Inpatient Quality Reporting Program

Support Contractor

The Clinician Perspective on Sepsis Care: Early Management Bundle for Severe Sepsis/Septic Shock

Presentation Transcript

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November 16, 2016
2 p.m. ET

Candace Jackson: Hello and welcome to the Hospital Inpatient Quality Reporting Program Webinar on the Clinician Perspective on Sepsis Care: Early Management Bundle for Severe Sepsis/Septic Shock. My name is Candace Jackson and I will be your host for today's event. Before we begin, I would like to make a few announcements. This program is being recorded. A transcript of the presentation, along with the questions and answers, will be posted to our inpatient website, www.qualityreportingcenter.com, generally within ten business days. If you registered for this event, a reminder email, as well as, the slides, was sent to your email about two hours ago. If you did not receive that email, you can download the slides at our inpatient

website, again, that's www.qualityreportingcenter.com. And now, I would like to introduce our guest speakers for today, Dr. Sean Townsend, Bob Dickerson, and Dr. Lemeneh Tefera. Dr. Townsend has been Vice President of Quality and Safety at California Pacific Medical Center in San Francisco, California since 2010. He is also a practicing intensivist in the Division of Pulmonary and Critical Care at (CMPC) and Clinical Associate Professor of Medicine at University of California San Francisco. Dr. Townsend has been a faculty member at the Institute for Healthcare Improvement since 2005, most recently teaching at the 2nd Annual Middle East Forum in Doha, Qatar in 2014. He has also been a principal member of the Surviving Sepsis Campaign leadership team since 2005. And, he continues to advance national sepsis work, most recently finalizing the nation's first core measure in sepsis, working with Dr. Emanuel Rivers. Dr. Townsend is an author of the 2008 and 2012 *Surviving Sepsis Campaign International Guidelines on the Management of Severe Sepsis*. 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 Saint 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 a 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 a hospital setting, for the Surviving Sepsis Campaign. Dr. Tefera serves as a Medical Officer and Lead Physician Advisor for the Centers of Medicare & Medicaid Services Sepsis Measure, as a policy advisor for the Merit-Based Incentive Payment System Program, and as a senior advisor at the Center for Program Integrity. He is also a practicing emergency medicine physician. Again, any questions that are not answered during our question-and-answer session at the end of the webinar, will be posted to the qualityreportingcenter.com website

generally within ten business days. We do ask that if you submit a question through the chat feature, that you be very specific, and if possible, reference the slide number that you are asking about. Please be aware that not all questions submitted through the chat may not be answered during the presentation. Thank you again to everyone for joining. Dr. Townsend, the floor is yours.

Sean Townsend: Thank you very much, Candace. I appreciate the introduction, and the opportunity again to address everyone regarding SEP-1 or first sepsis quality measure for the United States, take care of patients with severe sepsis and septic shock. And, ensure that the best practice, best evidence-based practice is available to our patients.

I'd like to review our objectives. What we intend to discuss today is, of course, the management bundle itself, which includes the basis, rationale, and content of the management bundle. We'll explain the importance of the collection of the bundle, and recognize significant updates that have been made since SEP-1 was introduced in October 2015. We'll take certain questions, and we'd like to be able to assist people with understanding the baseline analysis of the data that we've generated so far in collecting SEP-1 as a measure.

Several acronyms will be used throughout the presentation. We've tried to gather them here for your review. You may want to take some of this down if you're not familiar with what they represent, although I'm sure many people who have been working in sepsis are used to seeing several of these terms.

Overall, there is a disclaimer I need to provide to you. The presentation was current at the time that we published it and uploaded it to the World Wide Web. Medicare policy changes frequently, and therefore, links to the source documents have been provided with the document for your reference. This presentation was prepared as a service to the public, and is not intended to grant any specific rights, or impose particular obligations. This presentation may contain references or links to statutes, regulations, or policy materials. The information provided is only intended to be a

general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review specific statutes, regulations, and other interpretive materials for full and accurate statement of the contents. And all the presenters in today's presentation have indicated they have no conflict of interest.

