



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

Presentation Transcript

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Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Candace Jackson: Hello and welcome to the Hospital IQR Program SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: Version 5.2a Commonly Asked Questions and Version 5.3 Measure Updates webinar. My name is Candace Jackson and I am your Hospital Inpatient Quality Reporting Program Support Contractor Lead from the Hospital Inpatient Values, Incentives, and Quality Reporting Outreach and Education Support Contractor. I will be hosting today's event. Before we begin, I would like to make a few announcements. This program is being recorded. A transcript of the presentation and the questions and answers will be posted through the inpatient website www.qualityreportingcenter.com in the future. If you have registered for this event, a reminder email and the slides were sent out to your email address about two hours ago. If you did not receive that email, you can download the slides at the inpatient website. Again, that's www.qualityreportingcenter.com. If you have a question as we move through the webinar, please type your question into the chat window with the slide number associated to your question at the beginning. As time allows, we will have a short question-and-answer session at the conclusion of the webinar. Applicable questions that are not answered during the question-and-answer session will be posted to the qualityreportingcenter.com website in the upcoming weeks.

I would now like to welcome and introduce our guest speakers for today: Noel Albritton, Dr. Lemeneh Tefera and Bob Dickerson. Noel is a registered nurse and performs as the Lead Solution Specialist for the Hospital Inpatient and Outpatient Process and Structural Measurement, Measure Development and Maintenance Team at Telligen. Prior to working on the hospital inpatient measure development and maintenance contracts, he worked in the direct hospital environment, as well as mental health and correctional settings. So consistent in the programs to discuss one measure, and by always focusing on the end goal of quality care, Noel's team at Telligen has been instrumental in imposing severe sepsis and septic shock patient care. With constantly improving efforts, he and his team continue to work diligently to improve abstraction guidance for the SEP-1 measure. Dr. Tefera serves as a Medical Officer and Lead

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Physician Advisor for the Centers of Medicare & Medicaid Services Sepsis Measure, as a Policy Advisor for the Merit-based Incentive Pay Management System program, and as a Senior Advisor at the Center for Program Integrity. He is also a practicing emergency medical physician. Bob is a Lead Program Analyst at Mathematica Policy Research. He is a registered respiratory therapist with a Master's of Science Degree in Health Services Administration from the University of Saint Francis in Joliet, Illinois. Most recently, Bob has been supporting the Centers for Medicare & Medicaid Services for Development and Maintenance of Hospital Clinical Quality Measures. He has been involved with the development and maintenance of the SEP-1 measure since its inception. Bob has extensive healthcare-process and quality-improvement experience, including the development and implementation of intervention, processes, and systems in the hospital setting to support multiple national quality measures. His experience includes facilitation of interventions, implementation of process improvement, data collection, and measurement associated with clinical care processes for severe sepsis and septic shock in the hospital setting for the Surviving Sepsis Campaign. Noel, the floor is yours.

Noel Albritton:

Thank you. I would like to thank everyone for joining us today. The objectives for our presentation include understanding the most commonly asked questions for version 5.2a, identify and understand the rationale behind the guidance in the notes for abstraction for version 5.2a, and explain the upcoming changes to the measure and guidance in version 5.3.

As we go over these questions, and when you are submitting questions, please keep in mind that the words in your question are the only thing that the measure writer is evaluating. If your medical record provides additional or conflicting times or information, then you cannot base your abstraction on the answers given. As the measure writers, we are not looking at the entire patient medical record. The answers we give are in reference knowledge and not a final fact.

Our first frequently asked question pertains to the Blood Culture Acceptable Delay data element. The Blood Culture Acceptable Delay

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

data element was added to the manual version 5.2a, to allow patients that may have been started on an antibiotic within a specified time frame, a way to continue in the SEP-1 measure when a blood culture was not collected prior to starting IV antibiotics. The recommendation for severe sepsis and septic shock patients is to collect the blood culture prior to starting IV antibiotic therapy. However, there are particular circumstances addressed in a Blood Culture Acceptable Delay data element where the blood culture collection prior to starting an IV antibiotic is not required, such as, patients being treated for specific infections before severe sepsis is identified or in patients who received a pre-op antibiotic in the 24 hours prior to severe sepsis presentation.

The first question. Within the Blood Culture Acceptable Delay data element, is there a time frame for physician, APN, or PA documentation that delaying the antibiotic would be detrimental to the patient?

A time frame is not specified for the physician, APN, or PA documentation that awaiting to start an IV antibiotic in order to collect a blood culture would have been detrimental to the patient. Keep in mind the physician, APN, and PA documentation should be explicitly linked to the blood culture collection abstracted for SEP-1 rather than a different blood culture collected later in the stay. The physician, APN, and PA documentation should reflect that delaying the IV antibiotics so that a blood culture could be, would be, detrimental to the patient, or the documentation should reflect that the patient is deteriorating rapidly. The example on this slide demonstrates physician, APN, and PA documentation that indicates the patient is deteriorating rapidly by stating the patient's condition as worsening, and needs to begin IV antibiotics stat.

Another frequently asked question pertains to the broad spectrum or other antibiotic selection bullet point regarding a lab report or physician, APN, or PA documentation indicating a causative organism and susceptibility is known when the appropriate antibiotics from Table 5.0 or 5.1 are not initiated. It is an explicit reference needed for physician/APN/PA documentation indicating the causative organism and susceptibility? And, does the physician/APN/PN documentation need to be within 24 hours?

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

In order to consider susceptibility to be known, a lab report for physician/APN/PA documentation referencing the lab report is necessary. Physician/APN/PA documentation stating the patient has a history of MRSA, starting vanco, would not suffice for identifying known susceptibility. The first example of an acceptable physician APN documentation includes the date and time the culture was collected to demonstrate the acceptable time frame. The culture result, MRSA positive with the susceptibility result vanco per confirmed sensitivity via lab, demonstrates documentation that references a lab report. Furthermore, we can identify that the antibiotic was started January 2, 2017, at 0900, which would be within 24 hours of the culture collection. In the second example, the physician documentation reflects the culture was collected within the time frame since the severe sepsis presentation time was within three hours of the culture collection. The physician/APN/PA documentation also includes the sensitivity findings; therefore, with Zyvox administered within three hours of severe sepsis presentation, “Yes” could be selected for the broad spectrum or other antibiotic selection data element.

This slide contains several examples of unacceptable physician, APN, and PA documentation. The first example lacks the date and time for the culture that was collected at the urgent care clinic yesterday. Therefore, it is not possible to determine that the culture was collected within the specified time frame of 24 hours prior to the antibiotic being started or within three hours following severe sepsis presentation. The second example reflects a culture was collected during a recent hospitalization and the patient has been receiving IV vanco twice a day for the past nine days. However, this documentation does not include documentation of a culture collection within the specified time frame nor does this documentation identify known susceptibility. Therefore, this documentation would also be unacceptable. The last example, right lower leg wound, history of MRSA, pharmacy to dose vanco, demonstrates unacceptable physician/APN/PA documentation, as this example does not indicate a culture was collected nor identify known susceptibilities.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Our next topic for version 5.2a questions is crystalloid fluid administration. First, are physician/APN/PA orders required for “prior to arrival” fluids administered by EMS?

