Inpatient Quality Reporting Program

Support Contractor

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

Presentation Transcript

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October 6, 2015
2 p.m. ET

Matt McDonough: Good afternoon or morning, depending on where you are. Thanks for joining us for today's webinar. My name is Matt McDonough and I'm going to be your virtual host for today's event. Before we get into the content of today's event, I'd like to cover some housekeeping items with you, so that you know how today's event is going to operate and how you can submit your questions to our panelist throughout the course of today's event. As you can see on this slide, audio for this event is available via internet streaming. It means that you're hearing my voice over your computer speakers hopefully and that no telephone line is required. But, you do need to have those speakers or headphones connected to hear that streaming audio feed. Now, if you don't have speakers or headphones or they're working intermittently, we do have a limited number of dial-in

telephone lines. Please send us a chart message and we'll get those dial-in lines out to you as quickly as possible, if you need one. Also, as a standard matter, this event is being recorded and will be published on the website. The raw version of this will be published and a fully captioned version will be available within the next few weeks.

So, if you're streaming audio today, you may encounter some common issues such as your audio breaking up over your speakers. Or, if your audio suddenly stops completely, here's how you can resolve that situation. Simply, click the pause button that's located in the upper left side of your screen, as illustrated on this slide. Wait about five seconds once you do that, and then click the play button. Your audio feed should resume and should also be caught up to our current speaker, if it's lagging behind a little bit.

Now, if you hear my voice with a terrible echo right now, that usually means you're connected to this event in more than one browser or more than one browser tab. That means you're hearing my voice twice over multiple audio feeds. Easy to fix this one, simply close those multiple connections, just leave one of them open and once you're hearing only one audio feed that echo will clear itself up.

Now, we are in a listen only mode today, but that doesn't mean that you can't submit your questions to our presenters today at any time. In the bottom left corner of your screen, as illustrated here with the yellow arrow, there is a chat with presenter box. Simply type your question into that box, and click the send button. All of our presenters that are online will see your questions that are submitted today, and as time and as resources and as the availability of answers allows, we'll answer as many questions as we can today. But, please do keep in mind that all of your questions are being archived for a future Q&A document.

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

Candace Jackson: Thank you, Matt. Hello and welcome to the IQR Open Door Forum *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, www.qualityreportingcenter.com within two days and will be posted to QualityNet at a later date. As this is an open door forum there are no slide decks for today's event. And now, I would like to introduce the subject matter experts 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 sustains 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, lead physician and policy adviser for the Centers of Medicare & Medicaid Services' Hospital Value-Based Purchasing Program. The aim of this program is to link Medicare's payment system to the quality of care provided, not simply the quantity of care. His team's mission is to transform Medicare from its historical role as paying the bills to a new paradigm where Medicare promotes better care and population health by linking payment to the measures 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.

Dr. Rivers serves as the vice chairman and director of research in the Department of Emergency Medicine and a senior staff attending physician in the Surgical Critical Care Unit and the Emergency Department at Henry Ford Hospital in Detroit, Michigan. Additionally, he's a full clinical professor at Wayne State University and serves as a consultant for the American Board of Emergency, American Board of Internal Medicine, Centers for Medicare & Medicaid Services and the National Quality Forum. Dr. Rivers implemented the first national sepsis measure, the National Quality Forum sepsis measure 0500, which was approved in March 2013 and now has been adopted by CMS as SEP-1. Dr. Rivers received his Bachelor of Science, Master of Public Health, and Doctorate in Medicine from the University of Michigan in Ann Arbor, Michigan.

We also have with us today Bob Dickerson. Bob Dickerson is the Lead Health Informatics Solution Coordinator for the Measure Development and Maintenance team at Telligen. He’s a registered respiratory therapist with a Master of Science degree in Healthcare Services Administration from the University of St. Francis in Joliet, Illinois. Most recently, Bob has been supporting CMS with development and maintenance of hospital, clinical, quality measures. Bob has extensive healthcare process and quality improvement experience, including development and implementation of interventions, processes and systems in a hospital setting to support the national quality measures. His experience includes facilitation and intervention implementation, data collection, and process improvements related to severe sepsis and septic shock in the hospital setting for the Surviving Sepsis campaign.

We will now start our open door forum with the first question. The first question we have is: what are acceptable, initial IV fluids for resuscitation with the SEP-1 measure? Dr. Townsend, would you like to address this question?

Sean Townsend: Sure I would. Thank you very much for the opportunity to address this. The measure– it's acceptable for crystalloid fluids to be used for the resuscitation of patients with severe sepsis or septic shock. We've typically referred to normal saline as being the go-to product and the most available resuscitation fluid in emergency departments and hospitals across the country. Most studies that have been done on septic shock have said resuscitation with crystalloids is the initial first step. So, normal saline is our preferred choice.

