

NATIONAL QUALITY FORUM

Moderator: Reva Winkler
December 5, 2012
1:00 p.m. ET

Operator: Welcome to the conference. Please note today's call is being recorded.
Please standby.

Reva Winkler: Good afternoon, everybody, and welcome to this conference call of the Infectious Disease Steering Committee. This is Reva Winkler at NQF, and I'm joined with my colleagues Alexis Morgan and Adeela Khan. Thanks very much for joining us today.

This call we're using open lines for everybody who is joining in. So, we really do need to be a little bit cautious about muting line when you're not speaking so that everybody doesn't hear what else is going on in your life.

The purpose of today's call is we have two agenda items. The first one is to review the public comments that were submitted for measure 0500 on sepsis. Then secondarily, we will be doing a reconsideration of the hepatitis C measure that you all determined if you wanted to take another look at.

Your colleagues, David Spach and Ray Chung are on some tight time lines today, and so we're looking to start that conversation around 2 o'clock Eastern so that they can leave their clinical duties temporarily to join in the call. So, we will want to kind of watch ourselves to be able to have that conversation at that time.

So, today – so first off is the discussion of the comments that we received on the sepsis measure. Because these two agenda items are rather distinct, we will provide the opportunity for public comment at the conclusion of the

discussion of sepsis and, again, I said conclusion of the discussion of the hepatitis measure.

So, in terms of the comments received on measure 0500, the sepsis measure, we received comments, rather lengthy and extensive comments, from eight organizations. The comments kind of split into two camps about half of them supporting the measure and the other half raising issues and concerns about the measure.

Most of the concerns that were raised were of a technical nature around the specifications. And so, we did send the comments to the developer and requested their responses. The responses along with the lengthy comments, we have a relatively lengthy document for you that I hope all of you have had a chance to look through because it really does give you a pretty fair picture of what the comments are and the developer's response.

Now, I believe we do have the developers on the line, Dr. Townsend and (Dr. Rivers), if there any questions for them. Certainly, they've already provided a lot of detail in the responses.

So, today, as before, in our previous conference call, the action item for this committee is to look at the comments submitted and then ask whether after reviewing discussion of the comments, does the committee wants to reevaluate or reconsider the measure based upon the criteria or maintain their recommendation of the measure? So, we do want to be sure to remember what the purpose of our conversation is today.

So, with that, to begin the conversation around the comments that were submitted, I'll turn it over to Dr. Septimus and Dr. Brotman.

Edward Septimus: Hello, everybody. Thanks for joining the call, and we appreciate the comments that we got back on this particular measure. I think for the sake of trying to find and also organize this section of the comments, I've summarized the concerns around four buckets, and I think we'll discuss each one of those among ourselves as the subcommittee will then ask the developers if they want to comment on that and as we already just mentioned, at about 1:45, if

not earlier, we will then ask for public comment. So, that will be the schedule.

So, the four buckets was, number one, the reliability of triage being time zero; the second was around the evidence of a CVP measurement in the emergency department; the third was the feasibility of (extracting) the composite measures; and the fourth but not mentioned by all was the evidence around drawing blood cultures.

So, before I go any further to the committee members, does that – do you think that summarizes the four buckets that we need to discuss in the next 30 to 40 minutes? Is there anything that I missed?

OK. Hearing none, we'll then move forward. The first one is the issues surrounding the reliability of triage being time zero, which of course is how the surviving sepsis documentation and literature has been around. First, let me ask the committee members if any of them have any question around is that reliability of triage and then any questions we may have for the developers.

Aaron Milstone: This is Aaron. I'm sorry I'm confused about the protocol. Are we going to – I thought when we had started – were we going to go decide whether we're going to reevaluate this, or we just kind of discuss and I'm confused what we're doing here.

Edward Septimus: Well, after we review of the comments, we will then decide whether we want to (inaudible) ...

Aaron Milstone: Oh I see, OK.

Edward Septimus: ... the current measures based on the comments.

Aaron Milstone: OK.

Edward Septimus: Does that make sense, Aaron?

Aaron Milstone: Sure.

Edward Septimus: OK. We've already voted on, (it's all or you don't). So, any comments around the reliability of triage being time zero?

Tiffany Osborn: I think that there were quite a few comments that were brought up both from the developer, as well as from additional commenters that I think definitely merit conversation.

Edward Septimus: Oh, (who's this)?

Tiffany Osborn: Because we did not – this is Tiffany Osborn, sorry. We began this ...

Edward Septimus: I know (it's you).

Tiffany Osborn: Yes, hi.

Edward Septimus: I don't think everybody knows who your voice is. So, if you'll announce your ...

Tiffany Osborn: Yes, sorry about that – sorry, yes. This is Tiffany Osborn. I think that we didn't really discuss time zero in our discussion during this year's subsequent discussions and both the developers and the commenters brought up important issues on that that I think the committee would probably want to have a little bit more information on.

Edward Septimus: Tiffany, would you like to have a developer's comment on that? Is that what you ...

Tiffany Osborn: I think yes.

Emanuel Rivers: I would like to ...

Tiffany Osborn: I think that that would be very helpful because that was not something that we have discussed prior to this particular time.

Edward Septimus: And that is correct.

Emanuel Rivers: This is Manny Rivers. And before, I would like to bear out the reality of triage time versus the time of question in terms of the measure element.

When we look at the literature and you go back and you look at the Rivers article in 2001 and Shapiro in 2006, you look at the Jones article, the (Linde) article, the actual time from hospital arrival for triage until actually eligibility for goal directive range 42 minutes to 111 minutes.

So, when you look at the actual concern about the majority of patients who present with eligibility for the bundle, they actually are diagnosed at triage. And so, it makes it almost a singular issue that we're actually wanting the same when it comes to actual picking up these patients. So, the concern of a patient developing the enrolment criteria or the eligibility criteria and the reason of their ED stay is within the natural history of clinical care.

Some patients will do that. But the majority of the patients are actually detected upon presentation which makes the concern about delays and perhaps didn't analyze which is not the purpose of this measure but the whole idea of not being able to pick up these patients in a timely fashion is now borne out by the literature, and I can provide that table because it doesn't reflect what the reality of sepsis management.

Tiffany Osborn: Dr. Septimus, this is Tiffany. It might be helpful for the committee to sort of have a summary of what the concerns were so that they understand the context of what Dr. Rivers is referring, too.