Back to sepsis itself as a diagnosis. I just want to take the opportunity to remind the audience that the reason that SEP-1 is such an important measure is, that sepsis remains the number-one cause of inpatient deaths across the country, in our acute-care facilities. And this is some data from one health system in Northern California with 26 hospitals; happens to be my hospital system, Sutter, Health. And, what you'll notice is, if we looked at the discharges in 2014 for patients who have diagnosis of sepsis, you see that either simple sepsis, severe sepsis, or septic shock in blue, red, or green in the pie chart, were 11 percent of the patients that were discharged from my facilities in Northern California in 2014. That's about 11 percent of all patients had a diagnosis of sepsis. However, if you look on the other side of this chart, you'll notice in the right, if we look at the number of deaths that occurred, about 48 percent of those patients also carried a diagnosis of sepsis. Either, again, simple, severe, or septic shock. And so, what we clearly see then, is that the number of deaths, about 50 percent of deaths, in the hospitalized patients, are associated with the diagnosis of sepsis in some way or another. And, this is not just specific to one health system. I use this as just one example, but we know that nationally, the same statistics are certainly true. Patients throughout the country have a common cause of illness at the end of life oftentimes with sepsis. And, this is why there's such opportunity in this disease, and why we've chosen to apply quality measures to help address the situation. We know that not all patients who have death associated with sepsis could be saved, but certainly, with such a large fraction of patients that could be treated better, 48 percent or so, we know we have opportunity to address many of those patients and save many lives still.

To do this, we've implemented, as you are all aware, the first quality measure, SEP-1, as it's known, and there are a couple of slides I'd like to

show you here over how that particular measure operates. There are both three-hour and six-hour pieces of the measure. And on this slide, what you're looking at, are the three-hour elements that have to start from the time the clock begins. We call that, the time of presentation. In the bottom, there's a little asterisk that indicates that the time of presentation is defined as, the time of earliest chart annotation consistent with all the elements of severe sepsis or septic shock having been ascertained through chart review. And so, this essentially means that, it's a point in time in the chart where all the elements line up. That there's a suspicion of infection. There are two SIRS criteria that are positive. And, that there's some element of organ dysfunction that can be identified. When that point lines up, that's the time of presentation, and that's when the clock begins for SEP-1. Once that is ascertained and known, you have these four elements that apply. First, we recommend the measurement of lactate. Second, that blood cultures are obtained prior to administering antibiotics. Third, that the patients actually receive broad spectrum antibiotics. And then, if the patient is hypotensive, or has a lactate that's greater than or equal to four, patients receive a fluid bolus of crystalloid at 30 ml per kilogram. And all those are three-hour elements of the SEP-1 measure.

You're now looking at the six-hour elements that occur with the SEP-1 measure. And again, they're listed here. And they're from six hours from the time of presentation, as I previously defined it. So, here, the first element is to administer vasopressors; and, this is for patients that have hypotension and didn't respond to initial fluid resuscitation, with a goal of maintaining mean arterial pressure greater than 65 ml of mercury. Second, for patients who have persistent hypotension after that fluid bolus, or if their lactate was greater than or equal to four, we have to reassess volume status and tissue perfusion somehow. And I'll explain that in the next slide what those mechanisms are. And then, third, is remeasurement of lactate if the initial lactate was elevated. And elevated, of course, was greater than two on the previous slide. And these are elements of SEP-1 essentially. If you provide all of these elements of care within six hours of time of the clock starting, then typically speaking, providers will be able to pass this measure, and have done the right thing for patients with severe

sepsis or septic shock. I would like to just spend a few moments, talking again, about the elements that are available to providers, to pass the reassessment of volume status and tissue perfusion on the next slide.

I'd like to take an opportunity to address the elements of the reassessment of volume status and tissue perfusion here, using Table 1. Please note, essentially, there are two components to a volume status and tissue perfusion reassessment. A provider can either do a repeat focused exam, or any two of the bullet-pointed hemodynamic measures could also be accomplished. The provider need only reference that they've either completed the focused exam, or completed any two of those elements to receive credit. The actual results of the hemodynamic measures need not be recorded; merely, the indication that they've been reviewed by the provider. These elements will satisfy a review volume status and tissue perfusion to patients who either remain hypotensive after the initial fluid bolus, or if they had a lactate greater than, or equal to, four initially.

So, I mentioned to you before that time-zero was a point in time at which all of the elements of severe sepsis lined up in the chart. Please note that there are several ways that information can be obtained. The second bullet point, we've indicated that pretty much anything in the chart is fair game to make a determination of when those elements line up. So, nursing flow sheets are acceptable. Nursing charting is acceptable. Flow sheets that emerge from respiratory therapy or laboratory reports that come from the laboratory. Anything with the time stamped that we can determine when respiratory rate was elevated, or when creatinine was elevated, or when a patient had tachycardia, will allow us to attach a value to the SIRS criterion, or the suspicion of infection, or the organ dysfunction, that qualifies for starting the clock. There is a possibility that time-zero could be triage time, and this would be in the circumstance, if all the signs and symptoms were present at triage. You can imagine a case, for example, for a patient that, presenting at triage with a swollen red hot leg, fever, and tachycardia, as well as, hypotension. That patient would have all the elements required for starting time-zero at triage. They've got a potential cellulitis. So, it's a suspicion of infection. They've got a fever and

tachycardia, which will get you to a SIRS criteria. And, they've got, at least, initial hypotension, which would qualify the patient for severe sepsis. And so, in that particular instance, triage time could actually be time-zero, if properly documented.

