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Hospital-Based Sepsis Care: The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care

Presentation Transcript

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Candace Jackson: Good afternoon and welcome to *Hospital-Based Sepsis Care: The Evolving Definition of Sepsis and the Role of the ED Medical Director and Quality Team in Sepsis Care* webinar. My name is Candace Jackson and I am the Hospital Inpatient Quality Reporting Program support contract lead from the Inpatient Value, Incentives, and Quality Reporting Outreach and Education Support Contractor. I will be hosting today's event. Before we begin, I would like to make a few announcements. This program is being recorded. A transcript of the presentation will be posted to the inpatient website, www.QualityReportingCenter.com, in the upcoming weeks. If you registered for this event, a reminder e-mail and a link to the slide was sent out to your e-mail a few hours ago. If you did not receive that e-mail, you can download the slides at www.QualityReportingCenter.com. This webinar has been approved for 1.5 continuing education credits. If you would like to complete the survey after today's event, please stay on until the conclusion of today's event. After the question-and-answer session, we will display a link to the survey that you will need to complete to receive the continuing education credit. The survey will no longer automatically be available if you leave the event early. If you do need to leave prior to the conclusion of the event, a link to the survey will be available in the summary e-mail sent out one to two business days after the event. If you have questions as we move through the webinar, please type your question into the Ask a Question window with the slide number associated and we will answer as many questions as time allows. After the event, if you have additional questions, please submit your questions to our speaker at the e-mail address that will be provided in the presentation. Our speaker for today's event is Dr. Bobby Redwood who is the chief of emergency medicine at Cooley Dickinson Hospital and Bob Dickerson who is a senior clinical program analyst for the Behavioral Development and Inpatient and Outpatient Measure Maintenance Support Contractor.

This event will provide a physician's perspective on the evolution of the definition of sepsis and the SEP-1 measure as it relates to population health and sepsis care in the emergency department.

At the end of this presentation, participants will be able to understand and discuss various sepsis definitions, discuss how the sepsis identification criteria used in the SEP-1 core measure can differ from how sepsis is identified in your facility, understand and discuss the difference between a guideline and a measure, discuss common organizational strategies for achieving success in the early identification and treatment of sepsis, and discuss the role of the emergency department medical director in sepsis quality improvement work.

This shows the acronyms and abbreviations used in today's presentation.

As noted, if you have questions for Dr. Redwood that do not get addressed in today's presentation, those should be sent to Dr. Redwood at the e-mail address on the slide. Questions related to the Hospital IQR Program SEP-1 measure and specifications should be submitted to the question-and-answer tool at the link noted on the slide.

We would like to make note that the viewpoints shared in this presentation are those of the presenter and do not necessarily represent CMS's view. I would now like to turn the presentation over to Dr. Redwood. Dr. Redwood, the floor is yours.

Dr. Redwood: Good morning everyone and thank you, Candace, for that warm introduction. The talk today is based on hospital-based sepsis care and, specifically, the emergency department, the evolving definition of sepsis, and the role of the ED medical director and quality team in sepsis care. If you look at this photo here, this is my home hospital, Cooley Dickinson Hospital in western Massachusetts, where I'm chief of emergency medicine. You know you are running into a rough shift when you see the ambulances are already double-parked, so there is probably some sepsis in that department today.

I have no financial disclosures. I do want to disclose that I'm a poor artist. CMS is very finicky about copyright laws, which we appreciate. So, there are some original graphics drawn for the presentation today. I hope you will appreciate that I'm a amateur in that respect but, obviously, I am an

expert on sepsis care. I have one unique part of my training, I'm dual trained in emergency medicine and preventative medicine, which is the medical specialty of public health. I only call that out because what we are really talking about with the SEP-1 core measure is preventative medicine in action. This is a population health-based experiment. We are doing tertiary prevention. In other words, we are treating a broad population of patients in order to save the lives of the sickest cohorts, and that will come up again and again during this presentation. Sometimes as clinicians or physicians in the trenches, we get lost in the individual patient encounter when, in fact, the SEP-1 core measure is about treating a population of patients and screening a population of patients to find and identify that sickest cohort and get them the treatment they need sooner rather than later.

Let's dive right into it. We are going to start with definitions. Now, this might sound pretty basic, a sepsis definition but, as this crowd knows, sepsis is anything but basic. We are really talking about an evolving definition, a journey that we started in 1991 with a consensus conference on a sepsis-1 definition that has really progressed into the modern era with SEP-3 and the SOFA score. We'll get into the differences and nuances between those two definitions and how as a provider or a physician in the trenches you are supposed to work in these two worlds, and there are really two worlds here.

Diving right in, the 1991 consensus conference definition of sepsis SIRS. Now, there is probably some dispute about that, but I can tell you on a daily basis, we use the 1991 consensus definition, often referred to as sepsis-1, and it is the definition used by the SEP-1 core measure. The reason that this definition endures is because it is a very powerful definition. Anything in medicine that has survived 30 years, like this definition has, has some very strong utility to it. What I like about the SIRS criteria and the 1991 consensus conference definition is that it is very logical and follows the pathophysiology of sepsis and septic shock. It starts with systemic inflammatory response. What we are talking about here is an elevated or low temperature, a heart rate greater than 90, a respiratory rate greater than 20, or PaCO2 grade less than 32, or a white

blood cell count greater than 12,000, less than 4,000, or greater than 10 percent bands. Essentially, we are talking about our immune system springing into action. Now, the immune system can spring into action for multiple reasons. It could be bacterial infection, bacteremia, and sepsis, but it could also be just a run of the mill virus that has not spread to the bloodstream or a mimic like an asthma attack or panic attack or diabetic ketoacidosis. That is where the next step comes in. Now, we are talking about sepsis, SIRS criteria plus a source of infection. So, if you think about infection, the common players are pneumonia, cellulitis or a skin infection, or a urinary tract infection. Those infections all start locally. So, pneumonia is in the lung and alveoli of the lung. A skin infection is a bacterium underneath your skin, but it is when it feeds into the bloodstream that we start to see real bacteremia and first signs of sepsis. That triggers severe sepsis. That is sepsis plus end organ damage. Now, the pathophysiology here is quite clear. Our immune system is now exerted (inaudible) cascade, and we don't want to get too clinical here, but the blood vessels in your body have become porous. They are expanding, and you are third spacing fluid. So, the fluid that is usually intravascular is now extravascular, meaning that your blood pressure is going to drop. That is the final category, septic shock, severe sepsis plus hypotension. Our organs are no longer being profused. Our mean arterial pressure is less than 65, and we are starting to exhibit end organ damage. This is the definition of septic shock in the 1991 consensus conference definition. In the emergency department, that really catches our attention. These patients have a very high chance of in-hospital mortality and are easily our sickest patients in the emergency department.

Now, let's contrast the 1991 consensus definition with the 2016 third consensus definition, or sepsis-3 as it is commonly referred to. This definition really hones in on sepsis as life-threatening organ dysfunction caused by a dysregulated host response to infection. Now, that is a mouthful, of course, but what they are really identifying is that sickest cohort of the third criteria in the sepsis-1 definition, those patients who are already having organ dysfunction and whose host response is no longer responding appropriately. An immune response is supposed to be a good

thing, right? Yet, we know the human body can overreact and that it can lead to a position where the immune system is hurting us. The key changes here are that the severe sepsis category has been removed entirely and that organ dysfunction is quantified using the Sequential Organ Failure Assessment, or the SOFA score. What this does is create a higher bar for septic shock. Meaning septic shock is now sepsis with a vasopressor requirement to maintain a mean arterial pressure greater than 65 and lactate less than 2 milliliter per liter after fluid resuscitation. If you think about the two definitions, the first definition, the 1991 consensus definition cast a very wide net and identifies a large cohort of patients that have the potential to progress to septic shock; whereas, the 2016 third consensus definition, or sepsis-3, captures a smaller bucket of patients, those who are already showing organ dysfunction and are heading quickly on their way to a more severe definition of septic shock.

