Inpatient Quality Reporting Program

Support Contractor

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

Presentation Transcript

Moderator:
Candace Jackson, RN
Inpatient Quality Reporting (IQR) Program Lead, Hospital Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Contractor (SC)

Speaker(s):
Sean Robert Townsend, MD
Vice President of Quality and Safety at California Pacific Medical Center

Lemeneh Tefera, MD, MSc
Medical Officer at Centers for Medicare & Medicaid Services (CMS)

September 10, 2015
2 p.m. ET

Matt McDonough: Good afternoon everybody and thank you for joining us for today's webinar. My name Matt McDonough and I'm going to be your virtual training host for today's event. And, before we start today's event, I'd like to cover some brief housekeeping items with you so that you understand how today's event is going to work, and how you can interact with our panelist on today's event.

As you can see on our screen, we are streaming audio over the Internet. If you hear my voice, then you know that. It means there are no telephone lines required, but you are required to have computer speakers or headphones to hear the streaming audio feed.

Now, if at some point today, you have difficulty with that streaming audio feed, we do have a limited number of dial-in lines available. Please send in

a chat message if you need one of those and we'll get that out to you. Also, today's event is being recorded.

Now, during today's event, you may encounter some common difficulties with streaming audio, so we do have a couple of slides here to help you with that. If your audio starts breaking up or suddenly stops, you can correct that. Simply click the Pause button that's located in the upper left part of your screen, wait five seconds, and then click the Play button. Your audio stream should resume and you should hear the audio again synched up with the slides as previous.

Now, if you hear an echo on the call right now, if you hear a very bad echo on my voice, that usually means you're connected to our event today in two separate browsers or tabs. So, simply close one of those browsers or tabs and the echo will clear up. And you can see what that might look like on your screen now. Close all of them, just keep one of those tabs open, and you should only hear one audio feed.

Now, our attendees are in a listen-only mode in today's event. It doesn't mean that you can't submit your questions to our panelist. The left side of your screen has a Chat with Presenter box. Simply type your question in that box and click the Send button. Once you do that, your question will be seen by all of our panelists and, as time and resources allow today, we'll answer as many questions as we can.

That is going to do it for my brief introduction. So, without further ado, I'd like to hand it over to our first speaker of the day.

Candace Jackson: Thank you, Matt. Hello and welcome to the IQR webinar *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'd like to make a few announcements.

This program is being recorded. A transcript of the presentation along with the Q&As will be posted to our inpatient website, http://www.qualityreportingcenter.com within ten days and will be posted to *QualityNet* at a later date. If you registered for this event, a reminder

email, as well as the slides, were sent out to your email a while ago. If you did not receive the email, you can download the slides at our inpatient website, again, at http://www.qualityreportingcenter.com.

And now, I would like to introduce the speakers for today's event. Dr. Townsend is the vice president of Quality and Safety at the California Pacific Medical center in San Francisco, California, where he manages the Department of Quality and Safety, Accreditation, Infection Control, Clinical Documentation, Integrity, Quality Informatics, AIDS Case Management, and Matrix Oversight of Risk Management. He is also a certified Quality Delivery System leader. Dr. Townsend designed, implemented, and sustained the Patient Safety Alert System to manage sentinel events, as well as numerous other projects, processes, and systems for the medical center. Dr. Townsend's other titles include Critical Care Physician at the San Francisco Critical Care Medical Group and Assistant Clinical Professor of Medicine at the University of California, San Francisco.

Dr. Tefera serves as a the medical officer, and policy adviser for the Centers for Medicare & Medicaid Services' Hospital Value-Based Purchasing Program. The aim of this program is to link the Medicare payment system to the quality of care provided, not simply the quantity of care. This key mission is to transfer Medicare from its historical role as paying the bill to a new paradigm where Medicare promotes better care and population health by linking payment to the measures of quality of care provided by our hospitals. Dr. Tefera also serves as an attending physician in the Department of Emergency Medicine at United Medical Center in Washington D.C., as well as adjunct associate professor in the Department of Emergency Medicine at the George Washington University School of Medicine. Next slide, please.

Before I turn the presentation over to Dr. Townsend, the purpose of today's webinar is to provide physicians, medical directors, clinicians, nurses, clinical documentation teams, and pharmacists with insights that will help them to better understand the *Early Management Bundle, Severe Sepsis/Septic Shock* measure. Next slide, please.

At the end of today's presentation, participants will be able to describe the basis, rationale, and content of the *Early Management Bundle, Severe Sepsis/Septic Shock* measure and recognize the updates that have been made to the measure since its introduction. Next slide, please.

This slide has some of the acronyms that will be used in today's webinar. And next slide, please.

I would now like to turn the presentation over to Dr. Townsend. Dr. Townsend, the floor is yours.

Sean Townsend: Thank you, Candace. I appreciate the opportunity to address everybody today on SEP-1, the nation's first core measure for sepsis, and I'd like to give you some perspective on both the science, the clinical science, the measurement, and how this measure will improve care for our patients across the country.