Yes. Physician/APN/PA orders are required for all fluids used towards the 30 milliliters per kilogram volume. The order requirements for all fluids, whether administered prior to arrival or after arrival to the hospital, are the same. The physician/APN/PA order must contain the type of fluid, the volume of fluid, and a rate or time over which the fluids are to be given or the term the bolus, or wide open, or open with an appropriate supporting documentation are acceptable for the rate.

These two scenarios demonstrate examples of acceptable physician/APN/PA orders for fluids administered prior to arrival. As we are all well aware, often crystalloid fluids administered prior to arrival to the hospital are not accompanied by a complete physician’s order. In the first example on this slide, you can see the ED physician specifically included the volume administered prior to arrival in the order for 30 milliliters per kilogram of fluids. With the ED physician’s order, including the volume administered prior to arrival, this would suffice the physician order requirements for crystalloid fluid administration noted previously. Documentation of fluid administration such as a start time, end time, or rate, etc., is still required to be in the medical record, reflecting the fluids were infused. With the order and with documentation of fluid administration in the medical record, the prior-to-arrival fluids would be accepted toward the 30 milliliters per kilogram total volume. The second scenario involves the use of a protocol used to administer fluids prior to arrival that reflects a physician, APN, or PA order. Two examples of protocols that have met the physician-order requirements for crystalloid fluids administration are standing orders as approved by an EMS medical director or state-authorized EMS orders. It’s important to note these protocols must meet the order requirements noted previously, which are in the Crystalloid Fluid Administration data element. The protocol must also be in the patient’s medical record and documentation of fluid administration, such as the start time, end time, or rate must also be

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

included in the medical record. In our experience, these order sets and protocols are often problematic, as they do not contain all of the required information. As a result, you should more closely scrutinize order sets and EMS protocols. Also, changes to the manual for version 5.3, which we will review in later in the presentation better address the alignment of actual pre-arrival fluid administration and required physician documentation.

Another area of discussion that also pertains to crystalloid fluid administration is regarding the bullet point that references a volume ordered that is within 10 percent lower than the 30 milliliters per kilogram volume. One frequently asked question is, “Can we administer within 10 percent less than the 30 milliliters per kilogram volume or must the physician order a volume that is within 10 percent of 30 milliliters per kilogram?”

The fluid volume ordered that is within 10 percent lower than the 30 milliliters per kilogram volume is acceptable. This is only referring to the ordered amount of crystalloid fluids, not the administered amount. For example, if the patient required 2200 milliliters to equal 30 milliliters per kilogram, and the physician ordered 1000 milliliters of normal saline twice with no further crystalloid fluids ordered within the time frame, the patient could receive the complete ordered volume of 2000 milliliters; and Value “1” (Yes) could be selected for crystalloid fluid administration. The start time of the second 1000 milliliter infusion would be the crystalloid fluid administration time since the order completes the target volume. With the complete ordered amount of 2000 milliliters being completely infused, the completion of 2000 milliliters would begin the hour to assess for persistent hypotension.

Abstracting a volume of crystalloid fluids that is within 10 percent lower than the 30 milliliters per kilogram volume is unacceptable if more than 30 milliliters per kilogram is ordered. Per the example, at least 30 milliliters per kilogram is ordered, since the patient requires 2200 milliliters, can the physician order 3000 milliliters? Abstracting the crystalloid fluid volume less than 30 milliliters per kilogram, or abstracting 1400 in this case, as the crystalloid fluid administration time would not be correct.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

To build on the previous example, if a volume of 30 milliliters per kilogram or more is ordered by the physician, APN, or PA, the complete 30 milliliters per kilogram volume must be administered. In this example, the patient requires 2200 milliliters to equal 30 milliliters per kilogram; and the physician ordered 3000 milliliters of normal saline via three orders. Since at least 30 milliliters per kilogram volume was ordered, selecting Value “1” or “Yes” for crystalloid fluid administration would be correct if the complete 2200 milliliters was infused. The crystalloid fluid administration time in this case would be 1500 since there are multiple orders and 1500 is the start time of the infusion that completes the 30 milliliters per kilogram volume. The completion time of the 2200 milliliters would need to be calculated to determine the hour to assess for persistent hypotension. In this scenario, 2200 milliliters completed at 1512, so we would assess for persistent hypotension in this scenario between 1512 to 1612.

Next, we will address a frequently asked question regarding the second exception statement provided in the five focused exam data elements in which physician/APN/PA documentation of their performance or attestation of their performance of a physical exam, such as focused exam, etc., within the specified time frame can be used to suffice all five focused exam data elements. Most often we receive the question, “Can the section heading Physical Exam found on the H&P be used as physician/APN/PA documentation of having performed a focused exam?”

The title or heading “Physical Exam” alone would not suffice as physician/APN/PA documentation of having performed a physical exam. Although the findings documented under a physical exam heading could be used to meet individual focused exam data elements, the two exceptions added to the focused exam data elements in version 5.2a are meant to provide physicians an alternative method of documentation that would suffice the focused exam data elements in a broader sense. The exceptions are intended to allow more flexibility in what documentation will suffice the exams, but also maintains documentation requirements that are still necessary to suffice the exam. Therefore, the exceptions listed

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

within each focused exam data element continue to require the physician, APN, or PA to specifically document, and do not allow for simply the title or heading of infection to suffice for the required physician, APN, or PA documentation. Several examples of acceptable documentation for this second exception include physician/APN/PA narrative documents physical exam performed or physician/APN/PA selection option in the EMR stating that performance of a physical exam, focused exam, etc., that includes a time stamp. The first example reflects the most common method of meeting the exception bullet point. Narrative documentation of the physician/APN/PA performance of the physical exam or focused exam is typically how this exception is met. Physicians may also select an option within the EHR that indicates their performance of the physical exam or focused exam, as long as a time stamp for the documentation is available.

Further examples of acceptable physician/APN/PA documentation of a focused exam include:

“I did the sepsis reassessment.”

“Patient’s septic shock focused exam was repeated.”

“A focused exam was performed after fluid resuscitation.”

A flow sheet question, “Sepsis focused exam performed,” and the selection of “Yes.”

“Septic shock perfusion assessment completed.”

“I have reassessed tissue perfusion after bolus given.”

“Sepsis reevaluation, repeat focused exam demonstrates.”

“Sepsis reevaluation was performed.”

“Review of systems completed.”

And a, “Twelve-systems review pertinent positives as documented.”