Digging deep on the Third Consensus definition, they use the SOFA score, the Sequential Organ Failure Assessment score, that really goes systematically down the body and tries to tell us not just that there is organ failure, but which organs are failing. It starts with the respiratory system by measuring arterial oxygen pressure or fraction of inspired oxygen. It moves onto the cardiovascular system, measuring the mean arterial pressure or vasopressor requirements. The liver system and bilirubin levels, our kidney function or renal system, measuring the creatinine levels, our coagulation cascade, measuring the platelet levels, and our neurological system using the Glasgow Coma Scale, for example. Now, this is very elegant and very useful in terms of identifying that sick cohort, but anyone who works in the emergency department knows that you are not given all of these variables on patient presentation. In fact, during times of ED crowding, if your lab is backed up, if a sample gets hemolyzed, you may not have some of these values well past 3 hours into your ED stay. So, what is an emergency physician or provider to do in the moment with a patient in front of you before you can calculate a full SOFA score?

This is exactly the controversy. Our first controversy of the webinar, in fact. ED versus ICU. Which sepsis definition should we use? Well, let's take a moment to think about the care environment in the ED versus intensive care unit. The emergency department typically has more beds. In general, the patients are less sick than the ICU. We have moderate to high resource care. So, we do have a lot of access to sophisticated care in the ED. Now, we are going to be seeing many sepsis false positives. Again, the panic attacks, asthma exacerbations, pulmonary embolism, these are examples of false positives that come to the ED and many will actually be treated and go home. In the emergency department, the primary role is diagnosing, stabilizing, and sorting patients. That diagnosis part is key. Oftentimes when a patient goes to the ICU, the diagnosis of sepsis is already quite clear. In the emergency department, it is not so clear. Finally, lab values, as we stated earlier, are not always available on initial presentation in the emergency department. Depending upon how well your system is working that day, they might not be available at all for at least a few hours. Now, the intensive care unit is generally a different environment. There are fewer beds, but the patients are much sicker. It is by definition very high resource care. As we know during this era of COVID-19, ICU beds are precious and you want to make sure you get the right patient to the right level of resources at the right time. As we said, there are going to be fewer sepsis false positives. That is because typically the workup has been done in the ED or on the floor and the patient is arriving at the ICU with a pretty good idea that sepsis is present. You will still be waiting on blood cultures, obviously, but you have identified a source of infection, you have identified organ dysfunction, and the patient is now well established as ICU-level care. The role of the ICU, of course, is continuing to stabilize and ultimately treating life-threatening conditions, which is quite different from the ED. We are getting treatment started, but the ICU is making sure that patient actually goes home, neurologically intact, highly functioning, and essentially treated. Again, lab values in the ICU are typically available. Initial labs have been drawn and resulted in the ED and now it is time to monitor those for continued dysfunction or improvement.

Goal-Directed Therapy: We presented the controversy, and now is the time to talk solutions. This is an ED-focused lecture, so we all know that sepsis involves the continuity of hospital care, really from pre-hospital to ED to floor to ICU. If you are on a sepsis committee, you are talking about all of these in conjuncture. I hope that the quality improvement professionals, intensivists, and hospitalists on the call today can appreciate the challenges that we live in the ED, living between these two definitions. My recommendation is that, in the emergency department, you use Systemic Inflammatory Response Syndrome, or SIRS, criteria as a screening tool to identify patients who are a high risk for progression to sepsis and septic shock. I remind everyone that this is not a diagnostic tool. Sometimes we talk about SIRS criteria as a diagnostic tool, but it is a sorting tool. What we are trying to do is we are trying to sort that high cohort of patients, so we don't miss any sepsis or septic shock. The ultimate diagnosis comes, as we know, from blood cultures and often comes a few days down the line. Now, likewise the SOFA scoring system for organ dysfunction is a determination of resource needs. So, later on in the ED workup, we are actually going to be talking about using the SOFA score to say whether this patient is appropriate for the medical floor or ICU. Ultimately, that is the recommendation. In ED triage, screening with SIRS criteria or 1991 consensus conference definition of sepsis and, during the ED service, broaden that workup to include SOFA and sepsis-3. For example, someone is having an asthma attack and has a respiratory rate of 30, a heart rate of 120, maybe it is driven by a virus and they have a low grade infection, I'm going to say, "Yes, We have SIRS positive criteria here, a possible infection. We are going to draw blood cultures. Send two lactates. Administer 30 ccs per kilogram normal saline fluid bolus and start broad spectrum antibiotics." When I get the labs back and I realize that the lactate is low, heart rate and respiratory rate responded to albuterol and other therapy, and we have a low suspicion for bacteremia and sepsis at this time, I can calculate a SOFA score and say this patient doesn't need an ICU-level of care. In fact, I'm questioning whether they have sepsis at all. This is patient appropriate for the floor. We can wait for blood cultures and do a level-of-care upgrade as needed if they become sicker. That is just one example.

Now, some of you might be thinking, "Well, why are you using SIRS and the 1991 consensus definition when we have Q-SOFA?" When the SOFA score originally came out, people recognized pretty quickly it was not applicable to the ED environment for the reasons I stated. You are not going to have labs back at time 0. The Q-SOFA score actually addresses that. It has us measure respiratory rates, evaluate for altered mental status, and evaluate the patient's systolic blood pressure. If you have two of those three present, then you would say the Q-SOFA is positive and you have higher suspicion for sepsis. Of course, that is in conjunction with the source of infection, much like SIRS criteria. Now, there's also a problem here. The problem is which one actually does better. In medicine we talk a lot about sensitivity and specificity. Sensitivity is about ruling out disease. Specificity is about ruling in disease. In the emergency department, we want a very sensitive screening criterion. Again, we want to cast a wide net so that we do not miss any sepsis or septic shock.

Up until a couple years ago, this question had actually not been answered. You had some shops using SIRS criteria and other shops using Q-SOFA and pointing fingers at each other and saying, "Who is doing a better job?" The head-to-head comparison came of Q-SOFA versus SIRS came out in 2018 and this was a game changer in my mind. It showed that SIRS criteria was 81 percent sensitive and 41 percent specific. Q-SOFA was 42 percent sensitive and 88 percent specific. Said in plain language, SIRS criteria is better at ruling out sepsis and Q-SOFA's criteria is better at ruling in sepsis. Now the question becomes, "Which environment do you use which score?" Again, in the ED, I would recommend using the more sensitive test. That is the SIRS criteria. Cast a wide net and make sure that we don't leave anyone in the waiting room with sepsis even if we think it is a panic attack, or asthma attack, or diabetic ketoacidosis. Let's go ahead and bring them back, start the work up, and they can deescalate the work up if it proves to not to be sepsis. Now, operationally, patients who screen positive should be prioritized. You get a prompt history and physical exam and that might help you detect infection or organ dysfunction early on in the workup. At that point, we would apply the SEP-1 intervention for SIRS-positive patients with a clinical source of infection. We have been

doing this for years, it is probably old hat by now, easier said than done, of course. Blood cultures times two, lactate times two, 30 mL/kg crystalloid bolus, normal saline or lactated Ringer's solution and broad-spectrum antibiotics with attention to the potential source of infection. Now, we know there are going to be confounders. We are living in the era of COVID, of decompensated DKA, or diabetic ketoacidosis, or pulmonary embolism, and that is why we are going to reassess our patients frequently. This isn't just putting someone on a path and leaving them on this path. It's identifying a patient who may be critically ill, starting care intervention, and then assessing on a regular basis to see if your diagnosis is correct and the interventions are actually working.