Candace Jackson: Thank you. Dr. Rivers or Dr. Tefera, do you have anything to add?

Emanuel Rivers: If one choses to use colloid, obviously that is a clinical decision. Colloids do carry an increased plasma volume of one to five, in terms of volume given. So, adding colloid, although not consider an equivalent with crystalloid therapy, is a clinical decision that can be made.

Lemeneh Tefera: And, just to be clear about besides normal saline, the specification also allows for Lactated Ringer's.

Candace Jackson: Thank you. So, to recap, the responses for this question. The only acceptable crystalloid fluids are 0.9 percent normal saline or Lactated Ringer's solution. Colloids can be given in addition to crystalloids, but colloids cannot completely substitute crystalloids for the purpose of the measure.

Our next question is: what information must be included in the physician/APN/PA order for crystalloid fluid? And, Dr. Townsend would you like to address this question?

Sean Townsend: It's most helpful for purposes of the abstractors, who will be reviewing this information, if the order is complete. So, if the order contained, not only the name of the resuscitation fluid, either Lactated Ringer's or normal saline, but also the entire volume to be infused and the time over which it is to be infused, those things will make it possible for the abstractors to determine whether an appropriate quantity of fluid was given to the patient.

Candace Jackson: Dr. Rivers, would you like to add anything to this?

Emanuel Rivers: No, that is fine.

Candace Jackson: And Dr. Tefera?

Lemeneh Tefera: Sorry, nothing further.

Candace Jackson: OK. So, to recap this question, the response is: standard documentation requires a provider order to include the crystalloid type, a route and rate or time over which this fluid is given. This is the current standard of documentation for fluid and medication. Sepsis one requires providers follow this existing customary standard. The orders must include a volume equivalent to 30 millimeter per kilogram and a rate or timeframe over which to give the crystalloid fluids. The terms bolus, wide open, or STAT in an order does not specify a rate or time over which to infuse the fluid and cannot be used. The order can be a single order or series of orders, as long as the total volume is equivalent to 30 milliliters per kilogram.

Question three: are there any exclusions for the 30 milliliters per kilogram crystalloid fluid replacement– or requirement? – Excuse me. Dr. Townsend?

Sean Townsend: Candace, can I ask you just to repeat the question one more time?

Candace Jackson: Are there any exclusions to the 30 milliliters per kilogram crystalloid fluid requirement?

Sean Townsend: Oh, the crystalloid fluid requirement of 30 ml per kilogram applies to patients who have either hypotension or who have a lactate greater than four after having other signs and symptoms of sepsis, including a suspected infection in two SIRS criteria, as well as organ dysfunction. Those patients all qualify for fluid administration. In terms of exceptions for the fluid administration, the measure has not identified any cases other than– any cases of all that are exempt from the administration of the fluid requirement. And, the reason for this is if that these patients are presenting to us in septic shock rather than any other condition. Often times clinicians

will worry about congestive heart failure or associated renal failure that these patients may have and fear that the patients would become intubated. However, the studies that have been done both Dr. River's initial trial, and the subsequent trials that were done in septic shock, show no higher rates of intubation in patients with associated congestive heart failure or renal failure. As such, there are no lists of exceptions for this particular fluid administration.

Candace Jackson: Dr. Rivers, would you like to add anything or comment any further?

Emanuel Rivers: Yes. In addition to Dr. Townsend's statement, we did a sub-analysis of those patients who are on end stage– who're with end stage renal disease who are on hemodialysis, approximately 10 percent of our patient population. And, what we showed is that with that fluid challenge, there was actually a decrease in the amount of patients who eventually required mechanical ventilation as well as mortality. So, there was significant benefit even in renal– end stage renal disease patients.

Candace Jackson: And Dr. Tefera, do you have anything else to add?

Lemeneh Tefera: Nothing further.

Candace Jackson: OK, thank you. Our next question: what weight should be used when determining the 30 millimeters per kilogram volume and rationale as to why? And Dr. Townsend?

Sean Townsend: I can tell you that this has been a recurrent question throughout the history of the Surviving Sepsis campaign and in these– the NQF measure, now with SEP-1 as well. And, the answer to the question to be clear is actual body weight. There are reasonable debates to be held about whether we should be using ideal body weight, especially for morbidly obese patients, but it's not ever been carved out from the clinical trials on septic shock resuscitation. Such patients have never been actually clearly identified as being part of the trial and the sub-analysis done of the effect of the volume infusion on those patients. Thus, all we have is actual body weight to go by, at this point in time in the literature. And so, we've recommended that degree of infusion for patients.