I'd like to begin by talking a little bit about the importance of the disease state. And it's important to note that in most healthcare systems, sepsis is the number one cause of inpatient deaths in the hospital. And, this data that you're now seeing here are specific to one healthcare system, but they represent data from many healthcare systems. This system shows that for 2014, the number of discharges of patients that came to the hospital had a presenting diagnosis of sepsis in 11 percent of cases. And, this could be simple sepsis, severe sepsis, or septic shock. However, if you examine deaths in 2014, 48 percent of the patients had some diagnosis of sepsis, either simple, severe, or septic shock associated with the deaths in this healthcare system. This system represents a facility with more than 20 hospitals in total, and these data are easily replicated across the country. And, it's not unusual to imagine that patients would die in the hospital with sepsis as the fact that sepsis is often the final pathway for many patients when they do die in the hospital. However, the number 48 percent should be strikingly large and call our attention to the fact this is the number one case of deaths within hospitals across the country.

To address this, we've had several types of efforts across the country over the years. And much of the work began in the form of bundled care, which were initially promoted by the Institute for Healthcare Improvement to improve the care of patients across the country by lumping together certain care patterns that were effective in lowering mortality. The bundles were eventually turned into measures and the measures were approved through the National Quality Forum. And ultimately, the measures were taken up for consideration as part of the Core Measure Project and part of the Inpatient Quality Reporting data set.

I'm going to start by looking at this slide here and telling you all about the old NQF measure, and this is old on purpose. This has been updated, and I'll explain the update to you in just a moment. But, when the measure was at the National Quality Forum, NQF, it was known as Sepsis 0500. And, the care pattern that is on this slide is a pattern of care to be completed in the first three hours of the patient's presentation. And, you can see what those elements of care were. The first was to measure lactate. The second was to obtain blood cultures prior to antibiotic administration. The third was to administer broad-spectrum antibiotics to patients. And then fourth, patients received 30 mls per kilogram of crystalloid, if they're hypotensive or if their initial lactate returned greater than four. So, all those four typically apply to patients that we define as having shock, that is hypotensive or lactate greater than four. Now, please note at the bottom of this slide that the time of presentation was defined previously as a time of triage in the emergency department for patients who presented via the emergency department. And, if they didn't come in through the emergency department, the time of presentation had been defined as the time that the chart annotation lined up consistent with all the elements of severe sepsis or septic shock. So, the patient would require both a suspected infection, two SIRS criteria, and organ dysfunction, all lined up correctly in order to define the time of presentation. Now, this will change under the new regimen and I want to explain that to you in just a moment on a subsequent slide.

Also, in the old NQF bundle 0500, there were six-hour elements of care. And the six-hour elements of care refer to patients who were essentially in shock. And these had three components, as well. The first was to apply vasopressors, and that applied to patients that were hypotensive and didn't respond to the initial fluid resuscitation to keep their mean arterial pressure greater than 65. And then, if there was persistent arterial hypotension, despite getting that 30 ml per kilogram of fluid, the patients were asked to have a central line placed, central venous pressure checked, and checking the central venous oxygen saturation. And finally, under the old measure, patients had their lactate checked. I mentioned that these were old because these requirements have changed and I'll explain some of the science that went through in the last couple of years that changed these requirements at NQF and are now part of SEP-1, the nation's first core measure for sepsis care.

And so, let's start with explaining how it could be that we initially had included for six-hour elements of care, both central venous pressure and ScvO2. This came to be as a result of many trials, not just a single trial. There were several studies done that looked at what we call quantitative resuscitation. This means resuscitating patients to a particular target as opposed simply doing an empiric resuscitation. And so, in this slide here, you're looking at several studies that were done between the '90s and the middle 2000s, which demonstrated a benefit to early care to patients with severe sepsis and septic shock, if they receive resuscitation to certain parameters. And the early trials, or trials before organ failures that then are listed in the top of this slide, and they're listed as Lin, Rivers, Alia, Yu, Yu, and Tuchschmidt. And, you can see that in those slides, in this particular meta-analysis, by virtue of the fact that these treatments effect what's to the left of the line, in each case, it indicates that these patients received benefit from early targeted therapy to improve their hemodynamics during the course of resuscitation. In the bottom, you have some late trials listed, meaning that they resuscitated after the onset of organ failure. And you can see that the benefit was less pronounced with many trials showing some lack of benefit, only one showing a clear benefit. But if you combine them together, they were pooled to show that

an overall treatment effect suggesting a quantitative resuscitation, that is, resuscitating to certain targets, was beneficial in this handful of studies.

The Surviving Sepsis campaign, at that time, took this evidence and endorsed it to suggest that early goal-directed therapy, that is therapy directed at targets, were appropriate strategies to take care of patients with severe sepsis and septic shock. In particular, the Rivers trial in 2001 was the most prominent of these studies and provided the best evidence, and provided us the term early goal-directed therapy, which included amongst many other options, optimizing central venous pressure, and optimizing central venous oxygen saturation, ScvO2.

To look at that trial just a little more closely, the in-hospital mortality listed on the far left, mortality at 28 days is in the middle, and then 60-day mortality is on the right. And standard therapy is dark blue, whereas early goal-directed therapy, the intervention is listed in light blue. So, in-hospital mortality dropped from 46 percent down to 30 percent when patients received this targeted resuscitation strategy, early goal-directed therapy. And, because of this large treatment effect, the number needed to treat to prevent only one death was between six to eight patients. And the basis of this strong evidence, and the other trials that I listed in the previous slide, the initial sepsis measure included a requirement for patients in septic shock to receive early goal-directed therapy. This has been updated and the science has changed.