There are various pieces that have to require, have to occur, rather, at appropriate times in completing bundles. I mentioned that there are three-hour elements and I mentioned that there are six-hour elements. And the actions are listed here in blue, in the left-hand side, that are part of the SEP-1 measure. And then, what they apply to, which diagnosis those actions apply to, are shown in respectively here, in green, and then, in red. And so, using this chart, you're able to determine, for example, that the initial lactate question is part of the three-hour severe sepsis element that must be collected. And, additionally, for patients with septic shock, that would also have to be collected. That's the same for blood cultures and antibiotics. And then, for repeat lactate collection, that requires a severe sepsis, and that also applied a patient with septic shock. Likewise, you can look at per-fluid and vasopressors, and then, the repeat volume status and tissue perfusion assessment. So, the so-called six-hour elements, for example, don't necessarily apply to those severe sepsis patients, but do apply to those with septic shock, as you can see in the far right.

The necessity of timing all this, creates a complication, and I want to point this out to providers who are on the call, because it's not quite possible for providers, nurses and doctors alike, licensed independent practitioners, to hold all this information in your head, but I do want to show to you by way of example. Before I go into details of this, I would like to tell you what I recommend to providers when they're trying to comply with the measure in real time, taking care of patients. Essentially, if the point, when you begin to suspect severe sepsis, or septic shock, may be operating in the patient you're taking of, if you glance at your watch at that point in time, and you assume that to be time-zero, you're probably going to be a little earlier than the time in the chart, which all that documentation lines up. But it's a good place for you to begin to start the clock for yourself. And then, if, from that starting point, you say, "I'm going to take six hours

to get all the things that are necessarily, that have to be done, for this patient with severe sepsis and septic shock. And I know what those are, because I've reviewed those slides, that we just saw what these elements are." If I'd get all those done in those six hours, there's a tremendously high likelihood that you'll end up complying with the measure. The fact of the matter is, there will be different timestamps actually associated this, when the quality department and the abstractors review the chart and pick this, and pick out, those particular elements. But the complexity of it is such that, in real time, clinical providers can't follow that complexity. So, I would suggest you follow the rule I just set up, which is, a real practical pearl. Take a time-zero when you think it might be shock or severe sepsis, and then execute all therapies in the next six hours. Almost certainly, you'll comply with the measure. But I do want to show, now, go through an example at least, with everyone, of how the measure actually ascertains as times. And probably, be able to demonstrate to you, why it's the case, that if you'd follow the rule I suggested, you'll actually have more time than you need. So, let's take an example here, of the two clocks that start. Here, we have initially a patient who developed severe sepsis at 3 o'clock, but the patient wasn't hypotensive, and did not fail to respond to fluids until 5 o'clock. And so, you might be asking, "Well, when, if this patient had shock because they're [hypotensive,] did the shock-clock start?" And the answer is actually 5 p.m., right? This patient did receive fluids, and they did not respond until 5 o'clock. So, they had initial hypotension that was responsive and shock starts at five. Severe sepsis begins at three. So, you can tell, you've got two different clocks you'd have to be holding in your head right now; not something that most clinicians are likely to be doing while they're caring for patients, at a busy emergency department, for example. And then, secondly, now that – the question then becomes, so, does the six-hour window to complete the physical exam, which is a six-hour element begin at 5 p.m. with a shock-clock? Or does it begin at 3 p.m., when severe sepsis was first noted? And if you go back to that table we just had previously, it was on slide 14, you know that, the elements that apply for the physical exam, apply to the six-hour element, and it should begin with shock as a shock-clock. So, really, this patient has from 5 p.m. until 11 p.m., six hours later, during which time, you would begin

to need to, you would need to have completed the focused exam for severe sepsis or septic shock.

So, in the example, the severe-sepsis clock starts at three; the shock-clock starts at five. The presentation of severe sepsis will then trigger certain counters, which have to be completed within three hours. And the three-hour counter for severe sepsis includes initial lactate collection, antibiotic administration, and that blood cultures are collected prior to antibiotics. The severe sepsis also has a six, has a six-hour, counter element that we have to consider, and that's the repeat lactate, if the initial lactate was greater than two. So, all of those elements are timed to the severe-sepsis clock, which began at 3 o'clock in the afternoon.