Several examples of unacceptable documentation include the title or heading of a section such as “Physical Exam” within an H&P as we have previously discussed. The title “Physical Exam” on this tab would not suffice the exception for physician, APN, and PA documentation, even

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

though some of the focused exam data elements are met within this documentation. The physician documentation “focused exam reviewed” also would not suffice for the physician/APN/PA documentation of their performance of a physical exam or focused exam. The documentation of the review of a focused exam does not indicate the performance of a focused exam, but their review of the focused exam, which is not part of a second exception statement bullet point. The PA documentation, “I performed a skin assessment and peripheral pulse evaluation,” would not be acceptable for the second exception bullet point, as the documentation does not indicate a more comprehensive exam was performed.

Another frequently asked question pertaining to persistent hypotension in which value should be selected for a particular scenario. The following scenarios present a variety of ways in which hypotension may be documented in the hour following 30 milliliters per kilogram of crystalloid fluid.

In scenario one, a single hypotensive blood pressure is documented in the hour following the completion of 30 milliliters per kilogram. If only one hypotensive blood pressure is documented in the hour following 30 milliliters per kilogram of crystalloid fluids, Value “3” would be selected for persistent hypotension. In the second scenario, a single normal blood pressure is documented in the hour following completion of 30 milliliters per kilogram. If only one normal blood pressure is documented in the hour following 30 milliliters per kilogram, Value “2” would be selected for persistent hypotension. In scenario three, there are only two blood pressures documented in the hour following the completion of 30 milliliters per kilogram and both blood pressures are hypotensive. Value “1” would be selected for persistent hypotension in this case. Scenario four presents a case where a variety of blood pressures were documented in the hour following 30 milliliters per kilogram. There are multiple hypotensive blood pressure readings, but the hypotensive readings are followed by a normal reading. In this scenario, Value “2” would be selected for persistent hypotension because the blood pressure appears to be normalizing by the last blood pressure reading; and vasopressors are less likely to be pursued. In scenario five, there are, again, multiple blood

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

pressure readings presenting in a combination of normal and hypotensive values with the last reading being hypotensive. Since the last two consecutive blood pressure readings are not hypotensive, Value “2” would be selected in this scenario. In the sixth scenario, there are, again, multiple blood pressure readings presenting in a combination of hypotensive and normal values. Since the last two blood pressure readings are consecutive hypotensive blood pressure readings, Value “1” would be selected for this scenario. As you will notice, most often the last two blood pressures in the hour following the completion of 30 milliliters per kilogram of crystalloid fluids are naturally evaluated to determine the appropriate value for persistent hypotension.

Another topic related to persistent hypotension is determining 30 milliliters per kilogram crystalloid fluid completion time, which also determines the start of the hour to assess for persistent hypotension. While an example is in the data element for calculating the completion time when we would administer consecutively, this question pertains to the fluids administered simultaneously. So how is the 30 milliliters per kilogram completion time calculated when multiple liters are infusing simultaneously?

If the crystalloid fluid volume being administered via multiple infusions administered simultaneously, calculating the 30 milliliters per kilogram completion time must be performed to determine the hour to assess for persistent hypotension. The example demonstrates the calculation to determine the 30 milliliters per kilogram completion time when multiple infusions are administered simultaneously. In this example, the patient requires 1800 milliliters to equal 30 milliliters per kilogram. The first infusion of 1000 milliliters in one hour is started at 0800. The second infusion of 1000 milliliters in one hour is started at 0816. Both infusions have a documented infusion end time one hour after initiation. To start the calculations, determine the milliliters per minute infused for each infusion. As you can see, both 1000 milliliter infusions were administered over one hour. The milliliters per minute infused were both 16.67 milliliters per minute.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Keeping in mind that both liters are infusing at the same time, the milliliters per minute infusing at various times must be determined. As you can see, between 0800 and 0815, only one liter was infusing at 16.67 milliliters per minute totaling 250 milliliters infused during that time. From 0816 to 0900, both liters were infusing at the same time at 33.33 milliliters per minute. The 33.33 milliliters per minute is determined by adding the milliliters per minute of both infusions. The 33.33 milliliters per minute times 44 minutes equals 1467 milliliters. Therefore, by 0900, 1717 milliliters have been infused leaving only 83 milliliters needed to reach the 30 milliliters per kilogram volume. By dividing 83 milliliters by 16.67 milliliters per minute, we can determine that 83 milliliters would take about five minutes to infuse. Lastly, we can add five minutes to the 0900, leaving us with the 30 milliliter per kilogram completion time of 0905, which means the hour to assess for persistent hypotension would be 0905 to 1005.

This example includes three physician orders for crystalloid fluids that are infusing simultaneously at various times. The patient requires 1395 milliliters to equal 30 milliliters per kilogram. The first order is for 1000 milliliters with a start and stop time documented. The second order is for 1395 milliliters with the rate included, but also has a start and stop time documented. The third order for 1000 milliliters over one hour. The first infusion starts at 1754 and stops at 12:08 a.m., which is 374 minutes. The second infusion included a rate in the order that has a start and stop time that is slower than the rate in the order. So the start-stop time will be used to determine the rate of the infusion. The second infusion at 1852 and stopped at 00:08 a.m. which is 315 minutes for this infusion. The third infusion started at 2010 and stopped at 2110, which is 60 minutes.

The first infusion of 1000 milliliters divided by 374 minutes equals 2.7 milliliters per minute infusing. The second infusion of 1395 milliliters divided by 315 minutes equals 4.4 milliliters infusing per minute. The third infusion of 1000 milliliters divided by 60 equals 16.7 milliliters per minute. The first infusion was infusing alone from 1754 to 1852, which is 58 minutes. So for 58 minutes, fluids were infusing at 2.7 milliliters per

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

minute, which is a total of 157 milliliters infused between 1754 to 1852. From 1853 to 2009, two infusions were running simultaneously. For 76 minutes, fluids were infusing at 7.1 milliliters per minute, which is 2.7 milliliters per minute plus 4.4 milliliters per minute, so for those 76 minutes 554 milliliters were infused. With the 157 milliliters infused between 1754 to 1852, and the 500 milliliters infused from 1853 to 2009, 697 milliliters have been infused, which leaves 698 milliliters still needed to meet the 30 milliliters per kilogram volume of 1395 milliliters. For the remaining fluid volume, we can divide 698 milliliters by the milliliter per minute of all three infusions, since they are all running at the same time starting at 2010. So 698 milliliters, 698 milliliters divided by 23.8 milliliters per minute, which is 2.7, 4.4, and 16.7 milliliters per minute, combined. This equals 29 minutes, so the remaining 698 milliliters infused in 29 minutes at 23.8 milliliters per minute. Therefore, add 29 to 2010 which equals 2039 for the completion of 1395 milliliters, which is our 30 milliliters per kilogram volume. So persistent hypotension would then be assessed between 2039 to 2139. It's important to remember that the hour to assess for persistent hypotension begins when the 30 milliliters per kilogram volume completes. So if fluids are ordered via a single order for 30 milliliters per kilogram, the completion time of that single order would be the start time to assess for persistent hypotension.