Now, Controversy 3: Sepsis Definition Payor Denial. I'm sure you have all had the experience where a biller or coder e-mails you back and says this payment was denied even though the patient had sepsis. It was denied because they did not meet sepsis-3 criteria or have a SOFA score documented. This is the world we are living in. We are currently between two definitions of sepsis. I'm going to try to help you live in those two worlds until we have achieved clarity as a society. Let's start with an example. In 2015, before the sepsis-3 definition came out, a 65-year-old male with pyelonephritis, WBC of 23,000, temperature of 104, heart rate of 120, lactate of 5, and mean arterial pressure of 67 would be sepsis by definition. Now, in 2017, that patient is not septic. They do not meet the full criteria for sepsis-3. Obviously, that is a bit of an extreme example. I think we can all look at this and be concerned that this patient is progressing to sepsis and septic shock, but if you are going by the technical definitions here, we don't really have that threshold of organ dysfunction to call that sepsis-3 yet. Now, ICD-10 is still around, and it has not abandoned the 1991 consensus conference definition of sepsis. At the same time, certain payors are issuing diagnosis-related group denials for sepsis, citing that the sepsis-3 definition was not met. So, what is a provider to do?

First of all, let's just take a deep breath. Don't get hung up on semantics. We are all in this together, and we have all had this experience. Let's say

that you have fully moved on and you enjoy using the sepsis-3 definition, you like the SOFA score. You say, "Why on earth are we talking about the 1991 consensus definition of sepsis?" I would recommend that you think of sepsis, the 1991 definition, as high-risk for progression to septic shock. If we discount it totally, we discount the utility of the SIRS criteria and that very logical pathophysiologic mechanism that we talked about on the very first slide. I would treat that patient per the CMS criteria for the SEP-1 core measure recommendations. Then for billing purposes, you can go back and try to document a SOFA score. If you see a dysregulated host response to infection, you might want to put those exact words in the chart, and then finally document the source of infection and any organ dysfunction that you find. We can very easily live in these two worlds where we treat clinically with sepsis-1. Then, when we have enough information later on in the work-up, we document appropriately for sepsis-3.

This final slide is too small to read, and I don't expect you to read it. Yet, it is a very useful slide provided in the annals of emergency medicine in 2021 that gives us a true summary of the different sepsis definitions throughout the ages and a breakdown of which is which. If you are a medical director or chair of your sepsis committee, you may want to use this resource to explain your clinician where we have come since 1991 and how you can use both SIRS criteria and SOFA in synergy instead of thinking of them as two things in opposition.

All right. I thank you for your attention to that first part of the presentation. Now, we are going to turn it over to Bob Dickerson who can talk about the nuts and bolts of the SEP-1 core measure and how to think of it clinically.

Bob Dickerson: Thank you, Dr. Redwood. For the next few slides, our objective is to discuss how the sepsis identification screening and identification criteria that Dr. Redwood very nicely reviewed are used in and for purposes of the SEP-1 measure and how that can differ from methods used at the bedside to identify the presence of severe sepsis and septic shock.

Let's start by reviewing how cases get into the SEP-1 measure initial patient population. Then we'll review how the criteria are used to identify severe sepsis. The transition data processing flow ensures that only valid data are used in the measure algorithms. The initial population algorithm for SEP-1 evaluates each case to ensure that the data meets the population for the measure. For the SEP-1 measure, if the case has an ICD-10 clinical modification code, that is in Table 4.01 of Appendix A of the specifications manual, the case will continue in the sepsis initial patient population. If the case does not have an ICD-10 code from Table 4.01, the case will not be included in the SEP-1 measure initial population.

Now, this slide provides the list of codes included in Table 4.01. As I mentioned, cases within ICD-10 code from the table are included in the initial patient population for SEP-1. You will notice that the table includes ICD-10 CM codes for severe sepsis without septic shock and severe sepsis with septic shock. Those are identified with a red circle on this slide. However, the list of ICD-10 CM codes is not limited to only severe sepsis codes, but it also includes many other sepsis codes. Now, the intent is to cast a wide net to capture a larger initial population of patients who likely have severe sepsis or septic shock. Abstraction of the *Severe Sepsis Present* data element then identifies those patients that meet the SEP-1 clinical criteria, which we will discuss further in just a couple of minutes. Now, the measure stewards included the sepsis codes in addition to severe sepsis codes based upon testing which revealed that many patients who had clinical evidence of severe sepsis were assigned sepsis codes. Some patients who did not meet severe sepsis or septic shock clinical criteria were being coded to a higher level of severe sepsis codes. So, let's take a look at the next step in the initial patient population algorithm.

All of the cases with an ICD-10 code that is in Table 4.01 are next evaluated for the presence of the ICD-10 code UO7.1 for a diagnosis of COVID-19. Now, if this code is present, the case will not be in the SEP-1 initial patient population. If this code is not present, the patient case will remain in the initial population and continue through the sepsis initial patient population algorithm.

The last steps in the initial population algorithm are checking for age and hospital stay. So, patients who are less than 18 years of age or who have a hospital length of stay greater than 120 days are removed from the initial population. At this point, we have the SEP-1 initial population. From this population, you extract medical records of a sample set of patient cases who are eligible for the SEP-1 measure.

The measure algorithm then begins with the transfer from another hospital or ASC and the clinical trial data elements. Now, the algorithm excludes cases from the measure that were transferred from another hospital or ASC to your facility or if they were enrolled in a clinical trial related to sepsis care at your facility. Patient cases who are not transferred in and who are not in clinical trial proceed to the measure algorithm to the *Severe Sepsis* data element.

As we saw earlier, ICD-10 coding initially identifies cases for the SEP-1 initial patient population, but because coding is not exact, the *Severe Sepsis Present* data element is used to exclude patient cases that do not meet the defined set of severe sepsis screening criteria used in this data element. Now, I want to point out that SEP-1 does not dictate nor limit the severe sepsis and sepsis shock screening criteria that clinicians use at the bedside. CMS recognizes that there are variations in screening criteria that are available and used at the bedside; rather, SEP-1 defines for purposes of measure abstraction a common set of established criteria that abstracters from various hospitals across the U.S. will utilize for abstraction of medical records to determine which patients from their initial populations remain in the measure. This helps ensure the same criteria are used to determine which patients remain in the measure and which ones are excluded. Let's take a closer look at the criteria for identifying severe sepsis in the *Severe Sepsis Present* data element and how that criteria are used.

For the measure, severe sepsis can be established by documentation of clinical criteria or physician/APN/PA documentation of severe sepsis. To establish severe sepsis by clinical criteria, the documentation of infection, two or more SIRS criteria, and evidence of organ dysfunction must be documented within six hours of each other. Now, SEP-1 utilizes this

criteria for establishing severe sepsis based on the earlier consensus definitions that Dr. Redwood reviewed which does include using SIRS criteria. As Dr. Redwood referenced, recent studies since the 2016 third consensus conference definition have consistently demonstrated that SIRS-based screening criteria are more sensitive than Q-SOFA-based criteria and therefore identify at-risk patients earlier. Now, this is consistent with the intent of SEP-1, which is to identify patients with severe sepsis and septic shock early in the clinical course. Then, measure whether evidence-based care was initiated early in the patient's treatment. To give clinicians the benefit of the clinical judgment, if the SIRS-based clinical criteria are not met based on abstraction guidance, but a physician, APN, or PA documented the patient has severe sepsis or septic shock, this will also retain the patient in the measure. If the documentation does not meet the severe sepsis screening criteria, and there is not clinician documentation that the patient has severe sepsis or septic shock, the patient case is excluded from the measure. Now, this is not saying that the patient does not actually have severe sepsis or septic shock, it is just for purposes of the measure that the patient case would be excluded.

