Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.2a Commonly Asked Questions & v5.3 Measure Updates

Questions & Answers

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Antibiotic (ABX)/Blood Culture (BC)

Question 1: **Slide 13: If the urgent care center is part of your health system and those records are available in the electronic medical record (EMR), can we look to see what time those cultures were sent?**

Yes, prior-to-arrival records can be used as long as the documentation is within the current medical record.

Question 2: **Additional clarification related to slides 12 and 13: Data Element Description: Was a broad spectrum or other antibiotic administered intravenously in the time window 24 hours prior to or three hours after severe sepsis presentation date and time = If patient received intravenous (IV) Ancef within the three-hour window, will you consider Ancef as "Other Antibiotic" and choose Value "1" to answer the said data element? Or should the antibiotic need to be either in Table 5.0 or Combination Antibiotic Therapy in Table 5.1 to be able to select Value "1"?**

For the Broad Spectrum or Other Antibiotic Administration data element, any IV antibiotic administered within the specified time frame will suffice selecting Value "1." Tables 5.0 and 5.1 are only reviewed upon reaching the Broad Spectrum or Other Antibiotic Selection data element.

Question 3: **Are patients receiving IV antibiotics for greater than 24 hours prior to severe sepsis time excluded from the Sepsis measure?**

Yes, if an IV antibiotic was received in the 24 hours prior to severe sepsis and was also greater than 24 hours prior to this (but not more than 72 hours prior), the case would be excluded.

Question 4: **Can a resulted urine culture be used for the Broad Spectrum or Other Antibiotic Selection data element?**

Culture and susceptibility testing in a lab report or physician/advanced practice nurse (APN)/physician assistant (PA) documentation referencing a urine culture collected within the time frame and susceptibility in a lab report can be used for an IV antibiotic administered within the three hours following the Severe Sepsis Presentation Time for the Broad Spectrum or Other Antibiotic Selection data element.

Question 5: **Can emergency medical services (EMS) draw blood cultures in the field?**

Yes, the data element does not limit who can collect the blood culture. Simply documentation of the date and time the blood cultures were collected is required to be within the medical record.

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?**

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 medication administration record [MAR] for pneumonia).

Question 7: **Definition for antibiotic selection for *Clostridium difficile (C. difficile, C. diff)* states oral vancomycin and IV Flagyl is an acceptable antibiotic selection. What if the vancomycin is given IV?**

For the *C. diff* exception, oral (PO) vancomycin with or without oral or IV Flagyl is acceptable. IV Flagyl at this time, alone is not acceptable. IV vancomycin alone, is also not acceptable.

Question 8: **For the Blood Culture Acceptable Delay data element, does the delay documentation have to be explicitly stated as the reason for the delay or can the abstractor "infer"?**

The delay documentation does not have to be explicitly stated. However, the documentation does need to communicate beyond reasonable doubt that the patient's condition is worsening or that antibiotics need to be started right away, or any multitude of reasons that would cause a delay.

Question 9: **If a patient is diagnosed with septic shock 10 days into the stay and has been on antibiotics for nine days prior to the diagnosis, what antibiotic dose can I use? A dose that was given either within 24 hours or three hours after the diagnosis, or does it have to be a new antibiotic given within that time frame?**

Please refer to the multitude of examples provided in the new tables added for version 5.3 of Broad Spectrum or Other Antibiotic Administration Date and Time data elements within the *Specifications Manual for National Hospital Inpatient Quality Measures* (aka specifications manual).

Question 10: **If patient presents to the emergency department (ED) at 0600, receives IV antibiotic for urinary tract infection (UTI) at 0730, then meets criteria for severe sepsis at 1030, and blood culture is obtained at 1030, would I answer "Yes" to Blood Culture Acceptable Delay, based on note for abstraction "within 24 hours prior to severe sepsis presentation, IV ABX were started in the hospital for an infection before severe sepsis was identified…"?**

Yes, in this scenario, since IV antibiotics were initiated for an infection within the 24 hours prior to the severe sepsis presentation time, this would be an acceptable blood culture delay.

Question 11: **If the patient refuses lab draws (i.e., a blood culture and/or repeat lactate) and it's documented in the lab-draw part of the electronic record, does it also have to be documented by the physician in order to exclude the case?**

The Administrative Contraindication to Care, Severe Sepsis data element only specifies physician/APN/PA or nursing documentation of a refusal. Regardless of the location within the medical record, as long as the refusal is documented by the physician/APN/PA or nurse and is within the specified time frame, it is acceptable.

Question 12: **If there is no IV access and it is documented, unable to obtain IV access, awaiting peripherally inserted central catheter (PICC) line, and an MD/APN/PA does not order the antibiotics as intramuscular (IM) to be administered within the three hours following severe sepsis criteria being met, will this result in a failure in the measure?**

Unless antibiotics are administered within the 24 hours prior to three hours after the severe sepsis presentation time, the case will not pass the Broad Spectrum or Other Antibiotic Administration data element.

Question 13: **In slide 50, is "or" missing in the first bullet? The first bullet states "24 hours prior to three hours," the sub-bullet states, "24 hours prior to or three hours after." Please clarify.**

The time frame for the Broad Spectrum or Other Antibiotic Administration data element includes the 24 hours prior to the severe sepsis presentation time to three hours after.

Question 14: **Just to clarify. We do not have to have blood cultures drawn before antibiotics re given.**

Blood cultures should be collected prior to IV antibiotic administration. The data element, Blood Culture Acceptable Delay, allows for particular scenarios in which a blood culture may not have been necessary or possible prior to IV antibiotic administration. However, the Surviving Sepsis Campaign and SEP-1 measure continue to recommend blood culture collection prior to IV antibiotic administration.

Question 15: **Just to clarify. If the provider documents their reasoning for ordering specific antibiotics, based on sensitivities, even if they do not meet the acceptable antibiotics per the measure, this is acceptable?**

If the physician/APN/PA documents a reference to a culture collected within the specified time frame, the causative organism, and the susceptibility, it would suffice, as long as the susceptible antibiotic was administered within three hours of the severe sepsis presentation time.

Question 16: **Some patients are coming in in full arrest or in the verge of arresting. Will that be considered as acceptable delay for blood culture and antibiotic?**

If there is physician/APN/PA documentation indicating there was an unacceptable delay, a delay that could be detrimental, or reflects the patient is deteriorating rapidly, it would be an acceptable delay. Also, if the patient expires within six hours of the severe sepsis presentation time, the case would be excluded.

Intravenous Fluids (IVF)

Question 17: **Slide 54: What if the verbiage "septic shock" is not in the record but the patient met criteria with severe sepsis and initial lactate greater than or equal to 4—and the refusal of fluids is documented as per the example?**

For the *Specifications Manual for National Hospital Inpatient Quality Measures, Version 5.3*, if the patient refused fluids, then Value "4" would be selected for the Crystalloid Fluid Administration data element. The case would be excluded prior to reaching the Septic Shock Present data element.

Question 18: **Are there any exceptions to giving the crystalloid fluids, such as patients who are in congestive heart failure (CHF) or end-stage renal disease (ESRD)? The ED doctors do not give the amount of fluids needed or they may not give any at all to severe sepsis patients with lactate greater than 4.**

No, simply based on the documentation of CHF and ESRD, an exception for not administering 30 mL/kg of crystalloid fluid is not provided in the measure.

Question 19: **Can within 10% of ideal body weight (IBW) be used to complete fluid bolus?**

If the physician/APN/PA ordered a volume within 10% of 30 mL/kg, it is acceptable. If the physician/APN/PA is using the IBW to determine 30 mL/kg and then orders a volume that is within 10% of the IBW 30 mL/kg volume, it would be acceptable. It is not acceptable to administer less than the volume that the physician/APN/PA ordered.

Question 20: **Can you please clarify slide 58, "Crystalloid fluids that are used to dilute medications are acceptable"? Does that mean if the patient was given vancomycin in 250 ml of normal saline (NS), we could abstract that as 250 ml toward the crystalloid fluids?**

Yes, crystalloid fluids used to administer medication or mix medication is acceptable. However, the fluids are still required to be administered at an acceptable rate.

Question 21: **Could you please clarify slide 19? Did you say that the time we should use for fluid administration time would be when the third liter was administrated, not when the first one was started?**

On slide 19, the correct crystalloid fluid administration time would be 1500 since at least 30 mL/kg was ordered. With multiple orders written, the start time of the infusion that completed the 30 mL/kg volume would be used. A volume within 10% of 30 mL/kg would not apply to this example because the physician ordered a volume that was at least 30 mL/kg.

