Hospital Inpatient Quality Reporting (IQR) Program

Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Contractor

SEP-1 and the 2021 Sepsis Guidelines Update: New Evidence, New Recommendations Presentation Transcript

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November 16, 2022
2:30 p.m. Eastern Time (ET)

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Candace Jackson: Good afternoon. Welcome to the *SEP-1 and the 2021 Sepsis Guidelines Update: New Evidence, New Recommendations* webinar. My name is Candace Jackson, and I am with the Inpatient Value, Incentives, and Quality Reporting Outreach and Education Support Contractor. I will be hosting today's event. Before we begin, I would like to make a few announcements. This program is being recorded. A transcript of the presentation will be posted to inpatient web site, www.QualityReportingCenter.com in the upcoming weeks. If you are registered for this event, the slides were sent out a few hours ago. Again, this is at www.QualityReportingCenter.com, if you did not receive the slides. The webinar has been approved for 1.5 continuing education credits. If you would like to complete the survey for today's event, please stand by after the event. We will display a link for the survey that you would need to complete for continuing education. The survey will no longer be available if you leave the event early. If you do need to leave prior to the conclusion of the event, a link to the survey will be available and a summary e-mail one to two business days after the event. Our speakers for today's event are Dr. Bobby Redwood, Physician Improvement Advisor for the Wisconsin Hospital Association, and Bob Dickerson, Senior Program Analyst for the Behavioral Development and Inpatient and Outpatient Measure Maintenance Support Contractor.

The purpose of this webinar is to provide a summary of high-level updates and the Sepsis 2021 Guidelines, highlight how these updates may affect clinical care of the septic patient, and highlight how these updates may affect hospital-level protocols and procedures relating to the SEP-1 core measure.

At the conclusion of this webinar, participants will be able to identify three or more key 2021 updates to the sepsis guidelines, identify one meaningful change in patient care and relation to the 2021 updates, and identify one meaningful change in clinical documentation in relation to the 2021 updates.

This slide lists acronyms and abbreviations used in the presentation.

If you have questions as we move through the webinar, please type the questions into the Ask a Question window with the slide number associated, and we will answer your question as time allows after the event. If we don't get to your questions during the question and answer session, please submit your question to the QualityNet Inpatient Question and Answer Tool at the link provided on the slide. If you have a question for Dr. Redwood that do not get answered during the presentation or during Q&A session, please send those to Dr. Redwood at the address listed on the slide.

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

Dr. Bobby Redwood: Welcome, everyone, to our November National Provider Call. This is *SEP-1 and the 2021 Guidelines Update: New Evidence, New Recommendations.*

My name is Bobby Redwood. I am an emergency physician and a preventive medicine physician. Preventive medicine is a medical specialty of public health and population health. So, I am really interested in sepsis. I am interested in it because I'm seeing patients on a daily basis in then emergency department. Then, of course, afterwards I am looking at my spreadsheets, looking at hospital-level data, and trying to prevent sepsis or treat patients when they present with sepsis. So, I also hold a role with the National Quality Improvement and Patient Safety Council of the American Council of Emergency Physicians. I am a physician improvement advisor with Wisconsin Hospital Association. All of this points to looking at data, which is the reason we are all here today. This is a national experiment, the SEP-1 core measure, on how we can improve sepsis outcome, how we can decrease mortality/morbidity, and it is an ongoing conversation, and I'm excited to share with you some of the new innovations that we've come up with today.

Now, for many of you, you've been attending these calls on yearly basis. For the uninitiated, we're here today to talk about the key 2021 updates to

the sepsis guidelines. So, the Surviving Sepsis Campaign is an international consortium that provides guidelines for management of sepsis and septic shock. These guidelines come out every two to three years. We are now in the fifth iteration of these guidelines. They were released in October 2021, and I think a year is actually a pretty good time to address these guidelines. It's not only totally apparent to in-the-trenches clinicians when they first come out, they have to disseminate through quality improvement professionals, through our quality committees to really get to the front line staff. We had a year to digest these guidelines, and I think it is a great time to talk about some of the key highlights and how they have affected sepsis care in the outpatient, emergency department, and inpatient setting. Our conversation today is not going to include all 93 recommendations for the management of sepsis. The next slide will break down what we're going to talk about specifically.

So, today, obviously, we have an hour. We're going to talk about evidence-base recommendations related to these key topics: screening and early treatment of sepsis; management of infection and source control; hemodynamic monitoring; ventilation, which is new; long-term outcomes, which is new; and then goals of care, which is new. So, I think that's a lot to cover, but we're going to hit the high points. Then, you always have references if you want to go to whole committee recommendation. They really made it quite acceptable this year, these guidelines. There is an executive summary and bullet points, and, if you want to home in on any core topics, it is quite easy to find it and get to the information you want.

Now, here's the breakdown. Of these 93 statements, these 93 guidelines, 15 are strong recommendations, about 16 percent, and 54 are weak recommendations, a little more than half. Fifteen are best practice statements, and nine are statements declaring "no recommendation." In this presentation, we're going to focus on strong recommendations, new recommendations, and best practices. "Weak recommendations" doesn't mean they won't become a strong recommendation at some point, but we are waiting for more evidence or better quality evidence before we take a call one way or the other.

So, first, let's talk about the impact of fluid management on patient care as it relates to 2021 Surviving Sepsis Campaign Guidelines. The campaign has traditionally taken a strong position on recommending 30 milliliters per kilogram for hypotension or lactate greater than or equal to four mmols per liter. As we are all aware, the debate in the literature is to what degree this recommendation has the potential to cause more harm than benefit and whether there are subsets of patients where a more stepwise approach would be a better pursuit. That would be CHF or end-stage renal disease. Now, over the past three years, we've seen a flurry of evidence and investigation on this topic. We have also seen a higher level of scrutiny and peer review from previous publications on this topic, which are available at last meeting of the Surviving Sepsis Campaign. At this point, the totality of the evidence is low enough and the quality is weak enough that the campaign felt comfortable downgrading the initial fluid bolus to a weak recommendation. Clinically this really doesn't change much for me. The important part of my clinical decision tree it is to determine whether the patient truly had sepsis or is at high risk for progression to septic shock. My next step in the emergency department is to perform thorough clinical exam to ensure they're not in an active over fluid state, and, at that point, I'm resuscitating at 30 milliliters per kilogram, regardless of comorbidities. The caveat, of course, is if a patient does have a comorbidity that makes them for susceptible to fluid overload, for example congestive heart failure with an EF of 10 percent, then I'm administering the fluid in smaller doses and frequently reassessing the patient for clinical changes that suggests fluid overload. Interestingly, balanced crystalloid is suggested over normal saline. This is really a fascinating body of evidence where we have seen, over the course of like 25 years, recommendations shift from balanced crystalloid to normal saline and back to balanced crystalloid. The grounds for this recommendation is concern that large amounts of normal saline have the potential to cause acidosis, which could compromise pH and the electrolyte optimization later in the hospital course. From an operational standpoint, clinically, it's pretty simple to make the switch from saline to crystalloid, for example lactated ringers. One caveat, you really do want to make sure the team puts balance crystalloid into an ED order set.