And so, it's important that we address new evidence that changed that science, and understand what that means for the care of patients with severe sepsis and septic shock. The new trials that came out were, there were several of them, there were three: ProCESS, which was a study done in the United States at 31 academic medical centers; ARISE, which was a study done in Australia and New Zealand, mainly; and then finally, ProMISe, which was done essentially in the United Kingdom. And, what these trials all studied was using early goal-directed therapy to resuscitate patients to certain targets versus providing usual care where central venous pressure and ScvO2 were not required to be checked. In fact, they were excluded from being assessed in the course of delivering care to these

patients; although, if the patients needed central lines for other reasons, they could have them. It's just that central venous pressure and central venous oxygen saturation were not assessed. The first trial came out in March of 2014, and this was the ProCESS trial, and it was published in the *New England Journal of Medicine*. And, the conclusions from the ProCESS trial, demonstrated there was no difference between usual care, that is care without checking central venous pressure and ScvO2 and optimizing it, versus early goal-directed therapy, which demonstrated, which had the same mortality rate as the usual care arm when adjusted statistically. The second trial was listed here, and this is the ARISE trial, which came from Australia and New Zealand, and it was published subsequently in 2014, I believe in October.

Let's look more closely at what these two trials showed us. Let's take a look at ProCESS more closely. ProCESS looked at three particular arms, and they're listed across the top of this particular chart. The first arm of the trial was protocol-based early goal-directed therapy. The second arm of the trial, patients received a different kind of protocol-based therapy called protocol-based standard care. And the third arm was usual care. This was the arm in which patients were allowed to be treated by physicians, as the physicians chose, with the absence of checking central venous pressure or ScvO2, central venous oxygen saturation. And you can see, just to point at the bottom, that the primary outcome was 60-day mortality, in the row across the bottom. And, mortality in the protocol-based early goal-directed therapy arm was 21 percent. In the usual care arm, mortality was 18.9 percent. When adjusted statistically, there was no difference between these numbers. You couldn't actually call one more effective or less effective than the other. And so, the conclusion essentially was that usual care was just as efficacious as doing early goal-directed therapy for patients.

ARISE showed similar results. Although you may have difficulty reading this particular table, I've highlighted the relevant parts in red here. And I will just point out that the mortality rate at 90 days was 18.6 percent in early goal-directed therapy, and usual care, 18.8 percent. Again,

statistically, not different by any means, suggesting that usual care, without the use of central lines to guide therapy to quantitative targets was equivalent to early goal-directed therapy, which was previously required.

I do want to point out one other additional thing about these trials. And, I'm going to look at all three of them here on the left-hand side in the column, stacking ProCESS, ARISE, and ProMISE above each other. And then, if you could compare in the row the non-fluids, whether or not central lines are placed and whether or not vasopressors were applied, you can see that there was actually some similarity between the outcomes of the trials and the process of the trials. And, in particular, I'd like to note that all the patients in both ProCESS, ARISE, and ProMISE, the large studies on septic shock that were recently completed, all received essentially perfect three-hour bundle care. In other words, before they were enrolled in the trial, lactate had been checked, blood cultures had been obtained before antibiotics, broad-spectrum antibiotics had been delivered, and those were all requirements in order to be common roles in the trials. And, they had received fluid bolus, if they're hypotensive or lactate was greater than four.

So, although the three trials have been in some ways claimed to be the death knell for protocolized care for sepsis cases, that's not exactly true, if you consider that they all received the elements of the three-hour bundle, as part of the protocol, before they were enrolled. Secondly, if we look at the amount of fluids received in patients overall, in comparing ProCESS, ARISE, and ProMISE, we see that they were all very similar but ProCESS received the most fluids. If you look at central line placement, patients did not fail to get central lines in the control arms in usual care. In other words, even though it was not required to check the central venous pressure or to check the central venous oxygen saturation in these trials, patients still receive central lines mainly for administration of vasopressors. And, if you look at the percentage of patients who received central lines for the usual care, in ProCESS, it was 57.9 percent; in ARISE, it was 61.9 percent; in ProMISE, it was 60.9 percent. So, it's clear that many patients still had central lines placed.

Finally, looking at vasopressor utilization overall, in between the arms, you can see in the final column it was 10.8, 8.8, and 6.7 percent respectively.

So, to draw some conclusions from these trials, the Surviving Sepsis campaign and the stewards of the measure at NQF had to conclude that requiring monitoring in central venous pressure and ScvO2 via central venous catheter didn't confer a survival benefit in patients who are fully resuscitated with all the three-hour elements and had received timely antibiotics compared with controls. And thus, we could no longer require, as part of the measure, the measure in the CVP and ScvO2 in all patients with lactate greater than four or who are hypotensive after an initial fluid challenge. And so, the measure had to be updated and changed. And so, those five that I showed you initially about the old measure, I'm now going to show you updates to those so you understand essentially what's different between what was the former paradigm and where we stand today in terms of SEP-1.

