Inpatient Quality Reporting Program

Support Contractor

Early Management Bundle, Severe Sepsis/Septic Shock

Presentation Transcript

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Matt McDonough: Good afternoon everybody and thank you for joining us for this afternoon's webinar, *Early Management Bundle, Severe Sepsis/Septic Shock.*

My name is Matt McDonough, and I'm going to be your virtual training host for this afternoon's event and before we start our event and hand this over to our presenters today, 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 throughout today's event.

Now, on your screen, you see some bullet points and the first one says that audio is available over internet streaming. If you're hearing my voice over your computer speakers, then you know this and you are streaming audio. It means that no telephone lines [are] required to listen to today's' audio stream. But, you do need to have computer speakers or headphones connected and the volume turned up and it needs to be working correctly.

Now, if at any time during today's event there is some audio difficult, we do have a limited number of dial-in telephone lines available, simply send us a chat message and request that dial-in number and we'll provide it to you as soon as possible so that you can dial-in and hear our audio feed over your telephone today.

Now, just because the audio feed is streaming over the computer (and if you are not a dial-in), it doesn't mean that you can't submit questions to our panelist today. You can type your questions into the chat panel. And, an illustration of what that chat panel looks like is on the slide here. To the left side of your screen, there is a chat panel. At the bottom, there is a chat with presenter box. Simply, type your question into that chat with presenter box and click the send button.

Now, when you send in a question, all of our presenters that are online today will see your question. And, as time and as resources allow, we will answer those questions as we can; but, all questions are being archived and recorded to be stored and answered at a later time.

Now, going back to our audio slides before we begin, we do have a large audience on today's event. So, what I would like to do is, if you have an audio difficulty, if your audio is streaming and it's breaking up, in the upper left-hand corner there is a pause button. If you're getting choppy audio or you lose audio connection simply push that pause button, you're going to wait about five seconds and then click – it will turn into a play button. Then, click that play button as well. That should reset your audio feed and you should be reconnected to our audio stream.

Also, if you are hearing a very bad echo on the call right now, if my voice is echoing badly, that means that you're connected in more than one browser or more than one browser tab. So, what you'll need to do to correct that issue is to close one of those browsers or one of those browser tabs. You're hearing a multiple audio streams because of that. When you go down to one browser that echo will go away.

That's going to do it for my brief introduction here today. So, without further ado, I would like to hand this over to our first speaker of the day.

Candace Jackson: Thank you, Matt. Hello and welcome to our IQR monthly Webinar, *Early Management Bundle, Severe Sepsis/Septic Shock.* My name is Candace Jackson and I will be your host for today's event. And 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 Web site at http://www.qualityreportingcenter.com/ within two days and will be posted to *QualityNet* at a later date.

If you registered for this event, a reminder e-mail as well as the slides were sent out to your e-mail approximately one hour ago. If you did not receive the e-mail, you can download slide at our inpatient Web site again at http://www.qualityreportingcenter.com/. And now, I'd like to introduce our guest speakers, Dr. Laura Evans holds many titles.

She is the Associate Professor of Medicine at the NYU School of Medicine. She is also the Medical Director of Critical Care at Bellevue Hospital Center, and Associate Chief of Medicine at Bellevue Hospital Center, and the Associate Program Director of Pulmonary and Critical Care Medicine Fellowship Training at the New York University School of Medicine. Dr. Evans received a Presidential Citation from the Society of Critical Care Medicine in 2015.

Mary Therriault is the Senior Director of Quality and Research Initiative at the Healthcare Association of New York State where she represents member concerns and interests with CMS, as well as developed education plan and coordinates state-wide effort to improve performance. Mary is an Instructional Faculty for online education at Excelsior College in Albany, New York as well as an adjunct faculty at Hudson Valley Community College in Troy, New York.

Dr. Sean 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 Medical Group and Associate Clinical Professor of Medicine at the University of California, San Francisco.

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The purpose of today's Webinar is to: provide participants the basis, rationale, and content of the *Early Management Bundle Severe Sepsis/Septic Shock* measure; to explain the importance of data collection of this measure; and to provide detailed improvements that has been seen since the collection question of this data.

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At the end of the presentation, participants will be able to: recognize the improvements that have been identified since collection of the Sepsis Bundle Measure; described the basis, rationale, and content of the Sepsis Bundle Measure; and explain the importance of a collection of this measure.

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

Laura Evans: Thank you so much, Candace. Good afternoon everyone and thank you to all who've been able to join the Webinar this afternoon. Our first course of action this afternoon will be just to go over the New York State experience. Mary and I will start with describing a bit of the experience we've had in New York State over the past two and a half years with reporting for Severe Sepsis and Septic Shock.