From a safety standpoint, there are eight drugs in the in vitro setting, in the laboratory setting, that were found to be incompatible with lactated ringers. These are ciprofloxacin, cyclosporine, diazepam, ketamine, lorazepam, nitroglycerin, phenytoin, and propofol. So, you may get a best practice alert from your EHR that these should not be administered with lactated ringers. The other one that is really important to mention is Ceftriaxone. It can actually cause a precipitate when given in the same line as lactated ringers. So, it's best to give this medication in separate IV lines or to choose a different antibiotic. That's one that might actually come up clinically more frequently.

In practical terms, one of the most significant changes that I am seeing in the SEP-1 core measure is that it now allows providers to pass the measure even when giving less than the 30-milliliter per kilogram crystalloid bolus. This is an example of population health-level quality improvement work done right, where CMS has heard the feedback from front line clinicians, reviewed the latest evidence and expert recommendation, for example the guidelines we're talking about today, and tweaked the core measure to reflect current best practices. This is exactly how it's supposed to work in large scale quality improvement work. For quality directors, medical directors, and front line providers in the audience, the main takeaway from a documentation standpoint is that the reason for giving less than 30 milliliters per kilogram must be clearly documented as well as the exact fluid amount that was given. For many of us, this is a new way of thinking or at least a new way of documenting. IT professionals, quality improvement professionals, and medical directors, you can certainly help us out by creating a smart phrase, a macro, or a documentation template in the electronic health record to make sure that these two key points are easily included in our sepsis documentation.

All right. When it comes to hemodynamic measurement, this round of guidelines has really laid out some new useful suggestions. First, it is suggested that we can use capillary refill time to guide resuscitation in addition to other assessments. I love this suggestion. I find it to be so intuitive and something that most of us have already been doing.

My ICU colleagues tell me that they have become quite facile with passive straight leg raise, but, in my experience, in the ED setting, capillary refill time is strongly preferred among frontline providers. When you push down on the nail bed and it blanches white and stays there, it's quite clear that the patient is sick and requires resuscitation. Likewise, when the nail bed promptly pinks up again, it is an indication that things are going in right direction. Now the second suggestion it is to administer vasopressors via peripheral IV in a medium to large vein for the first six hours to avoid delays related to central venous line placement. All I can say here is: Thank you, thank you, thank you. Any of you working clinically know the production pressures have been simply staggering these past few years. When you add the nursing shortage on top of that, it can be really time consuming and sometimes not realistic at all placing central line in first six hours of a resuscitation. Having the option to administer a vasopressor via peripheral IV gives the front line provider the opportunity to get the pressors going early and then they go do something else that you have to do. You can go see a stroke patient. You can go see the STEMI patient. You can then come back and place central line when you have the appropriate time and mental space the procedure really deserves. The third suggestion here is to administer IV corticosteroids to patients in septic shock and vasopressors. This has been a longstanding practice for patients who are on chronic steroids with sepsis. The idea here is that low doses of glucocorticoids appear to restore vascular responsiveness to norepinephrine in a disc related host response to infection, which, of course, is the definition of sepsis. The discussion about whether steroids have a similar affect in non-steroid dependent patients has a been ongoing for almost three decades. The ADRENAL trials and the APROCCHS trials, both randomized controlled trials performed in 2018, showed a mortality benefit for low dose steroids for septic shock. So, I'm happy to see this formal recommendation from the Surviving Sepsis Campaign.

This next set of recommended practices really hinges on the fundamental point of balancing prompt antibiosis in critically ill patients with the ever-growing threat of multi-drug resistant organisms and the principals of antimicrobial stewardship. First, the committee recommends that if you

are suspecting septic shock or a high likelihood of sepsis, you give broad spectrum antibiotics within one hour. Now, I am an antibiotic stewardship guy, of course. I'm also emergency physician, and I could not agree more with this recommendation. When someone is dying in front of you, you want to hit that infection hard and fast to give that patient the best possible chance of survival. The key here is actually clenching the diagnosis. You want to have a reasonable degree of confidence that the abnormal patient presentation is due to infection and the subsequent disrelated host response to that infection. This principle sort of bleeds into the second recommendation. If you believe the patient is at low risk of infection, consider "time limited" and close monitoring and deferring antibiotics until an infectious diagnosis is more clear. Really, they're just saying, "Take a beat and make sure you have your diagnosis locked down." This kinds of reminds me of a patient I saw in the ED. Actually, I see him frequently. He has chronic venous stasis edema in both legs, but he's also prone to panic attacks and concentrates on the concern that the redness of chronic edema is infection. He will come into our ED tachycardic, no fever, looking more panicked than sick. He flags positive for possible sepsis, but the vast majority of the time, his labs come back normal, and his presentation normalizes with a tablet of lorazepam. Giving this patient broad spectrum IV antibiotics 10, 20 times a year, which is how frequently he comes into my ED, could really cause him harm by increasing his risk for multi drug resistant organisms. This is a great example of "time limited" close monitoring. We don't want to blow this patient off, we don't want to say it's not sepsis, but we have suspicion it's a panic attack, but we want to take a beat and get more information, and see if we have better data after he has medication and labs drawn.

First, let's all agree, as the Surviving Sepsis Campaign does, that we should reserve MRSA coverage for patients who have a high risk for MRSA or who have an established history of such. I know when I trained in emergency medicine, the paradigm was double coverage for any skin infection. So, any cellulitis would receive antibiotics. We thought we were doing right by our patients by covering for that ever growing threat of MRSA. We were just applying more selective pressure and to low level

infections and increasing the prevalence of MRSA in our community. The same principal applies to the sepsis patient. If there is high risk of MRSA, go for it. Otherwise, this is a time to hold back on IV medications like antibiotics and preserve efficacy of our limited antibiotic arsenal that we have against MRSA.

All right, at this juncture, I would like to step out of the clinical trenches and pass the presentation over to Bob Dickerson. He is going to discuss SEP-1's alignment with our updated guidelines.

Bob Dickerson: Thank you, Dr. Redwood. In this portion of the presentation, we'll discuss the alignment of SEP-1 with the updated Surviving Sepsis Campaign international guidelines for the management of sepsis and septic shock that were published in October of 2021.

Before we review specific guideline updates, I want to briefly share a bit about the evidence ratings and what the different levels of evidence ratings mean. The guidelines make use of the GRADE rating system to determine the levels of evidence that support each recommendation. That would be the grading of recommendation, assessment, development, and evaluations, such the acronym of GRADE. GRADE is a widely used framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations. I note that GRADE is subjective and is not perfect. It cannot be implemented mechanically. There is, by necessity, a considerable amount of subjectivity in each decision. So, for example, two different people evaluating the same body of evidence could very reasonably come to different conclusions about the certainty of the real impact or effect of that evidence to the expected impact or effect. What GRADE does provide is a reproducible and transparent framework for grading certainty in the evidence. Essentially, the guide authors used GRADE to assess the evidence and the impact to affect the interventions described in the evidence will likely have on patient care outcomes. The ratings range from very low, where the impact is probably very different from the desired or estimated impact, to high where viewers have a high degree of confidence the reported impact will be the same or similar to what they expect.