Question 22: **Does the fluid bolus need to be completed within the six-hour time frame or does it just need to be initiated and meet the 30 mL/kg guidelines for amount infused?**

For the Crystalloid Fluid Administration data element, infusions are required to be initiated within the time frame. Infusions are not required to be completed within the specified time frame.

Question 23: **Does the protocol have to be scanned into the chart or do we just need to have a copy of the EMS protocols available in our ED?**

The order for fluids (protocol) would need to be in the patient's medical record.

Question 24: **Doesn't EMS typically provide IV fluid boluses through their own protocols? If the EMS documentation is included in the EHR, wouldn't this be acceptable? An ED physician wouldn't give orders for a non-ED EMS staff.**

Regardless of whether the protocol is of the hospital or EMS agency, the protocol sufficing the order requirements for Crystalloid Fluid Administration

data element would need to be in the patient's medical record. We have found some ED physicians do write fluid orders that include the prior-to-arrival fluid volume, which in turn suffices the order requirements for the Crystalloid Fluid Administration data element.

Question 25: **Do we need an order or not if the fluids are given by EMS? Thanks.**

For specifications manual version 5.2a, yes, a complete order is required. For manual version 5.3, an order is not required but there must be documentation of fluid administration.

Question 26: **For crystalloid fluid administration prior to arrival, version 5.2a: If EMS state-authorized orders are part of the medical record and the fluid orders have all required elements except a rate, it's ordered as a "bolus," can we count any fluids given by EMS as "completed" at least by time of arrival at the hospital if there is a start time but no specific end time documented? EMS documents time of arrival at facility in their records.**

In order to include the fluids ordered as a bolus, a rate, duration, or start and stop time would need to be included in the documentation of fluid administration. Simply arriving at the ED would not suffice for a fluid stop time.

Question 27: **For crystalloid fluid administration, if 2400 ml 0.9% sodium chloride (NaCl) ordered (30 mL/kg) to infuse over three hours at 800 ml/hr documented on MAR started at 0700, documented on MAR stopped at 0900. Would you answer (1) Yes or (2) No to crystalloid fluid administration?**

"Yes" could be selected for the Crystalloid Fluid Administration data element since there is a start and stop time for the single order for 30 mL/kg.

Question 28: **For crystalloid fluid given to dilute medications, what is an acceptable rate for this to be included? It wasn't mentioned.**

The acceptable rate for all fluids used toward the 30 mL/kg volume is greater than 125 ml/hr.

Question 29: **For prehospital fluids, is it either medical doctor (MD) order including EMS fluids or EMS documentation of fluid volume/time/rate in the medical record?**

For specifications manual version 5.2a, a physician/APN/PA order is required for all crystalloid fluids, as well as documentation of fluid administration. For manual version 5.3, a physician/APN/PA order is not required for prior-to-arrival fluids. However, there must be documentation of fluid administration within the medical record for all fluids administered prior to arrival.

Question 30: **For the 10% IVF, do the physician's orders need to specify the less 10% or should full 30 mL/kg be ordered?**

The allowance for a volume of within 10% of the 30 mL/kg only pertains to an ordered volume of fluids within 10% of 30 mL/kg. IV fluids that are administered should not be less than what was ordered.

Question 31: **For the 30 mL/kg, this would suggest that total volume administered is the priority and not the mls/minute?**

A total of 30 mL/kg must be administered at a rate greater than 125 ml/hr.

Question 32: **For slide 55, how should ideal body weight be determined?**

The IBW should not be calculated by the abstractor. The physician/APN/PA should include documentation indicating the patient has obesity or BMI greater than 30 and that the IBW is being used. The physician documentation should include either the IBW or total volume of fluids ordered based on the patient's IBW.

Question 33: **For version 5.3, slide 58, does this mean that NS with added potassium (KCL) or bicarbonate, given at 30 mL/kg, or at 150 ml/hr, is allowed to be used when answering the question?**

Crystalloid fluids with added electrolytes is addressed in the Crystalloid Fluid Administration data element. Crystalloid fluids mixed with potassium (KCL) would be acceptable if administered at greater than 125 ml/hr. Crystalloid fluids mixed with bicarbonate would not be acceptable.

Question 34: **I find slides 15 and 16 in conflict with slide 56. Do we need an order for EMS to administer fluids prior to arrival?**

Slides 15 and 16 are referencing specifications manual version 5.2a and slide 56 references manual version 5.3 changes. For manual version 5.2a, a physician/APN/PA order is required for all crystalloid fluids, as well as documentation of fluid administration. For manual version 5.3, a physician/APN/PA order is not required for prior-to-arrival fluids. However, there must be documentation of fluid administration within the medical record for all fluids administered prior to arrival.

Question 35: **If 10 % more than 30 mL/kg is infused, do I need to do the math to find the stop time?**

Unless exactly 30 mL/kg of crystalloid fluids are ordered and administered, calculating the completion time of the 30 mL/kg volume would be required.

Question 36: **If fluids were given in the operating room (OR) during the surgery, are we allowed to count those crystalloids towards the resuscitation time and date?**

Yes, fluids given in the OR can be used toward the 30 mL/kg total volume.

Question 37: **If the infusion is ordered at 1000 ml over 20 minutes and shows up that way on the electronic MAR but the down time of the infusion is 60 minutes after it is hung, which time is accurate for completion time: the rate-based expected down time or the actual recorded infusion down time?**

If the start and stop time for the infusion is documented, this would be used rather than the ordered rate.

Question 38: **If MD documents concern patient showing signs of pulmonary edema or CHF, is this sufficient documentation for reason for stopping fluids prior to full amount administered?**

No, if fluids were stopped prior to the completion of the 30 mL/kg total volume, Value “2” would be selected for the Crystalloid Fluid Administration data element.

Question 39: **If patient has multiple hypotension six hours prior to or within six hours following severe sepsis, when do you start counting three hours for IVF administration?**

For specifications manual version 5.3, the crystalloid fluid administration time should be between six hours prior to within three hours of the second hypotensive blood pressure reading, which is the blood pressure reading that identifies initial hypotension.

Question 40: **If the physician orders a bolus to infuse over one hour, can we look at the start time on the EMR and calculate the completion time one hour from the start time of the fluid bolus?**

Yes, with the start time of the bolus infusion documented, the infusion completion time would be in one hour, unless a later stop time is documented.

Question 41: **In version 5.3, it looks like an EMS protocol is not required to be in the record if crystalloid fluid is given in ambulance or at skilled nursing facility (SNF) prior to ED arrival. Is this correct?**

In specifications manual version 5.3, an order is not required for prior-to-arrival crystalloid fluids. Documentation of prior-to-arrival fluid administration is required to be in the medical record.

Question 42: **In the guidelines, it says to use the earliest time at which crystallized fluids were initiated. This does not correlate with what slide 20 states to use the time of 1500 as the crystallized fluid administration time. What is the correct time to use?**

Slide 20 provides an example of multiple physician orders being used to meet the 30 mL/kg total volume. The Crystalloid Fluid Administration Time data element provides guidance to use the start time of the infusion that completed the 30 mL/kg volume when multiple orders are used to meet the 30 mL/kg volume.

Question 43: **In the new version 5.3, if the fluids are initiated via multiple orders, which time frame is acceptable? Is it still the time when the "last fluid order" is initiated?**

Yes, all infusions ordered via multiple physician orders need to be initiated within the specified time frame.

Question 44: **Slide 18: Regarding the crystalloids, we are to use start time of the second bolus instead of the first bolus?**

Slide 18 demonstrates two physician orders for 1000 ml each. Since there are multiple physician orders used, the start time of the second infusion would be abstracted.

Question 45: **Patient had crystalloid fluids ordered at 30 mL/kg. Patient had two IVs, one at 150 ml/hr and one at 125 ml/hr. Patient is getting a total of 275 ml/hr. Can the second IV be counted in this instance as the total amount of fluids is greater than 125 ml or is it not counted as it is not considered a bolus but a maintenance IV?**

Only the crystalloid fluids administered at greater than 125 ml/hr would be counted toward the 30 mL/kg total volume. Crystalloid fluids administering at 125 ml/hr or less would not be used.

Question 46: **Regarding slide 56, do we still need to place the EMS protocol on the patient record for fluids administered prior to arrival?**

No, since an order is not required for prior-to-arrival fluids in specifications manual version 5.3, only documentation of the prior-to-arrival fluid administration is required to be in the medical record.

Question 47: **Slide 15: Since the anesthesiologist documents the amount of fluid administered but does not need to write an order for the fluids that are administered during a procedure, are the fluids that are administered by the anesthesiologist when severe sepsis presents during the procedure allowed to be included in the 30 mL/kg requirement?**

Slide 15 is referring to crystalloid fluid administration in specifications manual version 5.2a, in which a physician order is still required for crystalloid fluids. In version 5.3, a physician order for fluids administered in the OR is not required.