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I'm sure with this group on the call is well aware of the data around the morbidity and mortality associated with Severe Sepsis and Septic Shock. This was really galvanized and personalized in New York State with a well-covered story of a tragic death of a 12-year-old boy, Rory Staunton, who died of sepsis and really lead and galvanized the state into state-wide action.

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So, the death of Rory Staunton from the septic shock lead New York State Department of Health to implement State-wide requirements that began with – the effort began in the fall of 2012.

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The New York State requirements that were delineated in... again in the fall of 2012, required each acute care hospital in New York State to develop an evidence-base protocol for the recognition and treatment of Severe Sepsis and Septic Shock. It had to cover both adult and pediatric populations and it additionally have to cover both patients presenting to the emergency department, as well as patients on inpatient units within the hospital. Each acute care hospital as part of the State-wide requirement were required to report adherence to protocol elements and our sepsis mortality, which the State will then develop a risk adjustment model for.

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Beyond the case of Rory Staunton, which really put a very personal face on the experience in New York State, sepsis nationally is the leading cause of death within U.S. Hospitals. And, it's estimated to strike 750,000 Americans each year with a mortality rate that – it seems to be falling overtime with effective implementation of evidence based treatment, but it still remains in the 20 to 50 percent range, depending on which study that you read and because of the similar number of deaths to those who are caused by heart attacks. Within New York State, the New York State Department of Health predicted that with effective implementation of these sepsis regulations that we had the potential within New York State to save the lives of between 5 and 8,000 New Yorkers per year.

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So, you can imagine that the implementation of these state-wide regulations was a very complex endeavor. And, this slide summarizes some of the efforts that went through that. Again, lead by the New York State Department of Health. The State... the Department of Health used the consensus conference definitions for Severe Sepsis and Septic Shock.

Again, mandated the adaption of evidence-base protocols for early identification and treatment of a both adults and children with Severe Sepsis and Septic Shock. We additionally required both initial and periodic staff training to facilitate recognition of sepsis and knowledge of protocols. The protocols... the effort started in the fall of 2012. Each acute care hospital had to submit a protocol to the State by September of 2013. And then, the timeline for implementation of that protocol was very tight with full of implementation expected by December 31st of 2013 with data collection following thereafter.

So each acute care hospital has to collect and submit detailed protocol here in the state and we'll go through that in a little bit more depth. And then, the Department of Health is working on developing a risk adjusted Severe Sepsis and Septic Shock mortality [measure] for public reporting.

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Within this effort, the New York State Department of Health formed a sepsis advisory committee, which was comprised of clinical leaders throughout New York State from our hospital associations in consultation with key national experts. And, the sepsis advisory committee addressed a lot of issues in their meetings. But, amongst them, were protocol requirements, data collection requirements, methods about risk adjustments, and concerns about public reporting.

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So, New York State and the Department of Health developed a detailed data dictionary, which we're not going to go into great depth here because it does differ somewhat from the CMS data collection for Severe Sepsis and Septic Shock. So, rather than to engender confusion, we won't go into detail about the New York State data. But, suffice to say that for each case of Severe Sepsis and Septic Shock right now New York State is not permitting sampling.

So, for each case of Severe Sepsis and Septic Shock, each acute care hospital within New York is collecting approximately 100 data elements per case that go through both patient demographics, patient characteristics, adherence to your protocols and process, patient outcomes, and enough clinical detail to enable risk adjustment. This has gone through reiterative revision overtime, on a most current version as 1.43. So, it's the 43rd version and it's posted online at the IPRO Web site within New York State.

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For, process adherence measures within New York State for adults, we are reporting getting reported back to us our adherence to the NQF0500 Severe Sepsis Quality Measure. For children, it's a little bit more complicated because there is no NQF approve measure for children.

So, the sepsis advisory panel from New York State did create some quality measures that are being reported for the pediatric population. And again, this applies to all patients within the entire medical center, the emergency department, the intensive care unit, other inpatient units not just patients presenting to the emergency department.

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The development of a risk adjusted outcome measure has been a real work in progress right now. Where [...] New York State [...] is not reporting risk adjusted mortality, as there was no clear methodology that existed for sepsis specific mortality risk adjustment. However, New York State is working with the New York State Cardiac Services, as well as some other national experts, to develop that risk adjusted model to compare across each other’s – and peer comparison.

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I'll go through just a couple of details about some of the things that we've noted so far in our experience in New York State with sepsis data reporting. And, that's been one of the issues that came up, was about case identification. And again, I'm not going to go into enormous detail because this methodology may differ somewhat from the CMS methodology that will be reported... expected to do nationally.

So, within New York State, two different case identification methods are permitted. We are allowed to use retrospective data to use coding to start to identify patients who've been discharge and go back to collect data on those patients. The New York State also permits us to identify patients prospectively to identify them as close to real time during their hospitalization as possible.