The evidence ratings derived from applying the GRADE methodology to the evidence are used in addition to other factors such as the applicability to the patient population, assessment of benefits versus risks, availability of the intervention, and cost associated with the intervention. These are all used in conjunction to identify the strength of the recommendation itself. To arrive at this, a series of factors or questions are considered. So, first of all, they look at is the quality of evidence high or moderate. The higher quality of evidence the more likely the recommendation will be strong. Next, ask this question: What is the degree of certainty about the balance of the benefits versus harms and burdens associated? The larger the difference between the desirable and undesirable consequences and the greater the certainty around the difference, the more likely recommendation will be strong. Now, if there's a smaller net benefit and a lower degree of certainty for that benefit, then it's more likely the recommendation will be weak. Another question is: What is the level of certainty, or how similar is the evidence compared to the reviewers' values? Now, the more certain, the closer, the evidence aligns with values and preferences, the more likely recommendation will be strong. Lastly, they consider what are the resource implications. So, the lower the cost of the intervention is compared to the alternative and other costs related to the decision, such as fewer resources consumed, the more likely the recommendation will be strong. After having covered that, I next want to review some of the actual recommendations that have direct relevance to the SEP-1 measure and discuss these recommendations how they're incorporated into the measure.

As Dr. Redwood mentioned, there are 93 recommendations outlined in updated guidelines. Many of which are not directly applicable to the SEP-1 measure. We will review nine of the recommendations, starting with recommendation number two, which is new and recommends against using qSOFA as a single screening tool for identification of sepsis or septic shock due to the poor sensitivity, and instead use other tools such as SIRS criteria. Now, as I walk through the measure specifications and algorithm that includes the criteria for determining the presence of or the suspicion of sepsis or septic shock, please keep in mind that SEP-1 does

not make use of SIRS criteria alone. The measure also requires documentation of suspected or confirmed infection, any sign of organ dysfunction in making this determination.

The SEP-1 initial population is determined on ICD coding present in the patient's medical record. If the medical record has a diagnosis code from measure table 4.01, the patient is included in initial population, or the IPP. This is not changed from previous versions of SEP-1.

Table 4.01 includes all of the ICD-10 diagnosis codes on this table. The IPP includes not only two codes for severe sepsis with septic shock and severe sepsis without shock but also casts a wider net by including other sepsis codes listed on this table. We review ICD-10 codes annually and update this table as appropriate. The codes used for IPP have not changed from previous versions of SEP-1.

Next, the SEP-1 algorithm looks for the presence of the UO7.1 code for a confirmed diagnosis of coronavirus in the medical record. If this code is present, the patient is removed from the IPP. This provides the population patients from which facilities can derive their SEP-1 sample population if case volume meets sampling criteria.

Data abstraction or patient cases identified for sampling starts next. There are three other data elements you will abstract before arriving at this point. They are *Transferred from Another Hospital or ASC, Clinical Trial, and pregnant 20 Weeks Through Day 3 Post-Delivery*. The *Severe Sepsis Present* data element is the point where SEP-1 applies specific criteria to identify purposes of the measure whether a patient has sepsis. If criteria for this data element are met, the abstractor selects Allow Value 1 and the patient remains in the measure and extraction continues. If, however, the patient, does not meet the data element criteria for presence of severe sepsis, the abstractor selects Value 2 and the patient is removed from the measure, extraction stops, and the patient case is not used for calculating measure performance calculations. You will submit that case as part of your IPP, but they will not be included in the denominator.

Now, for purposes of identifying patients with severe sepsis for SEP-1, three clinical criteria must be met or there must be physician/APN or PA documentation of severe sepsis. The three clinical criteria are documentation of infection, two or more SIRS criteria, and evidence of organ dysfunction. These must be documented within six hours of each other. As I noted earlier, SIRS is not used alone because it's just one piece of the sepsis recognition puzzle. Now, SEP-1 has utilized these criteria for establishing severe sepsis since its inception. The evidence continues to support this as a valid method for early identification of patients with severe sepsis. As we all know, early identification is key to being able to initiate early treatment which saves lives. To give clinicians the benefit of the clinical judgment, if the SIRS-based clinical criteria are not met based on abstraction guidance, but there is physician/APN or AP documentation that the patient has severe sepsis or septic shock, this will also retain the patient in the measure. If the documentation in the medical record does not meet the *Severe Sepsis Present* screening criteria and there is not clinical documentation that the patient has severe sepsis or septic shock, the patient case is excluded from the measure. I want to emphasize that SEP-1 does not dictate nor does it limit the severe sepsis and septic shock screening criteria that clinicians use at the bedside. CMS recognizes that there are variations in criteria available and used at bedside. Some of the other options are called out in the guidelines. Rather SEP-1 defines for purposes of measure abstractions a common set of criteria that abstractors from all hospitals across the U.S. utilize for determining which patients from their initial populations remain in the measure. This helps ensure the same criteria are used to determine which patients remain in the measure and which ones are excluded. This, all patients are included based on a standard, medically acceptable, common set of criteria.

The next recommendation is one that was established in previous versions of the guidelines and suggest measuring lactate for patients suspected of having sepsis. We are including this one in the discussion today because it carries the weak recommendation with low quality of the evidence. This does not mean that lactate is not important. The primary reason for the strength of this recommendation for the guidelines is two-fold.

One: Lactate alone is not sensitive or specific enough to rule in or rule out sepsis. Two: It may not be readily available in some resource- limited settings. However, elevated lactate levels in patients with infection is well established as being associated with a high likelihood of sepsis. This is pointed out in the guidelines. The recommendation is, therefore, a weak recommendation, for the use of lactate as an adjunctive test.

In line with the literature and this unchanged recommendation of the guidelines, SEP-1 incorporates lactate in a supportive role for determining the presence of sepsis or septic shock. No single lab value, sign, or symptom is used to identify whether a patient has severe sepsis or septic shock for SEP-1 purposes. The measure stewards took into consideration the strong association between elevated lactate levels and mortality in patients with suspected infection or sepsis and incorporated this lab value as a required data element. This was done not from a perspective that it would ever be used alone to determine the presence of sepsis or severity of sepsis but rather because of the association that tie elevated lactate levels with severe illness and progression towards septic shock that when used in conjunction with other criteria serves as a strong prognosticator.

The next recommendation is number five, which is downgraded from the previous versions of the guidelines to suggest that at least 30 milliliters per kilogram of IV crystalloid fluid should be given within the first three hours of resuscitation. Now, this downgrade is not saying that fluid should not be given; the guidelines note that timely and effective fluid resuscitation is critical to stabilize patients with sepsis-induced tissue hypoperfusion, rather it comes from a perspective that, at the time of the update, there were no perspective studies comparing different initial resuscitation crystalloid fluid volumes in sepsis or septic shock. Studies of fluid volumes tend to be retrospective and compare volumes of less than 30 milliliters per kilogram to volumes greater to or equal than 30 milliliters per kilogram. While many of these studies reveal that even patients with heart failure and renal disease have septic shock tend to benefit from larger fluid volumes, they are retrospective and do not compare various fluid volumes. The guidelines therefore recommend that

fluid administration should be carefully monitored and guided based on assessment of patient responsiveness. Now, from a perspective of concern for over and under fluid resuscitation of fluids, this does make sense. While retrospective studies have shown that many patients are receiving volumes of 30 milligrams without experiencing harm, some patients may respond well to volumes less than 30 milligrams per kilogram and others may require more than that. There are currently studies under way intending to provide better insights than fluid resuscitation volume per patients with septic shock, and the measure stewards at CMS continue to review evidence as it becomes available. So, in the meantime, let's take a look at the crystalloid fluid aspects of SEP-1.