Edward Septimus: If you want, too, since I think you were the one who presented this at our face-to-face meeting. If you're comfortable, can you summarize that, or would like for me to summarize?

Tiffany Osborn: Whichever is your preference, I'm happy to go with whatever you would prefer.

Edward Septimus: Well, we like obviously have the person who discussed it face-to-face, so if you'd like, you can just highlight a couple of the points that were discussed in the comments.

Tiffany Osborn: Sure, OK. So – and we have both commenters and developers here so they can correct me if I am maybe summarizing in a way that it's not consistent with what their intention was.

But from the commenter perspective, as I understand the multiple comments that we got relating to that issue was that time zero right now, triage time is time zero, so, when we have this measure of these elements that have to be completed, they have to be completed within six hours and that the start time is time zero which is triage time.

Now, the comments by some of the commenters were that this is quite difficult because if somebody presents with severe sepsis or septic shock at triage, then it's applicable. If they present, say with pneumonia, but not necessarily shock at triage then developed shock during their stay at hour, say four, then the clinicians would only have two hours to complete this bundle.

And so, that was a concern for them regarding, one, actually being able to successfully complete the measure not having the sufficient time; two, the reliability and validity of treating a – of starting the clock to treat a disease that the symptom – you know, that didn't exist at the time the clock started; and three one of the – I think it was Dr. Phelan who had specifically asked about what are the ramifications as far as if this – if doing this were implemented with other, you know, nationally what's the (president) (were) setting, and I think what he had brought up.

So, those were the three items as I understand it. And then from developer side, the thought was – as Dr. Rivers was mentioning a second ago – well, the majority of these patients have severe sepsis and septic shock at the time of triage so that entity is one and the same. Additionally, the thought from a process improvement standpoint was that everybody is going to be – everybody can be subjective to the same time line. All hospitals across the country are subjected the same time line.

So, if you're only getting 50 percent of – if only 50 percent at the time you meet the measure, you know, it will fall within the average of the country and it's only if you're an outlier based on the average of country that you would be subjected to pay for performance or public reporting accountability as I understand. They may want to say if I've missed something.

Sean Townsend: This is Sean Townsend. I think you've summarized our thoughts pretty well, Tiffany. (From the measures, they all preside). I wanted to add to your comments. The key thing that I think we need to be focused on is that although the theoretical concerns which have been addressed as possible challenges (to validity) are well stated by the commenters and that I think responded to in detail as well.

The fortunate thing for us on this call on this day is that we have data to be the arbiter of the discussion and the data that we presented in the submission reflects that even the RAND analysis that there is sufficient evidence available to us that the – using signal-to-noise ratios. There is significant evidence to suggest that the reliability to compare one hospital to another is borne out through using triage.

And so, the key point to make it here is, in my mind, that regardless of the theoretical concerns, all of the variability that's been exposed and (unpeeled) they're suggesting here has been evaluated in a very large patient data set, and that variability is accounted for and we still find despite all of that that it's a reliable start point to begin the clock. And so, when we talk about majorities in bell curves in most patients in most hospitals, they have adjudicated the question quite well in favor of the measure.

Tiffany Osborn: And from the commenter side?

Edward Septimus: They don't comment until 1:45, Tiffany. OK, so they'll have an opportunity to comment.

Tiffany Osborn: OK.

Edward Septimus: One question, Sean or Manny, there's obviously some measures of three hours and some measures at six hours. And so, in terms of the measure, we're looking at six hours to complete it or three hours?

Sean Townsend: The overall – so there are two components. There are the items that should be completed by hours three and then items that get completed by six hours. So, you would fail the composites if the three-hour items weren't completed in three hours or the six-hour items weren't completed in six hours.

Edward Septimus: Yes, thanks for the clarification. I think there was some discussion about that but I wanted to make clear. Any the other comments from the subcommittee because I want to make sure we respect for people's time and we make sure we finish this in a timely manner before we go on to the next bucket.

Emanuel Rivers: Ed, do you mind if I make a comment?

Edward Septimus: Sure, go ahead, Manny.

Emanuel Rivers: Oh (inaudible) ...

Edward Septimus: I think people know your voice but again, try to ...

Emanuel Rivers: Oh. One of the recurrent things is being penalized or being held accountable but the key point in all of this is that there's what they call a Measure Applications Partnership that occurs after this process which still allows for stakeholders to have commentary and have influence on the clinical reality. So, when you look at the whole process and I think the endpoint is that the worry is that a busy emergency department which has a lot of other things going on will be burdened with a quality measure that they may not be able to meet.

I think that fear is somewhat not substantiated based on the process of how this actually will occur. And I actually talked with at a measure – to a director of CMS to make sure that this was – this concern was addressed and there's a Web site I'll provide that actually explains this whole process. But I think it's important to understand that it is not the sort of a punitive measure where people will be held as standards and then they would not be able to have influence on later in the phase of development on that side.

Tiffany Osborn: So, since the commenters cannot comment until after the discussion, I just want to bring up a couple of the things that stuck out my mind as this went forward so that it can just be out of my table and that you guys can address them. One was associated with time in the emergency department and the thought being that, you know, these patients depending on – and this is what one of – I think this was from either ACEP or (SAM) that said that you have

prolonged ED admissions where people, intensive care unit or critically ill patients can stay 12, you know, 14 hours or more. And the question that they had was well if time zero is triage time and the person developed symptoms after hour six, then they've already not met the measures there. You know, how would you respond to that concern?

Sean Townsend: This is Sean. I'd like that take if I could. The first response to that I think is – I can't (press enough) upon the committee is that our data already assumes those one length of stay. And so, those are not unaccounted for in our analysis.

And there's – an interesting, you know, dynamic that arises here, you can raise a theoretical concern about some outlier case that does have the potentials to occur admittedly, but you don't need any data to bring with you to justify how often that occurs or to explain how often the outliers affect the metric but yet the – you know, if you think of it from the developer side using a (way) of giving you plenty of data just as reliable in circumstances that include those outliers. So, I would ask for consideration of the data for the first arbiter to that question.

The second comment I would make is in regard to that is we're not aligned with regard to how long patients stay in the emergency department. The Government Accounting Office has published that the average length of stay in the emergency department in the United States is six hours. So, these cases are clearly not normal when someone goes to the emergency department for 12 and 29 hours or what have you. Those cases are unusual and don't represent the norm.