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So, what we've learned so far about retrospective case identification is that it's definitely a little less time consuming to find patients. It's easier for our quality management staff to find these patients and it doesn't require change to our existing workflow. However, there is some potential for bias, there is some nice literature that suggests that when we use coded data to identify these patients we're more likely to capture those patients who are more severe and less likely to capture patients with less severe cases of severe sepsis or septic shock. And, for me as a clinician, it's been difficult for us to use the data from coded, or more difficult to use data from coded, cases for performance improvement because it's... there's a built-in timeline and for me to provide feedback to my clinical staff on the unit about performance regarding an individual case.

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One way to get around that is to prospective case identification lead by identifying patients through an active screening process and that does probably give us a more complete population with a little bit less bias towards the more severe cases. It also enables us to provide real time feedback to providers to go guide our quality improvement efforts. However, it's extremely time consuming and it really required us to change our existing workflow to facilitate identification.

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One other area where New York State Department of Health put a great deal of time and effort [...] was determining Time Zero. And, again this is – New York State has so far been using a different Time Zero than CMS will use. That New York State Time Zero was asking us for either the earliest time that the patient met criteria for severe sepsis or septic shock or the time of protocol initiation. And, that can include many different time points: when a code sepsis is called; when there is [an] electronic time stamp in the electronic [...] health record that the protocol was began; a paper order sheet; or rapid response team called.

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Or, through a process of detailed chart abstraction you can find the earliest time in the medical record that the patient meets the definition of severe sepsis or septic shock. And, the quality management folks really spend an enormous amount of time reviewing each chart in detail to try to determine this.

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So, so far after approximately two years now of collecting data, there's obviously been some challenges around this. When you go on-calls with New York State Hospitals about where those challenges have been for process adherence, it's been really around focused both on the 3-hour bundle and the 6-hour bundle.

On the 3-hour bundle challenges have again come around this issue of administration for fluid – of fluids and some clinicians' reluctance to give fluids to patients with either history of congestive heart failure or renal failure. [...] People at acute care in New York State have done a lot of work around their clinical documentation to enable us to get the data elements out of the medical record.

There have been some concerns around antibiotic stewardship. [...] And Mary may be able to go into a little bit more detail about these issues around patients transferred from one hospital to another and the rule of pre-hospital care. And some of these issues have remained unresolved.

With the 6-hour bundle, many of you are probably aware, that there's been an evolution of the evidence-base around the 6-hour bundle and some discussion of evidence based treatment around that and maybe Dr. Townsend will allude to that later on in his presentation. So with that, I'm going to actually stop. I'm going to hand it over to Mary Therriault to talk about the HANYS response and what HANYS has done to help New York State Hospital meet these requirements.

Mary Therriault: Terrific, next slide please.

So, as the Healthcare Associations of New York State, we began hearing very quickly from our members asking for help to do all the things that were part of the mandate from the Department of Health; to educate all staff, not just clinical staff but people who would be in the pharmacy, in the labs. That was one of the things that was very clear. DOH wanted to have the entire hospital understand the importance of severe sepsis.

We also asked – we're asked to help to collect and submit that data so our staff time were spent, as you heard, being on the advisory committee. We began to have our own HANYS sepsis advisory committee. We did a lot of technical and clinical assistance. We worked with national experts and to have education programs from all over the country. We actually created a data collection worksheet, which I'll show you in a moment.

We did a resource guide so people would not recreate the wheel. And, our resource guide actually had sections. So, if you needed help in your emergency department, or you needed help with children, or talking to your CEO, we put them in sections to go find that information. We also have a web site that we created and we did all sorts of different ways of communication with our members.

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Our HANYS Advisory Committee was very important through the last couple years. Certainly as an advocacy association, we needed to hear about what was happening on the ground floor. We also needed to have other members give input that could not attend the sepsis advisory committee.

We looked at resource needs. We actually had a time stamp of how long it took so people would know what kind of staffing they would have to get. We also looked at all sorts of the issues just in getting started and sharing best practices was so important to the group.

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The two groups that we worked with very closely, the surviving sepsis campaign and we worked with the American Hospital Association, and the HRET, which was very important to getting the evidence-base practices down.

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The accomplishment our members appreciated the most is [that] we spent a great deal of time creating a collection tool and that collection tool had dropdown windows [...] where it has references to the data dictionary. And then, was in the format necessary to get this up to a secure web site at IPRO that is part of the DOH initiative.

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I talked a little about the education. We continue to that in 2015. We have Webinars that are archived for folks right back to 2012. We also did a CUSP series. We help people to look at the practice right at the staff level. But, the most successful thing we had was the office hours. Dr. Laura Evans did those with us. People submitted questions ahead of time and it was just a very, very positive experience that our members had.