Candace Jackson: And Dr. Rivers, do you have any…

(Crosstalk)

Emanuel Rivers: No, no ideas no comment.

Candace Jackson: And Dr. Tefera?

Lemeneh Tefera: I just– I'd just note that this issue of ideal versus actual weight is not specific to the SEP-1 measure. It comes up with multiple other medications and it's an ongoing discussion. But, I'd just like to remind folks that this is not unique to this measure.

Sean Townsend: And, I guess I can make one more remark. This is Dr. Townsend again. In all cases, you know, regardless of whether there is a measure in place for the care of patients, I think all of us will agree, if it's the case that in your clinical judgment something was unsafe for a particular patient, then those are the decisions you should rely upon as opposed to the guidance of the measure. The measure is simply for the majority of care, a majority of cases that we encounter with this condition. The expected care should conform to the measure. If there was an extraordinary case of a patient that weighs 700 some odd pounds, for example, and you felt unsafe in your actions, then you should clearly make the decisions you think are appropriate for the patient.

Candace Jackson: Thank you. We would now like to ask our first polling question. And, the first call-in question asks: from the questions and responses that have been provided, do you now have a better understanding of a crystalloid fluid administration requirement? And the responses are yes or no and we will give this just a second.

Matt McDonough: Hey, Candace I apologize. The poll was inadvertently closed early so let me go ahead and reinsert that poll question.

Candace Jackson: OK.

Matt McDonough: The slide deck keeps moving, unfortunately from a– I'm not sure why, but this poll question is now open and you can now provide your answers to this question as we... thank you.

Candace Jackson: We'll just give this a second for everybody to provide their responses.

Based from the responses that we are receiving, it says up here that everybody does have a better understanding of the crystalloid fluid administration. Dr. Townsend, Rivers, or Dr. Tefera is there anything else you would like to add in regards to crystalloid fluids? Any other comments or responses that you can provide?

Sean Townsend: No, thank you.

Emanuel Rivers: This is Dr. Rivers. One thing I'd like to reiterate is that we were very aggressive with central venous monitoring in our study and even after the fluid challenge, we found the predominant number of patients continue to have lower central venous pressure that required additional fluids. So, on the whole, there were no patients that were sent into pulmonary edema or respiratory failure as a result of fluid challenge.

Candace Jackson: Thank you. OK, our next question, there is some confusion regarding when triage time is used. For the Surviving Sepsis campaign it was used for all cases in the ED, can you please clarify when triage time is used and Dr. Townsend can you respond to that question?

Sean Townsend: SEP-1 differs from the traditional use of triage time in the Surviving Sepsis campaign for sure. Triage time can be the time of presentation under SEP-1 only if the patient arrives at triage with all the necessary qualifications for severe sepsis or septic shock. The most likely presentation, triage for example, would be septic shock where it can be easily identified that a patient has a productive cough, fever, tachycardia, and is hypotensive for example. These particular criteria would at least satisfy severe sepsis for initial hypotension and possibly septic shock later on, if the patient received fluids and had recurrent hypotension. So, these are– but that's the conditions under which triage time would be the appropriate time to use for SEP-1 abstraction. However, the measure does

require that all the clinical criteria are present and aligned before the counter presentation can be determined. So, if the patient is not positive at triage, then the patient would be identified by the alignment of documentation of suspected infection, documentation of two SIRS criteria, and then an organ dysfunction at any point in time. The last point in time, as long as all those are within three hours or each other, would qualify as the time of presentation.

Candace Jackson: Thank you. Dr. Rivers do you have anything to add to that?

Emanuel Rivers: No additional comment.

Candace Jackson: Dr. Tefera?

Lemeneh Tefera: No further comments.

Candace Jackson: So just to recap…

Bob Dickerson: Hey, Candace?

Candace Jackson: Yes?

Bob Dickerson: This is Bob Dickerson, I just wanted to make one comment that I believe I heard Dr. Townsend's response say they need to be met within three hours of each other, and it's actually, per the specification guidelines, they need to be met within six hours of each other.

Sean Townsend: That's great Bob, thank you for correcting me. I appreciate it. I probably misspoke.

Candace Jackson: Thank you, Bob. So just to recap our answer, triage date and time are only used for patients who arrive to the ED with severe sepsis or severe sepsis as it is identified at triage. This would require that all the clinical criteria be present prior to or during triage, or the physician documents severe sepsis or septic shock prior to or during triage, or documents the patient has severe sepsis or septic shock on arrival to the ED. If severe sepsis is identified after triage, either while still in the ED or after admission to the hospital, the date and time would be when the last of the clinical criteria

are met or the physician documents severe sepsis or septic shock, whichever is the earlier of the two.

Our next question: what information must be included in the physician/APN/PA order for a fluid challenge? Dr. Townsend.