Thirdly, we know from looking at the papers that have studied early goal-directed therapy, and there three papers in particular, or four papers, I would draw your attention to it, on which we can provide citations for Alan Jones, Steve Trzeciak, (Bryan Wynne) and (H. Shapiro) have all published a literature on early goal-directed therapy. And the average time from triage to qualification for early goal-directed therapy is between 20 and 90 minutes in the those papers. So, well within the three-hour range to begin to meet the composite.

Tiffany Osborn: May I ask you one question on that just for point of clarification just to make sure we're on the same sheet of music. Were those – did those papers include severe sepsis and septic shock, or were they just septic shock?

Emanuel Rivers: Well, if you look at the – within those studies, the variance of severe sepsis and septic (inaudible). In our study, we had a lot more severe sepsis, and (Alan Jones), he had 80 percent septic shock. So, you have some heterogeneity in terms of presentation, but the majority of the patients are actually are captured within the first hour or two.

Sean Townsend: (Plus) ...

Sean Townsend: I think it's important also is that this is a CQI. And what CQIs mean is that once you establish the sepsis program and screening becomes part of your protocol, then there's a less reliance on – (back in) diagnosed disease. And so, I think one of the things that the attributes of this program is that you will actually diminish those patients who will require a breadth of invasive monitoring just by early detection and then perhaps intervening much quicker. And there's a study that recently came out at Beaumont that actually showed that the screening aspect of this program capturing these patients early actually had a lot of impact – great impact on mortalities.

So, I think that to try to isolate out one variable to say that, you know, this is an overwhelmingly difficult process, I think the attribute is that there's a whole program is that could hospital continuous program even if at the ICUs are involved as well. So, when you talk about length of stays in the ED, the goal is to try to make this a multidisciplinary measure and not an isolated ED measure.

Tiffany Osborn: So, last question then regarding – from my perspective because I'm sure that other committee members have questions. How are you operationalizing this because I saw that it could be chart abstraction, it could be ICD-9 code? How would this be operationalized for this measure?

Sean Townsend: Well, think – this is Sean Townsend again. I think one major advantage to the measures using triage time in its favor is that the operationalization for

deployments in EHR makes this time easily available and one which can be used in the future to capture this time period reliably. So, the use of triage time is not the – it (adds) I think with a good operational perspective. I think it actually makes the timing easier.

In terms of how the measure is – data is collected, you guys of ICD-9 codes, typically what's happened when these measures have been carried to a national scale is that if, for example, say, CMS were to adopt it as with the other core measures, they identify based upon ICD-9 code. There's certain fraction of charts that qualify for any measure. They then randomly ask the hospitals to call certain charts and evaluate them to see if they meet the measure, and that's done by abstractors in quality departments throughout the country whether or not they use in EHR at this point in time.

So, I would not envision I think different than the current process in terms of that. Did I answer your question, Tiffany?

Tiffany Osborn: OK.

Edward Septimus: Why don't we go on to the next one which is CVP measure? And, again, the question around that is, is CVP measure accurate and useful in the first six hours to monitor volume replacement? And is there any harm? I think that's what I think summarizes it. Tiffany, would you agree with that?

Tiffany Osborn: Yes. And this was – we discussed this extensively and during the D.C. meeting specifically around the controversy surrounding CVP accurate and reliable measure of intravascular volume. We discussed that in ScvO2 fairly robustly.

Edward Septimus: Yes. And there are some very nice comments from both sides of this issue in the documents that were sent out. So, did any of the committee members have any questions, and then we'll ask Sean and/or Manny to comment on that?

Are there developers like to comment on?

Emanuel Rivers: Go ahead, Sean.

Sean Townsend: My comment – this is Sean Townsend again – that I would like to make is, you know, one of the remarks that were made in the comments was that CVP is not in of itself and proven to be reliable measures on intravascular volume. And I just would like to address that by saying that the answer is that’s essentially correct but nothing else has been – has shown to be more reliable.

And so, to call for something to substitute for CVP would imply that you have something more reliable to use because no person would say that for someone who’s severely septic or in shock that you shouldn’t have some estimate of their filling pressures for intravascular volume.

So, you don’t have a better substitute even though you have questions about the validity of CVP as an assessment for intravascular volume. It’s important to (decide to) composite though it’s something which I think can’t be ignored. Because we are dealing with a composite that calls for fluid administration as part of it and also for the assessment of ScvO₂, you need to have something that reflects adequate filling pressures or intravascular volume status. Because it’s essential to the composite as a measure, we continue to (inaudible) as part of the measurement.

Emanuel Rivers: Yes, may I add for a few comments?

Aaron Milstone: Can I jump in for a sec first?

Edward Septimus: Who’s speaking?

Aaron Milstone: This is Aaron Milstone. Just to backup a little bit, I mean, you know, we talk a lot about our (inaudible) meeting about what the goals were. And the goals of the measures are the improved outcomes, and I assume the main outcome that you’re targeting is death because sepsis already happened in these patients and what we’re doing is trying to reduce morbidity, and mortality, and death.

So, I guess, when I look at the components of the bundle and this is what we – I think Tiffany, kind of talked about this in the meeting – it was – though each of these components, you know, there are two ways we can do this. Looking at each component and its relation to the outcome, not saying that people with

low CVPs have worse outcomes because I think that makes sense, but does measuring CVP by itself improve outcome? And then the second is does including CVP in the bundle improve outcome?

And I understand the concept of using there's no better surrogate, and this is an important component of assessing fluid management. But, again, this is the quality measure just like we discussed with the central line checklist. And then it is, does having CVP is part of this component improve outcome? And I think just saying that in analysis there's an association – I read your comments. They were extensive. And does having CVP in that bundle improve outcome?

Sean Townsend: Hi, this is Sean.

Emanuel Rivers: And I ...

Sean Townsend: I think that – I would say yes. And the reason I would say yes is because, again, data would be the best I would adhere. There is no analysis that looks at the provision of early goal-directed therapy minus central venous pressure assessment. But there are – these 50 papers cited in the submission which indicate that when early goal-directed therapy is done, which includes this composite assessment of features, mortality does drop. So, while you can't (use) CVP out alone and have a good evaluation whether it alone decreases mortality, you do know that when it utilizes part of the composite, in fact, mortality does change.