Next, we'll talk just a bit about the difference between clinical guidelines that typically provide the recommendation evidence for patient care and the measures that assess whether the recommended care is being provided for patients.

On this slide you can see two similar definitions for clinical practice guidelines. The first one being from the CMS Measures Management System Blueprint. The second is from the Institute of Medicine consensus report *Clinical Practice Guidelines We Can Trust*. Now, while these definitions are from two different publications that were released about ten years apart, you can see the definition of clinical practice guidelines remains similar and has common elements and that they are systematically developed, based on review of evidence, and provide recommendation statements to support decisions that optimize patient care. Now, while the strength of evidence may vary for any given recommendation and a set of clinical practice guidelines, the recommendations statement considers a

combination of the evidence and assessment of the benefits and harms of the various care options. This means that a given care component could have weak to moderate evidence supporting it, but the risk is so low that the guideline writers recommend it because it can be beneficial and have minimal to no risk. Guidelines are designed to support clinician decisions to optimize care. Ultimately the decision to implement any given recommendation from a set of guidelines for a specific patient requires the clinician to consider the risks and benefits for that specific patient.

Similar to the previous slide, this slide includes two definitions for clinical quality measures. The first being from the CMS Measures Management System Blueprint, and the second is from the CMS (electronic health record) EHR Incentive Program, *A Quick Guide to Clinical Quality Measures*.

The key points that define a clinical quality measure are that it assesses or measures the degree to which safe, appropriate, effective patient-centered care is provided in a timely manner. We can also see that measures can assess processes of care, patient experience, or patient outcomes. Now, measures are not guidelines. Rather, what they assess is based upon guidelines. As guidelines and recommendations change, we evaluate the applicable measures to determine whether changes to the measures are warranted. Now, this process takes time for a variety of reasons. One of those being that the measure developers need to consult with clinical experts to determine the degree to which a measure should be or can be revised to reflect the most recent guideline recommendations or non-guideline evidence, and if so, strategies to operationalize the update to the measure. In some cases, this is very simple. In other cases, it can be a complex process. Now, as you all know, SEP-1 assesses the degree to which the processes of a bundle of guideline-recommended care are implemented in patient care in a timely manner. SEP-1 is a measure and not a clinical guideline. Now, keeping in mind what we have discussed about clinician use of guideline recommendations in clinical care and what measures assess, measures do not dictate care, rather they assess the degree to which recommendations are utilized or the degree to which recommendations impact outcomes. CMS recognizes that due to these factors and based on best clinician judgment of

guideline application that there will be some patient cases that will not meet SEP-1 enumerated criteria. As such, CMS does not expect 100 percentage performance on SEP-1 for each patient case abstracted and recognizes that there are some patient cases where, based on the best clinical judgment of clinicians, the most appropriate care for a given patient may not meet all numerator criteria.

So, let's bring this discussion full circle and back to what SEP-1 is assessing within three hours of the earliest documentation reflecting that severe sepsis or septic shock is present. While the strength of evidence varies for each of these critical elements, they are all elements of care that are recommended in the 2016 Surviving Sepsis Campaign International Guidelines for Management of Sepsis and Septic Shock. We recognize new literature has been published since these guidelines were released. To that point, as new literature is published, it is reviewed by clinical experts on a regular basis to determine whether, and if so, to what extent and how it can be incorporated into SEP-1. To illustrate, in the most recently released versions of the S*pecifications Manual for National Hospital Inpatient Quality Measures*, you will see revisions were made to the *Crystalloid Fluid Administration* data element that includes allowances for crystalloid fluid volumes less than 30 mLs per kilogram for specific patient-based situations. To wrap up this portion of the presentation, this slide outlines the critical patient elements addressed by SEP-1 for completion within 6 hours of the earliest documentation reflecting that severe sepsis or septic shock is present. With that, I will turn the presentation back over to Dr. Redwood who will talk about strategies for bringing best practices to the bedside.

Dr. Redwood: Thank you, Bob. I would also like to extend a thank you to all the quality improvement professionals out there. You know, as a frontline clinician, I don't think we always recognize the value of the implementation scientists that we have on staff. That is the word I like to use. Our quality improvement professionals are data scientists, they really help us bring best practices to the bedside. We are not actually that good at that in clinical medicine, there are so many best practices that have sat on the

shelf for ten years, twenty years, thirty years. Part of the innovation of SEP-1 is that we are actually putting our money where our mouth is and taking these best practices and bringing them to the bedside. We do it through sepsis committees. We do it through journal clubs. We do it through individual provider one-on-one feedback. It has been a journey going on experiment together. That is part of what I would like to talk about in this next section. It is how we can best leverage our tools, not just our quality improvement professionals, but our ED medical director, and our frontline clinicians to bring sepsis best practices to the bedside.

Now, for this portion of the presentation, I'm going to rely on a really unique experience I had. As a quality improvement professional with the Wisconsin Hospital Association and chair of my sepsis committee at Divine Savior Hospital, I was actually playing both roles. We were embarking on the journey at the hospital-level to improve sepsis care in the emergency department. Then, we were also visiting 80+ EDs around the state talking to everyone, talking to quality improvement professionals, and medical directors, looking at the big aggregate data for the state and seeing how we have moved the needle on sepsis mortality. The experience was really powerful. It was powerful because we were able to catalogue best practices from sepsis committees and frontline clinicians and share those throughout the state. I could put those to work in my hospital, work with my homegrown teams and see how they worked in my individual ED. If you have seen one emergency department, you have seen one emergency department. We understand that. No shop is the same. We have different electronic health records, different staffing models, different resources. You might be a rural shop, or you might be in an academic medical center. We are all trying to do the same level of sepsis care. It is really remarkable. What we will do in this section is give you a road map to success. If it seems like it would fly in your shop, by all means go forward with it. If it seems pie in the sky and you don't have the resources, maybe that is not applicable to you. Take the good. Leave the bad. I'm sure some of this is already being done at your shop. If you see something that you are already doing, be sure to give yourself and your team a pat on the back.

So, here's the road map to success that we identified. These are best practices that we found in high performing hospitals. Those institutions have somehow hacked it and done really well on SEP-1. I want to thank Bob for pointing out that doing well on SEP-1 is not 100 percent. If we scored 100 percent all the time, we would be clearly over treating some proportion of our patients. We want to get in the sweet spot. We want to identify the patients with sepsis and treat there cares early in their hospital course. The number one thing is having a team. Typically, it is an interdisciplinary team. I recommend that it include, at a minimum, as a floor, the ED and ICU. That means nursing professionals and physicians from both care environments, as well as quality improvement professionals. Of course, you can expand that. You can include hospitalists and people from the medical floor. You may want to include, if you are a surgical center, the surgery team. You may want to include case managers and other professionals who take care of sepsis populations. Obviously, you can expand that team. Next, after you have your team, it might take the form of a sepsis committee or sepsis task force, you want to establish a process for routine screening in all patient areas with a standardized screening tool. Now, in the emergency department, we are really talking about triage. There are some centers that do pre-hospital screening for sepsis, but typically the triage is the place where you want to do that. So, if you have a waiting room that is quite full, you want to actually prioritize triage, so nobody is waiting too long in the waiting room. That might mean having a provider in triage. That might mean doing a quick triage where you get vital signs and a one sentence chief complaint. You want to make sure you identify everyone very soon, essentially right after they are registered. The next trait of high performing hospitals that we saw were automated alerts for severe sepsis and septic shock. That is a broad phrase, automated alerts. In my hospital, we had a little orange box that popped up around patients who met SIRS criteria. You want to make you don't have alarm fatigue. If every patient gets an orange box, those orange boxes are useless. We set the threshold as a temperature of 100.9 or greater, heart rate greater than 90, or respiratory rate greater than 20. It is not quite SIRS criteria, but we needed to find the right level of signal versus noise so that people did not ignore it and get