First off, 30 mils per kilogram is the default volume for crystalloid fluids for SEP-1. This is from the perspective that the available evidence does demonstrate this volume is safely and widely used for most patients. The measure stewards in CMS recognize how, that for some patients, 30 mils per kilogram may not be the ideal volume and have updated the *Crystalloid Fluid Administration* data element in version 5.10 for abstraction of patient cases discharged effective July 1 of 2021 to allow for a lesser volume of fluid if there was clinician documentation that 30 mils per kilogram would be detrimental or harmful to patient and either a portion of the volume was colloids or the patient had advanced or end stage heart failure or the patient had advanced or end stage renal disease.

In version 5.11, for abstraction of patient cases discharged effective January 1, 2022, the crystalloid fluid analysis further expanded on to allow other reasons for lesser volumes if there is specific documentation by physician/APN or PA. As noted previously, 30 mils per kilogram remains the default volume if there is not clinician documentation of reason why a lesser volume was ordered and that lesser volume was given. Since these guidance changes were reviewed in previous CMS SEP-1 educational webinars, I will not review specific updates from the specifications manual.

Continuing along the theme of recommendations, crystalloid fluids remain the recommended fluids for first time fluid resuscitation. This remains unchanged as strong recommendation supported by moderate quality

evidence. The updated guidelines revised number 33 and now suggest using balanced crystalloids instead of normal saline. This carries a weak recommendation supported by low quality evidence. Normal saline, long a mainstay for fluid resuscitation, remains an acceptable option. While there is some inconsistency in the study results, evidence since the previous guidelines suggests lower mortality rates are associated with these balanced crystalloids compared to normal saline. Larger, randomized controlled trials ongoing at the time of the updated guidelines were released will provide additional data and insight into the types of crystalloid fluids that are most efficacious. Recommendation number 34 suggests the use of albumin for patients requiring large crystalloid fluid volumes remains unchanged.

So, what does all this mean for SEP-1? SEP-1 started out when first implemented in October 2015, restricting fluids to normal saline or lactated ringer solution, which is a balanced crystalloid fluid. In the next manual version update for the abstraction of cases discharged effective July 1, 2016, two additional balanced fluids, Normosol and PlasmaLyte, were added as acceptable crystalloid fluids options. In the following update to SEP-1 guidance to abstract patient cases discharged effective January 1, 2018, acceptable fluid language was further expanded to include all balanced crystalloid fluids as an option. The measure does not provide preference toward normal saline or balanced crystalloid fluids, but rather, it leaves this to the discretion of the treating clinician. Then with version 5.10, for abstraction of patients in cases discharged effective July 1, 2021, the allowance of a portion of fluid volume administered as colloids was added. In summary, with regard to the types of fluids used for resuscitation, SEP-1 allows use of normal saline, balanced crystalloid fluids and portion of fluids given as colloids at discretion of the clinician treating the patient.

The next recommendation we will touch base on are for timing of antimicrobials. Recommendation 12 has changed from previous guidelines in that it would prioritize the recommendation of administering antimicrobials ideally within one hour for patients with possible septic

shock or a high likelihood for sepsis. While the recommendation is strong, you can see the quality of evidence supporting it is identified low for septic shock and very low for sepsis without shock. Now, the timing of antibiotic administration in relation to suspected or confirmed septic shock, severe sepsis, sepsis, and infection has been thoroughly discussed in literature. Mortality reduction in relation to antibiotic administration timing appears to be strongest for patients with septic shock and weaker for patients without septic shock. Several studies have demonstrated increases in chances of mortality associated with each additional hour of delay in antibiotic administration for patients with septic shock. However, these same associations have not been universally observed in some other studies. There is no doubt that antimicrobial administration as soon as possible is essential in septic shock, severe sepsis, sepsis, or infection are confirmed as present or highly suspected. The evidence supporting ideal timing is less well established. As you may recall from an earlier slide, because of all the factors guideline writers take into consideration, a strong recommendation can be based upon low or very low quality evidence if the benefits outweigh potentially unintended consequences. This is the case with antibiotic timing recommendations in the updated guidelines.

Recommendation 14 was changed to focus on antimicrobial timing for patients with possible sepsis without shock and now suggest a time limited rapid investigation to further identify concern for infection, and if the concern is still present, administer antimicrobials within three hours from the time sepsis was first recognized. This carries a weak recommendation supported by very low quality evidence. This is because that, in these studies of this population of patients, the time sensitivity of antimicrobial demonstration was less consistent. Evidence, however, does suggest that higher mortality may be associated with delays of three to five hours or more.

As a point of comparison, previous guidelines recommended early administration of antimicrobials as soon as possible and within one hour of recognition. Reprioritization of the antimicrobial timing in the guidelines really does impact in SEP-1. Let’s explore that statement just a bit more.

To provide a bit of a refresher on antibiotic timing for SEP-1, let's review a snapshot of the antibiotic timing from the SEP-1 algorithm. The arrow coming down from the broad spectrum antibiotic timing decision box with antibiotic administration occurring 24 hours before to three hours after severe sepsis presentation meets SEP-1 antibiotic timing requirements. The arrow going to the right from the broad spectrum antibiotic timing decision box with antibiotic administration occurring more than 24 hours before or more than three hours after severe sepsis presentation does not meet SEP-1 antibiotic timing requirements. Now, the algorithm further evaluates the timing for this group of patients. So, if an antibiotic was given more than 24 hours before severe sepsis presentation, the patient is excluded from the measure. This is primarily because during original design of the measure this population was identified as one with more potentially complex disease process that required a more complex course of treatment than the SEP-1 measure was designed for. If the antibiotic was given more than three hours after severe sepsis presentation, the patient remains in the denominator but is not in the numerator and will not meet SEP-1 antibiotic timing requirement.

Circling back to the way guidelines have previously and currently prioritized antimicrobial timing, it is operationally very challenging to implement time frames based on vague or not clearly defined parameters such as "as soon as possible," immediately," and "ideally within one hour." The antibiotic administration time frame built into SEP-1 considers several factors by allowing administration of antibiotics within 24 hours prior to through the three hours after severe sepsis recognition. By accepting antibiotics given with 24 hours prior to recognition of severe sepsis, the SEP-1 time frame considers situations where patient is first identified with infection, is given antibiotics, subsequently further decompensates, and then goes on to develop severe sepsis or septic shock. Now, in situations like this the antibodies may not have sufficient time to take effect and giving more antibodies immediately following severe sepsis recognition wouldn't necessarily contribute further to resolution.

It is also consistent with the importance of early treatment for patients who are clearly identified as having severe sepsis or septic shock while recognizing real world patient care work flow issues that may limit the ability to administering antibiotic within one hour of recognition. Also, the time frame for antibiotic administration within three hours after severe sepsis or septic shock identification is in line with the guideline suggestion of a time-limited rapid investigation to further identify concern for infection, and, if the concern is still present, to administer antimicrobials within three hours from the time when sepsis was first recognized. Remember the situation Dr. Redwood described? The patient comes to ED on frequent basis, meets many of the criteria for early suspicion of sepsis, but, upon further workup, is identified as not having sepsis. The good thing so far is that this patient has not had severe sepsis or septic shock. If someday this patient ever arrives to Dr. Redwood's ED and work-up reveals he does have sepsis, this three-hour time period suggested in the guidelines that is built into SEP-1 since the inception of SEP-1 recognizes the importance of this type of work-up and timely administration of antimicrobial treatment.

With that, I'd like it hand the presentation back to Dr. Redwood who will take us through some additional points of importance and wrap up our discussion. Dr. Redwood, over to you.