So, the three-hour elements of care in SEP-1 are listed here. And so, they include again, the four elements that we said were consistent with the new trials and were part of the criteria for enrollment in those trials, in fact. And, they are also consistent with the prior paradigm of the old NQF bundle. They included measuring lactate levels, obtaining blood cultures prior to administration of antibiotics, administering broad-spectrum antibiotics, and then administering 30 ml per kilogram of crystalloid for patients who are hypotensive or who had a lactate greater than four. Now, I will note, and I think it's important for you to understand, that the time of presentation did change under SEP-1. Rather than calling the time of presentation triage time for patients who arrived at the emergency department, the three-hour elements of care in the emergency department now hinges upon lining up chart annotation just like you would for the medical-surgical floor. So, if a patient has a suspected source and then two SIRS criteria, and then organ dysfunction, the point at which the last of those is met, that's the point where the clock will start in the emergency department for care rather than triage time. And, in effect, this provides

more time for clinicians to make it a proper diagnosis for the care of the patient.

Also, the six-hour elements of care are where changes had to be made primarily. And, this is obvious because the six-hour elements of care, under the old measure, had required both the checking of CVP and ScvO2, which were now based on the new evidence, not able to be required. And so, there's no difference in item one where we apply vasopressors for patients who are hypotensive; but, in item two, if there is persistent hypotension after the initial fluids are given, or if the lactate returned greater than four, the requirement is to reassess volume status and tissue perfusion and document your findings according to Table 1. So, I'll explain Table 1 to you in just a moment. But the call here, rather than for CVP and ScvO2 is some method to reassess volume status and tissue perfusion. And we'll talk about the methods momentarily. And the third element is to recheck the lactate, if the initial lactate was elevated.

So, what's changed in SEP-1 pretty cleanly and pretty clearly, from the first two slides that I showed you in this deck, is now that we no longer call for CVP and ScvO2 outright, but some type of reassessment for volume status and tissue perfusion, and the time that the clock begins for triage for patients in the emergency department is no longer triage. There are other differences and I will address those momentarily, as well.

Table 1 lists the possible ways to reassess volume status and tissue perfusion, and they're listed here. The most basic and simplest way to do so is to repeat focused exam. And, this is essentially calling out that in the trials the patients received a high level of observation. Even in usual care, more than 80 percent of the patients in each of the trials were admitted to intensive care units, and intensive care units typically carry one-to-one nursing or one-to-two at worst, with high levels of monitoring and consistent staff and checks to make sure the patients are improving during the course of their care. Gleaning from that level of observation and the benefit of being in a trial, the conclusion was that a repeat exam by a provider to return to the bedside to assess whether the patient was responding to therapies was an appropriate proxy for that particular

circumstance. So, here, a patient can be reevaluated, if they require the six-hour elements of care, with a repeat focused exam, the elements of which are listed above. Simply, a provider returning to the bedside or, if you're a clinician and you prefer, something more precise or that is more quantifiable, those options are still available. And, two of the following items below are possible. You can continue to do early goal-directed therapy, since it was not proven to be harmful to patients, by checking the CVP and ScvO2 and from performing other optimizations appropriate with the early goal-directed therapy, but those remain options. But, there are yet other options, including using bedside cardiovascular ultrasound, to satisfy yourself that the patients are volume replete and able to effectively perfuse. And, this could be several strategies, which I will address. Or, there is a possibility for a dynamic assessment of fluid responsiveness, and this means essentially giving a fluid challenge either with a passive leg raise or actually a bolus of fluids in assessing cardiac output both before and after that fluid challenge or stroke volume. So, it's a bit intricate, but it can be done and an effective way to assess whether the patient would respond to additional fluids or not. But none of those are required. The basic, simple requirement is that a repeat exam occurs by a provider to ensure that the patient is improving.

So, let's talk about some of the changes between SEP-1 and the measure that was initially passed through the National Quality Forum. In SEP-1 time zero, regardless of whether the patient comes through the emergency departments or is identified in the medical-surgical floor or in the ICU itself, will always be the point in time where the chart annotations suggests all signs and symptoms are present. And, we can glean this information in the chart from a number of sources. In particular, it can come from nursing notes and lab flow sheets, anything with a timestamp, physician documentation, and any way that we can possibly put these numbers together from the information provided in the chart, we can line up the time zero. Time zero could be triage time still, if all the signs and symptoms of severe sepsis or septic shock are presently noted at the point of triage. And, I'll explain how that could happen in just a moment, as well.

In SEP-1, it's also important to remember that there are two clocks, and there are two counters. So, under SEP-1, for patients who qualify for severe sepsis, meaning they have a suspected source of infection, two SIRS criteria, and an identifiable organ dysfunction, at that point, when that annotation lines up with the chart as being true, the severe sepsis clock starts. And, as you'll recall, from looking at the elements of care, there are both three-hour and six-hour elements of care for patients with severe sepsis. The three-hour elements for severe sepsis include checking lactate, blood cultures before antibiotics, and providing a broad-spectrum antibiotic. The six-hour elements for severe sepsis could include rechecking the lactate, if the lactate was elevated. But, this is different than for septic shock where there is also a separate clock that begins. So, if that patient is slips into hypotension, not responsive to fluids, or if a lactate returned greater than four, a separate clock will start, and that's the shock clock. And that has three-hour and six-hour elements, as well.