alarm fatigue. It will be different for every hospital. That is part of the PDSA cycle, or Plan, Do, Study, Act cycle. It's finding the threshold that meets your clinical environment. Some hospitals actually have a code sepsis. Much like we do code stroke or code STEMI, code MI, or code trauma. We have code sepsis. When a patient has severe sepsis or septic shock, you actually overhead page it and the critical care team snaps into action. You might not have high enough volume to have a process like that, or you might not have the clinical staff resources to do something like that. Again, you want to customize this, so it works in your environment. Doing so involves that multi-disciplinary team, including clinicians and nurses. Now, if you have a screening protocol and an automated alert, the next step is standardized care protocols for patients who screen positive. The idea is that we want to get care started as early as possible. Now, in my shop, that means triage. I have a preference for nurse-initiated screening protocols and standardized care protocols. So, when someone meets sepsis criteria, we can get blood cultures times two started. We can get other basic labs started, including lactate with reflex. We can start a first liter of fluid bolus. Then, we can talk to the clinician about which antibiotics to start based on our suspicion for the source of the infection. By getting these processes started very early in the work-up, we have more leeway with the three hours to correctly assess the patient and start other cares, for example, a second and third liter of fluid if applicable. We can also determine a SOFA score so we know the level of care the patient is going to. Standardized care protocols don't have to be 100 percent either. There is room for clinician judgment in there. For example, if a nurse sees that a patient flagged positive for sepsis but feels it is clearly a panic attack and the heart rate and elevated respiratory rate are due to non-infectious sources, they can have a quick touch base with the advanced practice clinician or with the physician. They can say, "I don't actually think this patient is septic. What do you think? Can we bypass the standardized care protocol?" That is perfectly appropriate. What I love about the standardized care protocols is that not only do they get the care started early but they trigger us have to have conversations when there is a patient doesn't fit perfectly in either box. Now, with your sepsis committee, you have your cases flagged every month. If you are a small

shop, you might be flagging every single case like we did in Wisconsin. If you are larger shop like where I work now, you might take a sampling of cases. In either event, you will identify misses. What does misses mean? Misses means a patient was truly septic who didn't get all the SEP-1 core measure cares. These are so precious because what they do is identify blind spots in your care processes. They give you opportunities to do a QI intervention, like a Plan, Do, Study, Act cycle or a project that is significant to improve sepsis care in your hospital. Finally, you've got your monthly committee, you have your screening protocols, you are identifying your misses, you are doing a QI project every month, maybe every quarter, maybe every six months to improve sepsis care. It is now time to keep the conversation going. One of the best parts of the SEP-1 core measure is that it makes sepsis front and center. Trauma has always been front and center. STEMI has always been front and center, but sepsis has not always been front and center. It is one of the deadliest things we treat. In the olden days, someone might be parked in the back corner of your ED for four, five, or six hours before the urinalysis comes back. You realize they have a bad urinary tract infection, recheck the blood pressure, and lo and behold it is 80 over 40. We have changed the paradigm. We have taught our clinicians and the frontline staff to snap into critical care mode and we do it by talking about sepsis every month, month after month, and keeping the conversation going.

Now, on your sepsis committee you'll have a dashboard. This is an example of our dashboard from 2016 to 2019. That era when SEP-1 was getting going. We were all going through this experiment together. You see the bars go up and down, up and down, but a steady trend towards improvement. What we found during this process was that we were walking our way down the measure. If you look at the boxes up top, we would have monthly audits, as I'm sure many of you are doing, to see not only how we are doing on SEP-1 overall but how we are doing on each element of SEP-1. Early on in the experiment, we were failing at the very beginning. We were not screening patients appropriately, meaning patients were coming into our emergency department with sepsis and we were recognizing that late on in their visit. After we got our screening protocol

down, it was blood cultures. Did we have the right equipment? Were we ordering antibiotics? Where did the bottle go? Is the nurse going to do it? Is the phlebotomist going to do it? We mastered that. Then, we moved onto lactate. Initial lactate was easy. We put that in an order set, but repeat lactate proved challenging, as I'm sure many of you have had that experience. If you look at the time stamp on this graph, we were dealing with fluids. We walked our way down to the measure and we scored 38 percent that month on SEP-1 because we scored 38 percent on the 30 mL/kg crystalloid bolus. Looking at the measure in this way, it lets you home in on individual aspects that can be improved upon so you can do a deep dive with frontline clinicians and say, "What is the rub? Is it difficult ordering? Is it difficult getting supplies? Is it too easy to forget? Is it a problem with the clinical hand off or communication?" By getting into the weeds on those issues you can have an effective sepsis committee and come up with quality improvement projects that are really meaningful to frontline staff.

Now, I did a little bit of this already, but this is a journey. I kept a journal, or our committee kept a journal, of what we tried and what worked and did not work. So, we could come to the board and share a little bit about our experiences. We started looking at quarterly data and found that quarterly data just wasn't frequent enough. We wanted a better handle of how we were treating sepsis on a month-by-month basis. January and February, for example, are flu season. There are a lot of challenges that come in getting sepsis care right during flu season. Think about a respiratory pandemic like we are facing now with COVID-19. Looking at monthly data is more powerful than quarterly data, at least early on when you are getting your processes down. Then, we initiated the triage RN screening protocol. That went well. I was anticipating that people had issues with this. People love progress, but people fear change, and this was a big change. Yet, our RNs did so much screening for other diseases, they said, "You know what, let's just add this to the mix." They took it in stride and really adapted quite well. Our first take at a an order for blood cultures before antibiotics did not work very well. The order was clunky. It was hard to find. You had to go to a separate screen. We found that our frontline emergency physician were just

really not into it. It was only when we created a full sepsis order set that we got that part of it down. The reason they use the order set is because it is so easy to use. It saved them multiple clicks in the EHR. It was all right there. It was a well-designed order set by myself as an emergency physician that I said what am I going to really use? So, investing that time in a QI project, working with IT, and getting a really slick order set was worth its weight in gold. Now, with repeat lactate, we were actually quick getting patients up to the floor in the ICU. We didn't have time to do that repeat lactate in the ED a lot of times. Lactate was based on a hand off. We had meetings and didactics about a proper hand off. We had a hand off tool, it just wasn't working. Only when we created a reflex two-hour lactate, if the initial lactate was greater than 2 did we start to see success there. Initially our IT team didn't know if that could be created. They had to go to some of their colleagues in other hospitals, go back to the vendor and find a way to make that possible. When we found a way to make that possible, it was a game changer for repeat lactate. Now, in my previous hospital, an RN initiated sepsis order set was actually a failure. So, our nurses really didn't feel like that met their scope of practice. They felt a little bit unsure about starting antibiotics or fluids. We had to essentially compromise on an order set that only included lab and diagnostic orders. The world has changed since then and I am part of a larger system. We have had a lot more experience with sepsis. In my system we have an RN-initiated protocol that includes fluids, for example. That has really been a game changer, especially during our ED crowding crisis that we are seeing post-COVID. So, it is harder for physicians and providers to see patients in triage, and our RN-initiated protocol is getting a lot of mileage. So, we are really appreciating that workflow during the time of crowding. Finally, we did suggested antibiotic resource and order set for antibiotics. That sounds so intuitive, but it took a lot of work working with our IT colleagues and coming up with a plan for antibiotics that struck that correct balance between antimicrobial stewardship and effective antibiotics. Once we had those in place, we posted an ED scoreboard in a central location where it could be seen by patients and staff alike, so we could talk about how we were doing on sepsis. If we had a bad month, we could reflect on why we were having a bad month. That was paired with a suggestion box. We got some excellent suggestions

not just from nurses, doctors, and APCs, but from laboratory staff, from essential radiology services, even from custodial staff, talking about how to treat sepsis better. We learned that there were transportation barriers to getting patients to the ICUs and lab samples being hemolyzed because of XYZ. I'm sure you know these same examples in your hospitals, but you got to get local and you have got to get suggestions from the frontline staff to get a bird's eye view and a ground-level view of what's going on. Perhaps the most sophisticated thing is to leverage the EHR. We have created best practice pop-up alerts if IV antibiotics are ordered without blood cultures. You want to avoid that alarm fatigue. You don't want to overleverage this, but if you find there is one thing that you are really not hacking, that you have done all the best practices and you can't get there, maybe a BPA is the right answer.