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So, what's happening now in June 2015? New York State is beginning to have audits. They will be giving a percentage back to the hospitals with the patient list. They will be scanning the patient's entire chart in; and, that will be reviewed by clinical people, that's in that medical chart review. The other thing that's happening is they're doing very detailed data integrity reports. They're looking at the claims dater that, you know, Laura spoke about with the retrospective review. [They are] looking at the clinical database, which for many people, as you talked about, it's a concurrent database and seeing how it matches and doesn't match.

The next slide please.

So, what about HANYS advocacy? Right now, we're in the process of working with the Department of Health looking at how the differences and what's the same of the CMS measures from their data dictionary and specification manual. As you heard, we'll be talking about risk adjusted mortality, but we also are looking at morbidity that something that the department is concerned about and we are also.

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And I'm going to turn this back to Candace.

Candice Jackson: Thank you, Dr. Evans and Mary for providing that information for us. We would now like to go to the next slide and I will turn the floor over to Dr. Sean Townsend. Dr. Townsend it's yours –

Dr. Townsend, are you on mute?

Sean Townsend: I was, thank you very much Candace. I apologize.

Candace Jackson: Thanks you.

Sean Townsend: Well, thank you for introducing me. I'd like to take this opportunity for this part of the presentation to tell you a bit about how the first National Core Measure came about and how the evidence evolved to get us there. And, how we went from the National Quality Forum Measure to SEP-1 itself and some of the differences between the SEP-1 and what the previous measurement look like.

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But as a background to that, I want to introduce to you a concept, which I think is very critical as we introduce this to the country, which is that it's important to know that sepsis is the number one cause of inpatient deaths in United States. And, just as an example, I've taken this slide from my own health system Sutter Health in Northern California. And, we have 20 some odd acute care facilities. And, if you just look at our combined data for 2014, you will notice that in terms of discharges of all patients from our facilities, if you look at the diagnosis of sepsis (whether it's simple sepsis, severe septic or septic shock), 11 percent of patients had that as a diagnosis in their admission to the hospital.

But, if you look on the right-hand side of this graph, of those deaths recurred in our system, 48 percent of the patients died of sepsis within the system. And, so while the overall number of admissions is low it speaks to the high mortality rate that this condition continues to have. And so, you can imagine why this is a priority for us nationally, to focus on sepsis. After all, we have these patients in our care and now it's our time and opportunity to actually treat them with care patterns that can actually reduce mortality. And so, that’s why this measuring process has begun.

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This slide is entitled the old NQF 0500 bundle. And, I'm not going to... I'm going to explain to you what the bundle did. It had a 3-hour period and a 6-hour component, two different bundles. Within the first 3 hours of care, the NQF measure asked for: checking a lactate level; obtaining blood cultures before antibiotics were administered; administering broad spectrum antibiotics; and then, for patients who are hypotensive or (high to lactate), greater than or equal to 4 given 30 mL per kg of crystallite.

Now, you know, there's an ampersand here that indicates that the time of presentation for the old NQF measure was defined as the time of triage to the emergency department. And, if the patient was coming from a different care venue it was the time that the earliest indentation of the chart lined up with all the elements for severe sepsis or septic shock. That was how the NQF measure defined the triage time and we'll talk about some of the differences between NQF and SEP-1in just a moment.

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This is the 6-hour care pattern under the NQF measure. And so, for item 5, patients whether they are hypotensive and didn't respond to initial fluid resuscitation were to receive these suppressors. And then item 6 here indicated that patients who have persistent hypotension despite the volume resuscitation or a lactate greater than 4 had central venous pressured checked and central venous oxygen saturation check ScvO2 and these elements item 6 here were a proxy for a therapy for patients with severe sepsis and septic shock called Early Goal Directed Therapy. It was just essentially was a strategy to optimize the patient's hemodynamic function to ensure that the patient was perfusing well. This was part of the old NQF Measure initially and then overtime this had to be changed as new evidence submerged. The last slide was to measure a lactate level.

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So, this Early Goal Directed Therapy that I described is optimizing hemodynamics so that patients are perfusing their organs correctly. Another term for that general strategy is called Quantitative Resuscitation. It means resuscitating a patient to some target so that you are able to ascertain whether or not they actually are perfusing their organs well and correctly.

There were a number of trials that suggested this kind of guided therapy where we target a specific central venous pressure or central venous oxygen saturation could be effective for patients, if done in a timely fashion and they're listed on this slide. This is called the meta analysis for those of you that are familiar. But, what's important is that you see the horizontal line down the middle of the slide. Anything that will be left of that line indicates that there's a trial that was done that showed a positive effect that suggested that this quantitative resuscitation strategy was useful.

And, you can see from these top studies on the left, they've listed sequentially Lin, Rivers, Alia, and Yu for example. All those little dots might – to the left of the horizontal line suggesting that early therapies for patients with severe sepsis and septic shock targeting CVP and ScvO2, the hemodynamic parameters, were effective in reducing mortality for patients.