The three-hour elements for the shock clock include the fluid bolus for hypotension or for lactate greater than four of 30 ml per kilogram. And, the six-hour elements include the application of vasopressors, if hypotension persists, as well as performing elements in Table 1 that was identified in the event the patient has septic shock. So, it becomes more complicated to remember that there are two clocks and each clock has two counters. But, this is how the measure will in effect work. The net effect of this is actually to provide much more leeway to providers. Although it sounds complicated, it's important to remember the following things. Now, as opposed previously, providers are given more time to identify whether the patient is in severe sepsis or septic shock because triage time is no longer the beginning point for identification. It's the point in which all the elements line up, and that may be one to two hours into the time that the patient is already in the emergency department. So, more time is provided on that end. In addition, more time will be provided for patients because the severe sepsis clock may begin at a certain time, but the patient may not yet be in shock. If the patient then slips into shock, the septic shock clock will begin and well up to another six hours to provide the

elements of care for shock. The net effect of this strategy is to give providers yet more time to actually complete the required care.

So, let's use an example to explain how these two clocks would work. A patient developed severe sepsis at 3 o'clock in the afternoon, but did not become hypotensive and fail to respond to fluids until 5 o'clock. The question you may ask is: does the shock clock start at 5p.m.? And then if it does, if the shock clock does start at 5 p.m., does the six-hour window to complete the physical exam begin at 5 with the shock clock, or 3 when the severe sepsis was first noted? I'll let you think about that for a moment. But remember, the patient had severe sepsis at 3 and shock at 5. The answer is that the sepsis shock, severe sepsis clock, will begin with the presentation of severe sepsis at 3 p.m. The shock clock, which starts at the presentation of shock, at 5 p.m. The presentation of severe sepsis at 3 will then trigger the following counters to start at 3 p.m. The three-hour counter for sepsis would require completion between hours 3 p.m. and 6 p.m. of those three elements I said were part of the severe sepsis three-hour counter: initial lactate level, antibiotic administration, and blood cultures prior to antibiotics. The six-hour counter for severe sepsis would require by 9 p.m. that the lactate is repeated, if the lactate was greater than two initially.

The presentation of septic shock at 5 p.m., however, triggers the addition of the start of the shock clock, and that begins at 5 p.m. So, between 5 and 8, the three-hour counter, we then require the addition of resuscitation with 30 ml per kilogram of crystalloids. And, the six-hour counter would start, if hypotension persists, and that has to be completed by 11 p.m., giving you essentially much more time than you thought you had to start vasopressors and repeat the volume status and tissue perfusion assessment according to Table 1. So, although this patient started with severe sepsis at 3, but they do slip into shock ultimately at 5, you don't have to adjust 9, 3 to 9 to get the work done. It can actually be accomplished by 11 because of the addition of starting the shock clock later at the presentation of septic shock, after severe sepsis.

So, let's look at some of the elements in Table 1, which I think for a clinician it's important to understand what this will mean. I think it's clear what a physical exam, a repeat physical exam is, it means essentially that a patient is examined by the doctor at the bedside. The elements that are required are recorded in a note; and, if their physician has documented that the organ system has been examined, that's sufficient for abstraction, and you can satisfy the measure just simply by writing a note to the effect that you've done that exam. But, if you wanted to use some of the other measurements, the hemodynamic measurements, there's some questions that come up both for physicians and for data abstractors.

Let's start with the data abstractors for a moment. The people who will be reviewing the chart for the measure in the quality department of your facility, in your hospital, are not going to understand all of the details of the medical complex nature of checking the central venous pressures, central venous oxygen saturations, leveling devices... this type of thing. It's not their role or responsibility to know that. But, what they do have to do is identify whether the action was completed or not. And so, all we're asking abstractors to do is to respond, is to look for a response that yes or no, a CVP was checked. And, the clinician could put this in a note. And, it's not complicated for the abstractor to just say CVP checked, yes; CVP checked, no, in order to pull this information from the chart.

From a physician's standpoint, it's clear that certain reasons why we check CVP exist and one of those is to optimize the CVP, and clinicians will be familiar from their training that central venous pressures optimize when it's between 8 and 12 millimeters of mercury; and, this is something that as a physician, you would be expected to understand, to know. But, we don't expect data abstractors to have to look for documentation on what that value was.

Likewise, for ScvO2, the same thing applies. Again, if it was checked, the abstractor just needs to know: yes, it was checked or no, it wasn't checked. They don't need to understand the great details involved in it. As a clinician, you'll know, again, that the goal is greater than 70 percent, if it's

mixed venous oxygen saturation, and whether it's a central venous oxygen saturation. If it's a mixed, it's greater than 65 percent.

The other measures, other possible ways to satisfy Table 1, are listed here as well. One of them is: they could check a bedside cardiovascular ultrasound. And again, for abstraction purposes, all that has to be checked is, for an abstractor, is that the doctor writes that the bedside cardiovascular ultrasound was completed, yes or no. From a physician standpoint, it's worth knowing that there are four listed exams that may qualify for a yes. Those includes transthoracic echocardiogram, transesophageal echocardiogram, inferior vena cava ultrasound, or esophageal doppler. You can imagine, as a clinician that these are very complicated therapies, especially as you start thinking about IVC ultrasound and esophageal doppler. The others are more routine.