Question 48: **Slide 15 states need an order for fluids; however, slide 56 states an order is not required. Can you clarify?**

Slide 15 is in reference to specifications manual version 5.2a. Slide 56 is referring to manual version 5.3.

Question 49: **Slide 16, Scenario 1: What time and date would be used? The time/date of the order or from the EMS documentation?**

If 30 mL/kg is ordered in a single physician/APN/PA order, the start time of the first infusion would be abstracted for the Crystalloid Fluid Administration Time data element.

Question 50: **Slide 30: So if it states "wide open" or "bolus," it is our practice that the rate is 1L and it goes over an hour. Sometimes end time is not documented by the registered nurse (RN), but can I calculate it using the 1000 ml/hr?**

No, you cannot calculate it if an end time is not documented by the RN.

Question 51: **Slide 56: Would "bolus" or "wide open" qualify for a rate? Could I count documentation by EMS for fluids prior to arrival: 200 cc 0.9% NaCl bolus started at 0900?**

No, the documentation "200 cc 0.9% NaCl bolus started at 0900" alone would not suffice. The terms "bolus" or "wide open" are acceptable without a rate or infusion duration, if a rate or time over which the IV fluids are to be given **or** the fluid bolus completed time or end time is documented in the medical record.

Question 52: **Slide 57: The specifics of type, volume, start time, rate/duration/end time is necessary? If one is missing, cannot use?**

Correct. Although a physician order is not required for fluids administered in the OR, there must be documentation of fluid administration including the type, volume, start time, and rate/duration/end time.

Question 53: **Slide 59: So if fluids were initiated prior to the six hours even though some fluid was administered in the six-hour time frame, you can't use that volume?**

If a single order for crystalloid fluids is started greater than six hours prior to initial hypotension, the fluids would not be used. If multiple physician orders are used to meet the 30 mL/kg volume, only fluids started within the specified time frame would be counted toward the 30 mL/kg volume.

Question 54: **So do I understand that version 5.2 says we must have MD order for IVF given prior to arrival but with version 5.3 release, we no longer need a physician order for IVF given prior to arrival?**

Specifications manual version 5.3 was revised so that physician orders for prior-to-arrival fluids are not required.

Question 55: **So our ED MD would need to enter an order on our chart if EMS gave the initial bolus of, let's say, 500 cc NS bolus?**

For manual version 5.2a, a complete physician order would be required to be on the medical record for all crystalloid fluids.

Examination

Question 56: **Slide 23: Regarding the focused exam, is there a specific time clinically, that the exam should be done? I know the specification time frames, however, clinically, when would an exam be most appropriate (i.e., after the completion of the bolus)?**

The repeat volume status and tissue perfusion assessment would be most accurate clinically following the completion of the 30 mL/kg of crystalloid fluids.

Question 57: **Are the words "exam" and "assessment" interchangeable?**

For the purposes of the focused exam data elements, yes.

Question 58: **Can a statement under the Review of Systems section be used for focused exam? "A complete and comprehensive review of systems was negative except for those noted in history of present illness (HPI)."**

Yes, this documentation within the specified time frame would suffice for all five focused exam data elements.

Question 59: **Can focused exam findings be collected from multiple MD notes, at different times, within the specified time frame?**

The documentation of each focused exam may be documented at different points within the specified time frame and by multiple physicians.

Question 60: **Can you please clarify the focused exam requirements? Am I understanding that each element does not have to be documented, only a narrative with a date/time stamp? If so, when abstracting, would I use the date/time stamp when the narrative was documented? Thank you.**

If the physician "narratively" documents his or her performance of a physical exam, this would suffice for all five focused exam data elements without each focused exam data element needing to be addressed individually. The date and time of the physician's documentation of his or her performance of a physical exam would be used for each focused exam date and time data element.

Question 61: Do you have to have all the separate exam items documented?

If there is physician/APN/PA documentation of having performed or attested to performing a physical exam or assessment, each individual focused exam data element does **not** need to be documented. If there is not physician/APN/PA documentation of having performed a physical exam or assessment, each individual focused exam data element does need to be documented.

Question 62: For physical exam, if physical exam performed is documented, is this alone acceptable, or does the physician need to document each measure, for example, capillary refill?

The physician documentation of his or her performance of a physical exam, will suffice for all five focused exam data elements without each focused exam data element needing to be addressed individually.

Question 63: For the focused exam, one of the acceptable sources is the history and physical (H&P); does this contradict what is stated on slide 24? How would a physical exam within the H&P be unacceptable?

The first bullet point on slide 24 refers to the heading or title of a section within an H&P or medical record as not being acceptable for physician/APN/PA documentation. The exception bullet point regarding documentation of the physician/APN/PA performance of a physical exam is not looking for a section heading or title, or the findings of a physical exam. The exception is looking for physician/APN/PA documentation of his or her performance of a physical exam, which is most often reflected in narrative documentation.

Question 64: For the sepsis focused exam, the time frame is start of IV fluid resuscitation to six hours after septic shock presentation time. Do we use the start time of any crystalloid fluid administration or the start time that completes the 30 mL/kg requirement?

The time frame for the focused exam data elements is the Crystalloid Fluid Administration Date and Time to six hours after the Septic Shock Presentation Date and Time. Since this directly refers to the Crystalloid Fluid Administration Date and Time data elements, you should use the date and time you entered for these data elements as the start for the time frame within which to look for the focused exam.

Question 65: **Got a little confused regarding focused exam. So can we use the exam from an H&P? For example, on H&P has vital signs (VS), which is in the time frame the focused exam needs to be done, can we use these vitals?**

The H&P can be used to abstract elements of the focused exam. If the physician/APN/PA includes documentation in the H&P of a vital signs review that meets the requirements of the vital signs review data elements, it is acceptable to use.

Question 66: **If a patient gets transferred to critical care prior to completion of fluids and another physician (critical care physician) documents the required reassessment elements under the heading, Physical Exam, would this be acceptable?**

Documentation of the reassessment can be performed by a physician other than the physician who ordered the fluids, and is acceptable, provided the documentation under the Physical Exam heading meets the requirements set forth in the reassessment data elements.

Question 67: **If a physician completes his or her focused physical exam (including all elements with time stamp) following IV fluid bolus, but does not indicate one of these phrases on slide 23 (Example, "I did the sepsis reassessment."), is this still acceptable?**

Yes, each focused exam data element can be met by the physician/APN/PA documentation of each required element **or** by the exceptions, including physician/APN/PA documentation of his or her performance of an exam. Both are not required to meet the focused exam data elements.

Question 68: **If the elements for focused exam (e.g., cardiopulmonary, capillary refill) have been addressed under the Physical Exam tab of the H&P, are they acceptable if in the right time frame for the assessment?**

Yes, documentation of individual focused exam elements under the Physical Exam tab are acceptable.

Question 69: If there is more than one focused exam, which one do you use?

If there is documentation of multiple focused exams, abstract the date and time of the examination that was documented latest within the time window.

Question 70: In regards to the focused exam, no matter what heading the physician labels the assessment, all elements of the focused assessment have to be fully documented?

If there is physician/APN/PA documentation of having performed or attested to performing a physical exam or assessment, each individual focused exam data element **does not** need to be documented. If there is not physician/APN/PA documentation of having performed a physical exam or assessment, each individual focused exam data element **does** need to be documented.

Question 71: On slide 24, it states under acceptable documentation "review of systems completed" and "12 point systems review pertinent positives as documented" is listed. If within the H&P the MD documents "review of systems completed" and/or "12 point systems review pertinent positives as documented," would this be acceptable to meet the focused exam?

Per the examples on Slide 23, yes, physician/APN/PA documentation of "review of systems completed" or "12 point systems review pertinent positives as documented" would be acceptable.

Question 72: Our hospital uses a "severe sepsis focused exam" to reassess patients with sepsis, severe sepsis, and septic shock. If the "severe sepsis focused exam" is referenced by name within physician documentation, will this trigger a "Yes" answer to the data element Severe Sepsis Present in a patient who does not meet clinical criteria for severe sepsis? For example, a patient with simple sepsis with no organ dysfunction, and the physician documents "severe sepsis focused exam complete." With the inclusion terminology of "severe sepsis" within the Severe Sepsis Present data element, would this documentation automatically start our clock?

The physician/APN/PA documentation of "severe sepsis focused exam complete" by a physician is stating they completed the exam; it does not necessarily equate to the physician saying the patient has severe sepsis or that the patient is concerning for it.