Edward Septimus: And, Sean, could you comment on something that – this is Ed – between early CVP and the late CVP and does that make a difference over time?

Emanuel Rivers: May I interject, Sean?

Edward Septimus: Go ahead, Manny.

Sean Townsend: (Go ahead, if you want).

Emanuel Rivers: First of all, they are the fundamental, what I think, explanation for CVP, and CVP is a pressure. It's not a volume measurement. So, when you look at

CVP in a context of a pressure and just for instance the pacing can have a CVP at 32 have and ScvO₂ of 30, that patient won't get fluids. They'll get an (niantiril).

So, they are the clinical translation that must be understood before we start to collaborate CVP with volume because primarily it's a volume measure but it's also a measure that is manipulated to improve other aspects of the cardiovascular system. And when you treat cardiovascular physiology, the system is closed. It is not one variable. There's preload, there's after load, there's contractility, there's heart rate, coronary perfusion pressure. These are variables that are connected. They're not isolated out to say, "Can I get away with one other or the other?" And that is whether you're having bypass surgery, whether you're in septic shock, or whether you are undergoing hemorrhagic shock. These are manipulated variables that are commonly done.

And so, when you look at the evidence and there is a recent article that just was published by Mayo Clinic, that actually show that time to CVP goals correlated the 341 patients every single hour of delay in CVP measurement associated with an increase of 14 percent in (neuro) SOFA score. And then if you look at a recent article that is coming out of Boston, which actually looked at a huge database, Medicare database, and they looked at over 200,000 patients from the year 1998 to 2009, they showed that CVP placement actually went up from 5.7 to 19.2 percent. And actually, mortality associated with CVP placement decreased 9 percent. So, here you have direct evidence showing that there is improvement and morbidity or organ dysfunction, as well as mortality when CVPs are placed within the first 12 hours of hospitalization.

Tiffany Osborn: This is Tiffany. What would you say to those who would ask regarding the other studies like the surviving sepsis campaign study that looked at, you know, the different elements within the bundle and did not find CVP and ScvO₂ to not correlate with mortality.

Emanuel Rivers: Well, first of all, (Dr. Bryan Wynne) actually wrote a letter and sent it yesterday or today basically explaining his data which was misquoted in those assertions. And if you go back and you look at those studies, every one of

those studies show that ScvO₂ correlated with improved mortality, every one of them.

How do you get ScvO₂? You have to put a CVP in. So, it is almost – what do you – how can you jump over CVP and get ScvO₂ without monitoring through CVP and remember CVP is also a conduit for basal pressure therapy.

Sean Townsend: This is Sean ...

Emanuel Rivers: People who are in septic shock ...

Sean Townsend: That's a very good point. You know, none of the comments said ScvO₂ is inadequate, none of them. And so, if you want to ascertain ScvO₂ as part of the composite which was unquestioned, you have to have the central line in place. So, why not use it to help assess the (point) status. It's really part of the creation if it's there for you to use anyway?

Edward Septimus: Well, Sean, from what I'm hearing – this is Ed – it sounds like – obviously there are more than one element to the bundle and you have to use all of these measurements alone with optimized care. Would that be fair to say? I mean, just like Manny just mentioned, you could have a very high CVP, but you have a very low ScvO₂, and then the intervention there might be an inotrope.

Sean Townsend: Right. And we've been – you know, this has been at the history of the sepsis campaign. And the use of this measure set is I can't think of a conference or a hospital that I visited over the years where I haven't had to say it is the net effect of doing all of the therapies together that result in the mortality benefit and that there is simply insufficient data for most of the components to tease them apart.

Tiffany Osborn: I just need to ask you this one question – this is Tiffany again. I need to ask you this one question because we're talking a lot about these bundle elements. And we – there was something that was brought up by Dr. Phelan that – (Fallon) that probably should be addressed by the NQF people which had to do with the fact that they didn't feel that way we assess this compliance, that this composite measure was not in accordance with their – the NQF guidance on how the composite measures were supposed to be evaluated.

Reva or did somebody want to just comment on that really quickly because it was – he did bring that up and he said it wasn't NQF. Yes, you know, NQF guidance on evaluation of the composite measure and that we maybe did not approach it appropriately and we probably should just get that on a table and just, you know ...

Reva Winkler: This is Reva. In terms of composite measures, this is a very dynamic area. NQF had took a first pass at providing some guidance quite a few years ago when the typical composite was truly a some way of combining this thing individual quality measures into a single score, and the guidance was created around that concept.

However, with the experience with a whole bunch of new different types of measures that some people call composites, but I think that's certainly open to discussion, that such as the all or none or the any of many, which we see with complication measures or these bundle measures, those – that kind of guidance really was not helping steering committees and they were having difficulty with it.

So, just to let you know that we're in the process of reformulating that guidance around composite measures and to accommodate a much less rigid approach because of all these new types of measures that are coming along. What you need to think about though is the basics around the criteria for the measure. Is the measure evidence based? That's one of the important sub-criteria in the importance criteria. Is the evidence there? The second one is hasn't been tested for reliability and validity? And then the others around usability and feasibility. So, the criteria are essential – are the same. That does not change.

Tiffany Osborn: So, specifically what he said was – and he quoted that, “The individual measures included in a composite or sub-composite must be either NQF endorsed or assessed to have met the individual measure evaluation criteria as the first step in evaluating the composite measure.” So, if you could just specifically – I think when I e-mailed you on that you said that it was

currently being revised. So, I just to make sure that we have addressed his comment.

Reva Winkler: Right. One of the issues I think is the question that is difficult here is, are we able to break this measure down into individual performance measures? Not necessarily elements of the measure but different individual component because that's what the guidance talks about treating the individual performance measures contained within a composite.

And that we're steering committees such as this one, as well as many previously, are running into difficulties because many of these new style measures that bundle a lot of elements together don't lend themselves very well to being broken down so you can clearly identify what the individual performance measures are that have been (fully) aggregated into a "composite."

Edward Septimus: Yes. And this one is a little bit interesting and that it's a tiered measure, so that not everyone is going to need a CVP or an ScvO2. It depends upon a criteria. So, it's not – I don't know maybe not precisely what a composite measure will be but it has the feel that it could be.