But I've listed here, for example, for physician reference, some strategies to use, the IVC table index in order to understand what the meaning is of an IVC ultrasound. Just checking it, it's fine for the abstractor knowing it was done, he will pass the measure. But, clinically, you have to understand how to use the IVC measurements in order to make decisions about volume status. And so, there are several strategies. One is the table index and the formula as listed here. And then, it's worth noting that there is information that correlates IVC size to CVP and the table is listed below, giving approximate central venous pressures, and with the table sizes and respiratory change associated with that. And so, these are clinical standpoints that doctors must pay attention to, if they truly want to use this measure to improve care of patients as opposed to just simply satisfying the measure for purposes of abstraction.

Likewise, the final method that's included in the table is to assess volume status and perfusion is the use of a dynamic fluid assessment. And, there are a couple of ways to do that, and one of them is this passive leg raise, the other is through a volume of fluid bolus. But, for abstraction purposes once again, all they want to know is yes, you did it, doctor or no, you didn't do it, doctor. It doesn't matter to them in particular whether you did it right or wrong, but we hope clinically that physicians will use this

appropriately and learn to understand what it means to do a dynamic assessment or fluid assessment.

And so, to give you some examples, it's clear, as I've listed under physician reference here, that to do this correctly, the patient has to be properly seated in a semi-fowler position at 45 degrees. The upper body has to be lowered to horizontal and legs have to be raised to 45 degrees up. A time period has to pass, 30 to 90 seconds, to get maximal effect. And then, this is the key part, clinicians have to know if there was an increase in stroke volume of 10 percent as documented on a cardiac output monitor or a stroke volume in order to ascertain whether or not the patient is volume-responsive. This means then that you need to have some method of assessing either cardiac output or stroke volume. And, there are a number of opportunities to do that now, both with invasive devices and non-invasive devices on the market. But, you have to start with a baseline and you have to repeat that test at the end to know whether you have responsiveness. And so, it's not as easy as it appears simply to give a fluid bolus and see if the patient is better or not. You need some quantitative information to define that.

Lastly, for the repeat physical exam, I just wanted to point out that the criteria for abstraction do include all of the elements of the exam, which are included; and, those are both vital signs, presence of a cardiopulmonary exam, a peripheral pulse exam, documentation of capillary refill, and a skin exam. And some examples of how that may be listed by a doctor are here. But, as long as the particular organ is listed and indicated to be checked, that will be fine for abstraction purposes.

And so, those are some of the differences between SEP-1 and previous versions of the measure you may have heard about or worked with in the past. And I appreciate your time and I'm happy to answer any questions from the chat box as time goes by. Thank you.

Deb Price: Well, thank you, Dr. Townsend. And now, I'd like to talk for a minute about the continuing education process. 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 credits to their board using our new National Provider number 16578.

We now have an online CE certificate process. You can receive your certificate two ways. If you registered for this webinar through Ready Talk, a survey will automatically pop up when the webinar closes. The survey will take you to a certificate.

However, if you are in a room with somebody else listening to the event, and a survey will also be sent out within 48 hours, take that survey and pass it to other people in your room. After the completion of the survey, click Done at the bottom of the screen. Another page will open that asks you to register with our Learning Management Center. This is a separate registration from the ReadyTalk registration, which you used to get in to the webinar.

Please use your personal email so that you can receive your certificate. Healthcare facilities have firewalls up that block our certificate. This is what the survey looks like. It will pop up at the end of this webinar. Click Done at the bottom in the little gray bar when you are done. This is what will pop up after you click Done. It's kind of small, but you can see in green that there are two separate links on this page. If you have already received CEs and certificates through us, you will click on the Existing User link. And when you click on that link, you're going to use your entire email address.

If you have not received any certificates through us, then you click on the New User link. This is what will appear when you click on the New User link. You put your first and last name. Again, we would prefer you to use your personal email for the email, like Yahoo or Gmail or ATT, and that is because hospitals tend to have firewalls up. And, if they didn't have it up last month, they might have it up this month. So, you never know when you're going to be pushed out of the computer.

This is what the Existing User page will look like. The username is your complete email address and the password is whatever you set it up. And now, I'd like to turn the program back to Candace to go over questions that have been sent in by all of you attendees.

Candace, take it away.

Candace Jackson: Thank you, Deb, and thank you, Dr. Townsend, for presenting this valuable information to us. We do have Dr. Townsend and Dr. Tefera from CMS who will be answering questions, these are in no particular order, and we'll just take as many questions that we can to get us to the top of the hour.

The first question: you lay out evidence for most of the measures well. However the repeat examination documentation does not appear to be supported in any way. What evidence do you have that those specific examination elements, which is even one if missed, would constitute measure failure matter to patient outcomes?

Sean Townsend: This is Sean Townsend. I think that the – as I mentioned in the body of the discussion, what became clear from review of the trials and the evidence that supported these trials is that they did not fail to monitor and observe patients for six hours during the course of usual care. So, the first pieces of evidence pulled from these trials, is that those patients received high level and intense observation for six hours in usual care. So, that level of observation drives some evidence that that period of time is important to the care of these patients.