And I'm going to skip describing the bottom part of the slide but my point is it was an evidence basis that suggested that this was appropriate to recommend on a national basis to NQF 0500.

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This slide shows one particular trial, the most influential of those trials is shown to benefit to including early goal-directed therapy. This was the Rivers trial published in 2001 in "New England Journal of Medicine" and it shown on the far left hand side of this graph. Mortality drops from 46 percent to 30 percent in patients who received this quantitative resuscitation or early goal-directed therapy.

And in the subsequent two panels, you see at 28 days and at 60 days that mortality benefit persisted. And so, based on the strong evidence at the time for randomized control trial in a Henry Ford Hospital in Detroit, recommendations change on an international basis for all patients who had severe sepsis or septic shock to have CVP, central venous pressure and ScvO2, central venous oxygen saturation check. And that's how this became part of NQF 0500 as a measure.

This therapy though was not an easy thing to do and it required replacement of the central line in patients; meaning [that] central access had to be obtained, which is a procedure for a patient to undergo and that is a procedure [that] has known risk[s] that are carried with it. And although the risks are low with this – with this procedure, central line placement; nonetheless, there can be complications in care.

And for this reason, there were some resistance nationally to doing early goal-directed therapy, although some centers quite well perfected it and we're doing it out of consistently for patients. But in this background, in this setting, there are a couple of trials that were launched and funded by the National Institute of Health. One of them are the ProCESS trial in the United States and two other trials, one called ProMISE which was done in the United Kingdom and ARISE which was done in Australia, New Zealand.

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And so, I'll tell you a little bit about these trials because what they did is they tested the concept of whether we had to do this quantitative resuscitation, this complex therapy for sepsis patients or not. Versus, whether we just allowed the providers to provide usual care that they would render in the hospital, if the patients were admitted. It didn't require a checking of those two parameters, hemodynamic CVP and ScvO2.

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The first trial that was published came out in March of 2014 and this was after the NQF measure had been passed. And so, NQF had already been calling for the use of early goal-directed therapy when this trial came out. And the trial's findings, I won't surprise you, suggested there was no difference between – between early-goal directed therapy and providing usual care in terms of mortality for patients.

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This was confirmed by a second publication in the "New England Journal" in October of that year. This was the Australian trial called ARISE.

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If we look at the results of the process trial – and I don't want you to review all the data on the slide, it's too much information; but, I ask you to look at the bottom. The bottom row, which is Primary Outcome: 60 day mortality. In the first column, called protocol-based EGDT, that's early goal-directed therapy, mortality was 21 percent. In the far column, under usual care, mortality was 18.9 percent.

And so, the conclusion was that statistically those two numbers were not different in the trial. And so, the therapy had no benefit or also no harm in taking care of patients.

Next trial – slide rather.

And, this slide summarizes the results from ARISE. And all that's really important is the top red box, which shows the primary outcome, again mortality. And, it compares them in the early goal-directed therapy group versus the usual care group. And, mortality again you can see was the same 18.6 versus 18.8. And so, with two big trials like this published in a major journal, it was very clear that early goal-directed therapy had to come out of NQF 0500.

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And, the sepsis campaign reached the conclusions as well right away, so that we could change our published stance on what was necessary care for patients with severe sepsis and septic shock. And so, we stated at that time, that the required monitoring of CVP and ScvO2 by a central line. It does not clearly confer survival benefit in patients who had been fully resuscitated and received their antibiotics. And, this was a major shift to both nationally and internationally – in the way we would care for patients with severe sepsis and septic shock.

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So, this had to had implications as well at NQF and at CMS, which was looking at developing a measure at that time as well. And the SEP-1 measure is based on the NQF 0500 measure to a large extent. The NQF 0500 measure was ultimately altered and I'll describe to you how that alteration occurred, to not require early goal-directed therapy. And SEP-1 nears that alteration and does not require early goal-directed therapy.

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So, if we were to look at SEP-1 in what we called a bundle format, which is not a part of the specification. It is not specified as a bundle has an actual numerator and denominator statemen, which you can find in the specifications. But an approximation, I'm going to show you this. Nothing really changes with the first three-hour pattern of care.

We measure lactate levels. Obtain blood cultures before antibiotics. Give broad spectrum antibiotics and for patients who are hypotensive or lactate greater than 4, they still get that fluid bolus. None of this is controversial. This is standard care practice for most patients across the country with severe sepsis and septic shock and almost all experts would agree that this is the appropriate strategy.

What did change though is where the ampersan) is and you'll note that now under SEP-1, the time of presentation is not as I described before under NQF 0500. But rather, it's going to be the time again where the earliest chart annotation consistent with all elements of severe sepsis or septic shock lined up and so that's the difference between the two and we'll discuss that in just a moment.