When severe sepsis was documented as present on admission, which date and time should be abstracted for the severe sepsis presentation date and time? If the physician/APN/PA documentation indicates severe sepsis was present on admission, use the earliest documented date and time that the patient was admitted to the hospital. The admission date and time could be nursing or physician documentation. Admit orders or documentation reflecting the decision to admit the patient do not indicate when the patient was admitted. Since admit orders can be documented before or, in some cases, after the patient's actual admission to the hospital, the earliest documented admission date and time should be abstracted.

Lastly, for version 5.2a questions, we will address several questions pertaining to Severe Sepsis Present data element. First, we will discuss

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

these bullet points from the additional notes for abstraction for version 5.2a. To clarify, in order to disregard a SIRS criteria or a sign of organ dysfunction, there must be physician, APN, or PA documentation of SIRS criteria or a sign of organ dysfunction is normal for the patient, is due to a chronic condition, is due to an acute condition that is not an infection or due to a medication. The physician/APN/PA documentation must be prior to severe sepsis presentation or within 24 hours of severe sepsis presentation. The bullet points on this slide are meant to provide specific guidance for the documentation necessary to disregard these criteria. The goal of this bullet point and sub-bullet point provided in the additional notes for abstraction should take the guesswork out of how to interpret physician, APN, and PA documentation.

This sub-bullet point further specifies the physician/APN/PA documentation must include the abnormal SIRS criteria or sign of organ dysfunction, or a reference to the abnormal SIRS criteria or sign of organ dysfunction. An example of a reference to an abnormal value would be using terms, such as thrombocytopenia or hypotension, rather than documenting as this specific lab value or blood pressure. This sub-bullet point further specifies that if the SIRS criteria or organ dysfunction or reference is not included in the documentation, do not infer or assume the SIRS criteria or sign of organ dysfunction is due to the chronic condition, medication, or to a condition that is not an infection. This bullet point is intended to do as previously stated and take the guesswork out of abstractors having to make the determination as to whether the SIRS criteria or organ dysfunction is due to another condition or medication. Very simply, if the SIRS criteria or organ dysfunction is not included in the physician, APN, or PA documentation that includes the chronic condition, acute condition that is not an infection, or medication, the SIRS criteria or sign of organ dysfunction would not be disregarded.

This is the second sub-bullet point under the primary bullet point in the additional notes for abstraction. It also includes further specifications that the SIRS criteria or sign of organ dysfunction or reference to the SIRS criteria, organ dysfunction, and the chronic condition, acute condition

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

that's not an infection or medication should be in the same documentation. The sub-bullet point does refer to the same note and just to point out, this was intended to refer to the same documentation and we apologize for the confusion around that. This sub-bullet point is expanding on the primary bullet point to provide specific guidance as to how acceptable documentation should appear. This does not imply that simply a condition or medication documented in one section of a progress note or an H&P and an abnormal value or vital sign documented in another section of the same progress note or H&P are related. As previously stated, both of the elements of the physician, APN, or PA documentation are required to be in the same section and with the same time stamp. This also builds upon the main bullet point discussed in the previous slides, which requires the SIRS criteria or sign of organ dysfunction or reference to be in the same physician, APN, or PA documentation. This sub-bullet point further specifies explicit documentation is not required, meaning the physician, APN, or PA is not required to explicitly state, for example, "the lactate of 3.5 is due to a seizure," and disregard the elevated lactate. However, in order to disregard SIRS criteria or a sign of organ dysfunction, the physician, APN, or PA is still required to document the SIRS criteria or sign of organ dysfunction is due to a chronic condition, medication, or acute condition that is not an infection, in a way that does not require an inference to be made by the abstractor.

This slide provides examples of physician, APN, and PA documentation that the SIRS criteria or sign of organ dysfunction is due to a condition or medication without explicit documentation. The first example of creatinine 3.0 CKD with dialysis in the morning, simply includes the sign of organ dysfunction and the chronic condition in the same documentation without explicitly stating the creatinine of 3.0 is due to the chronic kidney disease. Since the sign of organ dysfunction is documented with the chronic condition, the abstractor would not be required to infer that the elevated creatinine is due to the chronic condition. Also, since this documentation includes the specific creatinine value of 3.0, only the creatinine of value of 3.0 would be disregarded. If another elevated creatinine is documented without the accompanying documentation, it

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

would be used as a sign of organ dysfunction. The second example of acceptable documentation includes “Continue Warfarin, monitor INR.” The sign of organ dysfunction, INR in this case, is documented as related to the medication in this documentation. This is another example of physician, APN, or PA documentation that would not require the abstractor to make any inference. Also, the document includes INR and nonspecific INR value. All elevated INR values not attributed to an infection or severe sepsis could be disregarded. Similarly, the next example of physician documentation, “Hypotensive after pain meds,” also reflects documentation that the hypotensive blood pressures are due to the medications. Therefore, the hypotensive blood pressure values could be disregarded. The last example of acceptable documentation, the physician includes end-stage renal disease with a baseline creatinine values of 2.5 to 2.8. This documentation also demonstrates physician, APN, or PA documentation that is not an explicit form, but also does not require inference or assumption to disregard the creatinine between 2.5 to 2.8. Creatinine values that are greater than 2.8 in this case should be used as organ dysfunction.

The next example demonstrates documentation that alone is not acceptable to disregard SIRS criteria or sign of organ dysfunction. The first example includes an elevated lactate documented in the lab section of an H&P and seizures documented in the assessment section of the H&P. The physician/APN/PA does not include documentation that links the elevated lactate to the seizures. To disregard the elevated lactate, based on this documentation alone, the abstractor would be required to infer or assume the elevated lactate was caused by the seizures. Therefore, the elevated lactate should be used in this case as a sign of organ dysfunction. The second example, the severe sepsis presentation date and time is 4/5/2017, at 0730, which is met by the organ dysfunction platelet count of 74,000. On 4/9/2017, at 0900, the physician documented thrombocytopenia secondary to chemo. The low platelet count would not be disregarded since the physician documentation is greater than 24 hours after severe sepsis presentation date and time.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

In this example, the physician note includes the patient's history with a list of home medications in one section and lab results. The physician does not indicate that the SIRS criteria or sign of organ dysfunction are due to a chronic condition or medication. In order to exclude the elevated white blood cell count, creatinine, or INR in this case, the extractor would have to infer or assume that the elevated lab values are due to the chronic conditions or medications. Therefore, based on this documentation alone, the SIRS criteria and sign of organ dysfunction, in this case, would not be excluded.

Another commonly asked question related to manual version 5.2a involves how to determine if an acute condition is or is not an infection, in order to determine if the SIRS criteria or sign of organ dysfunction should be used or disregarded.