When you achieve success, you want to celebrate that success. It is interesting because a lot of SEP-1 is a process measure. For frontline clinicians, process measures are good but outcome measures are gold. The ultimate outcome is mortality. So, between 2010 when this journey started and 2018, we saw a 32 percent statewide decrease in sepsis mortality across the state of Wisconsin. Now, was this due to the SEP-1 core measure? I don't think so. I think a lot was due to SEP-1 core measure, but a lot of sepsis care was being recognized and talked about on a regular basis. So, if you are a medical director with your group and you have someone who does not fully believe in the measure or believes there are other ways to treat, that is the point to emphasize. We are saving lives and decreasing mortality if by no other way talking about sepsis and keeping the conversation front and center. It is a very deadly disease. Any patient who is septic is one of the sickest patients in my emergency department and they deserve the time and attention we pay to patients with trauma, with STEMI, with stroke, etc.

So, this is one of my favorite parts of the presentation. I want to thank CMS for providing this platform. As an ED medical director, sometimes it is not totally clear what your role is, where your role begins or stops. Yet, somebody probably put sepsis on your plate. So, if you are going to do

something, you want to do it right. I would like to use this platform to share with you my experience as an ED medical director and best practices that I've learned to improve sepsis care in my organization.

So, one of the first things we do as the ED medical director is educate on SEP-1. If you want to be a good educator, you have to educate yourself first. So, I'm sure to reserve time every month to review the literature and read at least one or two articles on sepsis, to attend a webinar like this one, to attend a journal club, to find a resource out there. There are plenty of resources on sepsis and the SEP-1 core measure. With that background, you can actively participate or even share your sepsis committee or your quality improvement team. If you don't step up, someone else might, and that someone might not be an expert on sepsis like you are. As ED medical directors, we see this all day every day. This is our bread and butter. I really think it is our time to lead in a pathology we know enough about and are experts in that we should be leading. Now, you would be doing your team a disservice if they don't know their monthly metric. This is something that we have to keep track of. Now, the team might be annoyed initially, especially if you are performing, uhm, poorly on the SEP-1 measure, but it is important to show those metrics and to trigger that natural sense of not just camaraderie but competition. How can we do better? Where are we going from here? You will get a lot of feedback. You get the best feedback if you ask for it. I like to use a SWOT analysis. What are our strengths and weaknesses? What are our opportunities? What are our threats in sepsis care? You will get an earful, especially on weaknesses. People want to tell you about the things that are not working well. They may critical of the SEP-1 core measure directly, but that is gold. Even the people who are the biggest naysayers are the ones who often have the best perspective on what can be better. You just have to find a way to turn that energy into something more constructive. One way to turn that energy into something more constructive is to hold events like journal clubs, seminars, awareness campaigns, where people get involved and get into sepsis care. It is easy to gripe about a core measure. It is easy to gripe about a pop-up or order set, but when you get involved you see real solutions and that is one of my tips of success with my crew. Having

journal clubs. Having everyone give their input and listening to the frontline providers. That is where the best suggestions come from.

I said it earlier and I'll say it again. Everyone loves progress but change is hard. So, one of the things that you can do as an ED medical director is be that change catalyst. That often means going first. So, first, to really effect change, you want to have a relationship within the hospital. Sometimes in the ED department you feel like you are an island, especially if you are part of a private group and you cannot get involved in other hospital operations. If you want to treat sepsis effectively, you need to build those bridges. I'm talking about floor nurse supervisors, ICU nurse supervisors, administrative colleagues, hospitalists, intensivists. You want to reach out to multiple role groups to talk about sepsis and understand what works well in their departments and what doesn't work as well. This is not all about the emergency department, of course. Second, if you are in a leadership role with sepsis, there will be policies and there will be protocols. Those have to be reviewed by a frontline clinician. really meticulously reviewed. Missing something key in a policy or protocol could lead to ripple affects you don't want to see. That is one of the things I take most seriously. It is kind of dull work. It is not always the most intellectually challenging. Go through word-for-word and make sure that the recommendations made or the policies written actually reflect the frontline work experience. Next, you want to be available for special tasks. The quality improvement committee might be trying a new order set. They say, "Dr. Redwood, we have this new order set. We want to try it out, what do you think?" You say, "Well, I'm on shift on Wednesday from 6 to 2. Why don't you let me try out?" Try out the order set. Make notes. Do these extra little things in the clinical realm where someone might not know how to ask a clinician to do that. So, if you have quality improvement professionals working on the new BPA, you can say I'll try out that BPA. Raising your hand to go first is worth its weight in gold because people might not ask you to go first otherwise. You want to be available and to be a team player in that respect. In addition to that, you want to provide feedback. So often we try out a new process, but we don't get the feedback back to the people who are making it. I think that

happens a lot with the IT department. We are trying to leverage the EHR to be most effective for sepsis care, but do they know what is happening? Some EHRs collect that feedback real-time and you can give that feedback to the IT specialist in the EHR. If that is not the case, you want to keep a board in your ED where other frontline clinicians can write down that information. Be sure to attend the right meeting and make sure the right people have eyeballs on the feedback because we can't complain about things that don't work in the EHR without giving feedback to the team that designed them. Finally, consider tracking or incentivizing quality sepsis care within your ED physician group. As an administrator, you have administrative tools. In my shop, for example, we use the Ongoing Professional Practice Evaluation as a tool. We measure how well we each do in sepsis and include that in the physician scorecard or OP file. We incentivize our physicians for SEP-1 performance. Interestingly, we like to do it as a group. We either succeed or fail as a group. Again, I think that spurs that healthy competition where we are all rising together. Then, obviously, you want to recognize and award top performers. That might be a shout out at your departmental meeting. That might be a little Snickers bar with a great job on sepsis post-it note on it. That might be a personal phone call or text. You did really good work here. The more we can recognize our frontline staff the better. We all know that clinical medicine can be a thankless job and when someone hits it out of the park with sepsis you want to recognize that. All right.