Sean Townsend: The information that should be included in the order for a fluid challenge would be, as we discussed earlier in the call, we want to have the volume to the infused, the type of fluid that's being infused, whether Lactated Ringers or saline, and the time course over which that volume was to be given.

Candace Jackson: Dr. Rivers do you have anything to add to that?

Emanuel Rivers: No additional comment.

Candace Jackson: Dr. Tefera any additional comment?

Lemeneh Tefera: None.

Candace Jackson: OK, so to recap the fluid challenge performed data elements indicates a fluid challenge as the rapid infusion of 0. 9 percent saline or full strength Lactated Ringers, typically 500 millimeters in 15 minutes or 1000 millimeters in 30 minutes. The physician/APN/PA order must include wording, such as fluid challenge, fluid bolus, rapid fluid infusion, or similar terminology, and the type of IV fluid, the volume to be given, and a time frame over which to infuse it.

Our next question: what defines the start time of severe sepsis or septic shock, in which the clock starts for treatment? Would this be based on a documented diagnosis, a specific lab value, et cetera?

Sean Townsend: This is Dr. Townsend. The clock starts for severe sepsis or septic shock when all the elements of those diagnoses are present. So, establishing the presence of severe sepsis or septic shock is based either on clinical criteria being met by the physician, APN, or PA documentation, whichever comes first. The clinical criteria for severe sepsis are documentation of suspected infection, two or more SIRS criteria, or sign of an organ dysfunction, and

these must all occur within six hours of one another. When the last criteria is identified, the septic– the severe sepsis clock will then start. The clinical criteria for septic shock are the presence of severe sepsis with either persistent hypotension after the 30 ml per kilogram of crystalloid are infused or an initial lactate greater than four. As with severe sepsis, when the last of the criteria for septic shock is met, the septic shock clock starts. Again, physician, APN, or PA documentation of severe sepsis must include the word severe. Documentation of sepsis alone would not be sufficient.

Emanuel Rivers: This is Dr. Rivers, and again, the hemodynamic criteria of lactate, as well as hypotension, were used because many times patients upon presentation won't have laboratory values and also defined organ dysfunction immediately. So, the basis of having the hemodynamic criteria is you can make a quick and easy decision early, such as the emergency department.

Candace Jackson: Dr. Tefera, do you have anything to add to that?

Lemeneh Tefera: Just to emphasize that the criteria are not fully focused on the SIRS criteria. There are many folks who identify the SIRS criteria and feel that they're the driver for the diagnosis of severe sepsis. In fact, there has to be multiple criteria met to meet the definition of severe sepsis and that is clear in the specification.

Emanuel Rivers: And, this is Dr. Rivers. Once again, I would like to reiterate that these are what they call risk stratification procedures, so when you look at hypotension plus lactate, recent analysis in the Surviving Sepsis campaign database showed that hypotension or lactate greater than four corresponds with a mortality of 28 percent to 29 percent. So, these are not only diagnostic, but as well as prognostic risk stratifiers.

Candace Jackson: Thank you, OK. We would like to ask another poll question at this time. Matt, our second polling question?

From the clarification provided, is it now clear when the start time for severe sepsis or septic shock occurs? And we'll give a minute to let everyone respond.

And, from our polling questions, it does appear that most everybody does now have a clearer understanding as to when start time for severe sepsis or septic shock does occur.

So, we will move on. Our next question: do the data elements for the focused exam have to be found in a single provider note? And Dr. Townsend?

Sean Townsend: To be clear, the elements of the exam all have to be documented, but they don't have to be of a single provider note. So, being in different sources or in separate provider notes will be acceptable for purposes of abstraction for SEP-1. Just to note for the vital signs review, all the elements must be included, which includes temperature, pulse, respiratory rate, and blood pressure with values, and those should be in a single note.

Candace Jackson: Thank you. Dr. Rivers or Dr. Tefera, anything to add to that?

Emanuel Rivers: No further comment.

Lemeneh Tefera: No comment.

Candace Jackson: And our next question: are all cases evaluated for whether or not antibiotic given were consistent with those on tables 5.0 and 5.1 in the specifications manual? And, I will direct that question to Bob Dickerson.

Bob Dickerson: So, the only cases that are evaluated and compared to the antibiotics that are in table 5.0 and5.1 are going to be when the only time a patient received their antibiotics was within three hours following severe sepsis presentation. Any antibiotics received in the 24 hours prior to severe sepsis presentation are not subject to that comparison. And, if the patient receives the antibiotics on both the 24 hours prior and the three hours after, that patient would also not be one where you would have to check and see if there were any of their antibiotics on the table 5.0 or 5.1. So, it's only the situations where the only antibiotics received were in the three hours following severe sepsis presentation.