Emanuel Rivers: Yes. And, Ed, please allow me to make a comment, is that this measure crosses the boundaries of two specialties, and I think we must put this on the table is that there is some – there is a proficiency difference between emergency physicians universally in terms of putting in central lines, and I can understand that. If this measure was predominantly done in an ICU in the hands of an intensivist, it will be not of a question.

So, I think part of the commentary arises from the fact that if the patient needs it, whether they're in the ED or ICU, the issue is there a feasibility of placing a line in the ED both from the clinician perspective raises I think this to a level where of question in that sense.

Sean Townsend: Well, if I may – going to comment as well. This is Sean Townsend. Even, you know, you've been under this framework that you had previously published which you described as being more rigid, there was an allowance

made that's a sub-composites, or what I think you're now referring to as individual performance measures within composite.

It could be essential to the overall composite. And even though they may not be able to stand alone as component measures that they may have a reference and importance to the overall composite. And I think that's precisely the case with CVP here because it has recursive effects on other parts of the bundles.

So, you know, if you're going to be administering fluids to a certain number of ml's per kilogram, you are interested in knowing something about (Wayne) status, and that's where CVP has echoes of being important. Or if you're going to check ScvO₂, as Dr. Rivers has just pointed out, that's part of the – as part of cardiac physiology as it measures an output. Then it impacts there as well. So, it becomes essential to the composite whether or not I think it's capable with standing alone.

Tiffany Osborn: So, Reva, just to get to a bottom line on this, because according to what this says here, right, that individual measures had to be NQF endorsed, and that is not where we're at. Is that what you're saying, right?

Reva Winkler: (No.)

Tiffany Osborn: What you're seeing is that we are looking at this as a composite measure, and whether or not this measure was demonstrated to improve outcome or not as a measure and that this criteria – the NQF had out previously individual measures included composite must be either NQF – must be either NQF endorsed or assessed to have met the individual measure evaluation criteria as the first step in evaluating a composite measure. You're saying that this does not apply to this current measure. Is that correct?

Reva Winkler: What I'm saying is you're discovering as many previous steering committees are discovering that that very difficult to apply for these kinds of measures. And so, I would guide you to look at the measure against the criteria of, you know, important evidence, reliability, validity, usability, and feasibility.

Edward Septimus: OK. I think I'm going to have to kind of move us along. I'm sorry, but I think those are important issues – I think it's about (to pause). We can take

that. When we talk about blood cultures, I think the question raised about blood cultures is whether or not they're related to outcomes.

Any question from the steering committee? With Tiffany who's been looking at this for us. How about from the developer's perspective?

Emanuel Rivers: I like to bring forth an article by (Cardova) that was published and (offered by) the reference that actually looked at blood culture measurements in their operationalization of the bundle, and it showed it to be statistically significant in association with improved mortality.

In addition, if you look at (Lester Cardova) (in effect) they wanted to reference as we provided it in the original submission. And then (Nnand Kumar) who showed a five-fold increase in mortality if the first antibiotic choice was incorrect based on blood cultures. So, I think that those bodies of evidence hopefully should lay those fears that blood cultures (then affect) outcome.

Edward Septimus: I'm unclear how mismatching antibiotics has to do with the timing of the blood culture obtainment? I believe I understand that it's important to get a culture early on. I mean I'm just curious about – because do we have – that seems like a slightly different ...

Sean Townsend: What was the question?

Emanuel Rivers: I thought ...

Aaron Milstone: You mentioned that there was new paper that showed that the initial antibiotic selected mismatched the organism that grew in culture. There is increase in mortality.

Emanuel Rivers: There is. That's not a new paper. It's in 2000.

Aaron Milstone: Oh, no, no. I understand but I was trying to see how that evidence, that it's essential to get blood cultures prior to starting antibiotic.

Sean Townsend: So – and this Sean Townsend. You know, the question of whether it's essential to do it or not to obtain them prior to its – I think the only thing you

can say about that is that improved as you have, you know, because you're able to later change antibiotic in case you had to. That's the logic that we speak to behind the reasoning.

Aaron Milstone: No, I know. I guess the pediatrician we deal with all the time with lumbar puncture is where we see patients transported who don't get antibiotic because they're waiting for someone to do their lumbar puncture, and obviously that's not the recommendation. It's you give antibiotics as soon as you can.

Now, I understand that you need to put an IV and usually they get antibiotics. So, you can get a culture when you, you know, we're putting an IV (and withdrawing) blood but I was just looking for a little more clear data on how that's been assessed.

Edward Septimus: Really – this is Ed. Let me see if I can post a question in a different way. I understand what the comments were really getting specifically flowing above culture changes outcomes. There's no doubt that if the drug or drug you select on the front-end covers the eventual cultured pathogen, that outcomes are improved.

Aaron Milstone: Right.

Edward Septimus: And you don't get that information, of course, until 24 to 48 hours later. But the other thing is, you know, is this sort of a quality measure. I think the studies that Manny quoted, you know, one of the explanations could be people who are really paying attention to detail to make sure those cultures are done and this had an indirect measurement of other attention to details in managing that patient.

However, having said that, knowing what the pathogen is and of course even people with septic shock only 50 percent is an example have positive blood cultures but knowing what the pathogen is, you're able to first of all adjust therapy and turns out you missed the pathogen, number one. Secondly, you're able to stream the line or deescalate which may have an impact on collateral damage if you have to continue broad spectrum antibiotic when you haven't cultured a pathogen because you didn't get the cultures first.

So, it depends upon how the committee wants to look at this. Is it an outcome or is it really a quality measure that should go into the bundle.

Emanuel Rivers: Yes and ...

Edward Septimus: And that's how I (inaudible).

Emanuel Rivers: ... yes and I just wanted to reinforce that (Cardoza) actually looked at antibiotic – I mean, blood cultures as an isolated variable in relationship to performing the bundle and went back in data regression analysis and it stood actually as the only element that improved mortality.

So, again, I want to say that this has been examined in the context of a bundle application and actually when you look at the data post-tap show that blood cultures taken were actually associated significantly with improved mortality.

Edward Septimus: Thank you, Manny. I guess the last one I think we've sort of ...