Question 73: **Please reiterate whether a focused exam can be documented sometime after the start of the fluid bolus or does it have to be documented after the bolus is completed.**

The time window within which to look for documentation of a focused exam begins with the crystalloid fluid start time, not the fluid completed time.

Question 74: **Slide 22: What if the findings of the physical exam are contained under the heading, Physical Exam? The physician clearly performed the exam by listing the findings.**

If the findings documented by the physician under the heading, Physical Exam, meet the requirements of the exam data elements, they are acceptable to use. The slide references that the name of the heading, Physician Exam, alone with no findings documented under it or findings that do not meet exam data element requirements is not acceptable.

Question 75: **Slide 24: H&P section Physical Exam tab with "skin: pallor, peripheral pulses: present." Would that be sufficient to pass those two elements?**

Yes, if the documentation required to suffice individual focused exam data elements in documented within the findings of a physical exam, it would suffice the particular data element. The documentation of "skin: pallor" and "peripheral pulses: present" would both suffice those particular data elements.

Question 76: **We are a teaching hospital with interns and residents. If the perfusion exam is completed by one of them and they are not licensed yet, does the perfusion exam count or does it need to be co-signed by an attending physician or other licensed physician?**

The Introduction to the Data Dictionary section of the specifications manual provides guidance regarding medical students, interns, and residents. The Introduction to the Data Dictionary states, "Resident and intern notes should be considered physician documentation. Medical student notes must be co-signed by a physician."

Question 77: **What if the initial ED doctor started the fluid bolus and another provider does the focused exam in or out of the ED and documents it appropriately. Is that okay?**

Documentation of the reassessment can be performed by a physician other than the physician who ordered the fluids.

Question 78: **Will documentation of "patient reassessed" in the ED record pass for a focused exam?**

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

Hypotension

Question 79: **Slide 26: You only need one blood pressure (BP) reading for persistent hypotension?**

Slide 26 reflects two consecutive hypotensive blood pressures are required to select Value "1" for the Persistent Hypotension data element.

Question 80: **Slide 26: Can you explain the difference between Scenario 4 and 6—why does one work when the other does not?**

Scenario 4 on slide 26 reflects the last blood pressure reading to be "normal." Therefore, Value "2" is selected for the Persistent Hypotension data element since this appears to reflect the blood pressure is normalizing after fluids resuscitation and likely not requiring vasopressor administration. Scenario 6 reflects two consecutive hypotensive blood pressures remaining at the end of the range. Therefore, reflecting hypotension continues to persist after fluid resuscitation.

Question 81: **Does physician have to document "hypotension due to blood loss secondary to trauma"? Blood loss is not an infection; why do we have to include "due to trauma"?**

For specifications manual version 5.2a, the physician documentation "hypotension due to blood loss" is sufficient to disregard the hypotensive blood

pressure readings since this documentation considers the hypotensive blood pressures to be due to an acute condition that is not an infection.

For manual version 5.3, if hypotension is documented as due to an acute condition, in order to exclude it, documentation to show that the cause of the hypotension is due to a noninfectious source is required. Often severe sepsis or septic shock causes acute conditions in which hypotensive blood pressure readings are related to an acute condition that is actually caused by the infection, severe sepsis, or septic shock. Hypotension, in this scenario, should not be disregarded since it is actually due to the infection, severe sepsis, or septic shock. If there is further documentation indicating the acute condition causing the hypotensive blood pressure is due to a noninfectious source (trauma), the hypotensive readings would then be disregarded.

Question 82: Slide 26: For persistent hypotension, your Scenario 4 example would be correct for 2018, not 2017?

Scenario 4 provides an example that is correct for 2017 and 2018.

Question 83: For version 5.3, what happens if we need to abstract for persistent hypotension when the patient is in OR if we cannot use vitals documented in the OR?

If blood pressures were documented in the OR within the hour to assess for persistent hypotension, Value "2" would be selected since the blood pressure was documented. The value of those blood pressures documented in the OR would simply be disregarded.

Question 84: In regards to slide 60, would the time of initial hypotension be the time of the last low blood pressure reading?

Yes, the time of the second hypotensive blood pressure within the specified time frame would be used.

Question 85: In Slide 43, what time would you use for that creatinine that is fulfilling organ dysfunction? The draw time or result time?

The time the elevated creatinine was reported (resulted) would be used.

Question 86: **On Scenarios 4, 5, and 6, is there a time frame for this? Should all these be in an hour after completion of 30 mL/kg?**

If your question is referencing persistent hypotension, yes, only blood pressures documented within the hour following the completion to the 30 mL/kg infusion would be evaluated.

Question 87: **On slide 26, so do we just look at the last two BPs in the hour after crystalloid fluid administration (CFA) infusion?**

Specifications manual version 5.2a does not explicitly state to use the last two blood pressures within the hour. However, per the bullet points in the data element and *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure Version 5.2a*, the last two blood pressures within the hour are generally used to determine the presence of persistent hypotension.

Question 88: **On slide 26, you stated that in Scenario 5, the last two values were not hypotensive; therefore, you would select Value "2." However, 88/63, which is the last one in the scenario, is hypotensive. This is conflicting. I don't understand why this scenario would be Value "2." Can you please clarify?**

Per *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure Version 5.2a*, if there are multiple blood pressure readings and the last is low, but there are not two consecutive low readings, select Value "2."

Question 89: **Persistent hypotension: what if the first two BP readings are low but the last BP reading is within normal limits, and is achieved with vasopressor administration? Would this be Value "2" even though the patient was placed on vasopressors?**

Yes, Value "2" would continue to be appropriate.

Question 90: **Systolic blood pressure (SBP) was mentioned; what about mean arterial pressure (MAP) levels? Is less than 65 still appropriate to use?**

Yes, MAP readings of less than 65 would be used similar to SBPs.

Question 91: **Slide 25: How many readings are needed for persistent hypotension?**

To select Value "1" for the Persistent Hypotension data element, the last two readings in the hour following the competition of 30 mL/kg of crystalloid fluids would have to be hypotensive.

Question 92: **Slide 16: Is nursing documentation of EMS fluid intake enough to be counted for the IVF bolus?**

For specifications manual version 5.2a, a complete physician/APN/PA order is required for all crystalloid fluids used toward the 30 mL/kg volume. So, nursing documentation of fluid administration alone would not suffice.

Question 93: **Slide 26: For clarification. We must review all SBPs within the 60 minutes following fluid completion and even if there are two consecutive SBPs that are less than 90, we wouldn't count those if there is at least one SBP that is 90 or greater within the 60 minutes?**

If there are two consecutive SBP readings less than 90, followed by one or more that are greater than 90, this is not considered persistent hypotension.

Question 94: **Slide 60: Do these BPs have to be consecutive?**

No, the hypotensive blood pressures used for the Initial Hypotension data element in specifications manual version 5.3 are not required to be consecutive blood pressures.

Question 95: **Version 5.3: If there are two hypotensive BPs now required for initial hypotension, if you use one hypotensive reading for organ dysfunction and this organ dysfunction sets the clock, do you still need an additional hypotensive value to answer "Yes" to initial hypotension?**

The same blood pressure reading used as organ dysfunction criteria can also be used as one of the hypotensive blood pressures for the Initial Hypotension data element.

Question 96: **What about blood pressures to reassess persistent hypotension in the OR; are they excluded?**

Yes, blood pressures documented while the patient is in the OR would not be considered when determining persistent hypotension.

Sepsis Septic Shock Present

Question 97: **At our hospital, we are using a tool for septic shock assessment that goes into our assessment. However, in some cases this is the first mention of septic shock and septic shock criteria is not met. This tool is filled out by the MD. When this is done, should we use this as documentation of septic shock?**

If Severe Sepsis and/or Septic Shock is listed as the title, it would not be used for documentation of severe sepsis or septic shock. However, if severe sepsis or septic shock was documented by the physician/APN/PA within assessment, the documentation would be used for documentation of severe sepsis or septic shock.

Question 98: **Can the phrase "therapeutic international normalized ratio (INR)" be used for association between Coumadin use and INR?**

The documentation "therapeutic INR" appears to consider the reported INR values to be normal for the patient. Therefore, the reported INR values would not be used as evidence of organ dysfunction.

Question 99: **Can we take documentation from nursing or case management that a patient was admitted with severe sepsis and then use the admission order for presentation time? I always thought that type of documentation had to be made by MD/APN.**

Only physician/APN/PA documentation of severe sepsis is acceptable. If the physician/APN/PA documented severe sepsis as present on admission, the earliest documented admission time to the hospital would be abstracted.