As we have discussed, SIRS criteria or sign of organ dysfunction can be disregarded if documented by the physician, APN, or PA, and due to an acute condition that is not an infection. So how do we better determine, what constitutes an acute condition, may be determined to be infectious or caused by the infection, based on the physician, APN, or PA documentation in the medical record. If the documentation in the medical record does not determine if the acute condition is infectious or caused by an infection, the guidelines under criteria "a" in Severe Sepsis Present, should be used for determining if the acute condition is an infection or caused by an infection. This guidance indicates that if a condition is not identified as an infection, using a medical resource such as a medical dictionary, to determine if the condition is an infection, is acceptable. If the medical resource indicates a condition is an infection or caused by an infection, the SIRS criteria or sign of organ dysfunction should be used. If the medical resource indicates the condition may, or may not, be an infection or may be caused by an infection, or may be caused by something other than an infection, there must be additional documentation in the medical record, supporting the condition as an infection; such as an antibiotic ordered for the condition. This will require that supportive documentation clearly indicate the condition is an infection, or caused by an infection.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

This slide contains examples of supportive documentation that a condition is infectious or caused by an infection. The first example of an antibiotic order, links the condition to the antibiotic directly in the order; therefore, identifying the condition as infectious. The second example, considered documentation supporting the condition to be an infection, but found in another location in the medical records. For instance, the PA documented the condition as possible differential diagnosis. APN then moved the condition to an infection by stating colitis seems to have an infectious etiology. The third example refers to physician documentation that includes the medication, as well as a sign of organ dysfunction. However, in this case, the same section also includes an infection. If the thrombocytopenia is not specifically linked to the medication, it should be used as a sign of organ dysfunction. The fourth example includes supporting documentation in the same documentation as the condition. In the example, the physician documents the condition is likely due to an infection rather than a virus. All of these examples demonstrate possible ways documentation supporting a condition is an infection, may be present in the medical records.

The first example illustrates using a medical resource to determine if an acute condition is an infection. The physician includes the low-platelet count, along with the documentation, that the low-platelet count may either be due to an acute condition that may or may not be an infection, or a chronic condition, or a medication. With the inclusion that the platelet count is possibly due to an acute condition that is an infection, we should determine if the acute condition is an infection or caused by an infection. Upon consulting a medical resource, cystitis may or may not be caused by infection. Therefore, we would review the medical record for documentation supporting the cystitis to be an infection. Upon review, the physician's order for an antibiotic has an indication for cystitis. With the supporting documentation, the low-platelet count could be due to an acute condition that is an infection. Therefore, the low-platelet count could be used to meet organ dysfunction criteria. In the second example, the PA documents the patient's elevated lactate is due to a seizure. Then the APN documents that the patient's seizure correlated to the bacterial infection.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Since the acute condition is caused by the infection, the elevated lactate levels could be viewed as a sign of organ dysfunction.

In this third example, the physician documentation of a patient's ED presentation includes signs and symptoms, a creatinine of 2.4, acute kidney injury, and a possible infection. Although the documentation does not explicitly state the acute condition is caused by the infection, the documentation does include the elevated creatinine, AKI, and possible infectious etiology. Therefore, rather than disregarding the elevated creatinine because the acute condition that is, in itself, not an infection, the elevated creatinine would be used as organ dysfunction, because the documentation includes an infectious source that may be causing the organ dysfunction.

In this example, the PA documents the concern for infection, an elevated creatinine, and an acute condition in the same documentation. The PA explicitly documents the creatinine of 3.3 is due to the acute condition. Even though an infection is present in the same documentation, the explicit documentation by the PA allows the elevated creatinine to not be viewed as organ dysfunction, since there is no supportive documentation to indicate the acute condition is caused by an infection. If you recall, in the previous slide, the organ dysfunction, acute condition, and infection were also included in the same physician documentation. The difference is, in the previous example, the physician does not explicitly link the organ dysfunction to the acute condition. In example four, the PA explicitly linked the organ dysfunction to the acute condition, allowing the organ dysfunction to be disregarded, in this case, because the documentation does not support the acute condition is an infection or caused by an infection.

In this last example, the physician documented elevated lactate, chronic condition, and an infection in the same documentation. Since the elevated lactate is not specifically linked to the chronic condition, the elevated lactate should be used as organ dysfunction, with an infection included in the same documentation.

CMS, the measures steward, and the measure writers have been listening to feedback related to SEP-1 from abstractive facilities and organizations.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Recommendations and comments have been carefully considered and evaluated in relation to public evidence where available. Revisions to the measure for manual version 5.3 illustrate the outcome of this evaluation. Note, there are many factors involved in this process that potentially limit the ability to implement every change considered. However, CMS, measure steward, and measure writers continue to evaluate feedback and recommendations, and ways to improve upon the measure. The fundamental purpose of the SEP-1 measure, as with all CMS measures, is to identify opportunities for improvement in patient care that are consistent with published evidence and best practices. This fundamental principle is the basis for consideration of all revisions for the measure, while maintaining a balance of the effort involved in abstracting information from medical records. For the version 5.3 portion of this presentation, new bullet points directly quoted from the specifications manual are highlighted in yellow.

To start the version 5.3 changes, a new data element, Clinical Trial has been added. In order to select “Yes” for this data element, there must be a signed consent form for clinical trial, and there must be documentation on the signed consent form that during this hospital stay, the patient was enrolled in a clinical trial in which patients with the same condition as the measure set were being studied. Only patients enrolled in a clinical trial, studying treatment, or interventions, or patients with sepsis, severe sepsis, or septic shock, should be captured by this data element.

The algorithm flow prior to version 5.3 abstracted the Initial Lactate Level Collection data elements. Then the Broad Spectrum or Other Antibiotic [Administration] data elements. And then the Blood Culture Collection data elements. While the Surviving Sepsis Campaign continues to recommend lactate collection within three hours of severe sepsis presentation time, the algorithm has been revised to better accommodate the exclusion for patients whose broad spectrum or other antibiotic administration time, if greater than 24 hours prior to severe sepsis presentation time.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

The version 5.3 algorithm was revised so that Broad Spectrum or Other Antibiotic [Administration] data elements will be abstracted first. Then followed by the Blood Culture Collection data elements. Then the Initial Lactate Level Collection data elements. Patients with a broad spectrum or other antibiotic administration time greater than 24 hours prior to the severe sepsis presentation time, will now be excluded prior to abstracting the initial lactate level.

This bullet point was added to the data element: Broad Spectrum or Other Antibiotic Administration. It indicates that only IV antibiotics administered in the 24 hours prior to three hours after severe sepsis presentations are acceptable. IV antibiotics are acceptable with one exception. If there is explicit documentation indicating IV access could not be established, antibiotics administered via intramuscular, or IM, or intraosseous, IO, started in the 24 hours prior to or three hours after severe sepsis presentation, are acceptable to select Value “1.”

In this example, the patient has a severe sepsis presentation time of 5/1/2017 at 16:00. The ED nurse documents, “Unable to obtain IV access due to dehydration; awaiting tech placement.” The physician ordered Rocephin IM and the MAR included Rocephin IM was administered within the specified time frame. Since the nurse clearly documents IV access could not be established, the IM antibiotic administered within the specified time frame would be acceptable.