Dr. Bobby Redwood: All right. Thank you, Bob Dickerson. That was very enlightening and now back to the impact of the Surviving Sepsis Campaign recommendations and guidelines on patient care.

All right, team. While the intensivists and respiratory therapist audience might be salivating for the topic of vent setting, for many of us this is a topic where we prefer a nice algorithm built into an order set, so we're not pulling out a pen and paper and doing math in the resuscitation room. For those of us who get nervous about tweaking those vent dials, let's all take a collective sigh of relief as the Surviving Sepsis Campaign recommendation really just legitimized what has been standard practice for a decade.

First, if the patient has sepsis associated ARDS, use the low tidal volume strategy, just like ARDS has been telling us do for years: 4 to 6 milliliters per kilogram tidal volume is great. This recommendation is extended to all patients with sepsis induced respiratory failure, which I think is just so reasonable. We all know that septic patients have capillary leak syndrome and third space fluid. This third spacing doesn't spare the interstitial tissues around the alveoli in the lung. So, the physiology here is effectively similar to that of ARDS. Next, they recommend prone positioning in moderate to severe ARDS. While this practice has been in literature for some time, it might have felt a bit odd to do it pre-2019. It sure would have been in the ED setting, but now having endured almost three years of COVID, I think proning patients has become second nature to many of us. Prone positioning redistributes blood and air flow more evenly and reduces the imbalance and also improves the gas exchange. It is a low tech tool in your tool chest and it can really save a septic patient in respiratory distress. Moving on, the Surviving Sepsis Campaign is clearly stating that traditional recruitment maneuvers and pulmonary toilet are OK, but let's avoid the incremental PEEP strategy. This has likewise been the area of intense study for decades. The basic idea is that you want to minimize cyclical alveolar collapse and the corresponding injury in the lungs of patients with significant edema or alveolar collapse. Finally, the Surviving Sepsis Campaign found insufficient evidence to make a recommendation that we use conservative oxygen targets in adults with sepsis-induced hypoxemic respiratory failure. Yet, they did suggest that for these same adults, we use high-flow nasal cannula over noninvasive ventilation. High-flow nasal cannula is just another area where the medical literature has rapidly expanded over the past three years due to clinical innovations and lessons learned from the COVID-19 pandemic. So, hopefully, you all have those nasal cannulas in your ED/ICU or floor setting and at this point facile in using them. If you are not, this would definitely be a great journal club to do with your group or a lunch-and-learn with your respiratory therapists.

So, we have gone over a lot of clinical information for front line providers, and my colleague Bob Dickerson really did a deep dive on SEP-1 for the quality improvement professionals on the webinar. Let's take some time to

highlight the implications that these new guidelines have for hospitals and health systems in general. From the C-suite to the medical director to the IT support staff, how will this affect hospital care going forward? The guidelines recommend a standard operating system for identification and treatment of sepsis, as opposed to a performance improvement model only, which at state hospital association-level we have been recommending for years. Time and time again my team would perform a gap analysis between high and low performing hospitals on the SEP-1 core measure and find that the high performers had a comprehensive game plan for screening, confirming the diagnosis of, and treating sepsis. Now, it can take many forms, of course. There is no one size fits all here, and it may be a triage screening protocol for your ED, it may be a Code Sepsis on the floor, maybe have a house-wide order set that is audited regularly by the sepsis committee. The point is to have a curated plan, a plan that is reviewed regularly and integrated into the work flow. Of course, what I love most about this concept is that it's not just for sepsis. This is QI work done right. OK? We have similar plans for trauma. We do it for stroke. We do it for ST Elevation MI. And as we did QI work, we unlock a world of possibility for improving clinical management of complex disease processes.

Another key change made to these guidelines is a specific call out that qSOFA is insufficient as a single screening tool for sepsis. There was a lot of promise when qSOFA came out, of course, that this would be the one unifying tool, that any hospital, any department, any provider can use to screen for sepsis. We all learned that we're screening for different aspects of this disease, depending on our care environment and how severe the presentation is. For example, in the ED setting, SIRS, or Systemic Inflammatory Response Screening, is still king. We are screening a wide swath of patients, many with abnormal vital signs, seeking out those that are at high risk for progression to septic shock. Now, on the inpatient side, the conversation is more about looking at a smaller pool of patients, usually already confirmed to have sepsis or be on the sepsis disease spectrum and essentially triaging those to find out which ones require a high degree of nursing care or IT level of resources.

The take-home point: SEP-1 still uses SIRS and qSOFA may be right in some care settings, but there is no single screening tool for those at risk for screening for sepsis.

Now, this is a set of recommendations that is really key because it acknowledges the importance of setting our septic patients up for a successful recovery and post-acute care experience. Of course, we've known about sepsis readmissions and post sepsis syndrome for years, but until now neither of these topics have played a central role in the Surviving Sepsis Campaign guidelines. So, these are the recommendations. First, the committee recommends screening for economic and social support; involving patients and families in shared decision making around discharge planning; doing medication reconciliation at both ICU and hospital discharge, which is an important nuance because those drugs do sometimes change between ICU and the floor; including information about sepsis and common impairment after sepsis in the discharge summary; and assessing for physical, cognitive and emotional problems after hospital discharge. Now, if you're like me, you're reading this list and thinking: Shouldn't we be doing this for all our patients discharged in hospital, not just our septic patients? Again, this is a great example of how quality improvement work for one specific disease process can have positive ripple effects for the entire care delivery system.

All right. So, you are a medical director going back to your department reading, a sepsis QI champion reporting to your larger quality improvement committee, or maybe you're just a regular doc, or PA, or ARNP, ready to impress colleagues with the latest best practices. Here is one slide that you can take home to your colleagues on the 2021 updates from the Surviving Sepsis Campaign guidelines. So, first, these are the potential impacts on patient care. For fluids, crystalloids are now recommended, balanced crystalloids instead of normal saline. For hemodynamics, you can use cap refill. You can use peripheral pressors and a medium or large IV for six hours, and corticosteroids are recommended if your septic patient is on pressors. For antibiotics, try to get broad spectrum antibiotics within one hour or shock or likely sepsis.

If you are unsure about the diagnosis, it's okay to monitor for a little while and get a more clear idea of what the diagnosis is. In terms of vent settings, this is similar to the ARDS Net[work]: low tidal volumes, prone if they are showing ARDS, avoid incremental PEEP, but continue normal pulmonary toilet. For documentation, you want to document your fluid plan and rationale when giving 30 milliliters per kilogram. Implications for hospitals in relation to SEP-1: We want hard wire sepsis care processes into policies, protocols, and EHR build. So, you really have a cohesive plan for your hospital or health system on how to treat sepsis. ICU transitional care programs/attention to post discharge care is a new realm that we should all be involved in. It is great fruitful work for a sepsis committee at a hospital level.

All right. To address any questions, we're going to turn the presentation back over to Candace. Thank you, Candace.

Candace Jackson: Thank you, Dr. Redwood. Thank you, Bob, and both of you for providing all that wonderful information. I'm sure it's going to be beneficial to all of the providers listening today. We do have time now for a brief question-and-answer session. We'll get to as many questions as we can, and they are in no particular order. I'm going to start out with the question we've had coming in most frequently during this presentation today and hopefully provide some clarification and decrease some of the panic that may be going on. So, Bob and Dr. Redwood, can you provide clarification as to why this is saying 2021 Sepsis Guidelines Update, and why we are not following 2023 or how it's related to the specs manual?