Question 100: Can you clarify the last slide on the use of checklists and screening tools? The two bullets seem to contradict each other a little. Specifically, can you elaborate on the earliest timepiece?

Documentation within an order set, checklist, screening tool, etc., can be used if it is the earliest documentation for that particular criterion. For example, if severe sepsis is documented within a screening tool and it is the earliest documentation of severe sepsis, the documentation within the screening tool can be abstracted.

Question 101: Can you explain again why an INR value is not needed in the second example (bullet point) on slide 36?

The example on slide 36 references the INR in general rather than a single INR value. With the general reference to the INR that is "linked" to the medication, all INR values would be disregarded.

Question 102: Slide 35: Lactate of 3.5 is due to seizure—not organ dysfunction; slide 64: elevated lactate secondary to seizure—include as organ dysfunction. What is different between the two examples?

Slide 35 is in reference to specifications manual version 5.2a; slide 64 references manual version 5.3. In manual version 5.3, if there is no additional documentation to show that the seizure (cause) is due to a noninfectious source, then you cannot exclude it.

Question 103: Documentation of chronic obstructive pulmonary disease (COPD) exacerbation qualifies for infection criteria consideration or it has to be acute COPD exacerbation?

The documentation of "COPD exacerbation" would require supportive documentation indicating the condition is caused by an infection to be sufficient for criteria "a." With only "COPD acute exacerbation" listed in the Inclusion Guidelines for Abstraction, "COPD exacerbation" alone would require further documentation.

Question 104: Does all system inflammatory response syndrome (SIRS) criteria need to be documented at the same time or within the six-hour time frame?

In order to establish the presence of severe sepsis by clinical criteria, all three clinical criteria must be met within six hours of each other. The three clinical criteria do not need to be documented in any particular order.

Question 105: Do vital signs in the OR include the pre-op/holding assessment, which is typically in the operating room suite?

Simply vitals documented while the patient is in the OR would be disregarded. If the patient is in the OR during the pre-op or holding assessment, the vital signs documented while in the OR would be disregarded.

Question 106: During the Q&A session, can you clarify slide 32? Do we still take presentation time when a patient meets SIRS x2, organ dysfunction, and infection, or do we take presentation time from admission date and time?

The earliest severe sepsis presentation date and time should be abstracted. If the physician/APN/PA documented severe sepsis present on admission and the admission time to the hospital is earlier than the time the patient met all three severe sepsis clinical criteria, the admission time to the hospital would be abstracted.

Question 107: Example 4 on Severe Sepsis Present does not make sense. The PA note includes infection (pneumonia) and acute organ dysfunction, yet the example says that the creatinine of 3.3 should not be used as organ dysfunction.

Slide 44 explains why the elevated creatinine is not used as evidence of organ dysfunction. The creatinine in the example is documented explicitly as due to an acute condition. Additionally, there is no supporting documentation to link the acute kidney injury (AKI) to have an infectious source/origin. If there was supporting documentation connecting the two, you would have used it. Keep in mind, this guidance will change in specifications manual version 5.3.

Question 108: How about a patient on anticoagulation monitoring INR 2–3? Is this acceptable to exclude high INR for organ dysfunction?

This documentation appears to consider INR values between 2–3 to be due to the medication. Therefore, INR values between 2–3 would not be used as evidence of organ dysfunction.

Question 109: How do we answer if the baseline for chronic kidney disease (CKD) is not mentioned?

If a baseline creatinine is not documented the sub-bullet point regarding scenarios that include a baseline creatinine and documentation of CKD would not apply.

Question 110: How do you determine what the baseline creatinine level is? Is it based on first creatinine level obtained?

The baseline creatinine value(s) would need to be documented by the physician/APN/PA.

Question 111: How is "initiate sepsis protocol" interpreted in version 5.3? Is the word "sepsis" taken as documentation of possible infection?

If "initiate sepsis protocol" is physician/APN/PA or nursing documentation, it would be sufficient for criteria "a" for the Severe Sepsis Present data element. If "initiate sepsis protocol" is not physician/APN/PA or nursing documentation or is the title or heading of a document, it would not be sufficient for criteria "a."

Question 112: If two low BPs are required for organ dysfunction, is the same rule good for low MAP?

Only one blood pressure reading is required for organ dysfunction, evidenced by either an SBP less than 90 or MAP less than 65 mmHg. An SBP decrease of more than 40 mmHg is acceptable if it occurred in relation to infection, severe sepsis or septic shock.

Question 113: If a patient has documented ESRD and the creatinine is elevated and no mention that elevation is related to ESRD. This should be considered as organ failure? No mention of a baseline value of creatinine.

If there is physician/APN/PA documentation of ESRD and the patient is on dialysis, any elevated creatinine values would be disregarded. For patients with documented ESRD and on dialysis, a baseline creatinine is not required to be documented.

Question 114: If a second INR is still documented as elevated but it is not documented as related to Warfarin even though the first elevated INR is referenced to Warfarin. The second level would be equal to organ dysfunction?

If a specified INR value is documented as due to the medication (i.e., INR 2.0 r/t Warfarin), only the INR value of 2.0 would be disregarded. In this scenario, if the second INR value was greater than 2.0, it could be used as evidence of organ dysfunction.

Question 115: If in the chart the RN documents that the BP dropped after administration of pain medication, that would not be acceptable? Only acceptable if the MD, APN documents it?

Only physician/APN/PA documentation is acceptable to disregard SIRS criteria or a sign of organ dysfunction. Nursing documentation would not be sufficient.

Question 116: If the MD mentions in a note, CKD, and later, labs are summarized mentioning creatinine as CR 2.2, would the CR be excluded from the organ dysfunction?

Unless the physician/APN/PA documentation considers the elevated creatinine to be due to the chronic condition, the elevated creatinine would be used as evidence of organ dysfunction. If the chronic condition and sign of organ dysfunction are not in the same documentation, it would not reflect the organ dysfunction is due to the chronic condition.

Question 117: If only a creatinine of 3 is excluded due to ESRD by MD documentation, why can't a lower creatinine of 2.3 be disregarded if it is within 24 hours, though not stated?

A lower creatinine value can be excluded.

Question 118: If physician documents lactic acid (LA) high, however, unreliable due to patient's end-stage liver disease (ESLD), do we use the LA for organ dysfunction or try to find another indicator?

If the physician/APN/PA documented "lactate high, unreliable due to ESLD," the elevated lactate would not be used as evidence of organ dysfunction since this documentation appears to consider the lactate to be due to the chronic condition.

Question 119: If the physician documents "patient's leukocytosis is being treated as an outpatient, please disregard." The abstractor would not count the white blood cells (WBCs) as SIRS criteria? Would the abstractor also disregard the bands as SIRS criteria?

Since the documentation, "leukocytosis is being treated as an outpatient" does not consider the WBCs to be due to a chronic condition, medication, or a medically relevant reason, the WBCs would be used to meet SIRS criteria.

Question 120: If the provider documents "severe sepsis, suspect viral etiology," is this still considered "severe sepsis" or not, based on the viral etiology?

Because the SEP-1 measure is considered with bacterial infections, if the provider documents severe sepsis is due to viral etiology, they are essentially saying the infection is due to a virus. This should then allow for exclusion of the case.

Question 121: If there is physician documentation of patient has atrial fibrillation and on Coumadin, INR 3.3, would this suffice for documentation of organ dysfunction is not due to severe sepsis?

Since Coumadin is a medication from Appendix C Table 5.3, an elevated INR or activated partial thromboplastin time (aPTT) level should not be used as organ dysfunction. The patient would have to be identified based upon other clinical criteria or physician/APN/PA documentation of severe sepsis.

Question 122: **In reference to slide 44, when an acute condition may or may not be caused by an infection: if the physician initially states "hypotension due to sepsis versus pain medication" then later (but still within 24 hours) documents "had hypotensive episode related to pain meds," do we include or exclude the hypotension as a sign of organ dysfunction?**

With the documentation confirming the hypotension to be due to the medication, the hypotensive readings would be excluded.

Question 123: **In reference to the examples of acceptable documentation to exclude SIRS or organ dysfunction on slide 36, how about "hypotensive, hold beta blockers"? We see this frequently.**

Since the hypotension is documented as possibly linked to the medication, you would exclude all hypotensive blood pressure readings.

Question 124: **In regard to the hypotension after pain medication, is only the MD/APN/PA documentation valid or is the RN documentation of hypotension after pain medication administration acceptable?**

Only physician/APN/PA documentation would be sufficient to exclude an abnormal value that is due to a condition that is not an infection or medication.