The same concept, regarding IV antibiotics and the exception for IM or IO antibiotics, also applies to the broad spectrum or other antibiotic selection data element. If the broad spectrum or other antibiotic administration time is within three hours of the severe sepsis presentation time, the broad spectrum or other antibiotic selection data element must be abstracted. To suffice this data element, an acceptable antibiotic must be administered within three hours of severe sepsis presentation time. Again, the same exception applies; if there is explicit documentation that an IV access could not be established, antibiotics administered IM or IO can be used to suffice the broad spectrum or other antibiotic selection data element, as well.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

An additional option for selecting Value “4” for crystalloid fluid administration has also been added. Value “4” may be selected if the patient or authorized patient advocate refuses IV fluid administration prior to or within six hours following the presentation of septic shock. This refusal may reflect the complete refusal of IV fluids, or the refusal of a portion of IV fluids by the patient or authorized patient advocate.

In this example, for the refusal of IV fluids, the severe sepsis presentation time is 5/25 at 1200; initial hypotension at 1645, which would then require 30 milliliters per kilogram of crystalloid fluid to be administered for this severe sepsis patient with hypotension. 30 milliliters per kilogram are ordered and started at 1700. And the physician documents septic shock. The physician then notes at 1830 that the patient does not want to receive further IV fluids. Since the refusal is greater than six hours after the acceptable time frame for the Administrative Contraindication to Care, Severe Sepsis data element, and crystalloid fluid administration is abstracted prior to the Administrative Contraindication to Care, Septic Shock data element, by selecting Value “4” at crystalloid fluid administration, the case proceeds to the numerator population.

Also added to the Crystalloid Fluid Administration data element, if there is physician, APN, or PA documentation identifying the patient has obesity, the clinician may choose to use ideal body weight, or IBW, to determine the 30 milliliters per kilogram crystalloid fluid volume. If the clinician prefers to use the ideal body weight, the ideal body weight must be documented clearly and the clinician must state that the ideal body weight will be the weight used to determine the 30 milliliters per kilogram targeted, ordered volume. The two examples demonstrate clear documentation that the volume of crystalloid fluid ordered is based on the patient’s ideal body weight. The first example, the APN includes the patient’s BMI in the order, along with the volume and ideal body weight, indicating the volume ordered is based on the patient’s ideal body weight. In the second example, the APN documentation indicated the patient is morbidly obese and the order for fluid is based on the patient’s ideal body weight.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Two exceptions have been added to the Crystalloid Fluid Administration data element. The first exception addresses fluid administered prior to arrival to the hospital. Documentation of crystalloid fluids administered prior to arrival to the hospital that are part of the medical record, are 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, or PA order for fluids administered prior to arrival is not required. Specifically, to point out, a physician, APN, or PA order for fluids administered prior to arrival will not be required. However, a start time; type of fluid; volume of fluid; and rate, duration or end time must be documented, and included in the medical record.

The second exception to crystalloid fluid administration, addresses crystalloid fluids administered in the operating room. Crystalloid fluids administered in the OR by a physician, APN, or PA are acceptable without an order if an infusion start time; type of fluid; volume of fluid; and infusion rate, duration or infusion end time is documented. Also note for crystalloid fluid administration, the Isolyte fluid has been added to the Inclusion Guidelines for Abstraction list of acceptable crystalloid fluids. Other types of crystalloid fluids and balanced crystalloid fluids are acceptable as the Inclusion Guidelines for abstraction is not an all-inclusive list. Also for crystalloid fluid administration, the exclusion pertaining to crystalloid fluids given to dilute on occasion, has been removed. So crystalloid fluids given to dilute or mix a medication is acceptable as long as ordered and initiated within the time frame, at an acceptable rate, and meet the other requirements of the Crystalloid Fluid Administration data element.

Lastly, for crystalloid fluid administration, the time frame for extracting crystalloid fluids, in relation to initial hypotension, has been revised. In the previous manual, a time frame of six hours prior through to six hours after an initial hypotension was provided for abstracting crystalloid fluids, although the numerator statements continue to require the crystalloid fluid administration time to be within three hours of the septic shock presentation time. Based on the feedback regarding the previous

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

manual, the numerator statement has been revised for version 5.3, and the new time frame had been added to the abstraction guidance for crystalloid fluid administration. For version 5.3, crystalloid fluids started within six hours prior through three hours after initial hypotension are acceptable. A single order for the target volume of crystalloid fluids, starting within six hours prior to three hours after initial hypotension, is acceptable. If multiple orders are used, only crystalloid fluids started within the new time frame are acceptable.

The criteria for determining initial hypotension to be present has changed from one hypotensive blood pressure to two hypotensive blood pressure readings within the time frame. The time frame of six hours prior to severe sepsis presentation to six hours after has not changed. And the two hypotensive blood pressures do not have to be consecutive. Simply, if two hypotensive blood pressures are documented in the time frame and prior to the completion of the crystalloid fluids target ordered volume, Value “1” will be selected for initial hypotension. The example demonstrates a series of blood pressure readings obtained in the six hours prior to six hours after severe sepsis presentation. In this case, between 0900 to 2100, the patient had two hypotensive blood pressures documented. Therefore, Value “1” (Yes) can be selected for initial hypotension.

The Severe Sepsis Present data element for version 5.3 has also received updates and clarifications with the goal to improve abstraction guidance. We will further address several of these elements to the Severe Sepsis Present element. The first addition to the Severe Sepsis Present data element we’ll discuss is two new sub-bullet points for the creatinine under organ dysfunction. The first new sub-bullet points states if there is physician, APN, or PA documentation the patient has end-stage renal disease and is on hemodialysis or peritoneal dialysis, all recorded creatinine levels should be disregarded as a sign of organ dysfunction. End-stage renal disease and on hemodialysis or peritoneal dialysis, and creatinine levels or reference to elevated creatinine levels, do not need to be included in the same physician, APN, or PA documentation. Since patients with documented end-stage renal disease and on dialysis are

Hospital Inpatient Quality Reporting (IQR) Program

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most likely to have frequently fluctuating creatinine levels, we address these patients specifically with the addition of this bullet point. So in order to satisfy this bullet point, there must be physician, APN, or PA documentation of end-stage renal disease and documentation that the patient is on hemodialysis or peritoneal dialysis. While both the document of peritoneal disease and hemodialysis are required, they are not required to be included in the same physician, APN, or PA documentation in order to disregard the elevated creatinine value.

The second sub-bullet point added under creatinine is, if there is physician, APN, or PA documentation of chronic renal disease and a baseline creatinine documented, creatinine values elevated greater than 0.5 above baseline should be used as organ dysfunction. For example, if the physician documented that the patient has chronic kidney disease, stage two, with a baseline creatinine of 2.3, and the creatinine level is now 2.81, the creatinine is greater than 0.5 above baseline, and should be used as a sign of organ dysfunction. If the physician documented the patient has chronic kidney disease stage two, with a baseline of 2.3 and the creatinine is now 2.5, the creatinine is not elevated greater than 0.5 above baseline, and should not be used as a sign of organ dysfunction. Also, the documentation of chronic kidney disease and baseline creatinine are not required to be in the same documentation as the creatinine elevated greater than 0.5 above baseline.