Candace Jackson: Thank you, Bob. And Dr. Townsend do you have anything to add to that response?

Sean Townsend: No, I think Bob has it complete.

Candace Jackson: We will go ahead and go to our next question. Was there any other discussion from Dr. Rivers or Dr. Tefera regarding that question?

Emanuel Rivers: No, this is Dr. Rivers, none.

Lemeneh Tefera: None, thank you.

Candace Jackson: The next question we have: the requirement of broad spectrum antibiotics appears to be inconsistent with antimicrobial stewardship efforts and clinical guidelines. Can you please comment on this? Dr. Townsend?

Sean Townsend: I'd be glad to. The– I'd like to begin with reminding the callers that the majority of severe sepsis cases present with unknown ideologies or with unknown specific pathogen or the susceptibilities to that pathogen. And, I'd also remind everyone that the mortality associated with a single organ dysfunction in severe sepsis has been estimated to be about 20 percent, so that, one out of five patients end up dying from this disease. And, we know very well, if you guess wrong, if you picked the wrong antibiotic up front, the likelihood of mortality increases dramatically over time. So therefore, the Surviving Sepsis Campaign International Guidelines in evaluating the evidence, which were endorsed by the Infectious Disease Society of America, indicate that the initial choice should include a broad spectrum antibiotic to cover patients. This is just critical because there's a fivefold increase in mortality, if you guessed incorrectly. Now, as for the measure, SEP-1 only deals with the initial antibiotics, so in this regard that it doesn't contradict antimicrobial stewardship efforts. If antibiotics are started in the period 24 hours prior to presentation, the organism may be known and those antibiotics are not subject to comparison to the broad spectrum antibiotic tables or the requirement. If the antibiotics are given only in the three hours following the presentation of severe sepsis, the likelihood of knowing the organism is much lower, and those are susceptible to the antibiotic tables. There is still the opportunity to engage

antimicrobial stewardship in the management of these patients because the measure is only concerned with the initial 24 hour range, especially the six hour range. There can always be decisions made in subsequent time periods to curtail the antibiotics or cut back to something that's less broad. In fact, the Surviving Sepsis campaign guidelines recommend just that, that we continue to have anti-microbial stewardship because of the initial selection of broad spectrum antibiotics.

Candace Jackson: Thank you, Dr. Townsend. Dr. Rivers, would you like to add anything from what Dr. Townsend provided?

Emanuel Rivers: Just reiterate the article you refer to was in 2009 over 57,000 patients showing that fivefold increase in mortality with an incorrect antibiotic. In addition, there are studies that show that actually de-escalation early correlates with improved mortality. So, I think at both ends obviously aggressive antibiotic therapy, but also correct antibiotic therapy is key.

Candace Jackson: And Dr. Tefera, would you like to add anything else?

Lemeneh Tefera: Just to reiterate that CMS strongly believes and encourages the anti-microbial stewardship program supported by CDC and the White House campaign. CMS has had direct discussions with CDC regarding this measure and we both believe that early antibiotics is critical to the care of septic patients. So, this measure in our policy is consistent with both anti-microbial stewardship and CDC policy.

Candace Jackson: Thank you. Our next question: sepsis guidelines and the SEP-1 measure information form reference getting a repeat lactate [if] the initial is elevated. Our lab considers 2.2 to be the upper limit; can you please clarify what lactate level warrants a repeat and what level indicates the presence of septic shock? Dr. Townsend?

Sean Townsend: Sure, the key numbers to remember for lactate are always two and four. So, a lactate level of two warrants a repeat lactate level, and yes as the question indicates, this may be different than what your reference lab has determined to be the upper limit of normal for your facility, but on balance this is typically considering the literature to be an elevation, which is

thought to be abnormal and unusual. A lactate of two is also a qualifier under SEP-1 for an organ dysfunction. It suggests that the patient has sustained organ dysfunction. Lactate greater than four, on the other hand, is an indicator of tissue hypoperfusion. It indicates the presence of septic shock.

Candace Jackson: And Dr. Rivers, would you like to comment any further?

Emanuel Rivers: And, there will be some variation based on how lactate is measured. You can have– pin prick lactate tend to be measured in milligrams per deciliter or millimoles per liter so it's very important to know your reference point. They don't deviate a lot from 2.0, but there will be some that will be mildly lower or elevated above two. But, I want to re-emphasize the point that Dr. Townsend said, that lactate greater than four is a risk stratification procedure and across the board Surviving Sepsis campaign correlated mortality from 28 percent to 30 percent where an initial lactate of four even without hypotension.

Candace Jackson: Thank you. And, Dr. Tefera anything else to provide? Any additional information?