Question 125: **Is "unclear" a positive or negative qualifier? Such as, unclear if this is pneumonia. Thanks.**

The term "unclear" is not noted as a qualifier on the current list. There must be additional documentation in the medical record supporting the condition is an infection (e.g., antibiotic ordered for the condition) to be used to meet the suspected infection criteria.

Question 126: **Is dialysis included in the artificial interventions and subject to SIRS exclusion (e.g., hypotension)?**

Dialysis would not be included in the artificial interventions that are subject to SIRS exclusion.

Question 127: **Is the proper present-on-admission (POA) time when the provider documents the actual admission order to the hospital or is the present-on-admission time the time the patient presented to the ED?**

"Present on admission" would mean the earliest time that the patient was admitted to inpatient care. This would not be the time the provider documents the admission order. This would also not be the time that the patient arrived to the ED.

Question 128: **Is there a time frame required for physician documentation of ESRD/hemodialysis (HD) (for example, 24 hours before/after severe sepsis presentation) or do we need to review the entire medical record for this data element?**

For specifications manual version 5.3, there is no time frame as to when the documentation must be present.

Question 129: **On slide 32, do you mean date and time admitted or date and time arrived? If the severe sepsis or shock is present on admission, it is present on arrival, isn't it? Thank you.**

"Present on admission" would mean the earliest date and time that the patient was admitted to inpatient care. This would not be the time that the patient arrived to the ED. This would be different than documentation that states "present on arrival," in which you would use the earliest date and time of arrival. You also cannot use the admit order time.

Question 130: **On slide 35, what if a provider note attributes an LA 3.5 to acute hypoxia, but does not spell out a history of chronic lung disease with a current exacerbation, in the same note? Is that acceptable?**

The physician/APN/PA documentation of "LA 3.5 to acute hypoxia" appears to consider the lactate to be due to the acute condition. You would have to look for separate documentation to see if there is a link tying the acute condition (hypoxia) to an infectious source.

Question 131: On slide 42, in Example 1, do we need to look at time stamps for these? If MD note of cystitis is at 0800 but the order for Levaquin for cystitis isn't until 1000, can we use 0800?

Since "cystitis" has been determined to be an infection through supporting documentation, you can use the earlier time of 0800 for the suspected infection time.

Question 132: On slide 44, it states creatinine of 3.3 is due to acute kidney injury. Our patients are very complicated with septic shock diagnosed frequently. Physicians are always relating the acute kidney injury with the infection. We have always used the elevated creatinine if the patient has a diagnosis of septic shock and acute kidney injury. Now you are saying we are not allowed to do this?

Slide 44 was meant to illustrate an example under different circumstances. If the physicians at your facility are relating the AKI to infection, you should abstract it. AKI can be caused by an infection and the source of the AKI should always be investigated.

Question 133: On slide 63, is there a time frame for anticoagulation medication?

There is no time frame as to when the anticoagulation medication must be documented.

Question 134: On slide 67, what if the lab value was not spelled out? Could we exclude creatinines? Thanks.

The abnormal value or reference to the abnormal value must be documented. Therefore, if there was no specific abnormal value documented, but the documentation still referenced the creatinine, the creatinine values would be excluded as organ dysfunction.

Question 135: Our new ED software does not capture the exact time the MD is documenting, only the time he/she first sees the patient. The sign-off time may be hours after or even the next day. Can we use the time the MD sees the patient, as we really have no other choice unless written on paper?

If there is not a specific time associated with the documentation, using the note open time would be appropriate. Use the time that best represents the time the note was opened.

Question 136: Patient received anticoagulant: is there a time frame for which the patient must have received that anticoagulant to be able to exclude the INR or aPTT as a sign of organ dysfunction?

There is no time frame specified. If the patient was given an anticoagulant medication on Table 5.3, the INR or aPTT should not be used as organ dysfunction.

Question 137: If MD documents in discharge summary a summation of arrival to present events and states that SBP 80–90 is the usual normal for this patient, would we discredit SBP less than 90 as organ dysfunction or would the documentation have to be within six hours of the low BP used for organ dysfunction?

Physician/APN/PA documentation should be documented prior to or within 24 hours after severe sepsis presentation.

Question 138: If we use a sepsis screening tool in the emergency room (ER) and it says suspicious for infection, can we use that to say "Yes" to infection on new version 5.3?

Documentation of an infection, sepsis, severe sepsis, or septic shock **within an** order set, protocol, checklist, alert, screening tool, etc., may be used if the following is true:

The documentation or value and recorded date and time is present and is the earliest date and time recorded for the criteria.

Question 139: Can we use documentation of thrombocytopenia to exclude platelets less than 100,000 if currently on chemotherapy? Does it have to be the same note with version 5.3?

If there is physician/APN/PA documentation indicating the thrombocytopenia is due to the medication (chemotherapy), the platelet count would be disregarded in both specifications manual versions 5.2a and 5.3. Yes, both the platelet level and chemotherapy would have to be in the same documentation.

Question 140: Slide 42, Example 1: If there's no indication on the Levaquin order, do we consider the cystitis to be an infection?

Unless supportive documentation indicates cystitis is an infection or caused by an infection, it would not be sufficient for criteria "a." An antibiotic order alone without an indication for the infection, in the absence of supporting documentation, would not be sufficient for criteria "a."

Question 141: I have a question about "qualifiers" on slide 70. *QualityNet* responded to me about a month ago, that you have to have severe sepsis present before you can accept documentation of no severe sepsis. Slide 70 doesn't really say that, though. If you see documentation by an MD that severe sepsis is not present, but you don't have any documentation prior that you had severe sepsis, do you just answer "No" to severe sepsis present and stop looking any further?

If there is physician documentation that severe sepsis is not present, continue to review the medical record for the earliest time severe sepsis is present.

Question 142: Regarding Slide 32: Severe sepsis present on admission. The date and time of admission is as documented in the record. If you wish us to use the date and time the patient presented to the hospital, that is a different story. Please clarify.

Present on admission would be the time the patient was admitted to inpatient status. Present on arrival would be the time the patient presented to the hospital/arrival.

Question 143: **Severe sepsis presentation time: If the same physician note has both a "timed" infection, and an untimed entry of "sepsis" or "severe sepsis," does a timed entry take precedence, or do we use the note-opened time that is earlier than the "timed infection"?**

You would use the note-opened time to establish the presence of "severe sepsis."

Question 144: **Slide 32: If SIRS criteria is not met, but there is organ dysfunction documented as attributed to sepsis, but without the use of the terminology "severe sepsis," is the case included or excluded from the measure?**

If all three severe sepsis clinical criteria were not met within six hours of each other and there is not documentation of severe sepsis, Value "2" would be selected for the Severe Sepsis Present data element.

Question 145: **Slide 32 references "present on admission" if the first VS, sepsis screen, and hypotension are the first things documented, is the "admit" time or the time these items are documented, the time of severe sepsis?**

If VS, sepsis, and hypotension are documented as "present on admit," using the admit time would be appropriate. If it is not documented as present on admit, using the time they were documented would be appropriate.

Question 146: **Slide 32. 1. What is the definition of "admitted to the hospital?" The time the admission order is written? 2. If patient meets clinical criteria for severe sepsis prior to the time there is documentation of "severe sepsis present on admission," which do we use?**

1. Present on admit or "admitted to the hospital" would be when the patient was admitted to inpatient. This may not be when the order was written.
2. Use the earliest time that severe sepsis is present.

Question 147: **Slide 33. Patient that is tachycardia and MD documents patient has uncontrolled atrial fibrillation (Afib). Would you exclude the elevated heart rate?**

If there is physician documentation that the tachycardia is due to the uncontrolled Afib, then the next step would be to see if there is supporting documentation elsewhere in the medical record, linking it to an infectious source.

Question 148: **Slide 35: Lactate of 3.5 is due to seizure—not organ dysfunction; slide 54: elevated lactate secondary to seizure—include as organ dysfunction. What is different between the two examples?**

For slide 35, since the lactate is explicitly due to the seizure, it would not be used as organ dysfunction. Slide 54, talks about crystalloid fluids, not organ dysfunction.

Question 149: **Slide 36: Creatinine 3.0 is the only creatinine that would be identified as due to CKD? Any and all other elevated creatinine would not?**

Creatinine below 3.0 can be excluded.

Question 150: **Slide 37: To clarify, any documentation after 24 hours of severe sepsis time by the physician, relating organ dysfunction criteria to something else, is to be disregarded?**

Correct, the physician documentation linking organ dysfunction to something else must be prior to or within 24 hours prior to severe sepsis presentation.

Question 151: **Slide 41: Which documentation would be used as an infection source? The PA documentation or the APN note that links colitis and infection?**

Both documentations could be used as the source of infection since the APN note clearly identifies colitis as an infection. Therefore, any physician/APN/PA documentation of colitis can be used as the suspected infection as long as it is within six hours of all other criteria.

