Inpatient Quality Reporting (IQR) Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/ Septic Shock: v5.1 Measure Updates

Presentation Transcript

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Candace Jackson: Hello, everyone, and welcome to our *SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.1 Measure Updates* webinar. My name is Candace Jackson, and I will be your host for today's event. Before we begin, I'd like to make a few announcements. This program is being recorded. A transcript of the presentation, along with the Q&As, will be posted to our Inpatient website at www.qualityreportingcenter.com within 10 business days, and will be posted to *QualityNet* at a later date. If you registered for this event, a reminder email, as well as a link to the slides, were made available to you about two hours ago. If you did not receive the email, you can download the slides again at our Inpatient website at www.qualityreportingcenter.com. And now, I'd like to introduce our guest speaker for today. Bob Dickerson is the lead health informatics solution coordinator for the measures development and maintenance team at Telligen. He is a registered Respiratory Therapist with a master's of

science degree in Health Services Administration from the University of St. Francis in Joliet, Illinois. Most recently, Bob has been supporting the Centers for Medicare & Medicaid Services with development and maintenance of hospital clinical quality measures. Bob has extensive healthcare process and quality improvement experience, including development and implementation with intervention, processes, and systems in the hospital setting to support national quality measures. His experience includes facilitation and intervention, implementation, data collection, and process improvements related to severe sepsis and septic shock in the hospital setting for the surviving sepsis campaign. I would now like to turn the floor over to Bob. Bob, the floor is yours.

Bob Dickerson: Thank you, Candace, and hello, everyone. Welcome to the *SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.1 Measure Updates*. CMS, the measure steward and the measure writers have been listening to feedback related to SEP-1 from the structures, facilities, organizations, and professional groups. Recommendations and comments have been carefully considered and evaluated in relation to published evidence where applicable. The revisions to the measure illustrate the outcome of this review. Note, there are many factors involved in this process that may have limited the ability to implement every change considered appropriate and feasible. As such, CMS, the measure steward, and the measure writers continue to evaluate feedback and recommendations and ways to improve upon the measure. The fundamental purpose of the SEP-1 measure, as is 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 to the measure while endeavoring to maintain balance with the effort involved in abstracting information from medical records. During this call, we'll discuss revisions to the SEP-1 Measure in version 5.1 of the specifications manual, and focus on how these changes impact abstraction.

The objectives for this presentation are listed on this slide, and focus on identifying and understanding updates to SEP-1 data elements and algorithm flow in version 5.1 of the specifications manual.

Please note, this review will focus on algorithm changes and key data element changes in version 5.1 that primarily impact abstraction. We will not be discussing every edit. In particular, we will not cover changes that do not impact abstraction or they're limited to suggested data resources, inclusion guidelines for abstraction, or exclusion guidelines for abstraction. For a complete listing of changes to the measure, please refer to the Release Notes, version 5.1 that are posted on *QualityNet*. This slide includes a link to that location. Also available via this link are the SEP-1 additional notes for abstraction for version 5.1 of the specs manual. While there are points in this presentation I may reference these additions for abstraction, we will not be discussing the guidance contained in them. This document being posted this week should be used in conjunction with version 5.1 of the specifications manual for abstraction of SEP-1 cases. It contains additional abstraction guidance that address the situations revealed in your questions and comments that needed clarification but unfortunately were received after the timeline for being published in version 5.1 of the specs manual.

The administrative contraindication to care, which was the first data element in the algorithm, and effective from reliable through discharge has been removed and replaced with two similar, but more specific data elements. Those are the administrative contraindication of care, severe sepsis, and administrative contraindication to care, septic shock. We'll discuss the specifics of these data elements and where they reside in the algorithm as we continue. Now, this change results in transfer from the other hospital or ASC now being the first data element in the algorithm. For version 5.1, no changes were made to this data element.

The algorithm continues to the severe sepsis present family of data elements. There are no algorithm changes for these data elements, but there are a couple of edits to the severe sepsis present data elements.

In the Severe Sepsis Present, Notes for Abstraction, under Criteria C, Organ Dysfunction section of the first bullet point, edits were made to better clarify determining whether a decrease of more than 40 millimeters of mercury occurred in the systolic blood pressure. The clarification requires Physician/APN/ PA documentation be in the medical record indicating the decrease in systolic blood pressure occurred and that it is related to infections, severe sepsis or septic shock and not other causes. Now, a decrease in systolic blood pressure of more than 40 is a blood pressure criteria within other data elements such as septic shock present, septic shock presentation date and time and persistent hypertension. The same change in determining the presence of a decrease of more than 40 has been applied to these other data elements as well.

At the end of the Organ Dysfunction, Criteria C, is a statement reflecting to not use evidence of organ dysfunction that is considered due to a chronic condition or medication. An example is added related to decreases in systolic blood pressure associated with administration of blood pressure medication. It's important to note for Organ Dysfunction, determining if an abnormal allowable value or blood pressure is due to a chronic condition or medication. There must be some documentation that reflects or supports the abnormal allowable value of blood pressure, if considered to be due to a chronic condition or medication. Assumptions should not be made.

Next in the algorithm, a new data element that I've mentioned previously is added to the specific for Administrative Contraindication to Care, Severe Sepsis. Now, if allowable values one or two indicating yes are selected, the case is excluded from the measure. If allowable value three, indicating No is selected, the case will continue to the next data element. The next data element is Directive for Comfort Care or Palliative Care, Severe Sepsis. This is not a new data element, however, some changes have been made to it. Next, we're going to talk just a little bit more about Administrative Contraindication of Care, Severe Sepsis.