And so, for septic shock, there is also a clock that begins at 5 p.m. And, you won't be surprised to know then, that there are three-hour counters and six-hour counters associated with the elements that are required to complete SEP-1, with regard to septic shock. Looking at those three-hour elements, a counter would have start, to make sure that patients receive 30 ml per kilogram of crystalloid fluid in three-hours; so, by 8 p.m. And then, for six-hour elements, a counter begins which requires the administration of vasopressors and repeating a volume status and tissue perfusion assessment by 11 p.m. Now, it should be clear to providers, after these presentations, that I don't think it's possible to hold all that information in your head, in a given time. And so, the clinical pearl that I've provided to you, that if you begin your assessment of when severe sepsis or septic shock was suspected, and record that time in your head, and complete all the necessary actions within six hours of that time, you're likely to meet SEP-1, and complete the measure, and pass it. It's very important. And so, here, as you can see, for example, if at 3 o'clock in the afternoon, you had begun to suspect severe sepsis or septic shock. And then, within six hours, you did all of the necessary required therapies for that patient, you would be done by 9 o'clock. But as you can clearly see from the slide I was showing you, you still have a couple of extra hours to get those six-hour elements done for septic shock. So, the clinical pearl is,

just doing the timing yourself in your head provides you the opportunity to be compliant with SEP-1, and have time to spare.

And now, I'd like to turn over some of the content and updates on SEP-1 to my colleague, Bob Dickerson.

Bob Dickerson: Thank you very much, Dr. Townsend. So, I'm going to touch on some of the major updates to the SEP-1 measure made, based on feedback that we've received. I will cover these in two groups: as revision to version 5.1, which was effective on July 1, 2016, and as revision to version 5.2, which will be effective January 1, 2017. Now this review is intended to touch on the major changes that affect physician documentation, and what is considered acceptable, based on physician documentation.

The next three slides are an overview of major updates for version 5.1. The Administrative Contraindication to Care data element, which originally covered the entire hospital stay, was split into two data elements. One for Administrative Contraindication to Care, Severe Sepsis and a new data element, Administrative Contraindication to Care, for Septic Shock. Now, the content of each is specific to interventions required for severe sepsis and septic shock, and are effective for time periods associated with sepsis and septic shock. For severe sepsis, patient refusal of blood draws, IV fluids, or IV antibiotic must occur prior to, or within, three hours of severe sepsis presentation. And, for the septic shock data element, refusal of blood draws, IV fluids, or vasopressors must occur within six hours of septic shock presentation. Guidance was added to the Broad Spectrum or Other Antibiotic Administration Selection data element, indicating that it's acceptable if, in the three hours following presentation, antibiotics were ordered [they're] not on the antibiotic tables 5.0 or 5.1 if there's a culture result, or physician documentation, in the medical record that identifies a causative organism, and susceptibility testing, And, the antibiotic ordered was one that the organism is identified as being susceptible to. Some revisions were also made to data on the focused exam. The Cardiopulmonary Evaluation Performed data [on this] reflects this exam must be both performed and documented by a physician, APN, or PA.

The other data element that make up the focused exam no longer need to be performed by a physician, APN, or PA. They do need to be documented by physician, APN, or PA, and this documentation can be based on this exam having, having been, performed by someone other than the physician, APN, or PA. For the Crystalloid Fluid Administration data element, the terms, bolus, or wide-open, are acceptable in an order, in place of a rate or infusion duration. The 30 ml per kilogram target volume can be achieved through a single order, or a series of multiple orders. And if there's documentation indicating the fluids were stopped prior to the 30 ml per kilogram being completely infused, the abstractor must select No for this data element and the case will fall out of the measure. The list of acceptable crystalloid fluids has also been expanded to include balanced crystalloid solutions, Plasmalyte, and Normosol. Two new data elements were added, Initial Hypotension and Documentation of Septic Shock, to more clearly identify when crystalloid fluids are expected to be given, and help close an algorithm loophole.

Palliative care was added to the Directive for Comfort Care, Severe Sepsis and Directive to Comfort Care, Septic Shock data elements. Some revisions were made to the Vasopressor Administration data element to just mainly clarify the time frame for the IV vasopressor administration. And, revisions to the Vital Signs Review Performed data element remove the requirement that the physician, APN, or PA documentation must include the actual values. This change requires the names of the vital sign being reviewed to be documented. And, those must include the temperature, heart rate, respiratory, and blood pressure but the values of those respective vital signs do not need to be included in that documentation any longer.