Question 152: **Slide 44 notes creatinine 3.3 due to AKI…the creatinine of 3.3 should not be used as organ dysfunction. This appears to contradict the additional notes for abstraction, "If there is documentation that SIRS criteria or sign of organ dysfunction is due to an acute injury on chronic condition (e.g., acute kidney injury on chronic kidney disease) the criteria value may be used for determination of severe sepsis unless the documentation indicates the acute injury is due to a condition that is not an infection (e.g., acute kidney injury on chronic kidney disease most likely secondary to interstitial nephritis from chemotherapy).**

It would not be used as organ dysfunction since there is no supporting documentation that the AKI is an infection or caused by an infection. Additionally, the documentation does not indicate that the AKI is an acute injury on chronic condition.

Question 153: **Slide 63: Does this exclusion also apply if a patient is on any of these medications at home?**

If the documentation indicates that the patient has this as a home medication, the INR and aPTT should not be used as organ dysfunction.

Question 154: **Slide 63: Does this refer to anticoagulant given to patient, or does it apply if an anticoagulant is a home medication and patient presents with an elevated INR/partial thromboplastin time?**

If the documentation indicates that the patient has this as a home medication, the INR and aPTT should not be used as organ dysfunction.

Question 155: **Slide 69: Vital signs in OR excluded...does this include vital signs in the post-anesthesia care unit (PACU)?**

This would just refer to vitals that are obtained in the OR. This would not include the PACU.

Question 156: **Slide 72, first bullet point: Triage states "suspected infection" Yes/No. Is that bullet referring to this? Not being able to use.**

If the documentation of "suspected infection" is a title or heading of the triage note, it would not be used. If the documentation of "suspected infection" is found in the triage note, but it is not a title or heading, it can be used as criteria.

Question 157: **Slides 35 and 36: Is this referring to possible documentation by the physician would suffice to exclude this patient?**

Slides 35 and 36 are referring to the physician/APN/PA documentation to exclude the SIRS or organ dysfunction from being used as criteria.

Question 158: **So if a patient has an elevated INR and is on Coumadin, I cannot automatically disregard the elevated INR as organ dysfunction? The physician/APN/PA has to document that is why the INR is elevated in order for me to disregard?**

For specifications manual version 5.2, there would need to be physician/APN/PA documentation indicating that there is a link between the INR and the medication. This link does not have to be explicitly stated. The documentation of the INR in the same section of the documentation of the medication would be sufficient to exclude.

For specifications manual version 5.3, if there is documentation that the patient was given the Coumadin, the INR would not be used as organ dysfunction. There would not need to be additional documentation linking the INR to the Coumadin.

Question 159: **So if patient has history of Afib, it is listed on MD note patient has Afib. On that same note has VS, but correlation is not made with pulse and Afib. Can we use elevated heart rate for SIRS?**

The physician/APN/PA documentation would have to link the abnormal heart rate to the Afib. This link does not have to be explicitly stated. The documentation of the heart rate in the same section of the documentation of the condition that is not an infection would be sufficient to exclude. Simply having the Afib in one section of the note and an abnormal heart rate in another section, would not indicate that there is a link between the two.

Question 160: So if there is documentation, "patient has ESRD on hemodialysis" in H&P, this is not enough to disregard elevated creatinines during the hospitalization?

For specifications manual version 5.2, there would need to be physician/APN/PA documentation indicating that there is a link between the abnormal value and condition that is not an infection. This link does not have to be explicitly stated. The documentation of the creatinine in the same section of the documentation of the condition that is not an infection would be sufficient to exclude.

For manual version 5.3, this would be sufficient physician/APN/PA documentation that the patient has ESRD and is on hemodialysis or peritoneal dialysis.

Question 161: Some of the criteria of version 5.3 appears to be given here as 5.2a; specifically, Scenario 4 on slide 26, using only the last two BPs and the time frame of documentation of 24 hours on Slide 33. Please address.

Scenario 4 on the Persistent Hypotension slide presents a case where there is a variety of blood pressures in the hour after the 30 mL/kg infusion was completed. Since there are multiple hypotensive blood pressure readings, but the hypotensive readings are followed by a normal reading, Value "2" would be selected because the blood pressure appears to be normalizing by the last reading. In cases like these, vasopressors are less likely to be pursued. This guidance was developed to allow abstractors to provide more accurate answers when abstracting for persistent hypotension, since in clinical practice, providers would most likely look at the last blood pressures in the hour to determine whether vasopressors are really necessary. Therefore, this guidance should be applied for specifications manual versions 5.2 and 5.3.

Question 162: There is a typo on slide 37. The last bullet point should probably say, "the low platelet count would not be accepted as sign of organ dysfunction...."

The wording on slide 37 is correct. Even though there is physician/APN/PA documentation that references the abnormal value and indicates that the value is secondary to chemotherapy, this documentation is not within the appropriate time frame (prior to or within 24 hours of severe sepsis presentation date and time). Therefore, since the documentation is not within the appropriate time frame, the platelet could would still be used for criteria.

Question 163: Urgent care is not excluded from the measure. We have several transfer in from acute diagnosis centers that begins the three-hour bundle. Are these cases to be included or excluded?

The patient would be included in the SEP-1 measure.

Question 164: What about if physician documents patient has ESRD receiving dialysis and the creatinine level is 6 and the value is documented apart from the condition on the same note. Is the creatinine level of 6 to be disregarded as an organ dysfunction?

For specifications manual version 5.2, there would need to be physician/APN/PA documentation indicating that there is a link between the abnormal value and condition that is not an infection. This link does not have to be explicitly stated. The documentation of the creatinine in the same section of the documentation of the condition that is not an infection would be sufficient to exclude.

For manual version 5.3, yes, you would be able to disregard as any creatinine value is not considered if the patient has ESRD and is on dialysis.

Question 165: What happens if the physician documents cystitis versus ethyl alcohol (ETOH) abuse versus medication induced, and orders Levaquin without adding an indication? Is cystitis still applicable?

If the term “cystitis” can be considered an infection, when consulting other medical sources per the guidelines, the condition can be used as the suspected infection. If the condition may or may not be considered an infection when consulting other medical sources, an order for the antibiotic would suffice, as long as there is additional supporting documentation that the Levaquin is for the condition somewhere else in the medical record.

Question 166: What if a physician in the ER documents severe sepsis (which is not supported by clinical criteria/documentation) and then within six hours another physician documents just “sepsis” or simple sepsis?

The term “sepsis” cannot be used to negate the presence of “severe sepsis.” The physician/APN/PA must document that “severe sepsis” is not present within six hours of severe sepsis presentation in order to select “No” for the Severe Sepsis Present data element.

Question 167: With regards to slides 34 through 38, does this mean if a patient has ESRD and is receiving hemodialysis, which is documented in the H&P and on the patient's problem list, and their labs show a creatinine of 6.0, we would use the creatinine as organ dysfunction since the physician did not specifically state that this is elevated because of the patient's ESRD?

For specifications manual version 5.2, there would need to be physician/APN/PA documentation indicating that there is a link between the abnormal value and condition that is not an infection. This link does not have to be explicitly stated. The documentation of the creatinine in the same section of the documentation of the condition that is not an infection would be sufficient to exclude. Therefore, the creatinine of 6.0 would be used as organ dysfunction.

For manual version 5.3, yes, you would be able to disregard as any creatinine value is not considered if the patient has ESRD and is on dialysis.

Question 168: With slide 62, does the baseline creatinine need to be documented by the physician/APN/PA? Can this be nursing documentation or from labs?

The baseline creatinine would need to be documented by the physician/APN/PA. Nursing documentation would not be sufficient.

Question 169: Would "severe sepsis with shock" be sufficient documentation for septic shock or does the physician need to state severe sepsis and septic shock?

"Severe sepsis with shock" would be sufficient documentation for septic shock. Simply stating septic shock would also be sufficient.

Question 170: Would a lab value indicating a WBC of 13 (elevated) reported at 1300 and a temperature (or other vital sign SIRS criteria) documented at 1245 satisfy the criteria for two SIRS? If so, is the time of two SIRS 1300?

A reported abnormal value of WBC 13 reported at 1300 and an abnormal temperature would be sufficient to meet the criteria for SIRS, if 1300 was the earliest time that the abnormal WBC was reported/resulted. The later time of 1300 when two SIRS criteria were met would be used.

Question 171: You are now saying an MD has 24 hours to remove the state of a measure (e.g., not an infection or due to chronic condition)?

In order to disregard an infection, the physician/APN/PA must state that the infection is not present within six hours.