This data element essentially is the version 5.0b Administrative Contraindication to Care data element, but it's been edited to be specific for severe sepsis. The timeframe identified in the Definition, Suggested Data Collection Question, and Allowable Values is prior to or within six hours following presentation of severe sepsis. Edits were made to the second bullet point, the Notes for Abstraction, reflecting the consent form may be signed or unsigned by the patient, but must be witnessed by the healthcare personnel to take into account situations where refusal has occurred, but the patient is unable to sign or a decision maker is not available to sign the consent. And, the third bullet point was added to emphasize the timeframe in which reviews almost occur. And, either Physician, APN, or PA documentation refusal or a witness time consent form marked refused for either blood draw, fluid administration, antibiotic administration is required. Nursing documentation refused but it's not in a consent form it's not acceptable. While not explicitly stated in the data element, fluid and antibiotic administration isn't referenced to IV fluids and IV antibiotics, since these are the only routes acceptable for the SEP-1 measure. There is an inherent hierarchy to antibiotic abstraction. For example, if the patient refuses all medications or all antibiotics, this will be inclusive of IV antibiotics as well. If, however, the patient is refusing a specific medication, let's say for example, they refuse IV insulin, this is not inclusive of IV antibiotics because insulin is not an antibiotic. Similarly, if a patient refuses a specific lab draw or refuses blood draws from a specific source, this does not prevent drawing of all labs and does not constitute refusal of blood draws. For example, if a patient refuses an HIV blood test, they're refusing a specific blood test. They're not refusing other or all blood draws. And, refusal of an HIV blood test does not prevent drawing other labs that would be used for the SEP-1 measure. If a patient refuses an arterial blood gas, they're refusing a specific lab. Blood gases, they are drawn from a specific source, arterial. This is not refusal of all labs or other labs or other blood draws from other sources, such as venous. Next, we'll talk about the changes to the Directive for Comfort Care, Severe Sepsis data element.

Palliative Care has been added to the Directive for Comfort Care, Severe Sepsis data element. As such, the data element name has changed to be inclusive of palliative care, and a paragraph defining what palliative care encompasses was added to the definition. “or palliative care” was added to the suggested data collection question, allowable values, and notes for abstraction in statements containing the term “comfort measures only” reflecting the palliative care is also now acceptable. Now, in terms of abstraction, this essentially means that documentation of palliative care in the same context as comfort measures only is now acceptable.

At the Discharge Disposition decision box in the algorithm, the dispositions that direct a case to discharge time have changed. This change was based upon feedback from abstractors and facilities reflecting that Discharge Dispositions, other than expired, could also impact the ability to meet the requirements in drawing a lactate level, obtaining blood cultures, and administering an antibiotic within three hours of presentation, if the patient was discharged within three hours of severe sepsis presentation.

There are no changes to the Discharge Disposition data element itself. The changes are only in the algorithm flow. So now, if the disposition is either to home, Hospice Home, Hospice Healthcare facility, Acute Care Facility, Other Healthcare Facility, Expired, or Left AMA. The discharge sign will be checked to see when it occurred in relations to severe sepsis presentation. And, if it occurred within three hours of presentation, the case will be excluded.

As I alluded to in the last slide, the calculation that is formerly known as Sepsis Expired Time has now been changed to Sepsis Discharge Time to reflect that events other than death that occurred within three hours can result in excluding a case. And, this calculation is the discharge, date, and time minus the severe sepsis presentation date and time.

In version 5.0b, abstraction continued if the case did not meet criteria for any of the data elements listed on this slide. Most data would determine if

a lactate was drawn within three hours of severe sepsis or an antibiotic was given within three hours of severe sepsis or a blood culture was drawn within three hours of severe sepsis or a repeat lactate level was drawn within six hours of severe sepsis, if the initial lactate is elevated. Under that version, the manual abstraction continued even though not meeting one of these data elements would result in the case failing the measure. This continued abstraction enabled the collection of additional information for analysis regarding the most commonly missed components with severe sepsis care. Continued abstraction, however, did not make a difference in whether the case passed or failed the measure.

We received feedback that this continued abstraction represented a significant abstraction burden for hospitals. So, for version 5.1, CMS made the decision to forego the additional data collection in favor of reducing the abstraction burden. As such, if the requirements for any given data element are not met, the case will be directed to category D in the algorithm and fail the measure, ending requirements for further data collection. Now, for those who are familiar with the algorithm, this also reduces algorithm complexity and removes the sepsis three-hour counter, sepsis six-hour counter, and the shock vasopressor six-hour counter.

The algorithm flow next takes us to the Initial Lactate Level Collection of family data elements to which there is only one change. In both the Initial Lactate Level Collection date and time, notes for abstraction edits were made to the first bullet point to correct the typographical error. The word reported has been replaced with drawn. This makes these two data elements more consistent with other related data elements.

The algorithm flow next takes us to the Broad Spectrum or Other Antibiotic Administration family of data elements. No changes were made to the Broad Spectrum or Other Antibiotic Administration and Broad Spectrum or Other Antibiotic administration date data elements. Minor grammatical edits that we will not cover in this presentation were made to the Broad Spectrum or Other Antibiotic Administration time data elements. Edits were made to Broad Spectrum or Other Antibiotic

Administration selection data elements notes for abstraction in the second bullet point to further clarify abstraction of combination antibiotics given within the three hours following the presentation of severe sepsis. For simplicity purposes, this slide does not show the deleted text, it only shows the new text. Now, keep in mind, this data element is really only relevant if the only IV antibiotics the patient received were in the three hours following presentation of severe sepsis, and none were given in the 24 hours prior to severe sepsis presentation.