Lemeneh Tefera: Nothing further.

Candace Jackson: OK, thank you. And the next question: I am finding the criteria from when to administer the 30 milliliters per kilogram of crystalloid fluid to be a bit confusing. The measure indicates they should be given within three hours of septic shock presentation, but aren't they required to determine presence of septic shock, can you please clarify? Dr. Townsend?

Sean Townsend: I think I can address the question. The timing of crystalloid fluids depends in part on how septic shock presents. If septic shock presents a severe sepsis with persistent hypotension, by definition the crystalloid fluids would have to be already given. In this situation the patient will have presented with severe sepsis and hypotension, the crystalloid fluid will be given to treat the initial hypotension. The lack of a response indicates the presence of septic shock. In this case the crystalloid fluids started prior to septic shock presentation. If, however, the patient presents with severe

sepsis and a lactate greater than four, the patient is identified as having septic shock based upon the initial lactate level. In this situation, septic shock is not identified based on the administration of fluids. The fluids should be given, however, to treat the hypo– the tissue hypoprofusion evidenced by the fact that lactate is greater than four. So, in this case the crystalloid fluid started after septic shock presentation. In the event that septic shock presentation is based upon provider documentation, when the crystalloid fluids started may vary depending on the timing of provider documentation. And that is covered by the fact that we're allowed to have three hours within the time of presentation to determine the present septic shock.

Candace Jackson: Thank you, Dr. Townsend. And Dr. Rivers, would you like to add any additional information to that?

Lemeneh Tefera: No, just to refer the attendees to an article by Lee and Ches in 2004 where they showed that increased fluid administration in the first three hours of sepsis resuscitation is associated with reduced mortality. So, it's both a diagnostic and therapeutic maneuver.

Candace Jackson: OK. And that leads us to our last polling question: from the information provided do you have a better understanding of the broad spectrum of antibiotics, excuse me, from the information provided do you have a better understanding as to why broad spectrum antibiotics are used to treat severe sepsis?

Anyway, we'll give that a minute for everybody to present their responses.

And, it does look from our responses that are coming through that most everyone does have a better understanding of why we are using broad spectrum antibiotic to use– treat the severe sepsis.

Our next question: would a physician/APN/PA consultation documentation 24 hours after arrival of severe sepsis present on arrival make the time severe sepsis present triage time, even if the patient did not meet all three criteria for severe sepsis present?

And does one of our subject matter experts want to address that question?

Please let me know if you would like me to repeat the question?

Male: Could you please repeat the question?

Candace Jackson: Would physician/APN/PA consultation documentation 24 hours after arrival of severe sepsis present on arrival make the time severe sepsis present triage time, even if the patient did not meet all three criteria for severe sepsis present?

(Crosstalk)

Male: Sort of.

Male: Go ahead.

Sean Townsend: This is Sean Townsend, I was going to say that the question– I do have to say that I have trouble understanding some of the meaning to the question, but as I understand it, the question is asking if the consultation note that is entered into the records 24 hours after the time of presentation, indicates that the patient has severe sepsis or septic shock, would that make triage time the time of the patient was diagnosed as severe sepsis or septic shock. And, I'm assuming that the note would have to say that triage time was that time, and so that's the assumption I would have to make. And, I think that the answer to this question is no. It's not clear at all that the note, entered 24 hours in consultation after the time of presentation when none of the signs and symptoms of the disease were present, could indicate that the provider could assign triage time to be the time of presentation.

Candace Jackson: Thank you. Will anybody else on the panel like to provide any additional information?

Bob Dickerson: This is Bob. I think the response to a question like this is going to depend on information that we're– it doesn't sound like we really have in the question. Based on the description that Dr. Townsend gave, I would agree with him. You know if there– if there was documentation where a physician would indicate the patient arrived with severe sepsis depending

on what other documentation is in the medical record, that may actually result in a yes response, but I think there just doesn't seem to be enough clarity to that question to fully address exactly– a really good response.

Sean Townsend: I agree with Bob, I also– I prefaced my answer based upon the assumptions that I made, but I'm not sure that the questioner asked that question.

Candace Jackson: Right, thank you. Our next question: is a diagnosis like pancreatitis, viral gastroenteritis, cholecystitis, influenza, et cetera, acceptable for source of infection for severe sepsis?

Sean Townsend: This is Sean Townsend. I would say yes anytime there's a suspected– in fact, even absent the naming of the specific infection, suspected inspection stated is simply adequate documentation. So, as long as there is suspected infection, even without further declaration, that is a reason to consider the patient qualified in terms of the suspected infection requirements, the diagnosis of severe sepsis or septic shock.

Candace Jackson: And would any of the panel members like to add on to that?