In the next three slides, I will provide an overview of major updates in version 5.2 of the manual, which will be effective January first of 2017. A new data element called, Blood Culture Collection Acceptable Delay was added. Now, this takes into account situations where blood cultures were drawn after antibiotics was started, and it was considered clinically acceptable. So, this includes, for example, surgical cases where a pre-op

antibiotic was given and the patient subsequently developed severe sepsis. Cases for antibiotics were started prior to arrival and a blood culture was not obtained prior to the antibiotic. Cases where antibiotics were started for an infection before severe sepsis was present or suspected. And, situations where there is physician, APN, or PA documentation reflecting the antibiotic was started before the blood culture, because waiting would result in a delay into getting the antibiotic started. The data submitted that make up the focused exam (the capillary refill exam, cardiopulmonary eval, peripheral pulse eval, skin exam, and vital signs review) have expanded documentation option for what are acceptable in demonstrating that each of them performed. Each of these data still have the very specific documentation requirements that have been in there, demonstrating performed. But the revisions include two documentation options that represent exception to the more detailed requirement. And, you may hear these at different times referred to as, attestation statements. So let me walk through an example to help illustrate this. So, if there is documentation indicating that a physician, APN, or PA has reviewed or performed, or attested to, reviewing or performing a capillary refill exam, no further detail is required in the documentation. This statement, indicating they performed or reviewed the capillary refill exam, is acceptable and sufficient. This exception in the detailed documentation, is in each focused-exam data element, and is acceptable for each, as long as the name of the exam or evaluation is included in the statement, indicating that they have performed and reviewed it. Now the other new documentation option is a single statement that can be applied to all focused-exam data elements. So, if there is documentation indicating a physician, APN, or PA has performed, or attested to performing, either a physical exam, a perfusion assessment, reperfusion assessment, a sepsis-focused exam, severe-sepsis-focused exam, or septic-shock-focused exam, no further details are required. This statement will cover all focused-exam data elements, and is acceptable for the abstractor to select Yes for each focused-exam data element. Guidance was added to the severe sepsis and septic shock present data elements, indicating if there is documentation that severe sepsis or septic shock is present, that can be either identified to clinical criteria, or that there is physician, APN, and PA documentation.

And, within six hours following, there is physician, APN, and PA documentation indicating severe sepsis or septic shock was not present, the abstractor would select No for the respective data elements. And, the end result is that this would exclude the case from the measure.

There is new guidance to the severe sepsis present data element, which indicates the documentation of the suspected infection should be disregarded if, within six hours following that, there is subsequent physician, APN, or PA documentation indicating an infection is not present. And, in addition, the statement was added indicating to not use SIRS criteria if there is physician, APN or PA documentation indicating the abnormal value is normal for the patient, is due to a chronic condition, or due to a condition that is not an infection or a medication. For the Administrative Contraindication to Care, Severe Sepsis and Administrative Contraindication to Care, Septic Shock data elements, nursing documentation, patient refusal, is now acceptable. On the previous version, nursing documentation could only be used if it was on a witnessed-signed consent form that was marked, refused. So, there is no longer requirement for witness-signed consent form that is marked, refused.

As you may recall in version 5.1, guidance was added to the Broad Spectrum or Other Antibiotic Administration Selection data element, indicating that the causative organism is known, and susceptibility testing indicates the organism is susceptible to an antibiotic that was given, but was not on the antibiotic table, but this is acceptable. It was pointed out that susceptibility testing for C. diff is not really very feasible. So, to address this issue, a C. diff exception was added to version 5.2, which indicates, if the causative organism is identified as C. diff, susceptibility testing is not required. So, if the patient receives oral vancomycin, with or without, oral or IV Flagyl, in this specific situation, that that is acceptable in place of antibiotics from the table. Now to the Initial Hypotension, Septic Shock Present, and Persistent Hypotension data elements, guidance was added to disregard low blood pressure if a physician, APN, or PA documents the low values representing hypotension are either normal for

the patient, are due to chronic condition, due to a condition that is not infection, or due to a medication. And the last changes I'll cover, are the Crystalloid Fluid Administration data element. An allowable value has been added for patients with a ventricular assist device. So, if there is documentation indicating a patient has a VAD in place, the abstractor can select this new allowable value, and the case will be excluded from the measure. Now, to address the inherent variations that we have found in fluid volumes ordered and administered from the 30 ml per kilogram target, guidance was added indicating volumes up to 10 percent lower than 30 ml per kilogram target are acceptable. So this will take into account situations, such as, when, by calculation, the patient should have received 2,510 ml and 2,500 ml were ordered and given. And at this point, I would like to turn the presentation over to Dr. Tefera.

Lemeneh Tefera: Thank you, Bob. I would now like to review the national performance on the SEP-1 measure from the fourth quarter 2015 data that were submitted by hospitals. This slide here gives an overview of the submission from the hospitals. And, you'll see that greater than 99 percent of hospitals nationally successfully reported data elements for the SEP-1 measure. There were 210,997 patients in the initial patient population. And, of those, there were just over 96,000 eligible patients for the bundles. You'll also see that there are 114,000 patients excluded from the measure following the measure specifications.