Bob Dickerson: Hi, Candace. Yes, this is Bob Dickerson. I can address that and then Dr. Redwood, please, chime in with additional thoughts you have. So, the reason that this is titled 2021 Sepsis Guidelines Update is because the new Surviving Sepsis Campaign guidelines, international guidelines, for managing severe sepsis and septic shock were released in 2021. So, we're talking about sepsis guidelines. We're referring to Surviving Sepsis Campaign guidelines. The measure specifications, what the intent here is to draw, is to illustrate the relationship between the updated guidelines and the specifications for the manual. Now, it's important to keep in mind that

the CMS SEP-1 specifications manual, the guidance in there is not a guideline, like the Surviving Sepsis Campaign guidelines are. Rather, the measure specifications are utilized to help identify to what extent the guidelines from the Surviving Sepsis Campaign are being followed in the hospital setting. So, they will reflect what's in the guidelines. You may very well, and I can speak to this having been in the hospital setting working with implementation of severe sepsis protocols and templates and that type of thing, you may structure some templates for data collection occurring to guidance that is in the specifications manual so you can capture that information more easily. Yet, those in and of themselves, do not represent guidelines for care. They are the parameters for identifying how care is provided and how it is consistent with the actual guidelines in Surviving Sepsis Campaign. I hope that helps clarify that, and I apologize if I overemphasized that too much. I think it's an important differentiation to make.

Dr. Bobby Redwood: I think that's a great explanation. I would just chime in. You might see the topic of the webinar and say: This is outdated 2021. Yet, really guidelines like these, they do take a little time to digest, and, once they are out there in the clinical space, we often learn little tweaks or adaptations. I think a year out is a good time to be looking at these guidelines with a critical eye. Any physician champions or sepsis champions in the room probably did see these a year ago. They came out, and we reviewed them at my sepsis committee at our hospital. There's a lot of debate in literature that comes after the guidelines, and we get a better understanding when you have a little time to really operationalize these in clinical practice. I like looking at them a year out, but I do see how the sticker shock could make you say: Wait, is this old news? I really don't think it is old news. I just think it's a timely time to be reviewing it, especially in relation to the sepsis core measure, which of course is different from the Surviving Sepsis Campaign guidelines.

Candace Jackson: Thank you, both Dr. Redwood and Bob. Bob, are you able to give us an expected date or time frame when some of these recommendations will be reflected in the specifications manual?

Bob Dickerson: Yeah, that's another great question. One of the things that is really interesting, and the whole process I find interesting in a way, the whole process of maintaining guidance for chart abstraction or for any measure is there's also a process of getting updates and changes integrated into those. Now, one of the things that I hope we are able to illustrate during the presentation is that many of these recommendations or suggestions in the Surviving Sepsis Campaign guidelines are already in the SEP-1 measure. So, to that point, whether we will see changes based upon this in next year's manual, a year after that, or whatever the case may be, many of them are reflected in there. We are continually looking at updates as literature becomes available. I can't speak to any changes that may be pending for a version of the manual that have not been published yet. To the extent that these guidelines are already incorporated into the most recent version of the manual, which I think is effected for discharges January 1st of 2023, most of this is already in there.

Candace Jackson: One last question before we move on to a different topic: Can you tell us where we can get a copy of the 93 recommendations?

Bob Dickerson: Absolutely. They are available on the Surviving Sepsis Campaign web site. A real quick easy way to do this is just go out to Google and start typing Surviving Sepsis Campaign, and the first hits that you're going to get are a link to Pub Med for the guidelines. Society for Critical Care Medicine has the guidelines posted, as well as the Surviving Sepsis Campaign web site. So, that's probably the quickest and easiest way to find them.

Candace Jackson: Wonderful. Thank you, Bob. Let's move on to some crystalloid questions since that seems to be a big topic. Can we go to slide 16, please? Must the volume still be given at greater than or equal to 126 CCs per hour?

Bob Dickerson: This is Bob Dickerson again. I can address that from the perspective of the abstraction manual and how that's kind of set up. Dr. Redwood, please, jump in with any clinical tips that you have as well from experience at the bedside. The guidance in the manual does still pretty much require to count fluids towards your resuscitation volume. They need to be given at

126 milliliters per hour or greater. Anything less than that you cannot count toward your fluid volume. That hasn't changed in the manual. The prime reason for that is back when we were trying to differentiate fluids that were given as just maintenance fluid, kind of like an IV drip versus fluids given for resuscitation, we identify that based upon some nursing guidelines for fluid administration. Keep in mind this was back in 2014, 15, when we were developing this. They identified that as kind of a guideline cutoff that was used in that literature for fluids used for replacement versus for maintenance. That's where that came from, and it's still a parameter that's in the abstraction guidance. Dr. Redwood, any tips you have on fluid administration ratings or that kind of thing from a practical treating patient perspective, it sure would probably be welcomed.

Dr. Bobby Redwood: I think you usually said it quite well. I will share anecdote from my oral boards, when I just came out of residency. I wanted to give a patient a liter of fluid and the questioner asked me: How fast would you like to give that? I just sort of paused. I was dumbfounded. Ten minutes? He said: OK. Let's get a pressure bag, then. He was kind of giving me a hard time because it's hard to get fluids in that fast. I think nurses know intuitively that the maintenance fluids are somewhere between 75 and 125. As front line clinicians, especially early career, we may not really know what a bolus is or what time it's supposed to be given over. That's a differentiating factor here, 126 is when you get into giving fluids really quickly, and you are now resuscitating rather than maintaining. You know, being on the sepsis committee we're looking at all the fluids that have been given. People often say: Can't we count these maintenance fluids? You really can't. There are losses. The patient's body is just using fluids normally. If we want to be resuscitating, we should really be giving bolus fluid, and 126 is the floor, not the ceiling. Traditionally, those fluids need to be given even more rapidly than that.

Candace Jackson: Thank you both. Along that line, are the providers no longer required to give the 30 milliliters per kilogram? If not, what is the new requirement?

Bob Dickerson: Thanks.

Dr. Bobby Redwood: Can I field this one?

Bob Dickerson: Yeah, go ahead, and I'll jump in if there's anything to add. You'll probably respond very thoroughly.

Dr. Bobby Redwood: Thank you. This is Dr. Redwood. This was my fear when these guidelines came out. So, I'm so glad this question was asked. So, our patients still need to be adequately resuscitated for hypotensive shock. In my clinical practice, 30 milliliters per kilogram is the floor, not the ceiling, including comorbidity, including CHF, including end-stage renal disease. So, when I am working clinically, I am sticking with the 30 milliliters per kilogram, unless, unless, there is a compelling reason not to. So, I think the word of caution here is don't under resuscitate the patient. The classic example is you open the chart and you see a label on the chart. Let's say that I looked at patient's problem list and they have CHF on there. Well, there is a big difference between compensated CHF on medications and decompensated CHF. If I have CHF New York Heart Association Class 1 and I'm on proper therapy and not on any inotropes, that patient can take fluids just like any other healthy patient. Now, if you see that their last echo was done a week ago, and their EF was 10 percent, that's a whole other story. The same with end-stage renal disease, the patient with end-stage renal disease, they are third spacing their fluids, not just to their lungs, but to all compartments in their body. Quite likely, those patients are going to be getting dialyzed at some point during the hospital course. I feel very comfortable giving very liberal fluids to patients with end-stage renal disease or compensated CHF. Of course, you don't want to be reckless, you want to do it cautiously. So, you might start off with 500 CCs and give another 500 CCs, and make sure to go actually into that patient's room and relisten to lungs, talk to nurses, talk to your techs. Say: This patient is at risk for decompensation for fluid overload; let's keep a close eye on him. It's a little bit different than a healthy 30-year old with sepsis. Really, the standard is 30 milliliters per kilogram. Bob talked a lot about the retrospective evidence and how there is not a lot of prospective

evidence out there. There are single-center prospective evidence out for 30 milliliters per kilogram. It's just not quite the strength of evidence that we see in these larger control trials done across multiple academic centers. So, I'm excited to see what the next iteration of these guidelines come out with as we get more literature on this. Yet, in my clinical practice, 30 milliliters per kilogram really is the standard. Bob, did you have anything you want to add to that from a SEP-1 perspective?