Emanuel Rivers: As far as an emergency presentation, it's important to understand the risk stratification importance, so that if you have suspected infection along with refractory hypotension or with lactate greater than four, that puts patients into high risks categories, irrespective of whether the ideological cause is a pure infection or not.

Candace Jackson: Thank you. And the next question: are pregnant and postpartum women excluded from the initial patient population for the sepsis bundle measure.

Sean Townsend: This is Sean Townsend, there is non-exclusion for pregnant and post-partum patients or individuals from the measure.

Candace Jackson: Thank you and any other additional comments from any of the others?

Emanuel Rivers: No further comment.

Lemeneh Tefera: None.

Candace Jackson: Our next question: will you pull from more than one set of vitals to meet two pieces of SIRS criteria. And, I'm not sure if there's enough information to answer that question.

Sean Townsend: This is Sean Townsend, and I'll take a stab at it and Bob, if you think I answered incorrectly, I ask for your advice. But, I believe that, if the vitals are recorded sequentially, so for example at 11 o'clock, a blood pressure was taken and then at 1:15 a temperature was taken, you could pull from both of those different time points to determine two SIRS criteria. It's unlike the provider note situation where we're asking for all the vital signs be included in a specific location.

Bob Dickerson: This is Bob. I think you responded to that very well. There may be times where all vital signs are not recorded or taken at the exact same time or they may be sequential.

Candace Jackson: OK. And, our next question: could you help me understand how they determine what a normal systolic blood pressure is? I recall reading somewhere that this is the last of three consistent readings, does consistent also mean consecutive?

Sean Townsend: Oh boy. This is Sean Townsend that's a big question with again some assumptions that are hard to reconcile. I don't think that blood pressures to last three consistent readings for purposes of this measure.

Candace Jackson: And does any of the panel members have anything to add to that?

Emanuel Rivers: No.

Lemeneh Tefera: No.

Bob Dickerson: I would just add that this has been– this has been a question that we've received frequently, and it's really difficult to pin down an answer on it. So, we are critically looking at the data elements that have that within them and trying to identify a better way to address the drop of greater than 40 millimeters in mercury in systolic blood pressure.

Candace Jackson: Thank you. And our next question is in regards to the passive leg raise maneuver. What is the amount of time that the legs need to be raised to perform it correctly?

Sean Townsend: So, this is Sean Townsend, and I'll answer this by saying this. The answer to that question is of no matter whether you pass the measure. And by that, I mean that, as long as there's documentation that a passive leg raise test was performed, regardless of the results or how it's done, the abstractors will take that documentation as passive leg raise having been performed. Now, it's very important on the other hand to do it correctly from a clinician standpoint. Otherwise, this would result in a, to be colloquial, garbage in, garbage out situation where you're doing the testing correctly and you're not interpreting the results to be meaningful. So, what institutions typically to do with passive leg raising is they adopt protocols. I've seen various times attached to that number and different protocols are in use. And these are widely available, many of which you can download from healthcare systems that are using this test on the Internet.

Candace Jackson: And does anybody else who has any additional information that they would like to provide?

Male: No.

Candace Jackson: Thank you. The next question: does the lactate have to be drawn in the hour after crystalloid fluid administration, or can it be drawn earlier?

Sean Townsend: I see. The question– it appears to be regarding a repeat lactate requirement. And the question is; can it be done before crystalloid is completely diffused likely referring to the 30 and up kilogram fluid bolus. The answer is it could be done prior to the infusion of the crystalloid or after.

Candace Jackson: Thank you.

(Crosstalk)

Bob Dickerson: Candace, I would– I would. Yes, this is Bob. I would only follow-up with one– with one thing on that. I think the response is very good. To meet the measures that repeat lactate does need to be drawn within six hours of sever sepsis presentation. That would be the only caveat I would throw in.

Sean Townsend: Right.

Candace Jackson: Thank you. And our next question: is there a total volume limit, for example, five liters to the 30cc/kilogram rate?

Sean Townsend: OK, Candace can you repeat the question?

Candace Jackson: Is there a total volume limit, for example, five liters to the 30cc per kilogram rate?

Sean Townsend: No, it is truly– so that the 30cc per kilogram or 30ml per kilogram is a volume, not a rate. But, there is no upper limit to that volume. And that goes to the question we had earlier about ideal versus actual body weight. And, you could imagine in morbidly obese patients getting very high or close to that number.

Emanuel Rivers: Yes, this is Manny Rivers. If you look at the data and ranges of volume given during the first six hours, in a goal directed study, an average was five to six liters. And, that's over five hours– I mean, over six hours. If you look at the most recent trials, process varies anywhere from two to three liters. So, that gives you some ballparks. But, in general, most patients within pretty much a normal body have this and even larger over six hour time period– five and six liters is maximum.