Aaron Milstone: Ed, I just want to follow up on one thing. One thing that the reviewers or the commenters brought up that I think is important then we can talk about this when we get to the usability is if we – if there is agreement that that is an essential component or should remain in the bundle or be apart or should they remain. Is it component of this bundle? It does significantly add to the burden of data collection because, you know, capturing time stamps for blood culture draws and culture times to EMR is useful but it does add to the additional data collection.

Sean Townsend: This is Sean. You know, I've read that comment and I did just say it raised an eyebrow. I thought of it as a bit out of step with but actually happens when clinical chart abstraction on quality department. When you're required to measure a patient, for example, with AMI and you've pulled their medical record, there are a number time stamps that a person sitting in a desk with the paper chart or an EHR has to capture somehow. In fact, I couldn't really understand how one more time stamp was truly so burdensome. It's just as – seems to me they'd be effective life in clinical chart abstraction.

Edward Septimus: Thank you. OK, the last one is feasibility of abstracting the composite measure, I kind of get a little bit to what Aaron just mentioned and I guess the first – the committee and then the, of course, the developers who had a lot of experience of doing this can answer then we really need to make sure we have time for public comment.

Sean Townsend: You know, I guess that – to make a blanket comment – this is Sean again – in all of these categories, the thing that ends up the most important to me at the end of the day is that we take data and use this as an arbiter (to serve) answer these questions, and if we look at them from many other perspective, we've analyzed rhetoric alone. And I don't think that will be adjusted as to the severity of this disease process, the number of patients were effected by it and the tenures with the evidence we have that if used – if used against this measure, mortality is decreasing when possible engagement in performance improvement project.

So, I think the campaign data itself is a reflection of the feasibility and usability of this data. We know that 200 hospitals captured of the 30,000 patients over the four-year time frame and I can't think of a better testimony to whether it's feasible or usable and the tools and the complexity of the tools – we were transparent, of course, in this (division), we submitted those so that you can see it that that data was collected that number of hospitals in that number of patients.

Edward Septimus: And I can tell you from my organization standpoint that has 54 hospitals now engaged in a rather roust implementation; they are collecting all these data elements. So, I think it – I'm not saying it's not a burden, but I think when you make it a priority, you can get a way to do it and I think we feel that the data and already has shown that by doing this and paying attention to these elements to improve outcomes which, of course, is really what our central theme is, of course, in all of these measures. Since there is no one ...

Aaron Milstone: Ed, this is Aaron Milstone. Just out of respect and fairness, I mean, we never as a group discussed this measure in terms of these – you know, we stop at our committee meeting all together before we discuss usability and feasibility. So, I appreciate the comments of the developer, but it would be great to have

some more discussion with the other committee members about their thoughts on the matters since, again, that discussion has never happened. This was – again, this is an e-mail vote not a discussion that led to voting. So, I appreciate other comments on this by other members of the committee.

Edward Septimus: Well, I've already gone on record Aaron that it can be done and if it's a priority ...

Tiffany Osborn: So, but I think Aaron's point was he just wanted to know if any other members of the committee had, you know, any comments on it.

Edward Septimus: OK, well not to ...

Aaron Milstone: Ed, just to ask this from just the feasibility question, so in your hospitals do you guys – does each hospital have a nurse or a data person, an (instruction) or who's booking it every patient that comes in, the screen for this – or every inpatient. Because the inpatient criteria are more subjective in terms of what would need definitions for severe sepsis with hypotension. I mean is there someone who's full time in doing this at each institution?

Edward Septimus: Well, we do sepsis coordinators at our institutions not all of them are full time. It depends upon the size of the institution and we also have within our electronic medical record, we – initially, when I started down this pathway a decade ago, we were doing this with manual papers.

Now, we have some of the criteria and screening within the electronic medical record. We hope to get that completely automated but in the initial period, we did it by on paper. People were screened on paper, but we do have sepsis coordinators and they are the ones they are really the owner of the data.

Sean Townsend: Can I make a comment? This is Sean Townsend.

Edward Septimus: Can we hear from anyone else from the committee first, please?

Thomas Giordano: Yes, I can make a comment. This is Tom Giordano. I thought that there was a general preference to avoid quality indicators that required manual chart abstraction, am I wrong on that?

Reva Winkler: Tom, this is Reva. I think that what we're seeing is an evolution where the burden of manual obstruction is something to be superseded by better data collection. However, there's no hard and fast rule if you will that says that some measures, you know, that requirement manual obstruction are still fine and hopefully over time, electronic sources of the data are being organized because it requires less hand obstruction. So, yes we want to see that movement into the less – away from less burdens of obstruction but there's no absolute about it.

Mohamad Fakih: This is Mohamad Fakih. You know, I fully understand the burden of the data collection as far as chart of view. I think it's a huge (death) for hospitals that don't have code EMRs. And a lot of the hospitals do not have sepsis coordinators or people even quality that can support these efforts.

So, you know, I'm one of the people that was worried about feasibility and usability of this measure initially, and we need to put in perspective that's going to be probably a huge (death). I think it's a great measure but, you know, the issue is how it will be implemented and the benefit from this measure at this point if we don't have full EMR integration.

Edward Septimus: You really – this is Ed. And Sean, you may want to comment on the initial (inaudible) sepsis. You do not have to have full EHR to implement these measures.

Sean Townsend: You don't have the full EHR to ...

Edward Septimus: No.

Sean Townsend: ... (register) in fact, but the submission included paper tools from which you could capture all of this. The general comment I'd like to make to everybody on the committee and to the public in general here is that it would be a great mistake to assert that, you know, when we know and have the demonstration of 200 hospitals can do this in 30,000 patients that it's not feasible to collect those data or they can't be used in, you know, hospitals when 200 done it.

The last thing I'd want to say in this topic is it'll be a greater to service to our patients across the country, and I hope I can charge hearts and minds with this

statement. Severe sepsis and septic shock are the number one killers of inpatients in hospitals across the United States. It's true of each of your hospitals. And for us to say, "Well, because it's hard to collect information, we should bury our head in the sand and not collect it."

I think it's just a tremendous tragedy then we know that the estimates were really 2,000 for that 750,000 patients presented with this disease, and we know that the epidemiologic disease suggested at this point it's about 2 million. And with the aging population, we're going to hit 4 million or 5 million a year. To not measure is to not know the answer, and that doesn't seem from a public health perspective to be a good idea.