A new fourth bullet point was added to the Broad Spectrum or Other Antibiotic Administration selection notes for abstraction to account for situations where an IV antibiotic from Table 5.0 or an appropriate combination from Table 5.1 were not started or given within the three hours following the severe sepsis presentation, but there is a lab report or physician, APN, or PA documentation indicating the causative organism and susceptibility is known. In this situation, if an IV antibiotic identified as appropriate, based on susceptibility testing documented in the lab report or in physician documentation, is given within the three hours following presentation, you can select Value 1. The basic requirement is the lab report must include the name of the pathogen and the antibiotics susceptibility testing. If the antibiotics ordered are not on the antibiotic tables, the ones ordered must be antibiotics identified in the testing to which the pathogen is susceptible. The same would be true of physician documentation, there must be documentation indicating the name of the pathogen and that it is susceptible to the antibiotics that are ordered if they are not on the table. Now, this is to direct concerns related to antibiotic table options when the causative organism is known and the physician orders an antibiotic to match the specific organism susceptibility results, but that antibiotic does not happen to be on either of the tables. A timeframe is not attached to when lab results must be available in relations to severe sepsis or when the antibiotic was given. If the susceptibility testing demonstrated the pathogen was not susceptible to the antibiotic given and those antibiotics are not on Table 5.0 or 5.1, selecting value 2,

No, would be appropriate. No changes were made to the next family of data elements which is Blood Culture collection.

We'll now move on the Repeat Lactate Level Date and Time data elements. In the first bullet point in the notes for abstraction, "if the initial lactate is elevated (>2)" was added to the first sentence. While this does not impact abstraction, it was added in response to a large number of questions seeking clarification regarding when abstractor should be looking for a repeat lactate level. This is alluded to in the numerator statement in the algorithm, but not clearly identified.

This brings us to the point in the version 5.1 algorithm where two new data elements, initial hypotension and documentation of septic shock are introduced. Additionally, the sequencing of data elements related to crystalloid fluid administration was modified. We'll walk through the new data elements and algorithm changes in just a moment. First, I want to share some of the rationale for the changes and the potential impact they may have. The changes more clearly delineate the trigger events for when crystalloid fluid administration is indicated. If initial hypotension is present or the initial lactate level result is greater than or equal to four milliliters per liter or there is physician/APN/PA documentation of septic shock, 30 milliliters per kilogram of crystalloid fluid should be given. If none of these trigger events are present, crystalloid fluids are not required for purposes of the measure and the case passes the measure and abstraction is completed. Now, under the current algorithm configuration, there are some cases where the patient may not have received 30 milliliters per kilogram of crystalloid fluids or did not receive any crystalloid fluids that they could pass – they could bypass the septic shock portion of the algorithm and pass the measure. For those patients, this represented a major conflict with the provision of appropriate care for patient with severe sepsis and septic shock, as outlined in the severe sepsis and septic shock guidelines. The changes address these situations and are in better alignment with published guidelines. We have received some comments that these changes are not in alignment with the numerator, which states "and only a septic shock present received within three hours of

presentation of septic shock resuscitation with 30 milliliters per kilogram crystalloid fluid." Now, the changes do not alter this measure endpoint because the measure requirement for the timing of the crystalloid fluids is still within three hours of septic shock presentation, regardless of the trigger event for administration of the crystalloid fluids. The changes call out the trigger events for the crystalloid fluids, which previously were embedded in other data elements. As setup, this allowed for cases to pass inappropriately if crystalloid fluids were not administered based on some of the trigger events, and thus misidentifying opportunities for improvement.

The initial hypotension data element is referenced a moment ago as one of the trigger events for administering 30 milliliters per kilogram of crystalloid fluid in patients with severe sepsis. This data element limits the timeframe within which hypotension occurs to the six hours prior to or within six hours following severe sepsis presentation. The criteria for determining the presence of initial hypotension is the same as blood pressure parameter criteria for hypotension and other data elements. For initial hypotension, a minimum number of readings is not specified. As such, one is acceptable.

Now, to differentiate initial hypotension from persistent hypotension, keep in mind persistent hypotension can only be evaluated after the 30 milliliters per kilogram of crystalloid fluids have been completely infused. There is no such requirement associated with initial hypotension data element. Initial hypotension would therefore be hypotension present prior to the 30 milliliters per kilogram of crystalloid fluids being completely infused. This means initial hypotension can be present before the 30 milliliters per kilogram has started, or after it is started, but before it is completely infused.

The suggested data collection question is on this slide, and reiterates the time period. There are two allowable values for the initial hypotension data element. One, Yes, indicating hypotension was present at the time

period six hours prior to six hours following severe sepsis presentation. And two, No, indicating hypotension was not present in the time period.

The other new data element, Documentation of Septic Shock, represents another trigger event for administration of 30 milliliters per kilogram of crystalloid fluids. This data element is looking for physician, APN, and PA documentation of septic shock, within the six hours following the presentation of severe sepsis. Now, this is not to be confused with the septic shock present data element, which makes use of various criteria to indicate the presence of septic shock or physician, APN, and PA documentation of septic shock. This new data element serves only as one of the triggers for administration of 30 milliliters per kilogram of crystalloid fluids.

There are two allowable values for the documentation of septic shock. One, Yes, indicating septic shock was documented by a physician, APN, and PA within six hours of their sepsis presentation. And two, No, indicating septic shock was not documented within six hours of severe sepsis presentation.

If one of the crystalloid fluid trigger events occurs, then the case moves on to the crystalloid fluid administration family of data elements.

The primary edits to the Definition Suggested Data Collection Questions and Allowable Value includes reference to the three triggering events, initial hypotension, initial lactate greater than or equal 4, and documentation of septic shock.

In the Notes for Abstraction, the first bullet point was rewritten and the list of acceptable crystalloid fluids expanded to include two balanced crystalloid solutions, PlasmaLyte and Normosol. These were added in response to numerous requests from facilities that use these balanced crystalloid fluids more routinely and is supported by the literature. Edits for clarification purposes were made to the second bullet point adding, “OR physician/APN/PA documentation of septic shock” and to the third bullet point.