The use of the physical exam and the proxy for that level of observation is admittedly what it is, proxy. There is limited information available on the effectiveness of the particular exam itself, but there is some data supporting them and some data that does not support them. What's important to know, though, is that it's not really so burdensome for a physician to come back and examine a patient, check pulses, look at their skin, and decide on their own whether they take that information into account or not, that the patient is somehow perfusing. They're only asked

to document those things that the exam is comprehensive as opposed to entering the room and, like I say, again, without performing an exam of some sort. So, it's there to sustain the level of observation as noted in the most recent trials and facilitate the observation period for a six hour timeframe.

Lemeneh Tefera: Hi, this is Lemeneh Tefera from CMS. I'd just like to add that from patients and their families, we hear that the expectation that critically ill patients are reassessed and reexamined, our agency feels that this is a standard of care. And the physical exam option, again, is an option. Clinicians are still able to perform more invasive methods of reassessing volume status, and this option was added because of concerns that the invasive methods of volume reassessment did not necessarily show a benefit and were equivalent. So, we feel that having physical exam option shows flexibility and provides clinicians more options to successfully complete the measure.

Candace Jackson: Thank you. Our next question: do you think that the recent JAMA, August 18th, 2015, review, *Septic Shock, Advances in Diagnosis and Treatment* will have any impact on the Sepsis Core Measure and/or Severe Sepsis treatment?

Sean Townsend: I think that – this is Sean Townsend again. I think that all the literature is periodically reviewed in the course of development of a measure. So, I think it's very important for the public to understand that both at CMS and at the National Quality Forum, there's a commitment to review incoming evidence and to alter the measure as needed as the evidence changes. And I think the best example of that is the addition of physical exam option and the lack of requiring a CVP and ScvO2 in the new measure itself, which that evidence only came out in March of 2014 and then the two other studies during the course of the year after that. So, although the new article you referred to is essentially a review article, it does not radically change or alter therapies that are already included in the measure. It's certainly part of the literature that will be considered upon a second round of revisions for this measure.

Lemeneh Tefera: And, this is Lemeneh Tefera, CMS. I'd like to take that question to highlight the important aspect of the evolving care for sepsis is the changing landscape. From the initial years after early goal-directed therapy was introduced and the landmark Rivers paper, sepsis care has been transformed over the last decade. We see this in the fact that the usual care that patients received in the ProCESS, ProMISE, and ARISE trials, all included significant interventions that were not necessarily the standard and expected in the early 2000, late 1990s. So, we hope with the continued implementation of evidence-based sepsis care that we will drive and improve the care of septic patients nationally.

Candace Jackson: Thank you. The next question: some physicians are resistant to administer 30 milligrams per kilogram fluid bolus to patients with CHF or potentially sending patient into fluid overload. What is a good reference to show to this submission?

Sean Townsend: This is Sean Townsend again. I was just remarking this morning in a separate conference that I was at, that I've never succeeded in getting – not receiving that question in a conference when I deliver a speech on sepsis. The best evidence for this comes from the three trials that we've been talking about, ProCESS, ProMISE, and ARISE, as well as from the Rivers trial. And, in each of those trials, patients had comorbidities associated with congestive heart failure or renal failure. And, in each of those trials, there's no demonstration that patients with those comorbidities had an increased rate of acute respiratory failure, having received the fluid bolus. And so, Table 1 of those trials is where I'd point you to show that there's never been a statistically proven increase in acute respiratory failure for fluid bolus in those patients early on.

On the contrary, there's also no – there's never been a study done to indicate as a primary outcome whether that was true or false. So, I'm only able to point to secondary outcomes for you to give you that evidence. I do want to provide the following clinical perspective. It's very important to remember that patients who are presenting to you as septic shock are not presenting to you with their comorbidity that day, congestive heart failure or acute renal failure or chronic renal failure. They suffer all the same

pathophysiological derangements of any normal person without those comorbidities in septic shock. So, you have impaired venous return, excess arterial incapacitance, impaired cardiac dysfunction, cardiac dysfunction, if impaired, so the myocardium is not squeezing effectively, you have increased capillary leak and insensible losses. All those things screen for volume. And, if you don't treat the patient for their presentation with a shock and instead treat them for their secondary or comorbid condition and avoid treating their shock, the evidence is pretty clear in this Rivers trial that those patients who don't receive as much fluid actually become intubated and their organ failure progresses. So, it's a bit counterintuitive, but it always comes up as a question. And I'd like to encourage people to err on the side of administering fluids.

Lemeneh Tefera: This is Lemeneh Tefera. I'd just like to repeat Dr. Townsend's comment that to our knowledge there's no trial that has demonstrated heart failure patients (worsen with) fluid boluses. And again, it's important to remember that septic shock patients arrive in a severely volume depleted condition and that their resuscitation improves with the administration of appropriate fluids.

Candace Jackson: Thank you. Next question, what is your opinion of procalcitonin as a measure of sepsis, since it elevates much more quickly than lactate, then why not use that marker?