Edward Septimus: And just to throw at in, it also is the most expensive DRG in hospital.

Aaron Milstone: So, you know, I guess the – this is Aaron again. I do appreciate your comments and I completely agree with you, and what we struggle with and I remember struggling with is the committee when we met in Washington was not that certain measures that we did not support were not good and measures that would improve patient care, part of the decision that went into was why the measures were being brought as quality measures? And was it way or forcing the hand of hospitals to do something.

And I'm not saying that every hospital should not have a sepsis coordinator that tracks this and improves internal quality improvement, but I still struggle with what's the role of our group and that what we are going to be held accountable to as members of this committee to say that this measure should be supported as a quality measure that all of its elements are evidence based and that there's a usability that should implore every hospital in the country to do this because that's what happened with other things that I know you said there are (closets) in CMS, but a lot of quality measures do get picked up for reporting in pay for performance. And, again, that might not be bad, that might force the hand of this, but I don't know if our role is to force hospitals to do something just because we think it's right. I think that's driven by ...

Edward Septimus: Let me leave it – answer that and then I think we need to go to public comment. Reva?

Aaron Milstone: OK.

Reva Winkler: Yes. So, Aaron, your role as the steering committee is you're acting as a proxy for NQF members who are multi-stakeholder and who have an interest in identifying measures that can be used for accountability purposes. You're expected to use the criteria to evaluate the measures to determine if they need those criteria and make a recommendation to the NQF membership and board of directors.

So, that is what you were expected to do as a member of the steering committee. How these measures also ultimately argues remains to be seen though what – an NQF endorsement say is that, “Our membership, all of the stakeholders within NQF feel that the measures are suitable for use in accountability purposes.”

Edward Septimus: OK. With that, why don't we – the people – the public have been very, very patient. I'm sorry this discussion has taken a little bit longer, but we want to make sure that the folks in the public have an opportunity to express their support or concerns.

So, the lines are open to the public.

Jeremiah Schuur: Hello?

Edward Septimus: Yes. Please announce yourself and who you represent, please.

Jeremiah Schuur: Jay Schuur, I'm representing the American College of Emergency Physicians. We submitted a letter of comment. And I would make one public comment and that would focus on – and I know the committees discussed this but the focus on this issue of the readiness for this measure to be an accountability measure and our concern that in particular the timing stamp of “time of presentation” is not defined in a reliable way to be used in accountability measure.

The example that we would give is if you imagine a 70-year old patient who has cough and a fever and decides to go to the emergency department. And if they arrived and they have a fever but don't meet the criteria for severe sepsis

or septic shock, and they get a chest x-ray, they're diagnosed community-acquired pneumonia; community hospital maybe after three hours in the emergency department they get admitted. They go up to the floor an hour five from when they presented to the emergency department. Blood pressure drops, heart rate goes up, they meet the criteria of ultimately septic shock, and the measure would measure them.

If the same patient went to a University Hospital, an academic medical center, high-volume hospital, some place that has problems with boarding or crowding, it would be very likely that that patient at hour three might (inaudible) to admit might be made but hour four, five, six, seven would come and go and the patient would still be sitting in the emergency department. And so, with hour five, the patient develops criteria for sepsis, septic shock, and they measure – they enter the measures denominator. The way they would be measured is by the time of presentation.

You can imagine that both hospitals do the right thing or the do the wrong thing in terms of meeting the measures. But imagine they both get the care to patient within three hours for the three-hour bundle within six hours from the time the symptoms developed. The patient who was at the hospital with boarding and crowding stayed in the emergency department would fail the measure because the time from when they arrive in the emergency department until when those interventions were given is longer than – it's six, seven, eight hours.

Whereas the patient who got up stairs to a bed because the hospital doesn't have boarding or crowding would meet the measure because that definition is different depending on where you are in the hospital. And we're concerned that this is going to bias the results against hospital so they have endemic boarding and crowding and that the measure won't reflect the quality of sepsis care but will reflect the underlying issues around boarding and crowding in the emergency department.

The second point we would make about this is that if you think about the concept of what you're doing is essentially trying to hold providers and institutions accountable for care for a condition that is not yet developed

because we do know that while, some patients come in with severe sepsis or septic shock it is not unusual for a patient with infectious disease to come in without those conditions and in the first three, four, five hours meet those criteria and yet the measure presumes that at time of arrival to the emergency department, the provider should start treatment for that condition.

And the consequences to that are that very likely that there will be a good consequences of that emphasis is that there will be screening for sepsis and that's wonderful and ACEP has supported the surviving sepsis campaign and believes very strongly in treating this condition. But the concerning consequences that there will be over treatment with antibiotics, overuse of the (Mandel) elements as it's been demonstrated when the community-acquired pneumonia measures required that antibiotics be given within four and then within six hours. There are multiple papers that show that there was overuse of antibiotics to try to treat that condition based on time-based metric.

So, we appreciate the deliberations the committee has given. ACEP has completely behind the move to improve the quality of care around sepsis and the concern that we have is nothing about the movement to measure sepsis or improved care. It's about whether or not this measure as specified is ready to be used to measure for accountability.

Edward Septimus: Thank you very much for those thoughtful comments. Any other public moments before we go on to the next measure?

Emanuel Rivers: This is Manny Rivers. If I can make one comment?

Edward Septimus: Real quick, Manny, because we have to go on.

Emanuel Rivers: Yes. The recent article is just published in (Chatsfield) by (Carr) that actually looked at community-acquired pneumonia admission during the first 24 hours of hospitalization. They examined a cardiac arrest database and this data base was over 44,000 patients.

What they found is that within the first six to 12 hours, patients admitted from the hospital with pneumonia 12 percent of those cardiac arrest were admission diagnosis of pneumonia. So, the final arbitrate there many times is the patient

died. And so I think that we have to understand that this is a process and evolution. We go with the best data but there's currently a price to pay if you don't pick these patients up in the first point of hospital presentation.

Sean Townsend: Ed, may I also make one quick comment? Thirty seconds only.

Edward Septimus: Go.

Sean Townsend: This is Sean Townsend. I've chased the smart guy and I appreciate his concerns, and I appreciate the concerns that he said (praises). This concern about boarding and overcrowding leading to outlier of cases where someone is going to get dinged on the process measure is an interesting concern. Again, data should be our – we know from the GAO. Six hours is the usual length of stay in the emergency department, beyond that is not common.