A new bullet point, six, was added to better identify the requirements of the crystalloid fluid order. These includes the type of fluid, the volume, a rate, or infusion duration. If any of these are missing or order is not in case the fluids are to be given IV, Value 2 should be selected. Specifications in version 5.0b require the order include an infusion rate or infusion duration. We received a large volume of feedback reflecting crystalloid fluids for severe sepsis and septic shock are frequently ordered as boluses or as wide open and often do not include a specific administration rate or duration. A new bullet point, seven, was added indicating if all other requirements to the order are present, except a rate or infusion duration, but the crystalloid fluids are ordered as a bolus or wide open, this would be considered as an acceptable order. Edits were made to bullet point eight to make it more clear the rate is considered as maintenance usual or keeping open is 125 milliliters per hour or less. If the only crystalloid fluids are given at a rate of 120 milliliters per hour or less, you should select Value 2 because fluids given at this rate are considered maintenance and are not being given a rate sufficient for fluid resuscitation. If there are fluids given at both 125 milliliters per hour or less and some given at a rate greater than 125 milliliters per hour, the volume of fluids given at a rate of 125 milliliters per hour or less cannot be used for determining the total volume of 30 milliliters per kilogram.

A new bullet point, nine, was added to address questions regarding single versus multiple orders for crystalloid fluids. Now, the crystalloid fluids volume ordered may not always be written in a single order equivalent to 30 milliliters per kilogram. In some cases, the total volume may be written as a series of crystalloid fluid orders. This is fine as long as the total volume ordered is 30 milliliters per kilogram, and the orders meet the order requirements specified in this data element. If the total volume is less than 30 milliliters per kilogram, you would select allowable Value 2. We've received a large number of questions related to patient weight, which are not adequately addressed in version 5.0b. New bullet point, 10 and 11, address which weight to use in relation to the time of crystalloid fluid orders and use actual weight as opposed to ideal weight. During the

October 26 Webinar, we acknowledged that, while there may be different opinions on whether to use ideal or actual weight, the severe sepsis and septic shock trials have used actual weight. Nothing has changed in relation to this. So, for purposes of the measure, you should use actual weight. The priority is, if there's a weight documented prior to the crystalloid fluid order, to use that weight regardless of whether it is actual estimated. Now, if for some reason both an estimated and actual weight are present prior to the crystalloid fluid order, you would use the actual weight. Same thing, if there is no weight documented prior to the crystalloid fluid order and after the order there is an estimated actual weight, you should use the actual weight. New bullet point, number 12, indicates that if there is documentation indicating the crystalloid fluid infusion was stopped prior to 30 milliliters per kilogram being completely infused, to select allowable Value 2.

And, as with the Crystalloid Fluid Administration, the three trigger events were added the Crystalloid Fluid Administration Date and Time definition and suggested data collection questions.

To the Crystalloid Fluid Administration Date and Time data element, new notes for abstraction, bullet points 1, 2 and 3 were added to provide more guidance regarding the date and time to abstract when the fluids are ordered in a single order that includes the entire 30 milliliters per kilogram and when the volume equivalent to 30 milliliters per kilogram is ordered over a series of orders. The difference in these two situations is that, when a single order for 30 milliliters per kilogram is written, regardless of whether the fluids are given a single infusion or multiple infusions, the volume to infuse that is equivalent to 30 milliliters per kilogram is known and in that order. As such, when the fluids are actually started, it is known that 30 milliliters per kilogram are to be given. When a series of orders is written that are equivalent to 30 milliliters per kilogram, the entire volume equivalent to 30 milliliters per kilogram is not known and present in an order until the last order is written. As such, it is not until the last infusion that finishes the 30 milliliters per kilogram volume is it known that 30 milliliters per kilogram are to be given. New bullet point, four, indicates

that date and time to abstract in situations when a maintenance IV of crystalloid fluid is drawing and there's an order to increase the rate for administration of the 30 milliliters per kilogram volume. A couple of new examples were added under the fifth bullet point to help illustrate the various ways crystalloid fluids may be ordered and given.

With the algorithm flow changes in version 5.1, after the crystalloid fluid administration family of data elements, the case proceeds to the septic shock family of data elements.

Under letter B of the Septic Shock Criteria in the notes for abstraction of the septic shock present, septic shock presentation date and septic shock presentation time data elements, the guidance regarding determining whether there is a decrease in systolic blood pressure greater than 40 millimeters of mercury was changed so that requires to Physician/APN/PA documentation.

In the Septic Shock Present data element, bullet point six, if crystalloid fluids were not administered after the Presentation Date and Time of Severe sepsis, choose Value 2 was removed because it is no longer relevant due to other changes in abstraction guidance for SEP-1. This bullet point would allow selection of Value 2 for cases where septic shock was present based on criteria Physician/APN/PA documentation but no crystalloid fluids were given at all.

Next, the algorithm comes to the new data element Administrative Contraindication to Care, Septic Shock and the renamed data element Directive for Comfort Care or Palliative Care, Septic Shock. If the Administrative Contraindication to Care, Septic Shock is off of Value 1 or 2, which indicates Yes, the case is excluded. If Value 3, indicating No, is selected, the case continues. Similarly, if the Directive for Comfort Care or Palliative Care, Septic Shock is selected as allowable Value 1, indicating Yes, the case is excluded. If Value 2, indicating No, is selected, the case continues.