In order to exclude an abnormal value from being used as SIRS or organ dysfunction, there must be documentation indicating that the abnormal value is linked to a condition that is not an infection or medication prior to or within 24 hours of severe sepsis presentation.

Program Questions

Question 172: Does version 5.3 start with July 2017 discharges?

Specifications manual version 5.3 is effective with discharges starting January 1, 2018 through June 31, 2018, while manual version 5.2a will encompass all 2017 discharges.

Question 173: Is version 5.3 current or for 2018?

Specifications manual version 5.3 is effective with discharges starting January 1, 2018 through June 31, 2018.

Feedback

Question 174: Allowing IBW for fluid administration will dramatically change and possibly improve care. I see that version 5.3 doesn't go into effect until January 2018. We should be able to implement this improvement immediately. But if we do, we'll sometimes fail to meet that element of the measure from now through December. How does CMS reconcile that?

Changes to measure specifications and abstraction guidance are applicable during the effective period of the respective version of the specifications manual and not before. Implementing changes prior to the manual effective date is not feasible because it does not provide adequate time for vendors and the CMS Data Warehouse to implement programing changes to support abstraction.

Question 175: Are there any plans to allow physician documentation for reasons for not giving fluids at 30 mL/kg?

At this time, no revisions are planned regarding an allowance for physician/APN/PA documentation indicating a reason 30 mL/kg of crystalloid fluids were not administered. The measure stewards and measure team will continue to evaluate research and make specification manual revisions as evidence becomes available.

Question 176: Are there plans to switch from SIRS to sepsis-related organ failure assessment (SOFA)/quick sepsis-related organ failure assessment (qSOFA)?

At this time, no revisions are planned that replace the use of SIRS criteria with only qSOFA. Please refer to the link below:

https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890609291&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DSEP_defs_JAMA_Ltr_July2016.pdf&blobcol=urldata&blobtable=MungoBlobs

Question 177: Are they going to address provider documentation of crystalloid fluid administration being deferred or limited due to danger of, or actual, fluid overload?

At this time, no revisions are planned regarding an allowance for physician/APN/PA documentation indicating a reason 30 mL/kg of crystalloid fluids were not administered. The measure stewards and measure team will continue to evaluate research and make specification manual revisions as evidence becomes available.

Question 178: Can you please share the most recent benchmark data for SEP-1?

Benchmarks for the SEP-1 measure have not been established at this time.

Question 179: Differential diagnosis in the ED is a list of potential diagnosis. Having this as a definitive diagnosis in this measure is highly problematic and does not match a provider workflow, as this is only a list of possibilities. Has this concern been addressed and could it be considered removed from the diagnosis of severe sepsis?

While a differential diagnosis of severe sepsis or septic shock is considered an inclusion, physician/APN/PA documentation within six hours indicating severe sepsis or septic shock is not present will result in excluding the case.

Question 180: How would you recommend responding to physicians who argue the 30 mL/kg fluid bolus is contraindicated for heart failure (HF) patients? Does CMS have any studies on this topic?

There is no evidence that HF patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

Question 181: I am still receiving a lot of pushback from providers regarding 30 mL/kg in HF and chronic renal failure (CRF) patients. How do I best address them with an answer and where exactly can they find the resources/studies if they want to back up my answers?

There is no evidence that HF or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

Question 182: Is CMS considering extending these measures to the pediatric population?

At this time, CMS has no plans to extend the SEP-1 measure to pediatric populations.

Question 183: **Is there any plan going forward to address the CHF patient population as far as excluding them from the crystalloid fluid requirement? This is a big concern for our ED providers. Also, the renal patients; they are very hesitant to give the full crystalloid requirement in these populations.**

There are no plans at this time to exclude patients with CHF from the crystalloid fluid requirement. There is no evidence that HF or dialysis patients have any negative outcomes related to the fluid bolus. Rather, there is extensive evidence that these patients benefit from fluid resuscitation and have better outcomes when fluids are administered.

Question 184: **It is very difficult for nurses to check VS within an hour of 30 cc/kg fluid completion because almost all the times physicians don't order the exact amount of 30 cc/kg. Nurses are busy trying to provide care and can't figure out the end time of 30 cc/kg. Is there any way we can extend or accept the VS documented in a different time frame?**

Currently, there are no plans to assign a different time frame for evaluating persistent hypotension.

Question 185: **Most EMRs have a template for the provider that has section headings and one of those is often Review of Systems, but does not include the elements for reassessment.**

Physician/APN/PA documentation of having performed or attested to having performed a physical exam, assessment, or a review of systems is acceptable in place of documentation of the individual requirements of the five focused exam data elements.

Question 186: **On slide 26, persistent hypotension seems to sound like the abstractor should be "inferring or assuming" blood pressure is normalizing. Will CMS add specific directions regarding this?**

The specifications and guidance for determining the presence of persistent hypotension do not require inferences on the part of the abstractor. The guidance provides sequences of blood pressure values in regard to low and normal values and which allowable value to select based on the sequence combinations.

Question 187: On slide 32, the severe sepsis presentation for POA indicates "admission time"; shouldn't the time be triage time of sepsis-screening time rather than admission time, which could be hours later?

When severe sepsis is documented as "present on arrival," the triage time would be used. When severe sepsis is documented as "present on admission," the earliest actual hospital admission time is abstracted.

Question 188: Our residents will not use the phrase "severe sepsis." Will CMS ever change wording for the measure?

At this time, no revisions are planned to change the severe sepsis language.

Question 189: Presently there is no time frame for crystalloid fluid administration for initial hypotension. It seems patients can meet the measure if they've had multiple boluses over several days as long as the total amount is 30 mL/kg. Will there be clarification of this?

For specifications manual version 5.2a, the data element and *Additional Notes for Abstraction for the Sepsis (SEP-1) Measure Version 5.2a*, only include crystalloid fluids started within six hours prior to six hours after initial hypotension.

For manual version 5.3, only crystalloid fluids started in the six hours prior to three hours after initial hypotension can be used toward the 30 mL/kg volume. This guidance is in the Crystalloid Fluid Administration data element's notes for abstraction. If 30 mL/KG of fluids are not given during this time, choose Value "2" or "3."

Question 190: When will the SEP-1 core measure come into alignment with the new Surviving Sepsis Campaign 2016 recommendations?

All the treatment recommendations of the SEP-1 measure are in line with the guideline recommendations of the Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016.

Question 191: Regarding, fluid administration to IBW and the INR and anticoagulants, it is a shame we have to continue to fall out on these problem areas until January. Can't something be done about that, being six months away?

Changes to measure specifications and abstraction guidance are applicable during the effective period of the respective version of the specifications manual and not before. Implementing changes prior to the manual effective date is not feasible because it does not provide adequate time for vendors and the CMS Data Warehouse to implement programing changes to support abstraction.

Question 192: Regarding slide 29, how do you expect nurses who are trying to provide care to a sick patient and calculate the end time of 30 cc/kg so that vital signs can be checked and documented?

The guidance in the specifications manual is for use with abstraction of medical records, not to provide guidelines for nursing care. There is no expectation of the measure for the nurse providing care to calculate when 30 mL/kg have been infused and then start recording vital signs. The clinical expectation for any critically ill patient is that care be provided in an effective and efficient manner. This includes the taking of vital signs to determine how patients are responding to treatment. The frequency of those vital signs is governed by local policy.

Question 193: There is no way that the performance across the nation is at 99 percent. That's impossible.

Performance of this measure has never been stated or presented as being at 99 percent. What this comment may be referencing is that 99 percent of hospitals reporting on the measure are able to successfully submit data to the CMS Data Warehouse.

Question 194: Will the IBW table values be provided as a standard?

No, in order to use the IBW for crystalloid fluid administration, the physician/APN/PA must clearly indicate they are using the IBW and the patient is obese or has a BMI greater than 30. The volume to be administered per the IBW or the IBW should be clearly identified to determine if the appropriate volume was administered.

Question 195: **Will there be any revision to SIRS criteria for the obstetric (OB) patient to increase the parameters of heart rate (HR), respiratory rate, and WBC for the laboring mom?**

At this time, no revisions are planned that address OB patients and SIRS criteria.

Question 196: **You have mentioned SIRS and severe sepsis (both of which are falling out of favor). How are these measures being adjusted after the publication of the Rational Evidence-Based Evaluation of Literature in Emergency Medicine (REBEL EM) trial? Since you are mentioning organ dysfunction, can SOFA/qSOFA suffice in this documentation?**

Please refer to the link below:

https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890609291&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DSEP_defs_JAMA_Ltr_July2016.pdf&blobcol=urldata&blobtable=MungoBlobs