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And under SEP-1, the 6-hour pattern of care is also a bit different. So, item 5 and 7 have not changed. We still give vasopressors for patients who don't respond to fluids and we still re-measure lactate if the initial lactate was elevated. But item 6 is different and here what's called for is for patients who remained hypotensive or if their initial lactate was greater than 4, rather than calling for early goal-directed therapy, now we ask to re-assess volume status and tissue perfusion based upon those findings, which we have in table 1.

So, there are some strategies that you can use to document your re-assessment in volume status or tissue perfusion and those are some of the – next slide.

And, these are the strategies. So, SEP-1, we'll call for either repeat focused exam after the fluid resuscitation by licensing independent practitioner to include these elements here. Vital signs, cardiopulmonary exam, capillary refill, pulse and skin findings. Or, if you choose to do something that monitors the hemodynamics of patients, you can do that and so they are selected below to any two of the following items are appropriate.

Measuring central venous pressure, measuring central venous oxygen saturation depending on bedside cardiovascular ultrasounds and I'll tell you what some of those options are. We're doing a dynamic assessment for fluid responsiveness by doing passive leg raises or fluid challenges. And again, I'll describe what that strategy is like in just a moment.

So, the essential difference here between the previous iteration of the measure is that now there's no requirement for early goal-directed therapy and instead an option where you can do any one of the two following issues or the practitioner simply has to come back and do a repeat focused exam.

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So, let's talk about that difference in the change in Time Zero or when the time of presentation begins. So, under SEP-1, it's always going to be when the chart annotation suggests all the signs and symptoms are present. And so, what that means practically is you have to find a suspected source of infection.

You have to have two or more systemic inflammatory response criteria documented. Those are things like elevated white count, fever, low white count, etc. And then, you have to have an organ dysfunction, so some evidence that an organ is failing that will get you to severe sepsis and all of those things have to be found in the chart.

The sources of this information can be from nursing documentation, lab flow sheets or a physician has documented. And if all these things are time stamped, you can find the time. At which point, all the things are actually present and we call that Time Zero.

It could be triage time if all the signs and symptoms were present at triage. So, the best example, I think, is a patient in profound shock who arrives to the hospital. You know, raging pneumonia if it's obvious with cough, fever, hypotension, that patient is in shock at arrival and so the triage time would be an appropriate time to call the Time Zero.

If those things aren't obvious at triage, then you have to line them up through chart annotation.

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One other way in which SEP-1 will be different from the way that we previously measured care under NQF 0500 and in the sepsis campaign in particular, is [that] there will be two causes that are established. And, the first one is the point in time in which severe sepsis is noted and the second one is the point in time at which septic shock is noted.

In both of the times of – times of presentation for severe sepsis and septic shock have two counters, a three-hour counter and a six-hour counter. And so it describes patterns of care that have to be done for severe sepsis by hour three and hour six. And for septic shock by hour three and hour six from the time of presentation, so let me give you a clinical example of this.

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So, if a patient developed severe sepsis at 3 p.m. but didn't drop their blood pressure and become hypotensive and fail to respond to fluids until 5, you could ask the question, does the "shock clock" begins at 5 o'clock or is this start at 3 o'clock? And, if it begins at 5 o'clock, does the six hour window to complete the physical exam requirement, which is required under SEP-1, begin at 5 or does it begin at 3?

And, this is something that under the sepsis campaign, we would likely – would have said there was only one clock and it would have been at 3:00 p.m. and you only had until 9 o'clock to do this. Under SEP-1, that's going to be different.

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So, the answers are here. The severe sepsis clock would start with the presentation of severe sepsis. We said that was detected at 3:00 p.m. and the septic shock clock is going to start at the presentation of septic shock when the patient drop their blood pressure and that's a 5:00 p.m. And remember each clock has six hours and two counters.

So the patient – the presentation with severe sepsis at 3:00 will trigger the following counters to start at 3 o'clock. The sepsis three-hour counter where you would have to require an initial lactate measurement, antibiotic administration, and blood cultures. All of those things apply to the first three hours of care for patients with severe sepsis.

And then there's the sepsis six-hour counter, which would have to be completed by 9:00 p.m. for patients with severe sepsis and that is a repeat lactate level, if the initial lactate was greater than 2. So, all patients with severe sepsis are required to have those things, but patients with shock and other things and they're shown in the next slide.

So remember now, we detect the shock at 5:00, so the shock clock actually begins at 5:00 p.m. and that also triggers two counters, the shock three-hour counter, which would require 30 mL/kg of crystalloid fluid to be administered to the patient by 8:00 p.m. That'll have to be within three hours, remember? That's a three-hour requirement for patients with shock.

And then the six-hour requirements for patients with shock are under the shock six-hour counter, and that would get to be completed by 11:00 p.m., five hours or six hours after 5:00 p.m. And, that includes both vasopressor administration and then repeating the volume status and tissue perfusion assessment.