The new Administrative Contraindication to Care, Septic Shock data element is very similar to the Administrative Contraindication to Care, Severe Sepsis. This data element is looking for documentation of refuse of blood draw, fluid administration, or vasopressor administration prior to or within six hours following presentation of septic shock. Fluid administration and vasopressor administration is in reference to IV fluids and IV vasopressors, considered the only route acceptable for the SEP-1 measure. Now, similar to the refusal of antibiotic administration for Administrative Contraindication Care, Severe Sepsis, there's an inherent hierarchy to receive old vasopressor abstraction. If a patient refuses all medications or refuses vasopressors, this is inclusive of IV vasopressors. If, however, the patient is refusing a specific medication, for example IV steroids, this is not inclusive of IV vasopressors because steroids are not vasopressors. And then, the same logic regarding refusals of specific lab draw or specific source of the blood draw that we discussed earlier applies to this data element as well.

Same as Administrative Contraindication of Care, Severe Sepsis, there are three allowable values for this data element. The difference between Value 1 and 2 is that 1 is specific to Physician/APN/PA documentation of patient refusal and Value 2 is for refusal based on a witness consent form marked "Refused."

Changes to the Directive for Comfort Care or Palliative Care, Septic Shock are the same as those for Directive for Comfort Care or Palliative Care, Severe Sepsis that we reviewed earlier. The data element has been expanded to include palliative care, the paragraph reporting encompasses palliative care was added the definition or palliative care was added to the suggested data collection question allowable values and notes for abstraction.

The next change in algorithm should look familiar, as it mirrors the changes to the same section in the severe sepsis algorithm flow. At the Discharge Disposition, decision box in the algorithm, the dispositions that direct the case to discharge time have change from only expired Value 6 to

include other discharged dispositions reflecting the patient was discharged from the facility. Since discharge time was previously abstracted, it does not appear again in the section of the algorithm.

The calculation formerly known as Shock Expired Time was changed to Shock Discharge Time to reflect that if events other than death occur within six hours of septic shock presentation, the case is excluded. This calculation is the discharge date and time minus the septic shock presentation date and time.

At this point, the algorithm calculates the Crystalloid Fluid Admin Time which is the crystalloid fluid administration date and time minus the septic shock presentation date and time. The changes in the location, this calculation appears in the algorithm not the outcome of the result. If the crystalloid fluids are started more than three hours after septic shock presentation, the case will be assigned to category D and fail the measure. If the crystalloid fluids were started before or within three hours after septic shock presentation, one will be added to the shock two-hour counter and the case continues on the algorithm. The next algorithm changes are towards the end, which we'll go over in a few minutes. There are some additional data element changes I will cover next, in the order that they appear in the algorithm.

In the persistent hypotension definition, "or new hypotension" was added to address those cases that did not have hypotension present prior to starting crystalloid fluids or prior to completing the full 30 milliliters per kilogram but demonstrate hypotension after 30 milliliters per kilogram of crystalloid fluids is completely infused. Now, in these cases, the onset of new hypotension is not technically persistent because it was not present prior to the administration of 30 milliliters per kilogram of crystalloid fluids. It also would not be considered initial hypotension because this will require giving an additional 30 milliliters per kilogram, which would not be appropriate for most cases. This would represent a patient who has deteriorated clinically. Treatment would likely be very similar to cases where persistent hypotension was present, so it is included in the persistent

hypotension data element. Additionally, the requirement for Physician/APN/PA documentation is determined whether a decrease in systolic blood pressure greater than 40 is present was added "or new hypotension" was also added to Suggested Data Collection Question, to the first three allowable values for persistent hypotension, and to some of the bullet points in the notes for abstraction.

Next, we move on to the Vasopressor Administration data element to which edits were made in the Definition, Suggested Data Collection Question and Allowable Values that identify the timeframe within which vasopressors need to be given for purposes of the measure. The timeframe was added to the guidance. Abstractors were not looking for vasopressors given after that timeframe, which would not meet the intent of the measure.

Additionally, "demonstrated by persistent hypotension after crystalloid fluid administration" was added to clarify the reason or giving vasopressors. Since septic shock can manifest in different ways and vasopressors would only be appropriate for those cases where it manifests based on hypotension.

A new sub-bullet point was added under bullet point three that provides acceptable examples of administration that include vasopressor running and vasopressor given. If either of these is documented in the medical record, this documentation must clearly reflect it is in reference to one of the vasopressors listed on Table 5.2 in Appendix C. And, as identified in the notes for abstraction, the vasopressors on this table are the only acceptable vasopressors. The examples under the inclusion guidelines for abstraction, which included the name of the medication that is not on Table 5.2, were removed. In the fourth bullet point, "demonstrated by persistent hypotension after crystalloid fluid administration" was added. As demonstrated in the algorithm flow, but not previously clear in this data element, vasopressors are not indicated for cases of septic shock or persistent hypotension is not present. A new fifth bullet point was added

giving additional direction related to vasopressor initiation and the acceptable timeframe for this data element.

Similar edits specifying a timeframe and qualifying septic shock as demonstrated by persistent hypotension after crystalloid fluid administration will make the Vasopressor Administration Date and Time data elements. Also, similar to the vasopressor administration data element, a new sub-bullet point was added under bullet point three that provides acceptable examples of administration that includes vasopressor running and vasopressor given. Again, because the only acceptable vasopressors are those listed in Appendix C, Table 5.2, there must be clear reference that a vasopressor from this table is ordered and/or running. Examples under the inclusion guidelines for abstraction, which actually includes the name of a medication that is not on Table 5.2, have been removed.

Next, we're going to review revisions for the Focused Exam Data Elements that count towards the Repeat Volume Status and Tissue Perfusion Assessment. As you may recall, there are two ways the Repeat Volume Status and Tissue Perfusion Assessment can be completed. The first is by completing all elements of the focused exam. The other is by completing two from the any two of the following four group. Our discussion will first address changes to the data elements that make up the focused exam. For each one of these, there are three data elements, one for it being performed, one for the date it was performed and one for the time it was performed.