Slide 26 reviews the exclusion population. On the right, the table by color indicates that the largest proportion of patients excluded from the measure where those that did not meet the severe sepsis criteria, as defined in the specification manual. You'll also note that transfers were the second largest reason for exclusion from the SEP-1 measure.

This review of the breakdown looks at the number of cases considered for the SEP-1 measure and then, tracks bundle-by-bundle, the number of patients that were assessed for each bundle. Please note that, as patients advance from the severe sepsis to septic shock bundles, that the number of patients included decreases, and that will impact the percentages that I discuss in the coming slides.

Before touching upon the bundle performance from our first set of data, I just wanted to quickly review that we'll be talking about this three-hour bundle, which includes initial lactate collection, blood culture collection, and [antibiotic] administration, the severe sepsis six-hour bundle, which includes the repeat collection of lactate if the initial lactate is elevated. The septic shock three-hour bundle, which is 30 ml per kilogram bolus of fluids for patients that meet septic shock criteria. And, the septic shock six-hour bundle, which include administration of vasopressors for persistent hypotension, and a repeat fluid, repeat volume status assessment, as previously described.

Looking at the breakdown of the sepsis three-hour bundle, I'd like to point out, first, that we're looking at a denominator of just under 101,000 patients. And, the vast majority of patients for this bundle passed successfully. When we look at the reason that a patient did not pass this bundle, we identified that initial lactate collection was a big driver of not successfully passing this bundle. And, we think it's an important opportunity for improvement that we'd like to identify. And, we think that hospitals can implement process changes to improve their performance on the sepsis three-hour bundle.

Slide 30 looks at the severe sepsis six-hour bundle. And again, we see good performance that there are 50 percent nationally. And, considering this is the first quarter of data collection, and the challenges of the many components of the abstraction, we think this is a good start for this six-hour bundle component for the cases that did not pass the bundle. The biggest reason for not passing the bundle is failure to collect the repeat lactate within six hours. Again, identifying this issue, we think, helps hospitals understand opportunity for improvement, and to implement process changes to help collect the repeat lactates prior to the six hours.

Slide 31, moving to the septic shock three-hour bundle. Again, we think it's a very positive sign that over half of the cases pass the bundle successfully.

When we look at the cases that did not pass the septic shock three-hour bundle, we see that these are cases that did not receive the indicated amounts of crystalloid fluid administration. Again, we see this as an opportunity for improvement in the coming quarters of data submissions. Identifying that cases are not receiving the correct amount of crystal fluid administration can help institute that process changes, and help clinicians identify this issue as something to focus on for improvement.

Slide 32 looks at the septic shock six-hour bundle, which has two components. One is vasopressor administration for persistent hypotension. And we see here that, an overwhelming majority of cases pass this bundle, and vasopressors were administered appropriately. Again, we see an opportunity here to identify a hospital's cases that did not receive vasopressors despite the presence of a persistent hypotension, and we think we will see continued improvement in this bundle, in the coming data-collection periods.

The other component of the septic shock six-hour bundle is the reassessment of volume status. And, we see here that the majority of cases did not pass the measure. And, the reason it did not pass the measure was that the noninvasive assessments were not completed successfully, or the physical exam requirement was not completed successfully. Again, although this is a large percentage of cases that did not pass the six-hour shock bundle, we think identifying that this lapse in performance can help identify an opportunity for improvement for hospitals to focus on improving processes so that clinicians are aware when the six-hour time frame from start of the septic shock bundle is completed. And, to find ways to make sure that our patients are reassessed prior to the completion of that window.

Having reviewed the performance of the bundles individually, this slide looks at the successful completion of all the bundles combined, and shows that the pass rate is just above 34 percent. Looking at this, individual bundles, we've identified multiple reasons why cases did not pass the measure. And, those cases – those reasons include failing to collect the initial lactate, failing to collect the repeat lactate when the lactate was

elevated, not administering the correct fluid bolus as required for the three-hour septic shock bundle. And also, challenges in performing a repeat fluid status and physical exam within those six hours for the septic shock six-hour bundle. So, although the percent of cases that did not pass is large here, we think, by identifying the areas where our cases did not pass, we can help hospitals focus their energies on instituting process measures internally to be successful in coming reporting periods.

Slide number 35 is an appendix and reviews some of the exclusions, exclusions from the large population of patients. And, and as I said earlier, the largest exclusions are for patients that did not meet the severe sepsis criteria, and for patients that were transfers from outside hospitals.