Sean Townsend: This is Sean Townsend again. In 2012, the Surviving Sepsis campaign reevaluated the evidence for the use of procalcitonin as a screening tool for patients with severe sepsis and septic shock. We are committed to doing that again in the next iteration of the guidelines in 2016 and have done in the two previous ones, as well. The balance of the evidence and in consultation with our infectious disease experts suggests that the best utility for procalcitonin is not as a screening tool to identify patients who specifically have severe sepsis or septic shock, but rather as a means to discontinue antibiotics, if they've already been started in a condition that may not be sepsis or septic shock. So, to give you an example, a patient with pancreatitis oftentimes may not be infected, but does present with evidence of infection, with fever, tachycardia, elevated white count. But,

they can often just be – that can just be inflammatory criteria that is being satisfied by the true infection. Checking a procalcitonin in a patient in the ICU, who has had broad-spectrum antibiotics applied, and finding that it's normal or low would be reason to discontinue the antibiotic. But, elevated procalcitonin by itself is not particularly specific to identify a septic patient early on, any more specific in particular than lactate, even though it may have an earlier rise in terms of lactate as a variable, it's not specifically specific for that condition.

Lemeneh Tefera: I have no further comment on that.

Candace Jackson: Thank you. For teaching institutions: if a resident does the focused exam, then cosigned by an attending physician similar to usual workflow, does this meet sepsis criteria?

Sean Townsend: Again, this is Sean Townsend. The residents, who note it, if they're a licensed independent provider, can qualify by itself without an attending co-signature. This will perhaps vary from state to state, where some states provide trainees a trainee license, and therefore, they're a licensed independent provider. In other cases, this is not true, and so it may require an attendants co-signature. In any event, a trainee's note is acceptable, especially as you ask the question with the attending co-signature.

Lemeneh Tefera: This is Lemeneh Tefera. I'd just like to add that the addition of SEP-1 to the Inpatient Quality Reporting Program is not going to change the usual care for critical care patient's hospitals. Providers will continue to reassess and manage their patients as they see fit. The documentation will not necessarily change.

All we're looking for is to increase the quality and consistency of sepsis care. It is not the intention that the typical routines of institutions themselves will change, but I do not think that providers will need to think about that particular issue.

Candace Jackson: Thank you. For the next question, there were a couple of questions relating to this. Can a CVP reading be done with a PICC line as long as it is designed to do so and is in proper placement in the superior vena cava?

Sean Townsend: Again, it's Sean Townsend. All the evidence suggests properly designed PICC lines for that purpose are able to assess central venous pressure.

Candace Jackson: Thank you. Is any development of hypotension being defined as septic shock? I thought septic shock was hypotension not responsive to initial fluid resuscitation. For example, initial hypotension would be a component of severe sepsis and define shock as not responsive to fluid.

Sean Townsend: Your definite – this is Sean Townsend again. Your definition is correct. The initial hypotension does not define shock, but rather the failure to respond to fluids defines septic shock, and that's the point at which the six-hour elements of the septic shock counter become effective.

Candace Jackson: Next question: what is the rationale for using actual body weight versus ideal body weight for fluid bolus volume calculation?

Sean Townsend: This is Sean Townsend again. Admittedly, a difficult question and one over which physiologists can disagree. The trials that have been done have used the actual body weight for the most part. There is – there are very few patients, however, though it should be noted, who would necessarily be enrolled in those trials who are profoundly morbidly obese, for example. And so, data is limited on this particular point. So, to make an answer, which is qualified by the literature, is a bit challenging in this regard. That much being said, today, the standard has always been actual. And, we've not detyected harm from that being applied, as well.

Female: OK. Thank you. Next question: In regards to fluid rate or fluid count, why does it have to be performed by MD, APN, or PA? Surviving Sepsis does not know that it has to be performed by a physician, APN, or PA.

Sean Townsend: This is Sean Townsend. I have to be quite honest with this. I'd like to have an opportunity to answer it offline. As I'm remembering the wording of this, a licensed independent provider is required to do the exam and then the abstraction for the other elements is as indicated. I don't believe there's the LIP qualification. I don't want to make that a final answer yet, so I'd like to have a chance to clarify that in notes or transcript at some point.

Female: Thank you. And we do have time for one more question. Is normasol an approved crystalloid fluid? And, if not, why not?

Sean Townsend: Again, this is Sean. The approved fluids for the measure at this point include saline. And no other fluid was considered as a choice. Again, the reason for this is that there's very little evidence that one resuscitation fluid is more effective than another. When you start making such comparisons, you get down to studies with very small numbers of people, typically speaking. Even in large studies that compared saline versus albumin; the differences are minimal at the least. So, the decision was made since saline is routinely and readily available to proceed with that as an initial resuscitation fluid.

Lemeneh Tefera: This is Lemeneh Tefera.

Candace Jackson: Go ahead, Dr. Tefera.

Lemeneh Tefera: Yes. I just wanted to add that for those clinicians who thought there was indication for albumin, the measure does allow for supplementing fluids with albumin. Although, it could not be a complete replacement of the fluid bolus, but albumin can be included as a part of the fluid bolus.

Candace Jackson: Thank you. OK. We are at the time of our presentation. We again like to thank Dr. Townsend and Dr. Tefera for being on the call today to present this valuable information and be there to answer some of your questions. We hope that you have found this information beneficial and valuable to you and we hope that you have a good afternoon. Thank you very much.

END