In the focused exam group of data elements, most changes reflect the theme from current requirements that each must be performed by a Physician, APN or PA. Two requirements that each has documented by a Physician, APN, PA. This change theme is effective for the Capillary Refill Examination, Peripheral Pulse Evaluation and Skin Exam data elements. We do receive a significant amount of feedback reflecting the variations in how the elements of the focused exam are actually performed and documented. After reviewing this feedback, CMS, the measure

steward, and measure writers felt this variation warranted a change in the specifications related to determining the elements of the focused exam was completed. The consensus was that, while many of these elements may not be performed by a Physician, APN or PA, they need to be reviewed and documented by a Physician, APN or PA. As such, appropriate edits were made to the Definitions, Suggested Data Collection Questions, Allowable Values, and Notes for Abstraction for these data elements.

This change theme was not applied to all data elements in the focused exam. It was not applied to the Vital Signs Review because this is already based on being documented by a Physician/APN/PA. It did not require performance by Physician, APN, or PA under version 5.0b. The Cardiopulmonary Evaluation was changed from "performed by a Physician/APN/PA" to "performed and documented by a Physician/APN/PA." This is the only data element from the focused exam that must both be performed and documented by a Physician/APN/PA. It was felt that performance of the Cardiopulmonary Exam, which includes auscultation of the heart and lungs should be performed by a Physician/APN/PA when assessing volume status in a patient with septic shock. Next, we'll go over a couple of edits to specific elements of the focused exam.

For the Capillary Refill Examination Performed, to bullet point three in Notes for Abstraction "or make reference to peripheral perfusion" was added to both determinants that may be used. Peripheral perfusion was also added to the inclusion guidelines for abstraction. When abstracting, be careful not to confuse peripheral perfusion acceptable for the Capillary Refill Examination with peripheral pulses, which is acceptable for the peripheral pulse evaluation. They are not the same thing and cannot be used interchangeably.

Wording in bullet point two of the Skin Examination Date and Time Notes for Abstraction lacked clarity, and it was a bit confusing because it indicated it must make reference to both skin color and circulatory status, which overlapped with the Capillary Refill Examination data elements.

For version 5.1, the skin examination is focused on reference to skin color. A new third bullet point was added to provide terms that a skin assessment exam may include. Reference to color can include a color or absence of the color. For example, cyanosis represents a blue coloration of the skin and mucous membranes usually associated with blue oxygenation. While absence of cyanosis represents blue coloration is not present. In both situations, clearly a skin exam has to have occurred and the documentation is consistent with the requirements of the data element.

If any of the data elements for the focused exam are not performed per specifications in the manual, there is an opportunity to determine whether there was a Repeat Volume Status and Tissue Perfusion Assessment, based on performing any two from the any of the following four groups. This includes performance of Central Venous Pressure Measurement or Central Venous Oxygen Measurement or a Bedside Cardiovascular Ultrasound or either a Passive Leg Raise or Fluid Challenge. Please note if a Passive Leg Raise and a Fluid Challenge are both performed, that counts for only one element being performed. This is because they are just two different methods for achieving the same assessment to see if the patient will respond to additional crystalloid fluid volume after they have been given 30 milliliters per kilogram of crystalloid fluids.

For the Any Two of the Following Four group, the change theme from performance by a Physician/APN/PA to documented by a Physician/APN/PA was also applied to the Passive Leg Raise. The other elements in this group did not require a physician performance under version 5.0b. As such, no changes were made to the Central Venous Pressure, Beside Cardiovascular Ultrasound, and Fluid Challenge data elements. Next, we'll review changes to the central venous oxygen measurement data elements.

For consistency with the Central Venous Pressure Measurement data elements, the timeframe of "within six hours" after presentation of septic shock was added to the Central Venous Oxygen Measurement definition, Suggested Data Collection Questions, and Allowable Values. Additional

guidance was added in relation to presence of multiple measurements documented in the medical record and additional clarification with the Venous Oxygen Measurement must be from a central venous line.

Similar changes were made to the Central Venous Oxygen Measurement Date and Time definitions and Suggested Data Collection Questions.

Changes on the last page of the algorithm reflects the removal of the sepsis three-hour counter and a sepsis six-hour counter at the beginning of the algorithm, and removal of the shock vasopressors six-hour counter after the Persistent Hypotension decision box. A loop was added to the right of septic shock presence so that, if septic shock present is selected as Value 1, Yes, but a shock presentation time calculation is greater than six hours, the case will pass the measure based on care for severe sepsis and not be evaluated for septic shock.

This concludes the SEP-1 Measure version 5.1 Update Presentation. Now, this slide contains some resources for you. The first is a link to a SEP-1 fact sheet posted on *QualityNet*. The second takes you to the questions and answers tool on *QualityNet* where you can search for responses to some existing questions or submit your own. The third link takes you to the page in *QualityNet* where version 5.1 of the specifications manual, the release notes, a summary of SEP-1 changes for version 5.1, and the SEP-1 additional notes for abstraction for version 5.1 are all located. Now, while this presentation did not cover guidance in the SEP-1 additional notes for abstraction version 5.1 of the manual, these notes need to be used in conjunction with version 5.1 of the specifications manual when abstracting cases for SEP-1. Additional notes for abstraction represents guidance based on situations revealed in your questions and feedback that we were unable to incorporate in the manual due to the timing they were received in the relation to manual production timelines.

The next nine slides are a brief summary for your reference of the changes to the respective data elements in version 5.1 of the specifications manual.

Since we've gone through changes – primary changes to the measure, I will not be discussing these slides.