Slide 36, I'd like to focus here on some takeaways from what we've learned in the last year of having the set points measuring the inpatient quality reporting program. We've been listening to our stakeholders and instituting refinements to improve the measure. Those refinements have been, first and foremost, focused on maximizing beneficiary sepsis care. We intend to minimize clinician documentation burden. And, we think the changes that were reviewed today in version 5.1 and 5.2 of the specification manual were significant changes that decrease the documentation burden for clinicians. And, we also made changes that decreased the hospital-abstraction burden. And, we think, as we analyze data, in the, in the next several collection periods, we'll see improved performance because of these changes that will make successful completion of the, of the, bundles easier for clinicians and hospitals alike. And we look forward to sharing that data analysis when we have that available. At this point, I would like to hand back to Candace Jackson.

Candace Jackson: Thank you, Dr. Tefera. Prior to going into our question-and-answer session, I would like to turn the presentation over to Debra Price, who will go over our continuing education process. Debra?

Debra Price: Well, thank you very much. Today's webinar has been approved for one continuing education credit by the boards listed on this slide. We are now a nationally accredited nursing provider. And, as such, all nurses report

their own credits to their boards using the national provider number 16578. It is your responsibility to submit this number to your own accrediting body for your credit.

We now have an online CE certificate process. You can receive your CE certificate two ways. First way, is, if you registered for the webinar through ReadyTalk®, a survey will automatically pop up when the webinar closes. The survey will allow you to get your certificate. We will also be sending out the survey link in an email to all participants within the next 48 hours. If there are others listening to the event that are not registered in ReadyTalk, please pass the survey to them. After completion of the survey, you'll notice at the bottom right-hand corner, a little gray box that says Done. You will click the Done box, and then, another page opens up. That separate page will allow you to register on our Learning Management Center. This is a completely separate registration from the one that you did in ReadyTalk. Please use your personal email for this separate registration, so you can receive your certificate. Healthcare facilities have firewalls that seem to be blocking our certificates from entering their computer. If you do not immediately receive a response to the email that you signed up with the Learning Management Center, that means you have a firewall up that's blocking the link into your computer. Please go back to the New User link and register a personal email account. Personal emails do not have firewalls up. If you can't get back to your New User link, just wait 48 hours, because remember, you're going to be getting another link and another survey sent to you within 48 hours.

Okay, this is what the, what the survey will look like. It will pop up at the end of the event, and will be sent to all attendees within 48 hours. Click Done at the bottom of the page when you are finished.

This is what pops up after you click done on the survey. If you have already attended our webinar and received CEs, click Existing User. However, if this is your first webinar for credit, click New User.

This is what the new user screen looks like. Please register a personal email like Yahoo!, or Gmail, or ATT, because these accounts are typically

not blocked by hospital firewalls. Remember your password, however, since you will be using it for all of our events. You'll notice you have a first name, a last name, and the personal email. And, we're asking for a phone number in case we have some kind of backside issues that we need to get in contact with you.

This is what the existing user slide looks like. Use your complete email address as your user ID, and of course, the password you registered with. Again, the user ID is the complete email address, including what is after the @ sign.

Okay, now I'm going to pass the ball back to your team lead, to end the webinar, and to go over any questions that came in. Thank you for taking the time spent with me.

Candace Jackson: Thank you, Deb. This is Candace again, and we do have some time to go through a few questions. And our first question is, if a patient has a lactate greater than four, but does not have persistent hypotension, do we need to do a focused exam, diagnostic assessment of fluid resuscitation? If yes, what is the value of this exam, especially if the repeat lactate shows improvement?

Bob Dickerson: This is Bob. I can answer the first portion of that, is that, the measure does require, if there's a lactate greater than or equal to four, that the focused exam, the diagnostic assessment for fluid resuscitation, is required, because a patient with a lactate of greater than four and severe sepsis, has septic shock, and should receive the crystalloid fluids. In terms of the value of the exam, that might be something that perhaps Dr. Townsend could address a little bit better than myself.

Sean Townsend: Sure, Bob, absolutely. You know, the purpose of the repeat physical exam, is really to reassess perfusion and volume status. And, assessment of lactate, as in your example, is one evidence that the patient may not be perfusing adequately, such that, tissue begins to produce lactic acid. A repeat exam gives you the opportunity to ascertain whether that patient's perfusion has improved. So hypotension alone is not the only thing that's

improved on a physical exam. There are other features, which may be associated with poor perfusion, which include cool extremities, mottling, as examples. You know, the assessment of just vital signs alone are critical to knowing whether the patient has an adequate heart rate and respiratory rate to be providing the necessary vital capacities to, to, function. So, the assessment of the physical exam at – for the patient who is in shock with the lactate greater than four is just to assure the clinician that, in fact, the patient improved from the initial set of therapies they, they, began. So, in this regard, whether it's hypotension or lactate, there is still opportunity to come back and see the patient, to make sure that there are change, and a change for the better.

Candace Jackson: Thank you. Our next question, what score are you seeing from hospitals across the United States for Sepsis-1? We lack a benchmark and it would helpful to know how others are doing outside our organization.