It is time to summarize. We talked about the 1991 consensus definition of sepsis. It works really well in the ED. It is a basis of the SEP-1 core measure. Use it. Embrace it. Love it. Know that you will eventually be transitioning at some point in the hospital core towards sepsis-3, the 2016 Consensus definition that is typically used in the ICU, but we can probably bridge that late in the ED workup once we have the appropriate labs back. Q-SOFA score, as Bob eloquently pointed out, as well, lacks sensitivity compared with SIRS as a screening tool. So, in the ED we do recommend sticking with SIRS criteria. Just know that as a clinician we are going to straddle both definitions. Science is always evolving, and part of being an implementation scientist is getting those best practices to the

bedside immediately even if everything is not sorted out. Currently, we are living between two worlds. Ten years from now, I'm sure we'll be having a different conversation, but feel comfortable in the two worlds and use the definition that works for the right clinical environment. In terms of bringing best practices to the bedside, form a strong team, connect with your team, get organized, measure performance, find those quality improvement opportunities, do your PDSA cycle, celebrate success when you have success, and most importantly in the later stages, respond appropriately to slips. You know, we talked earlier about how you want to measure the data monthly. Maybe you hacked it already, maybe you are so good on sepsis that you are performing consistently high, you know, month after month. At that point it might be appropriate to go to quarterly measurement again, but when you have a bad quarter, you need to go month to month again and find out what happened, where was the slip and how you can address it. Finally, the role of the ED medical director. If you are an ED medical director, it is important you have a passion for sepsis care. Now, I think you can actually build a passion for sepsis care. It starts with the literature review. It starts with a plan to stay up on the literature. It can be going to conferences or going to webinars like this, but the more you get into this disease the more fascinating it becomes. I hope that you really enjoy it and enjoy talking about the pathophysiology with your hospitalists, intensivists, with your ED colleagues. If you don't, if you tried to cultivate that passion and it is not there, pass the project onto someone who does. There has to be one member of your ED team that is passionate about sepsis. Maybe that is your role as a leader, to find that physician champion and give them the resources they need to do the quality improvement work. Whatever the case may be in your department, you have to find somebody with a passion for sepsis care who really wants to move the needle because if this is a burden, or if this is an administrative check box that you have to do, you are not going to get very far. You have to really enjoy the pathophysiology about and see the value in those early antibiotics and early fluids so you can save lives. Then regardless if it is your passion project or you pass onto a clinician champion, use your position of influence and your administrative tools to reward those high performers and coach low performers. This is where it

gets so individual, hyper individual, in fact. You don't want your sepsis improvement recommendations coming from an anonymous level from the quality improvement team. You want them coming from the medical director. These powerful interactions are important. It might be a heads-up at the end of a shift. It might be something mentioned in a performance review or a collegial text or you might take someone out to dinner. You know the members of your staff. You know what people respond well to. If someone is performing high on sepsis, you want to be sure they are celebrated and recognized. If somebody has room for improvement, you want to really get down into the details and ask them, "Why did you make this decision? How did you come to this decision? Do you think that was effective?" Get deep down into the weeds. You'll have really interesting conversations. You may get some suggestions for quality improvement projects from that clinician.

All right. With that I'm going to pass it back to Candace who will introduce the question-and-answer session of this presentation.

Candace Jackson: Thank you, Dr. Redwood. Thank you, Dr. Bob, both of you, for providing such wonderful information for today. Again, yes, we will go into a quick live Q&A session as time allows. The questions will not be in any particular order. If your questions did not get answered today, we'll go to the next slide, please. If the question was directed to Dr. Redwood, please e-mail him at the address on this slide. If the question you have is related to the SEP-1 measure or specification, then those can go to the question-and-answer tool. So, we'll go ahead and get started with our first question. Our first question is, "Are blood products considered colloids?"

Bob Dickerson: Hi, Candace. This is Bob. Yes, that is a great question. For purposes of the measure and Dr. Redwood could probably speak to this from a clinical perspective, blood products are considered colloids and would be abstracted as such.

Dr. Redwood: Nothing to add, Bob, I agree.

Candace Jackson Thank you. Our next question is in relation to slide 22. Can we go to slide 22, please? The question is, "Why isn't lactate at 5.0 considered organ dysfunction?

Dr. Redwood: That is such a great question. The threshold of 2.0 is a contentious threshold. So, the early medical literature is really based. I see. They are asking if a lactate of 5.0 is considered organ dysfunction for SOFA.

Candace Jackson: Okay. Thank you. Go ahead, Dr. Redwood. Excuse me.

Dr. Redwood: I thought it was a different question. I didn't fully answer it. I don't believe that the lactate is included in the Q-SOFA score. While the Q-SOFA score screens for organ dysfunction, it does not include the lactate. That is the reason why.

Candace Jackson Thank you, Dr. Redwood. Our next question I believe is for Dr. Redwood. How have you reminded or educated providers on the proper exclusion documentation for patients that do not receive the 30 milligrams per kilograms of fluid? For example, your congestive heart failure patients.

Dr. Redwood That is a great question. That is a hot topic right now. That exclusion just came out in the last few months. I had actually a meeting about it earlier today. I'm of a mixed feeling about that. I actually think that the exclusion is important, but it is a pretty rare exclusion. Much more often, we are under resuscitating people. We did create something in our EHR and educated our frontline clinicians. I'm actually concerned that we might try to use it as a Get Out of Jail Free card, so to speak, and end up under resuscitating people. The threshold to exclude people is pretty high, and it includes New York Heart Association Class 4 heart failure. When I see heart failure on a chart, it is actually well-managed heart failure. I see a lot of patients with heart failure or CHF listed on their charts, but their EF is 55 percent or 65 percent and well managed. Those patients should get the 30 mL crystalloid bolus. I understand why that exclusion was created and I'm a bit reticent about to be honest. We'll see how it shakes out. It is a pretty new innovation.

Candace Jackson: Thank you, Dr. Redwood. Going in a different direction here. Would you encourage a hospital to exclusively use the SEP-3 definition at this time?

Dr. Redwood: I would not, definitively not. I understand why a health system would move in that direction because the evidence of moving in that direction, and certainly the global sepsis committees are moving in that direction, as well. Yet, it really doesn't apply to the emergency department setting, especially early on in the work-up. We just do not have the lab values needed to calculate a SOFA score which is the basis of the sepsis-3 definition. I think we have to live in the two worlds for the time being.

Candace Jackson: Thank you, Dr. Redwood. To further go on with that question, we keep hearing about the SEP-3 definition. Does CMS have any thoughts on-going with this definition in the future?

Bob Dickerson: Yeah. Hi. This is Bob.

Dr. Redwood: I have a lot of respect for the process that CMS uses. They do not engage in knee-jerk reactions. They really wait for a consensus in the literature or close to a consensus. Some of these things take years to sort out. With quality improvement, if you are moving the needle or moving the goal post of your data all the time, it makes the impact of the data less impactful. So, science can be very nimble and the implementation side should also be nimble but not as much. I like the approach of waiting until you have significant amount of articles out, when you have some consensus statements, and world experts weighed in and have those debates, and then change the definition at that point.

Bob Dickerson: I would agree very much with what Dr. Redwood just said. This is Bob. In addition, we need to think about what we presented in the webinar portion about what the purpose of a screening criteria is for the measure. That purpose is, as Dr. Redwood and I identified, to kind of cast that wide net. Identify patients early. We know the literature comparing the two tools is demonstrating that the criteria used in SEP-1 is better at identifying potential cases earlier and then the way that the measure works does cast your initial population.

Then you use the severe sepsis presentation criteria in there to kind of wean the patients out, to filter out; whereas, what we have seen with the SEP-3 definition, you are catching high-risk patients later in the course of their disease, which the focus of the measure is early identification and early treatment.

Candace Jackson: Thank you, Bob. Thank you, Dr. Redwood. Going to our next question. This is on slide 18. There we go. Dr. Redwood stated that we know that a sepsis diagnosis depends on blood cultures and they come days later. Can you explain that further?

Dr. Redwood: Sure. Sepsis is typically a bacterial infection. There is fungal sepsis, there is viral sepsis. So, you can have negative blood culture sepsis, that is possible. Yet, the majority of sepsis is bacterial. That is the gold standard is when you smear the blood on the little plate, you let it grow for three days, you see what organism grows, and then you do susceptibility with multiple antibiotics. So, a lot of times in the ED we don't have a clear picture of, you know, we know that a patient has systemic inflammatory response syndrome, but is it really sepsis? It is often quite mixed. So, we draw those blood cultures and sometimes we find out that answer days later. On a sepsis committee, you have a lot of hindsight bias or look-back bias where you have the complete picture because you are looking back on data from a week ago and you are seeing that clearly the patient grew E. coli in the blood. This source of infection was the urine. This urinalysis should have been acted upon, but you always have to put yourself in the real-time shoes of that emergency clinician treating that patient. They might have only been in the ED for a few minutes, and they are making critical decisions with limited information. That is the art of delivering messages to emergency physicians, as well, and part of the key role of the medical director on the committee is to remind the committee, "Hey, the information we are looking at now is based on days and maybe even weeks of care where we have a lot more data than we have in those initial hours." The gold standard for bacterial sepsis is blood cultures.