Another addition to the Severe Sepsis Present data element relates to the INR and aPTT. The sub-bullet point reads, “If the suggested data source shows the patient was given an anticoagulant medication in Appendix C Table 5.3, an elevated INR or aPTT level should not be used as organ dysfunction. Physician documentation is not required.” The table provided on this slide has been added to Appendix C, as specified by this new sub-bullet point. If a patient is currently receiving a medication on this table, an elevated INR or aPTT value would not be used as a sign of organ dysfunction.

Also new for version 5.3, if there’s physician, APN, or PA documentation prior to or within 24 hours after severe sepsis presentation

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

time, indicating a SIRS criteria or a sign of organ dysfunction is due to an acute condition, or an acute on chronic condition, the SIRS criteria or sign or organ dysfunction should be used. For example, in documentation of an elevated lactate secondary to seizures, the elevated lactate should be used as a sign of organ dysfunction. Or if APN documents acute kidney injury, creatinine 2.9, the elevated creatinine should be used as a sign of organ dysfunction.

The third example includes thrombocytopenia may be due to a medication, or may be caused by acute condition. Although SIRS criteria or a sign of organ dysfunction can still be disregarded in version 5.3 if documented by a physician, APN, or PA, and due to a chronic condition for medication, this documentation also includes an acute condition, acute ITP, that is possibly causing the thrombocytopenia. With a low platelet count linked to the acute condition, the low platelet count could be used as a sign of organ dysfunction. Similar to example three, an acute condition, chronic condition, and a sign of organ dysfunction is included in the documentation of example four. Without documentation indicating the cause of the acute condition, AKI, in this case, and without documentation that the patient is on dialysis, the elevated creatinine should be used as organ dysfunction, since this documentation attributes the elevated creatinine to be possibly due to the acute condition, the elevated creatinine should be used as organ dysfunction.

However, the next bullet-point states, “If there’s physician, APN, or PA documentation prior to or within 24 hours of the Severe Sepsis presentation time, indicating the acute condition is due to a noninfectious source or process, it should not be used. This bullet point provides guidance for determining if an acute condition with an associated reason for it is caused by an infectious or noninfectious source or process, by referring to Criteria “a” in the Severe Sepsis Present data element. For example, if an elevated lactate is documented as secondary to seizure post brain injury, the elevated lactate would not be used due to the documentation specifying the acute condition or seizure that has caused the elevated lactate was due to a noninfectious source, or the brain injury.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

This bullet point requires a physician, APN, or PA to include the source of the acute condition in the same documentation. If the documentation indicating the source of the acute condition is not present, the SIRS criteria or sign of organ dysfunction should be used.

In another example of the previous bullet point, the APN documents, “Acute kidney injury due to dehydration times three days, creatinine 2.9.” The elevated creatinine would not be used, as the APN demonstrates in this documentation, that the acute condition or acute kidney injury, in this case, that is causing the elevated creatinine is due to a noninfectious process, or dehydration.

The bullet point, referred to on the previous slide, pertains to if there is an indication in the physician, APN, or PA documentation, that the source of the acute condition is due to a noninfectious source or process. As a next step, you would have to determine whether the source of the acute condition, noted in the same physician, APN, or PA documentation, is infectious or not. You would use the Severe Sepsis Present criteria “a” to determine if the source of the acute condition is infectious. The guidance directs you to the bullet points 1, 2, and 3 on this slide, which are also under criteria “a” in the Severe Sepsis Present data element, to determine if the source of the acute condition is infectious or not.

Also new for Severe Sepsis Present data element, vital signs documented in the operating room, or OR, should not be used. And, SIRS criteria or sign of organ dysfunction due to artificial intervention, should not be used. The first bullet point only excludes vital signs documented while the patient is in the OR. Vital signs documented outside of the OR, such as a recovery unit, are not excluded, based on this bullet point. The second bullet point refers to excluding SIRS criteria or sign of organ dysfunction is due to the artificial intervention; but rather, as the example provides, if the respiratory rate of 24 and the respiratory ventilation is set at 24, the respiratory rate of 24 would not be used. If the respiratory ventilation was set at 24 and the respiratory rate is now 28, the respiratory rate of 28 could be used since it is greater than the rate of the artificial intervention.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Documentation of severe sepsis or septic shock using a qualifier may impact how the documentation is abstracted. A qualifier is a word or word group that limits or modifies the meaning of another word or word group.

A positive and negative qualifier table has been added to the Severe Sepsis Present and Septic Shock Present data elements. For documentation of an infection, or Severe Sepsis, or Septic Shock, accompanied by a qualifier, this table should be used. Documentation containing a positive qualifier should be used to meet criteria.

Documentation containing a negative qualifier should not be used to meet criteria. For example, if there is physician documentation, “Possible severe sepsis,” this documentation would be used to select “Yes” to severe sepsis present. If a physician documented, “Impending severe sepsis,” this documentation would not be used to select “Yes” to severe sepsis present.

This last topic relates to both Severe Sepsis Present and Septic Shock Present data elements. The bullet points regarding order sets, protocols, and checklists have been revised. The title or heading of an order set, protocol, checklist, alert, screen tool, etc., reflecting an infection, SIRS criteria, sepsis, severe sepsis, or septic shock, should not be used to meet criteria. Documentation of an infection, sepsis, severe sepsis, or septic shock within an order set, protocol, checklist, alert, screen tool, etc., may be used if the following is true: the documentation or value in recorded date and time present, and there’s an earlier date and time recorded for the criteria. These revised bullet points exclude the title or heading of the document, or section, from being used to meet the criteria “a” infections for severe sepsis present, SIRS criteria, or organ dysfunction. However, documentation within an order set, protocol, screening tool, or checklist, could be used for an infection, severe sepsis, or septic shock if the documentation or value within the order set, protocol, checklist, screening tool is the earliest date and time documented for the criteria.

I would like to thank everyone again, for joining us today. And I’ll turn it back over to Candace. Thank you.

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Candace Jackson: Thank you, Noel. And thank you so much for all that beneficial information. We do have time now for a few questions. Again, I'd like to remind you that we know there was a lot of questions submitted through the chat box during the presentation. And not all of them, we'll be able to get to today. So we will be answering and responding to all the questions, and they will be posted to the Quality Recording Center website at a later date. So our first question is, "Are SEP-1 national rates publicly available? Is there anywhere that they are reported online?"