Lemeneh Tefera: Hi, this is Lemeneh Tefera. I think there are two components to this question. One, is that, we announce that we will not be publicly reporting the results from the SEP-1 measure this year. The reason we made that announcement is that we felt, because of the multiple changes to the specification manual, because it is a challenging measure, we wanted to give hospitals, abstractors, and clinicians more time to get accustomed to what we think will be the longstanding components of the specification manual, which are represented in version 5.2, which starts January 2017. Regarding what hospitals can use currently for comparison, as I've shared during this presentation, I think, if you take a look at those slides and evaluate your hospital performance versus national performance, not only the overall rate, but to each bundle, that you'll see an opportunity to, to improve your internal performance. And, you'll see how your institution compares to others for your, you know, for your ongoing quality improvement work. Thank you for the question.

Candace Jackson: Next question. Per slide 14, it says that crystalloid fluid is not required for severe sepsis. Is this a change? Because, as of right now, if a patient has initial hypotension, fluid is required.

Bob Dickerson: This is Bob. I believe I can address that one, and thank you for this question. For severe sepsis that does not, that does not have, hypotension, the crystalloid fluids are not required. What this, so, in just severe sepsis in general, there is not a requirement for the crystalloid fluids. But, if you have severe sepsis, and have hypotension associated with that, that would be a trigger for the 30 ml per kilogram of crystalloid fluids. And, Dr. Townsend, is there anything you like to add to that?

Sean Townsend: I think Bob has said it correctly, and so, in that regard, this slide is slightly misleading. It is possible, as you, as the questioner, said, to have severe sepsis with initial hypotension, that responds to fluids, and doesn't progress to shock. So, in fact, there is an instance where, in severe sepsis, the 30 ml per kilogram crystalloid requirement is appropriate.

Candace Jackson: Thank you, Dr. Townsend. We do have time for one more question. And, that question is, the term, severe sepsis, was eliminated during the Sepsis-3 meeting, why are we still using the term, severe sepsis? It is confusing.

Sean Townsend: This is Sean Townsend. I think I can take a handle on this. It's untrue that the term, severe sepsis, was eliminated during the Sepsis-3 meeting, and then, universally accepted as the right thing to do. The authors of Sepsis-3 proposed that that was an appropriate strategy, but the authors admit, in that same publication, in *JAMA*, *JAMA* of this year, the strategy has not yet been validated. And that testing is required, to ensure that those definitions are workable. And, that validation and testing by the authors, on admission, has yet to have been done.

And, there is a number of reasons to not move towards adopting the Sepsis-3 definitions, removing severe sepsis as a term, which have been considered in literature, and I won't go into great detail here. The major concern with the Sepsis-3 definitions beyond the fact that they're not validated and not yet tested, is, in the, real world, is that, early identification may be compromised. The whole strategy behind SEP-1 in describing sepsis campaigns attempt to detect sepsis early, has been that early detection could save lives.

And so while SIRS criteria may, in fact, be not particularly specific for severe sepsis and septic shock, and they may be overly sensitive in identifying patients, that oversensitivity is a good thing. Because, we have to look carefully at patients who trigger SIRS criteria to assess them, whether they may actually be developing severe sepsis or shock. And that gives us the opportunity to intervene.

Sepsis-3 essentially just looks at organ dysfunction as the main criteria as to whether the patient has sepsis, as they called it, the old severe sepsis, and that's late identification. If you already have organ dysfunction, it's hard to save the patient and intervene. So SEP-1 is based on a different strategy. In reply to the initial authors' statements in *JAMA* who proposed Sepsis-3, Dr. Lemeneh Tefera, myself, and Manny Rivers replied on behalf of Medicare that we would not be using the Sepsis-3 definition at this time.

Candace Jackson: Thank you, Dr. Townsend. And, Dr. Tefera, do you have any closing remarks?

Lemeneh Tefera: Thanks, Candace. Just for the participants, that, that we instituted this measure because although there are over a million cases of sepsis annually, and we know that sepsis has a high mortality, between 20 and 40 percent, and high rate of cost to our health system, and variability of care across the country, this is the first measure addressing this issue. So we're very keen to continue to listen to stakeholder input. And, we hope participants see all the refinements and improvements we've made to the specification manual, to focus on quality of care for beneficiaries, while also improving the, any challenges from documentation, abstractions for clinicians and hospitals. So, we look forward to working together to continue the improvement of sepsis care nationally. Thank you, Candace.

Candace Jackson: Thank you, Dr. Tefera, and Dr. Townsend, and Bob Dickerson, for presenting today. We thank you all for joining in our presentation. And, hope that this information was of great value to you. And, we hope that you have a great afternoon. Thank you.