is there an acceptable delay for ESRD patients who go straight to dialysis on admission?

There are not any acceptable delay exceptions for antibiotic administration.

Question 225: Slide 69. With this information, do you believe SEP-1 will move forward to hospital value-based purchasing?



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CMS has provided no information at this time; this is a decision that CMS has yet to make. If SEP-1 does get included in the Hospital Value-Based Purchasing Program, this will be done through the rule-making process.

Question 226: **Slide 71. Can you define the parameter for the benchmark? Is it the top 10 percent?**

The benchmark is based on the Achievable Benchmarks of Care (ABC) methodology. For more information please refer to Weissman NW, et al. Achievable benchmarks of care: the ABCs of benchmarking. *Journal of Evaluation in Clinical Practice*. 1999; 5(3):269–281 at <https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1365-2753.1999.00203.x>.

Question 227: **Can you publish the exact specifications that were used to calculate the individual bundles from the patient-level data that are submitted for SEP-1? We've not been able to come up with a reliable way to parse the data this way and would like to replicate what you've done to compare ourselves and better drive performance improvement.**

SEP-1 was designed as a composite measure with a single overall performance rate and the logic for bundle-level reporting is complex. Because we are limited to data submitted for SEP-1, and that data is based upon reporting the overall performance, CMS is not able to drill down at the case level the same way a hospital can whom has additional case level detail data. Therefore, hospitals running their own bundle-level results may not match what is going to be reported in the Hospital Compare facility-level reports. We plan to provide some additional information about calculation of the bundle-level elements in the future. Bundle-level reporting in the Hospital Compare facility-level reports and downloadable database is planned for July 2019 and will include results, starting with cases discharged Q3 2018.



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Question 228: Are the graphs showing the breakdown of the bundles calculated using average or median rates of compliance?

The national rates are the average performance rates of all hospitals that submitted data.

Question 229: For the benchmark report, is the same patient counted for each bundle they are eligible for? For example, they would be counted in both the three-hour and six-hour bundles?

For the bundle-level reporting, the patient is counted in each bundle for which they are eligible. If a patient passes the overall SEP-1 rate and is eligible for every bundle, they are included in the denominator and numerator for each bundle.

Question 230: The slides detailing individual sub-metric performance, such as repeat lactate and fluids, really only address patients who have not failed at an earlier point. This can give a facility false information. For example, I have a patient who failed the antibiotic but has an initial lactate greater than 2. Because the algorithm shuts down at the point of failure, this patient never reaches the repeat lactate; so, his data are never included in your analysis. We may have bigger problems than realized by your data. My facility collects our own additional data in order to really know our rates for individual measures, such as fluids, etc.

CMS encourages hospitals to track their own performance rates for specific elements of care they identify are in need of improvement. SEP-1 was designed as a composite measure with a single overall performance rate. As such, taking into account the factors you point out is not possible.

Question 231: When is the next quarter of data going to be displayed on *Hospital Compare* for the sepsis bundle?

Bundle-level reporting in the *Hospital Compare* facility-level reports and downloadable database is planned for July 2019 and will include results, starting with cases discharged Q3 2018.



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Question 232: Are there any national mortality rates? Is there any evidence that the implementation of the SEP-1 measure has impacted outcomes, such as mortality related to severe sepsis? Can you comment on the “Compliance with SEP-1 Quality Measure Does Not Affect Sepsis Mortality” article from the American College of Emergency Physicians (<https://www.acepnow.com/article/compliance-with-sep-1-quality-measure-does-not-affect-sepsis-mortality/>)?

CMS is not aware of any national mortality rates for severe sepsis or septic shock that can be used for comparison or benchmarking. CMS is not able to comment on specific journal articles. CMS and the measure stewards take into consideration information from recent literature and updated practice guidelines during revisions to measure specifications, which occur twice per year for hospital inpatient quality reporting manually abstracted measures.

Question 233: The most recent report for the February 2019 refresh, for Q2 2017 through Q1 2018, shows the top 10 percent as 76 percent. Where is the benchmarks of greater than 80 percent coming from?

As discussed during the national provider call, the benchmark rate is based on the top 10th percentile performance rates of all hospitals reporting with an adjustment factor to account for hospitals with low volumes. The methodology used for the benchmark reports posted on *QualityNet* is different from that used to determine top 10 percent rates for *Hospital Compare* reports. The benchmark reports on *QualityNet* use the ABC methodology. For more information, please refer to Weissman NW, et al. Achievable benchmarks of care: the ABCs of benchmarking. *Journal of Evaluation in Clinical Practice*. 1999; 5(3):269–281 available on line at <https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1365-2753.1999.00203.x>.

Question 234: These data show how we are following directions (i.e., the bundle elements). Are there any data regarding the clinical improvement since bundle implementation and subsequent changes?

Like with any measure, the improvement in performance results are based on a combination of learning how to more accurately document and abstract, improvements to the measure specifications, and improvements in clinical care. It is difficult to sort out the contribution of each; and, for each



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hospital, the mix of what is contributing to increased measure performance may vary. The fewer changes made to the measure over time, the more likely increases in performance are due to improvements in care.

Question 235: **Can you elaborate on what will be included in the *Hospital Compare* bundle element reports?**

In addition to the SEP-1 overall performance rate, individual hospital severe sepsis three-hour and six-hour bundle results, septic shock three-hour and six-hour bundle results, state results, and national results will all be displayed in the facility-level report and the downloadable database. The facility-level report will report bundle results for facilities with fewer than 10 cases. The downloadable database will not report bundle results for facilities with fewer than 10 cases. The format of the information will be the same as for other measures reported in the facility-level reports and downloadable database.

Question 236: **Has severe sepsis incidences increased according to the data?**

CMS is not able to determine whether the incidence of severe sepsis is increasing, decreasing, or unchanged based upon the data. The data hospitals submit for SEP-1 represent a sample of the total number of cases and are not compared to total hospital admissions.

Question 237: **Is it correct that the compliance for every bundle element after the three-hour bundle is likely less than what is reported because patients who have already missed the measure for something else are not included? As such, these numbers are helpful for benchmarking but not true compliance with the bundle elements after the three-hour bundle.**

Correct. Because SEP-1 was designed as a composite measure with a single overall performance rate and to avoid unnecessary additional abstraction, once a case reaches a failure point, additional data are not abstracted and submitted. It is therefore impossible to know whether a case that did not meet requirements for the severe sepsis three-hour bundle may have met requirements for any of the subsequent bundles.