Sean Townsend: But, you know, I'd only add that, Manny, that's, you know, that's physiologically true. But, for purposes of measure, there's no upper limit capped.

Emanuel Rivers: Oh, yes. I agree. I was just throwing a clinical caveat out there.

Sean Townsend: That's right.

Candace Jackson: All right. Next question: can you please refer us– I'm sorry, OK. Can you please refer us to the clinical reference from lactate greater than four being considered septic shock, so that we may better provide education to our staff?

Sean Townsend: I would let Manny answer this question because he knows this literature better than anybody else.

Emanuel Rivers: If we go back in 1964, back when Max Terrywell published an article in *Science* where he looked at lactate level, and this is almost 50 years ago, he showed that lactate levels greater than four carried a hospital mortality of greater than 50 percent. In a subsequent article published in *JAMA*, and this was by Audo Won when he looked at lactate levels and this was in 1994, and this was actually some of the data we use to model the goal directed study. Again, lactates greater than four correlated with high hospitality mortalities. And so, when we did a prospective study in '96, we looked at 1,000 patients who presented at triage with lactate greater than four. And, what we found is that 99 percent of those patients ended up in an ICU during their hospitalization. So, those are kind of the sequence of studies that have shown that lactates greater than four. Surviving Sepsis campaign database: almost 30,000 patients looked at lactate levels and actually showed that lactate greater than four, with or without hypotension, carry mortalities in excess of 28 to 46 percent. And, this was published in *Critical Care* in 2014, and actually Dr. Townsend was one of the co-authors of the study.

Candace Jackson: Thank you. And our next question: is there data to support repeating on moderately elevated lactate of 2.1 has actual improved outcomes? The upper limit of our normal for our clinical assay is 2.2.

Sean Townsend: This is Sean Townsend. Let's see– I think the first part of the question asked, is there demonstration that repeating lactate greater than 2.1 is associated with better clinical outcomes for patients. And this– I'll make this pretty clear, I think, for the questioner. The requirement for repeat lactate is a subtle proxy, it's a hint, pointing you at the concept of lactate clearance. And, there have been several trials now, but two that were

prominent, which pointed to a reduction in lactate levels by 10 percent from their initial elevation as being suggestive of improved outcomes in mortality for patients. And so, although, you know, I can't tell you that every patient gets a lactate repeated greater than 2.1 will improve, if they have another value done. The purposes is to have the physician to have the capacity to compare the initial lactate to the second lactate and determine whether they're getting clearance, roughly 10 percent clearance. Because if that's the case, there is correlation then with reduction in mortality.

Candace Jackson: Thank you. Is there any other additional comment in regards to that question?

Lemeneh Tefera: I would just like to add to this, it may not relate to the, you know, the measure. But even intermediate lactate between four– between two and four, do carry incremental increases in hospital mortality. Keiser Hospital System, one of the largest databases, actually showed patients have incrementally even higher mortalities with lactates of two to four. So again, just a cutoff of four is not necessarily a strict cutoff because patients will vary their lactate level based on underlying disease. But, two to four still carry some clinical significance in terms of mortality.

Candace Jackson: Thank you for those responses. And we do have…

(Crosstalk)

Sean Townsend: Sorry. I just wanted to add if the questioner wanted to look at those papers, the most commonly cited paper is by Helen Jones, published in 2010, and I believe in *JAMA*.

Candace Jackson: OK, thank you very much. And, we do have time for one last question. Are oral antibiotics acceptable to pass the sepsis bundle? I am specifically referring to Augmentin listed on the therapy table.

Sean Townsend: This is Sean Townsend. That would be– I've heard– I haven't seen it with my own eyes. I've heard the statement that that was included in the table. If it is included, then it's included in error. PO antibiotics are not acceptable. And in subsequent efforts, we would remove that.

Candace Jackson: And does anybody else have any additional responses to add on to that?

Emmanuel Rivers: No.

Lemeneh Tefera: This is Dr. Tefera. Just to be clear, the specification makes clear that only intravenous antibiotics meet measure requirement. The antibiotic tables are a reference. That reference for the tables will be periodically updated. And, any changes to drug name, et cetera, will also be updated. But the specification itself is quite clear that only intravenous antibiotics meet measure specification.

Candace Jackson: Thank you. And again, that is our hour. It is the top of our hour. Again, I would like to thank our subject matter expert, Dr. Townsend and Dr. Rivers, Dr. Tefera, and Mr. Dickerson for being on our call today to answer these questions. I hope that you have a better understanding of some of the most frequently asked questions from this webinar. And we hope that you have the rest of the day, is a good one for you. Thank you very much for attending.

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