I want to sincerely thank everyone who submitted questions to us via *QualityNet*. Your questions and comments have helped identify areas of improvement for the measure that have resulted in some important revisions we have covered in this presentation and that are presented in the changes in version 5.1 of the manual. We are continuing to look at ways to improve this measure and simplify data collection based on your comments and questions. Candace, now back to you.

Candace Jackson: Thank you, Bob. And, we do have time to go over some questions and responses that were submitted during the presentation. These are some of the questions that were frequently asked during the presentation. Our first question is: for persistent hypotension, there has to be two consecutive hypotensive readings within one hour of crystalloid fluids completion. For initial hypotension, does it also require two consecutive readings or would one reading be sufficient for initial hypotension?

Bob Dickerson: Thanks, Candace. This is a great question. Now, because the initial hypotension data element does not specify a minimum number of readings, only one low reading is required to qualify for initial hypotension.

Candace Jackson: OK. Thank you, Bob. Our next question is: I want to make sure I understand the difference between blood pressure reading that could be used for initial hypotension and the ones that can be used for persistent hypotension. Can you please explain the difference?

Bob Dickerson: Thanks, Candace. Yes, I'd be happy to. I think it is helpful to review these with respect to one another and the purpose they serve for the SEP-1 measure.

So, let's start first with persistent hypotension, since that is the data element I think most people are familiar with. Persistent hypotension is determined after the full 30 milliliters per kilogram of crystalloid fluids

have been completely infused. So, in this case crystalloid fluid infusion completion is your landmark for determining persistent hypotension. And then, any blood pressure readings in the hour following this should be used for determining the presence of persistent hypotension. From this perspective, if hypotension was not previously present and now is, this new low blood pressure reading that occurs during this hour would be used in evaluating the presence of persistent hypotension. Now, this is referred to in the hypotension data element as new hypotension. Keep in mind, for persistent hypotension, there must be two consecutive low blood pressure readings consistent with the values and the data elements.

By contrast, initial hypotension is hypotension that serves as one of the triggers for the 30 milliliters per kilogram of crystalloid fluids. Taking this into consideration, along with the fact that new hypotension used in the persistent hypotension data element is hypotension not present before but it occurs in the hour following 30 milliliters per kilogram of crystalloid fluids, it would follow the initial hypotension would be hypotension present prior to the completion of the 30 milliliters per kilogram of crystalloid fluids. So, any hypotension present prior to the completion of the fluids would be considered initial hypotension. And for this one, only one low reading is required for initial hypotension.

So, to kind of summarize that, initial hypotension is hypotension that occurs prior to completion of the 30 milliliters per kilogram of crystalloid fluid and persistent hypotension is two or more consecutive low blood pressure readings that occur in the hour following completion of the 30 milliliters per kilogram of crystalloid fluids. And, this could be new hypotension, which is not present prior to completing the fluids. I hope that helps.

Candace Jackson: Thank you, Bob. Our next question; if a patient has initial hypotension and receives 30 milliliters per kilogram of crystalloid fluids, but it is given more than three hours after initial hypotension, will the patient fail the measure?

Bob Dickerson: Now, this is a great – this is a great question and the response is going to be not necessarily. Let me explain a little bit more. The timing of when the 30 milliliters per kilogram of crystalloid fluids must be started is in relation to septic shock presentation time, not the time of initial hypotension. You never enter a time for initial hypotension. The data elements reflect that it is either present or it is not present. You do enter a time for the crystalloid fluid administration and for septic shock presentation. And the algorithm performance to Crystalloid Fluid Admin Time calculation based on Crystalloid Fluid Administration Date and Time minus Septic Shock Presentation Date and Time. So, if the result of that calculation is less than or equal to 180 minutes, which would mean the crystalloid fluids are started within three hours of septic shock presentation, then the case passes this part of the measure. If this time is greater than 180 minutes for three hours, then the case would fail the measure. And, I hope this helps explain a little bit better.

Candace Jackson: Our next question: if a patient has initial hypotension, but does not have septic shock, is the 30 milliliters per kilogram of crystalloid fluids still required?

Bob Dickerson: And, another great question. Yes, it is. In situations where the patient has initial hypotension, per the measure, 30 milliliters per kilogram of crystalloid fluids must be given in response to the initial hypotension. Now, this serves to determine if septic shock is actually present. Based on the measure defined, presence of septic shock in situation of hypotension cannot be determined until the 30 milliliters per kilogram are completely infused.

Candace Jackson: Thank you, Bob. And our next question: how must palliative care be documented to answer Yes for the Directive for Comfort Care or Palliative Care, Severe Sepsis and Septic Shock data elements?

Bob Dickerson: OK. Thank you, Candace. While palliative care is defined separately and specifically called out in these data elements, for purposes of abstraction, you can think of it as another term in the inclusion guidelines for

abstraction. So, based on this, if palliative care is documented in any of the context that are listed under the second bulled point of the notes for abstraction, it is acceptable for selecting allowable Value 1, which is Yes. And, for your reference, putting palliative care within the following context would be acceptable so I'm kind of going through memory a little bit here. But, if palliative care is recommended, if there is an order for consultation or evaluation by a palliative care services, if the patient or family requests palliative care, if there's a plan for palliative care, if there is referral for palliative – referral for palliative care service or discussion of palliative care, it would be acceptable. And, those are the all of the same context within which the term "comfort measures only" would also be acceptable. I hope that helps to clarify that a little bit more.

Candace Jackson: Thank you, Bob. Our next question, I am confused about when I can start counting my crystalloid fluids. Can I include crystalloid fluids even more I have severe sepsis?