Candace Jackson: Thank you, Dr. Redwood. Going in a little different direction, and related to the COVID exclusion, in the specifications manual there is abstraction

guidance that says to select Value 2 if there is physician/APA/PA documentation that coronavirus or COVID-19 is suspected or present. Does this mean that the patient does not have to be coded as confirmed COVID to be excluded from the population? So, for instance, on an admission, a patient is tested for suspected COVID versus just an admissions screening. Is this patient excluded from the population assuming they otherwise met the sepsis criteria?

Bob Dickerson: Thanks, Candace. This is Bob. That is another great question. Originally, when COVID reared its ugly head earlier in 2020, we put in the abstraction guidance to help abstractors with being able to remove those patients because they COVID is a viral infection, and many times these patients appear septic, may not be initially, and may later develop bacterial sepsis. The initial treatment was not necessarily consistent with what SEP-1 would recommend, included for bacterial sepsis. We then later added the code, and the purpose of the code is to be able to remove those patients from your initial patient population. So, you don't even need to abstract them. Recognize that there may be some cases for whatever reason are not coded, but there is still clear documentation in the medical record from a clinician that they suspect or have confirmed that COVID is present. If that code for whatever reason was not assigned, they wouldn't be stricken from the initial population, you could have one in your group of patients to extract. We want to make sure there is a fallback for the extractor to be able to exclude those cases. So, I guess the short answer is if the COVID code is there, they are stripped out from the initial population initially. If that COVID code is not present for whatever reason, and there is documentation that they have confirmed COVID or suspected you, can exclude them through selecting Value 2.

Candace Jackson: Thank you, Bob. We'll go back to Dr. Redwood for a few questions. The first one is on slide 44. Go to slide 44, please. On this slide you mentioned you have a pop-up for blood cultures before antibiotics. This hospital is contemplating this action, but they are concerned about the noise. So, did you make the pop-up somewhat specific, or did you have it fire with any IV antibiotic order? What challenges or downsides did you experience?

Dr. Redwood: That is a great and nuanced question. Committee work is often the art of compromise. I did have a preference for this to be unique to sepsis. I was overruled, and we have a pop-up for any IV antibiotic. There is some noise there. It is not proved debilitating to our work, but it does generate more blood cultures, and there is literature to show that excess blood cultures waste healthcare dollars and they have false positive and have some harms to them. So, that is really it. You need to get into the numbers and see how many false positives you are generating and then run an analysis to see if that is worth it. We have a pretty active infectious disease team. They are on top of blood culture follow-ups and I think we are walking that line well, but there are risks and benefits to any decision and that is the exact risk, you send too many blood cultures. The other risk, of course, and I think you are alluding to this, is alarm fatigue. There are pop-ups everywhere and it is hard to get through a patient encounter without a lot of pop-ups. If there are too many, the emergency clinician will just power through them and will just not read them. I certainly have members of my team that are part of that camp. Again, that is a line we walk. When we have our electronic health record meeting, I often ask the question what BPAs have we retired lately? I think we are always adding BPAs and never retiring BPAs and you are not doing proper maintenance of your EHR. There are times when we get the workflow down that we don't need the BPA anymore. So, it is kind of a tug of war with quality improvements and then unintended consequences and there is no one size fits all for that. We do have it for all IV antibiotics, and it is working well but closely monitored by infectious disease.

Candace Jackson: Thank you, Dr. Redwood. Dr. Redwood, does Cooley Dickinson Hospital have a substance coordinator?

Dr. Redwood: We do. Let me put it this way. We have a sepsis committee with a quality improvement professional dedicated to sepsis. Staff on that committee is myself, an ICU physician, an ICU PA, a floor physician, and that is it. We kind of call in our specialists when we need to, for example, infectious disease. We are part of a larger health system that certainly has a sepsis coordinator. I would say homegrown we do not. That is something that we

could actually invest in. If we wanted to do more public awareness events, or if we wanted to have celebrations of teams on the unit, that is something that the coordinator could help with. I think everyone is experiencing this post-COVID budget crisis where you have to make difficult financial decisions, whether it is worth investing in or not. We have a system that is hardwired, and we are good at disseminating information, and we have not invested at the local level, but we are part of the largest system and could tap into their resources as needed. I think we have the best of both worlds. I understand that there are Critical Access Hospitals and rural hospitals that don't have the same types of resources and sometimes it is just you, the medical director or quality improvement professional. That does make the job more creative. How are you going to spend your time and what are you going to set as your priorities?

Candace Jackson: Okay. Thank you, Dr. Redwood. Dr. Redwood, what kind of program did you use for your monthly dashboard?

Dr. Redwood: Well, we have a program called Status. I no financial relationship with any of these. No disclosures. What I like about it is that you pull up real-time data. You can pull it up in a meeting. You can tweak the parameters and show people real-time. Then you can mark when you did certain quality improvement interventions. So, it is proven pretty slick in this era of Zoom, specifically. I have to admit I keep internal stats for myself and my ED team on the simple spreadsheet because I feel like sometimes you show too many graphs and people's eyes glaze over. So, for your quality improvement professionals and sepsis committee we are using Status because we want that level of detail and we want to mess with the numbers, but when I'm presenting to a broader audience, I keep it simple and do a single bar graph or single line graph with quarterly and monthly data.

Candace Jackson: Okay. Thank you. One more question for you, Dr. Redwood. What does your triage screening look like?

Dr. Redwood: It is pretty basic. It is SIRS criteria, then plus or minus the source of infection. There is a basic order set that includes the metrics of the SEP-1 core, the blood cultures, lactate times two, the fluid bolus. That is nurse

initiated and then antibiotics. For antibiotics we do ask that the triage nurse consult the physician for a quick discussion about source of infection.

Candace Jackson: Thank you. We have time for maybe one or two more questions here. Is the guideline still 3-hour bundle and 6-hour bundle, or is there a shift to 1-hour bundle from the 3-hour bundle? If so, please provide evidence that the 1-hour bundle has better outcomes.

Bob Dickerson: This is Bob. For the purposes of the measure, it is not changing at this point or in the foreseeable future from the 3-hour bundle and 6-hour bundle. I think Dr. Redwood can perhaps speak to this a little bit. I'm not sure that the literature is really clear or kind of set on that a 1-hour bundle is better. Clearly the earlier you can start the antibiotic, the better for the patient. There is some literature supporting that. Then, for purposes of the measure, we want to be careful that you don't get that window so narrow, that it is virtually impossible for people to meet it because there is a lot of processes that happen in getting an antibiotic started.

Dr. Redwood: Bob, I totally agree. We are really trying to move the science forward. It is a great clinical question. Is one hour better than three? I know for the Wisconsin Hospital Association, it is not ready for prime time, but we want to learn more. For so many other disease processes, we see that the science has really evolved. Door to needle time for STEMI or stroke gets shorter. Systems of care between inner hospitals and tertiary care centers keeps getting smoother. I see a time in the future where a one-hour bundle is a reality but not now.

Candace Jackson: Great. Thank you, again, Dr. Redwood and Bob. That concludes our Q&A session for today and our presentation. I would just like to thank Dr. Redwood and Bob for providing the information to us today. Can I have the next slide, please?

The CEU information is on slide and you can obtain your CEUs by clicking on the slide in the link in the slide and complete the survey. Again, we would like to thank you for joining us today. Have a great rest of your day. Thank you.