And, as we said, that's all items in table 1, it could be either to repeat physical exam or some of the hemodynamic checks that were on table 1. So, that's a very big difference between how the sepsis campaign used to measure care and what's called for now under the specification for SEP-1.

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So, I want to turn a little bit to the items that are in table 1, if I can for just a moment and tell you what this means for abstracters versus physicians. And, the intent of these slides that will follow are simply to clarify that although there's complexity in the clinical aspects of what is required at table 1, that clinical complexity is not required – is not necessary for abstracting the measure for abstracters.

So, if you chose to do one of the two options that – one of the four options are listed as two or four available, one of them is central venous pressure. And, all that the abstracters need to do is find whether or not central venous pressure was checked, and the answer is yes/no, it's binary.

If the doctor writes in a note, central venous pressure was obtained by – and it's a timed note, then that's all what the abstracter needs to have. I don't need the result of that number. I don't need to know how it was collected. I don't need to know what type of line was used and what catheter was deployed. All we have to know is that the physician has documented that CVP was checked.

For physicians of course, it's important to know what the results are and so the goal of the CVP should be between 8 and 12. And the assumption is that practitioners who choose this option would automatically choose to optimize that number but that's something they should know and not necessarily what the abstracters have to worry about.

Next slide.

Similarly for ScvO2 which is still an option to respond to simply yes or no again. The doctor writes ScvO2 is checked and there's a time stamp on that. If you find that information, then that's enough for the abstracter to say they met the measure under that category.

For physicians on the other hand, they need to know how to optimize that number. And so, if it's obtained from a different type of catheter Swan-Ganz Catheter versus a central venous catheter, then there's a difference in the Scv02 goal. And clinical will know this information due to their training that ScvO2 should be greater than 70 percent, whereas SvO2 would be greater than 65 percent. Again, a clinical complexity not required for understanding or use by abstractors.

Next slide.

So, this slide is for the bedside cardiovascular ultrasound option to complete item 6 in that bundle. And, I listed this here because if you – it is important for the abstracters to know which type of exams do we qualify for yes answers. So again, all we want to know is that the bedside ultrasound was done but you have to know what exams qualify.

And so, here under the third bullet point, the trans-thoracic echocardiogram is an appropriate study. The trans-esophageal echocardiogram is an appropriate study. And, IVC ultrasound, inferior vena cava ultrasound is also appropriate. And then, there's a strategy known as esophageal Doppler monitor. If a physician were to write any of those were done, regardless of the result, then that would be sufficient to have a yes response for having been completed.

To give you an idea of the clinical complexity though of this strategy, it's really isn't the yes/no. Under the physician's reference here, I've looked at a number of the clinical ways in which you can use the IVC ultrasound for example. And, one other thing for doctors to do is calculate the complex calculation called the caval index. The equation plus the here I won't go through it.

And then there's some correlation that exist between the inferior vena cava size when you measure with ultrasound and what the central venous pressure is, which you can find at the literature. And so, while we have – while this measure permits doctors the discretion to say they did the strategy or not, you have to understand that there's a lot of medical background that goes into what that strategy is. Again, not required to be known by abstracters.

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Passive leg raising is another opportunity for satisfying the measure, if required. And this again would just be documentation from a doctor that yes, I did a passive leg raise on this patient or no, I didn't do it or no documentation at all. This has to happen within six hours of the presentation with septic shock and so it would be part of the six-hour shock counter that would be triggered by presentation of septic shock.

And, the documentation would typically look like passive leg raise performed and then positive or negative, although the results again doesn't matter to the abstracter, just that it was actually conducted. Another strategy in addition to passive leg raising which is mentioned in the measure is you could do a fluid a challenge instead, which is the administration of a bolus of saline and then that is also appropriate as documentation that definitely challenges to administer.

For doctors, this is actually much more complicated than it reads. You actually have to know something called cardiac output before you do the procedure and then after the procedure or stroke volume. And getting those two numbers typically has been an invasive strategy that was required. Although, there are now some newer techniques that are minimally invasive or non-invasive all together that can be done in hospitals.

But, it is probably a surprise to many providers that, if you want to do passive leg raise or fluid challenge, that you have to obtain a value for cardiac output or stroke volume first and so it's not as easy as it sounds.

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And so, the last piece that I'll go over is the repeat physical exam. And here again for the abstracter, it simply was the exam done or not but the requirements for the exam are specified. And so each of the element has to be present in the documentation, that includes the vital signs which has to be – include temperature, heart rate, blood pressure, and respiratory rate.

And, a cardiopulmonary exam which would typically look like, "HEART:" with specific set of findings or "LUNGS:" with specific set of findings and a peripheral pulses has to be documented and capillary refill has to be documented and the skin exam was completed has to be documented.