Bob Dickerson: Yes. Just a couple of things, that was excellent. I think the key point here is how you give the fluids is very important. To that end, SEP-1 doesn't dictate how fast the fluids must be given, other than greater than 126 mils per hour, just as we referenced earlier to differentiate bolus for maintenance. It's not dictating you have to give it all in one bolus, you have to give it over 30 minutes, versus an hour, versus two hours, versus a couple of different boluses and see how patient responds. That is not what the measure is about. The measure is identifying what is kind of a default volume that had been the standard, 30 mils per kilogram, in the measure. Then, the updated guidance, which I believe happened a couple of versions ago, that allows for volumes less than 30 mils per kilogram are to provide allowance for these types of situations that Dr. Redwood just described, where maybe they are responding to a lower volume or there are truly concerns about fluid overload.

So, I guess from a requirement perspective for the measure, 30 mils per kilogram is still the default. However, if a physician documents they are giving less than that, and they have a reason for why they are giving less than that, then that is the target volume for that specific patient. So, we tried to build some flexibility based upon individual patient needs. I hope that helps explain from the measure perspective of what we're trying to do there and what we are looking at to reflect updated guidelines.

Candace Jackson: Thank you both, Dr. Redwood and Bob. I'm just want to kind of expand on that. So, if the provider documents a reason why less than 30 milliliters per kilogram should be administered, and documents that 0 milliliters should be administered, then that would meet the criteria for Value 1. Is that correct?

Bob Dickerson: Actually, that would not meet the criteria for Value 1 because the guidance does not have any allowances for no volume. In other words, the guidance reflects that some amount of fluid is being given, either 30 or less than 30, but there's no guidance in there about 0. So, to that end, that would not be acceptable for meeting the *Crystalloid Fluid Administration* data element.

Dr. Bobby Redwood: Just from a clinical standpoint, I'll just chime in here. Zero would be a very uncommon choice for a shock patient. The question isn't: Is this cardiogenic shock, or is this hypovolemic shock? If there is sepsis with CHF or some other cardiac comorbidity, what percentage of the shock state is cardiogenic shock? What percentage of this shock state is hypovolemic shock? Even patients in cardiogenic shock require some sort of trial of resuscitative fluid. Anything less than 500 CCs of bolus fluid would kind of actually raise my eyebrows from a clinical standpoint, and I would want to kind of flag that case for a departmental review, and say: Was this provider thinking correctly here? Did they really have solid justification for providing no fluids or such a small amount of fluid? They may be thinking too algorithmically and not really appreciating the nuance of shock, especially septic shock. So, if that's the case, I just want to have the departmental director do deep dive. Was that really justified, and what was the justification?

Candace Jackson: You probably responded to this question, but I'm going to ask it anyway. If a provider did elect to give 0 milliliters per kilogram to a patient who was in congestive heart failure with a New York Heart Association Class 4 in the setting of hypotension, can that provider skip giving the IV fluid and just give Levophed?

Bob Dickerson: Per the guidance again in the manual, that would not be acceptable. There would need to be some volume of fluids given. Dr. Redwoods, I don't know if you have any additional thoughts on that.

Dr. Bobby Redwood: I think that really ties in to what I just said. That would just be a little bit of odd care, and I would want that... I'm not saying it's wrong; there is a lot of nuance in medicine, and every patient is an individual case. That's when you would want another set of clinical eyes on it to just say: What was going on here, and was that decision to skip fluids entirely justified?

Candace Jackson: Okay. Wonderful. Thank you. I'm going to skip to a different topic now. Would we be able to go to slide 27, please? I believe during the presentation, Bob, on this slide, you mentioned that pregnancy is abstracted prior to *Severe Sepsis*. Can you explain what element includes abstraction of pregnancy?

Bob Dickerson: I know Noel Albritton from Tellegen is also on the call, and he works with the specifications. So, Noel, please feel free to jump in if I miss anything here. There is a data element that is called... I think it's *Pregnant 20 Weeks Through Day 3 Post-Delivery*. That data element falls in the algorithm right before we get to *Severe Sepsis Present*. If you back up to the previous slide, I'm not sure if that has the first part of the algorithm. That data element will fall between where we identify removal of patients based upon COVID diagnosis. There will be a couple of other data elements, one for patients transferred from another hospital or ambulatory surgery center and then another one for clinical trial. That data element for the pregnancy will follow right after that. Then, in the algorithm we go in to the *Severe Sepsis Present* data element. I hope that helps answer. Noel, any tips that you have in the flow of that, please jump in.

Noel Albritton: No, that was accurate, Bob. The only thing I would say is when you abstract, as far as abstraction goes, the *Pregnant 20 Weeks Through Day 3 Post-Delivery* data element, you're selecting where the patient 20 weeks pregnant and day 3 post-delivery and then moving on to abstract the *Severe Sepsis* data element, and you will use the clinical criteria specific to whether the patient was pregnant 20 weeks through day 3 post-delivery or not to establish severe sepsis.

Some folks I've seen in questions get confused with whether the case is excluded from the measure if the patient was pregnant, but the *Pregnant 20 Weeks Through Day 3 Post-Delivery* data element is not used to exclude the case, just to determine which clinical criteria will be used moving forward during abstraction.

Candace Jackson: Thank you both, Bob and Noel. I'm going to ask you questions now related to the lactic acid. If the lactate continues to rise, should it be repeated until it starts to trend down?

Dr. Bobby Redwood: This is Dr. Redwood.

Bob Dickerson: Go ahead, Dr. Redwood. I'll jump in according to what the measure specifications require, and I was actually going to ask that you address this from a clinical perspective. So, go right ahead.

Dr. Bobby Redwood: Perfect. I love that we're both so eager to throw it out there. I'm an emergency physician, so this would probably be a better question for an intensivist. Lactate is an independent marker of mortality, and it does tend to trend down once a patient has been adequately resuscitated and their sepsis is being treated sufficiently. I would continue to trend a rise in lactate unless some other reason. We know lactate goes up, for example, with seizures or certain medications. So, if you have some other explanation, like a patient has bad liver clearance and the lactate is still going up, then maybe you'd have a compelling reason to stop trending that. In general, I would continue to trend it until you start seeing it come down.

Bob Dickerson: This is Bob from the measure perspective. The measure does not require that you continue to trend it. The measure is looking for initial lactate, which if elevated, would then drive whether or not looking to see if a follow-up lactate was drawn. If that is the case, the measure does not look for value of that follow-up lactate. From that point, it's clinical judgment on whether or not that's something you should continue to trend.