Bob Dickerson: And, another great question. And, the answer to that one is going to be yes, fluid started before severe sepsis can be used. Now, the updates to the Crystalloid Fluid Administration data element that indicate to only abstract crystalloid fluid is given in the presence of severe sepsis with hypotension or the presence of the severe sepsis with a lactate reading equal to four, or physician documentation septic shock, are really to help focus the abstraction on fluids given associated with these trigger events, as opposed to fluids that may have been given for other purposes. So, crystalloid fluids are started prior to, and they're still running once severe sepsis with hypotension or severe sepsis with lactate greater than four or the physician document septic shock, they can be used, assuming they meet other requirements in the Crystalloid Fluid Administration data element. I hope that helps.

Candace Jackson: OK, the next question: for the focused exams data elements where "performed" has been replaced with "documented," can the examination evaluation be performed by a nurse and then documented by the physician?

Bob Dickerson: And thanks, Candace. This is a – this is a great question to help clarify some of those changes. Yes, for the data elements where this change has occurred, which are the capillary refill exam, peripheral pulse eval, and skin exam being actually performed by someone other than a Physician/APN/PA, such as a nurse, but documented by the Physician, APN or PA is acceptable.

Candace Jackson: Next question: why are crystalloid fluids ordered as a bolus now acceptable? If the crystalloid fluids are ordered as a bolus without an ordered weight, how am I supposed to determine the crystalloid fluid infusion end time for persistent hypotension?

Bob Dickerson: Thanks, Candace. This is another great question. Now, under version 5.0b, all cases where the fluids were ordered as a bolus without rate or infusion duration, they'll fail the measure. And, this is true even if an infusion rate is documented by the nurses or an infusion end time is documented in the medical record. Now, the change in version 5.1 indicates that orders for crystalloid fluids as a bolus without a rate or infusion duration are now considered acceptable orders. If an infusion rate or end time is documented by the nurse, these cases do have the opportunity to meet the measure instead of automatically failing the measure as they would under version 5.0b. Now, as alluded to in the question, you still need to know when the infusion ended to answer the persistent hypotension data elements. So, if the nurse documented the infusion rate and the end time can be calculated, just as you would if the rate within the order, or if there's documentation infusion end time, which can also be used, either of those will help you identify when the infusion was completed. Now, there will still be some cases where the fluids are ordered as a bolus and the nurse did not document the rate or an end time. And for these cases, you will likely not be able determine the infusion end time and, therefore, will not be able to determine that persistent hypotension was present.

Candace Jackson: Thank you, Bob. Is there a timeframe for when the lab report or Physician\APN\PA documentation identifying the causative organism or susceptibility must be present?

Bob Dickerson: Thanks, Candace. And, no, there is not a timeframe identified within the data element. And, since there is not a timeframe, if a physician orders an antibiotic that is not on Table 5.0 or they do not ordered a combination from Table 5.1 and then let's say, for example, two days later a lab report identifying the organism and susceptibility testing demonstrates the organism is susceptible for the antibiotics that were ordered and given, you can select the Value 1, Yes, for the Broad Spectrum or Other Antibiotic Administration Selection data elements.

Candace Jackson: Thank you, Bob. Our next question: if a physician documents in an order or a progress note something like Tigecycline for possible E. coli, is this acceptable to demonstrate susceptibility? Tigecycline is not on Table 5.0 or 5.1.

Bob Dickerson: OK. Thanks, Candace. This is a great question. And, the answer to this one is going to be no. While Tigecycline is not on Table 5.0 or 5.1, as written in this – in this question, this is a note for order for an antibiotic to treat an organism that may possibly be present. The note or order would need to confirm the organism is actually present and indicate that the organism is actually susceptible to the antibiotic ordered.

Candace Jackson: Thank you, Bob. And, we have time for one last question. If a weight is not documented before the crystalloid fluids were order but after the crystalloid fluids were given, there is an estimated weight documented, and six hours later after the patient is admitted to the ICU, there is an actual weight documented. Which weight should I use to determine if the fluid volume ordered was sufficient?

Bob Dickerson: OK. And thanks, Candace. This is another great question. Now, the data element indicates that if a weight is not documented prior to the crystalloid fluid order, to use the weight reported closest to and after the order. But, it also indicates to use the patient's actual weight and use the estimated

weight only if the actual weight is not available. So, in this specific situation, after the order, there is both an estimated weight and an actual weight. So, the actual weight is the one that you should use.

Candace Jackson: OK. Thank you, Bob. And, at this time, I'd like to turn our presentation over to Deb Price who will go over our CE process.

Deb Price: Thank you, Candace. Due to the time constraints that we've had by going over our one hour, I'm going to be going through these slides very quickly. I'm asking that anyone that needs to receive CEs, please review them – please review these last slides carefully. This slide number 71 indicates the boards that we are certified to get CEs for. OK.

And, after the slides close out, you're going to be getting a survey. And, you will also get an additional survey in 48 hours. So, if you are – you know, if you missed this one, just wait, you'll have another coming.

If you have any problems, please go back to these slides and review all of these slides.

This is what the survey will look like. And, at the bottom right hand side, you're going to see a little "Done" button. So, when you're done with the survey, click that button and …

… up will pop this page. This page has two links on it. One for people who have not had any problems getting their certificate, they would click on the "Existing User" link. If you have had any – if you've had problems with your CEs, click on the "New User" link.

And, when you click on the "New User" link, this is what will pop up. Put your first name, your last name, and we're asking that you give us a personal email. Personal emails like Yahoo or Gmail do not have firewalls up. Typically, the hospitals have firewalls that have been blocking our links.

This is what the "Existing User" page looks like. If you haven't had any problems with your CEs, just click on the "Existing User" link. Your

username is your complete email address including the after – what's after the @ sign.

And finally, I'd like to thank you for attending our Webinar. We apologize for going over the hour. But, it feels that the questions were very important. And, if there were questions that you submitted that we did not get to, we will have those within 10 business days on our qualityreportingcenter.com website. Thank you and hope you have a great rest of the day.

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