So, it turns out for the abstracter under the repeat exam, there are actually multiple parts. There are 10 parts in total, if you think of it, temperature, heart rate, blood pressure, respiratory rate, cardiac exam, pulmonary exam, peripheral pulses, capillary refill and skin exam. All those must be present to meet the physical exam requirement.

And, that's my next slide, that's what I wanted to tell you about SEP-1 and [what] some of the differences are from old NQF 500. And, if there are any questions, when it's appropriate, I'm glad to take them.

I'll turn it back to Candace.

Candace Jackson: Thank you Dr. Townsend and I'd like to thank all of our speakers for the information that they shared with us today.

Next slide please – oh no. Before we – go back please, OK, next slide please, sorry.

Before we see if we have any time for any questions that were sent in, I would like to tell everyone that questions that they submitted through the chat line will be responded to and posted at a later date, in about 10 to 14 days from now. So your questions will be responded to if it did not get responded to today.

I would like to also remind you that today's webinar has been approved for one continuing education credit by the boards listed on this slide.

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We now have an online CE certificate process. If you're registered for this webinar through Ready Talk, a survey will automatically pop up when the webinar closes. We will also be sending out the survey link and an e-mail to all participants within the next 48 hours. If there are others listening to this event that are not registered in Ready Talk, pass the survey to them.

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I would also like to take this opportunity to let everyone know that we will continue to have education regarding the sepsis measures in August, September and October. These education webinars will focus on the numerator and denominator of the measure, the exclusion, the algorithm and data abstraction guideline and this will be presented by Mathematica during these months, so there will be some information coming out shortly in regards to the three months of education regarding the sepsis measure.

At this time, we might have time for one question to be answered and Dr. Townsend. I think I would direct this to you and then, if we need Mary and Dr. Evans to voice in, we can. But, there was a lot of questions about when did the time of presentation occur.

So, for emergency department patient, that the criteria for severe sepsis or septic shock, is the time of presentation the arrival? For example triage time or the time that was severe sepsis or septic shock criteria are met during their ED stay?

Sean Townsend: I just wanted to be very clear, it's the time in the chart in which all the elements of severe sepsis or septic shock are present and documented. It is not necessarily triage time. So in an emergency department with the nurse written a note, there's a cellulitis at 10:05. There's a set of vital signs that shows heart rate of 120 and a respiratory rate of 30.

At 10:06 and at 10:07, a lab report comes back that says the creatinine is now elevated to 2.0. And the physician has documented similarly at 10:08 that the patient has a cellulitis, I now have all the elements present to say that there is severe sepsis in this patient. I have a suspected source, criteria, and an organ dysfunction. And the last time stamp element is the physician documentation at 10:08 and we'll take that as a start time.

Candace Jackson: Thank you Dr. Townsend. I have a couple of questions for Mary. One question that we got regarding, what does HANYS stand for? I don't believe we put on the slide show.

Mary Therriault: Sure.

Candace Jackson: Can you – [are you] able to explain that?

Mary Therriault: Yes, it's the Healthcare Association of New York State. We are an advocacy organization that supports the entire state for many, many things and sepsis being one of them.

Candace Jackson: Thank you Mary and we had a couple of questions asking if the HANYS' Data Collection Tool is available to be shared and if the Hospital Sepsis Care Resource Manual is available to be shared?

Mary Therriault: Yes, I will get those to you.

Candace Jackson: OK. And then another question that I saw quite frequently was in relation to the administration of crystalloid fluids. And the question we had was can you address the administration of crystalloid fluids, it is unclear whether the initiation of the 30 mg/kg is once severe sepsis is identified or once the patient is determined to be in septic shock?

Sean Townsend: The – it is the time in which the patient has hypotension it's when these fluids are administered. And after, if there's some response to the fluids, then septic shock is declared.

Candace Jackson: Thank you, Dr. Townsend.

Sean Townsend: The difference is actually between hypotension and septic shock. Hypotension triggers the fluid administration.

Candace Jackson: And we had question asking, is the measure for facilities with ICUs only and I will say for CMS it is all patients that meet the criteria for septic shock. Dr. Townsend or Mary or Laura, is there anything that you need to add to that?

Sean Townsend: No, I think that is correct.

Mary Therriault: That is correct – same and that's the same for New York, it's all inpatients, outpatients, emergency department and of course we have pediatric patients too.

Candace Jackson: Thank you and we seem to have a lot of questions asking if nursing documentation was acceptable for the SvO2 or CVP or does it have to be physician documentation?

Sean Townsend: The documentation has to be in the provider note.

Candace Jackson: Thank you and we are at the top of the hour now, so there will be no more time for any further questions. Again, we thank you for joining us today and I hope that you found the information provided to be very beneficial and useful to you. And thank you and have a good afternoon.

Operator: This concludes today's webinar. You may now disconnect. Speakers, please hold your line.

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