Candace Jackson: Thank you both. Maybe for this next question, we can get both the clinician and measure perspective also. Why do you use lactic acid instead of procalcitonin to diagnose sepsis?

Bob Dickerson: Dr. Redwood, do you want to go ahead and start on that one?

Dr. Bobby Redwood: Thanks, Bob. I'll go ahead and chime in. I mean I guess clarification neither of these is used to diagnosis sepsis. If anyone ever creates a biomarker to diagnosis sepsis that would be worldwide news, right. That doesn't exist. So, you look at this cluster of clinical syndrome data elements from their history and obviously land markers to try to put together a picture of dysregulated host response to infection. Procalcitonin is only FDA approved for avoiding antibiotics in lower respiratory tract infections. If someone comes in with COPD, and you are not sure if its viral or bacterial, then, it's FDA approved for helping make that decision whether antibiosis or not, then, antibiotic de-escalation in sepsis. So, when someone comes into the ICU setting with septic shock and you see the procalcitonin is trending down, that's FDA approved to deescalate antibiotics, but not really for antibiotic de-escalation. So, there's a flurry of evidence on that. I can give multiple webinars on the topic, but ultimately the jury is still out on when the appropriate use of procalcitonin to initiate antibiotics is. I have seen hospital-level protocol that include procalcitonin. I have seen literature out there speaking against that. So, I think the jury is still out on that, and we can expect to perhaps see the Surviving Sepsis Campaign weigh in on that in the future. In terms of lactate, it's just a tried and true, as I said before, independent marker of in-hospital mortality. It tells us how sick our patients are and how likely they are to die. That's a useful data point in terms of needing ICU resources or not. That's part of the reason it wasn't included in the SEP-1 core measure, I presume, because all the way back to the Emanuel Rivers and the early sepsis resuscitation literature and sepsis bundle literature that included lactate. It's been a pretty useful data point, especially in the emergency department setting. That really does change my management if I see a lactate of 10 versus a lactate of 1.

Bob Dickerson: That was very nicely stated, Dr. Redwood. Thank you. What Dr. Redwood just referenced was pretty much the reason why the measure makes use of lactic acid and not procalcitonin. They are not looking at the same thing. So, I know we have had questions in the past: Can I use procalcitonin instead of lactic acid? For the measure specification, no, procalcitonin is not acceptable because it's not an equivalent type of test, and the lactic acid has been used since measure inception and has been incorporated in guidelines since the first set, I believe since the first set of Surviving Sepsis [Campaign] guidelines were developed and continues to be something that is suggested as we mention in presentation as adjunctive because of the association between high lactic acid and in patients with infection high rate of severe sepsis and septic shock. There is that clear association as to rationale for why lactic acid remains. Then, everything that Dr. Redwood just stated regarding procalcitonin, I can't really add anything to that. That helps I think underscore why it is not included as an optional test or instead of lactic acid for SEP-1.

Candace Jackson: Thank you both. Random questions about different topics that were discussed today: The slides use the phrase "antibiotics given within three hours." Does "given" mean the antibiotic infusion started within three hours or was completely infused within three hours?

Bob Dickerson: Thanks. This is Bob. That is a great question. I appreciate you asking that. So, what the measure is looking for is the antibiotic being started within that three hour time frame. We recognize that different antibiotics may require very different infusion times. For example, vancomycin, you're typically going to give over about an hour. Other antibiotics you can almost IV push them, but the key is getting that antibiotic started within that time period. The other thing that we have heard from the field is that the time that an antibiotic is... The start of the infusion is consistently documented, but the time that the infusion ends and completely administered is inconsistently documented or sometimes difficult to find. That is another reason why we don't look at the point in time where the antibiotic is completely infused. I hope that answers that question.

Candace Jackson: For our next question, could we go to slide 42, please? This was probably directed to Dr. Redwood. Could you please explain the term "incremental PEEP not recommended"?

Dr. Bobby Redwood: Sure. Incremental PEEP is when you change your PEEP, increase it by 2 to 5. Go back and reassess the patient, increase by 2 to 5. Go back and reassess the patient. It's a lung recruitment strategy that is involved, basically tweaking the PEEP upward until you get that patient oxygenation level or breath sounds where you want them to be. Again, this is probably more for the pulmonologist, but there is some thought that the strategy can affects shear injury in the lung and was not recommended for this round of the Surviving Sepsis Campaign guidelines.

Candace Jackson: Thank you, Dr. Redwood. We do have time for a few more questions. Can you please address the COVID exclusion? If there is documentation of COVID and the PCR is negative, could this be discounted in the future?

Bob Dickerson: This is Bob again. That is a great question, and just to give a little bit of context to the whole thing with COVID, when COVID first hit us, and we had the pandemic at its height, we quickly learned that, for example, fluid resuscitation for patients who were coming in with sepsis caused by COVID was a different approach than a bacterial infection. So, the guidance then, we made adjustments to exclude those patients suspected or confirmed as having COVID, so that you didn't have cases that would fail the measure through no fault of anyone other than COVID-19. We know a lot more about COVID now. While it's still out there and will be out there I'm sure for some time to come, we are out of the height of the pandemic. We have better testing. So, I really appreciate this question because I can't speak for sure whether or not it will be incorporated in the future iterations of the measure. It is a wonderful question. This is something that would take to the measure steward for consideration because this is something that would reflect, from the treating clinician perspective, I suspect the patient may have it. I did the PCR. Whew! They don't have it, now I can treat them accordingly.

I really appreciate that, and we will take that to the measure stewards. Dr. Redwood, I don't know if you had any thoughts from like an ED physician at the bedside when you get cases like this, if you wanted to share.

Dr. Bobby Redwood: You know I was really impressed that the exclusion for COVID came out so quickly. It really is a new mimic. We talk all the time about sepsis mimic. The DKA can give you lactate of 20, and an asthma attack can give you a respiratory rate of 30. Right? Neither one of those are septic shock. COVID came along, and it was really a new mimic that changed the way we practice. I thought that CMS adapted quite well. Going forward, we're going to see, you know, there is such a thing as secondary bacterial infection, around ten percent, where you get a bacterial infection on top of COVID. COVID puts us in a state where our immune system's resources are being spent elsewhere and it gives opportunity for secondary infection to sneak in, perhaps even a hospital-acquired infection because people are already in the hospital and already on a ventilator. So, that's a very real clinical entity. That's what I see as often a delayed presentation of bacterial sepsis after a patient with COVID has been in the hospital for a little while. I thought the measure adapted well, and that the nuance of that is bearing out in the literature now. That's a real question in my mind, as a front line clinician. Often times COVID clinical presentation is quite obvious, but is there a secondary bacterial infection here? If so, what is the right approach to treating that.

Candace Jackson: Thank you, Dr. Redwood and Bob. Again, I like to thank Dr. Redwood and Bob for responding to our questions today through the live Q&A session. I know it's very beneficial to our stakeholders. Next slide, please.

If we didn't get to your question during the question-and-answer session, please submit your question to the QualityNet Inpatient Question and Answer Tool. If you have questions for Dr. Redwood that did not get answered during the presentation or during the Q&A session, you can send please those to Dr. Redwood at the address that is listed on the slide. Next slide, please.

As we stated earlier, this webinar has been approved for 1.5 continuing education units. To obtain your CEUs, access the link listed on this slide.

We'd like to thank you, Dr. Redwood and Bob, for providing this valuable information today. Thank all of you who have joined us today. We hope you have a great rest of your day. Thank you