Lemeneh Tefera: Hi, good afternoon. This is Lemeneh Tefera from CMS. We've shared the SEP-1 performance rates at several public conferences, including the Greater New York Hospital Association in April and the American Academy of Emergency Medicine in February. Those individual sites will have publicly available PDFs available. For participants on the line, just to give you a sense of overall performance. First of all, hospitals have been very successful at reporting the measure. There's over 99 percent successful reporting nationally, which is obviously very impressive considering all the data elements involved. For each bundle, we've reviewed for performance and the hospitals themselves received this feedback from their data vendor. It's certainly fair to say that hospitals in the three-hour bundle are performing very well. Roughly in the high sixties; 68 percent for example for Quarter 2 2016. For the six-hour bundle, again, close to 68 percent for Quarter 2 2016. For the three-hour septic shock bundle, in the mid-fifties percentile range. About 56 percent nationally. And depending on the six-hour bundle for vasopressors, or the physical exam reassessment for vasopressors; since the inception of the measure the performance has been in the mid-seventies. For the most recent quarter is 76 percent, Quarter 2 2016. The six-hour physical exam reassessment has a lower performance rate of around 30 percent; but we believe that was related to challenges in documentation for clinicians. And as abstracters now on this call, we've simplified the documentation requirements for clinicians, which is now an attestation only; and we expect the performance on the six-hour reassessment to improve in coming quarters. The overall pass rate for all

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

the bundles combined is in the mid-forties. That's 45 percent for the most recent quarter. Thank you for the question.

Candace Jackson: Thank you, Dr. Tefera. Our next question is in regards to slide 69. Vital signs in the OR are excluded. Does this include vital signs in PACU?

Noel Albritton: Hi, this is Noel from Telegen. This question is related to version 5.3 and only excludes vital signs obtained in the operating room. At this point, it does not exclude vital signs obtained in the PACU. Thanks.

Candace Jackson: Thanks. Our next question. Do all focused exam findings have to be documented at the same time?

Noel Albritton: Hi, this is Noel again. So, no. There's no requirement for all five of the focused exam findings to be documented at the same time. All five of those focused exam findings do need to be documented within a specified time period for each data element, but it is not required to be at the same time. Thanks.

Candace Jackson: Our next question. Please re-, excuse me, 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?

Bob Dickerson: Hi, this is Bob from Mathematica. That's a great question. The focused exam can be documented; the time frame starts when the fluid administration starts. And so, it doesn't have to be; it can—a focused exam that is performed after that point will be acceptable. And then there is a time frame of six hours after septic shock in which it has to be completed.

Candace Jackson: Thank you, Bob. Our next question. What if the initial ED doc started the fluid bolus and another provider does the focused exam, in or out of the ED, and documents it appropriately? Is that okay?"

Noel Albritton: Hi, this is Noel from Telegen again. Yes. As long as the focused exam is documented within the specified time frame, being in the ED or with the same physician that started the fluids, or ordered the fluids, is not part of

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

the requirement. So as long as the focused exam data elements are documented within that specified time frame, it would be acceptable.

Candace Jackson: Thank you, Noel. Our next question. Can EMS draw blood cultures in the field?

Noel Albritton: Hi, this is Noel again. Yes. The data element for blood cultures does not specify who can draw the blood cultures. As long as the collection documentation is in the medical record, it could suffice the Blood Culture Collection data element.

Candace Jackson: Thank you. Our next question. For the 10 percent IV fluids, do the physician's orders need to specify the less 10 percent? Or should full 30 milliliters per kilogram be ordered?"

Bob Dickerson: Hi, this is Bob from Mathematica. For that, it's, the 10 percent rule does apply to what the physician orders. So, if the physician orders less than 30 milliliters per kilogram but it's within 10 percent of that 30 milliliters per kilogram, that is considered an acceptable order. So when they—in the ideal world, the goal was for 30 milliliters per kilogram to be ordered. But in the—looking at, kind of, the real world, if the physician doesn't have an accurate weight on the patient and they're estimating a weight, or you do have an actual weight, but they're rounding the fluid volumes or rounding the weights, this accounts for variations of what may be intended to be 30 milliliters per kilogram, but may be a few milliliters less than that, is what is actually ordered. So as long as it's within 10 percent of the 30 milliliters per kilogram, that is acceptable.

Lemeneh Tefera: And this is Lemeneh Tefera from CMS. On a related topic, I'd like to also note that changes to our clinicians to identify ideal body weight as the weight being used for the 30 milliliters per kilogram bolus will be implemented. And these changes are really in response to clinicians expressing concern about slightly missing the target bolus, and also concerns about severely, morbidly obese patients. And we're trying to make sure that we modify the specification manual to stay true to the evidence base for the benefits of the fluids, but also allow enough

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

discretion so clinicians are comfortable making sure they are giving as individualized care as possible.

Candace Jackson: Thank you. Our next question. Will there be any revision to SIRS criteria for the OB patients to increase the parameters of heart rate, respiratory rate, and white blood count for the laboring mom.

Bob Dickerson: Hi, this is Bob with Mathematica. At this point, I am not aware of any plans. It is certainly something that we can bring up for discussion in the next version; as we're looking at revisions to the next version of the manual. The thing to keep in mind is that in order for a patient to be identified as having severe sepsis based upon the physiologic parameter, it's not only the SIRS criteria that have to be met, but there also has to be documentation of infection, and there has to be documentation of organ dysfunction. So just having SIRS criteria present does not mean that the patient will qualify as having severe sepsis. That's a great question. Thank you for asking.

Candace Jackson: Thank you, Bob. And we have time for one more question. When will version 5.3 of the specifications manual begin?

Noel Albritton: Hi, this is Noel from Telegen. Version 5.3, which will reflect the second half of our webinar today, will begin abstraction January first of 2018. So those changes for version 5.3 will not be effective until January 1, 2018. Thank you.

Candace Jackson: Thank you, Noel... Go ahead, doctor. Go ahead, Bob.

Bob Dickerson: Just to tag onto that. The date of January 1, 2018 is in reference to cases discharged January 1, 2018. So cases discharged prior to that date will be abstracted under the current guidelines that—where Noel was addressing a lot of the questions under version 5.2a. Thank you.

Candace Jackson: Thank you, Bob. I would just like to announce that this presentation was approved for 1.5 CEUs. Please review the CEU slides in the presentation; and if you have any questions you can contact us and we will assist you. Dr. Tefera, do you have any closing remarks?

Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Lemeneh Tefera: Thank you, Candace. Again, just to call out that this is the first national measure for sepsis in the Inpatient Quality Reporting Program. And despite the fact that it is a complicated measure, hospitals have really been responsive. And our performance data internally and the data that we've shared externally shows that from quarter to quarter, there's consistent improvement, improvement across the various bundles, across the data elements. And that improvement is resulting, again, in our internal analysis, in a strong association with improved quality of sepsis care. We are grateful for the support of hospitals. We continue to encourage feedback and comment to enhance and refine this measure and improve it. And we look forward to further comments that we weren't able to address during this call today. Thank you, everybody, for participating.

Candace Jackson: Thank you, Dr. Tefera. And I thank you for participating in our event today; and we hope that you have a great afternoon. Thank you.