We know from the papers on early goal-directed therapy from the time of triage to the initiation of early goal-directed therapy is on average 20 to 90 minutes. So to point to theoretical cases which could happen and see that they affect the overall large data set that we've presented as to the analysis, it's – don't take this in any way is disrespect to (one off) example which is accounted for in the data already that was presented although I appreciate the concern I think that we have to limit down to say this is an unlikely circumstance which will has no overall effect on the reliability between institutions.

Edward Septimus: Thank you, Sean.

Aaron Milstone: Can I make – can I make a follow-up comment?

Edward Septimus: Please.

Aaron Milstone: I don't think this is a one off concern or a theoretical case. There is whatever the GAO report says around the average length of stay, there are numerous hospitals – and my guess is that Manny Rivers Hospital is like this – that have average length of stay for admitted patients above six hours and the issue is not theoretical and the data that was submitted with the measure does not

actually address this time because in the surviving sepsis campaign, in the emergency department, they have not collected the time when sepsis started.

They collected the time of presentation but they don't have the tie of when patients developed sepsis. So, they can't actually speak to this with data. This is a new issue, a new area and I can guess there will probably be a number of papers that come out but to date I don't know of a data from surviving sepsis or anyone else that exactly examines this. We do know that a significant number of hospitals, and they tend to be safety net hospitals and Academic Medical Centers have average length of stay for admitted patients of over six hours.

Sean Townsend: Which, again, I would say, whether or not that's the case in 30,000 patients, we demonstrate that is a reliable indicator start triage. And whether or not those patients stay a long time, they can be identified within 90 minutes in most cases based upon the existing evidence basis.

I can't refute that which is not evidence. And this concern although it has a certain ring of appeal to it, it does not have data behind it, and we've demonstrated conversely that when you start a triage time, you use a reliable way to compare performance of hospitals with this composite measure, right? They just don't see any other coming to us from (Jay's quarter) that has a number of attachments that say it's not reliable.

Emanuel Rivers: May I – sorry to be redundant, but the last comment is this original study was started in 1997 at Henry Ford who sees 100,000 patients a year. We're right in inner city Detroit. We realized that a 50 percent mortality. We reduced that to 15 percent, and we reduced hospital cost 20 percent related to sepsis.

So, in the context of all of these distressed hospitals that, number one, need the care, number two, address the issue, it is a cost-saving maneuver for health care resources. And so, I want to make sure that people understand, yes, we're big, large, urban, inner city hospital with a poor payer mix, but it works in our program.

Sean Townsend: (Inaudible).

Emanuel Rivers: Whether we have outliers or not ...

Lisa Kirkland: Can anyone hear me?

Emanuel Rivers: ... it has decreased mortality in (inaudible).

Michael Phelan: Yes, Dr. Phelan is still here.

Lisa Kirkland: Hello? It's Lisa Kirkland. Can anyone hear me?

Emanuel Rivers: We can hear you.

Lisa Kirkland: OK. I'm an intensivist in Minneapolis, and I'm the chair of the advocacy committee for Society of Critical Care Medicine. I'm not here on this society's behalf. I'm here on my own. But my concerns about this measure have been voiced very well about the CVP, the SvO2 versus lactate monitoring and the blood – the antibiotics after blood cultures. And that was – that measure or that part of the measure has been proven not to work well as mentioned by the gentleman who mentioned the community-acquired pneumonia. I just wanted to get my two cents worth in. Thank you.

Edward Septimus: OK. You know, here in the ...

Michael Phelan: Mike Phelan here, can I speak up?

Edward Septimus: Who's this?

Michael Phelan: Mike Phelan.

Edward Septimus: Yes, go ahead.

Michael Phelan: First of all, I'd like to thank the committee and all of the comments and the deliberation that everyone is doing around this. One of those things I wanted to convey in comments was the idea of maybe modifying NQF 500 and not throwing the baby out with the bathwater.

I understand that sepsis and sepsis measurement would be a wonderful thing, but the concerns that have been raised by everybody, the timing, the EGDT,

and although I did not include in my comments because they took up three boxes of the NQF, I wanted to include something on the ScvO₂ measurements and the costs associated with buying the equipment, measuring it, and things like that. I kept that out but I think other people have raised it.

Regarding the blood cultures, I'm not sure, you know, you understand. It's not the obtaining of the blood cultures, it's when that measure gets operationalized and it's the timing where, you know, someone looks really sick and you're just kind of getting stuff going on the patient which I think is the more critical component getting antibiotic started.

Think of all the blood cultures you ran afterwards, and I know some of the data about how it may affect the overall results that just looking at a very simple bundled measurement that almost everyone can agree of the timing of the identification of sepsis, the starting of broad spectrum antibiotics, the obtaining of cultures, not including a timing thing and it becomes critical that we need that later if we can do that, some measure of critical (measures) like maybe a lactate, but that doesn't have to be inclusive, and starting or getting some IV fluids on board for that set of patients, to me – and I don't know if I conveyed it enough in the measure or in the comments that I said that I think we need to look at maybe in modifying NQF 500 and revisiting some of these other set of more controversial issues that things like CVP measurement, and I think we've kind of, as I said, whip a dead horse to its conclusion. But I'm just wondering, I know there wasn't a measure submitted but perhaps in the comment if this measured does not meet NQF criteria, say, a simpler measure maybe based on NQF 500 could pass muster with that suggestion or those suggestions.

And the idea that – someone mentioned that options for measuring, there are lots of other you know, vital signs you can measure. (Inaudible) you can measure, you can get more complex to measure into, you know, some point of care ultrasound data that is very good in this measure. But like the Swan-Ganz catheter, I'm sure Manny is very familiar with this, we use it a lot.

Unfortunately, the data didn't come up until much later although some of us who were practicing kind of saw that every patient that got a Swan-Ganz

catheter seems to die in the unit than patients who maybe weren't so critically ill – or is critically ill may have survived. And there's data and if you want me to support that with the Swan-Ganz catheter paper that says it's not the greatest tool to use for this type of measurement, I can support that.

But just those comments alone and everyone's support on this, I appreciate at least taking the deliberation and the time, and I appreciate you taking my comments.

Edward Septimus: And I appreciate your comments, the committee does, and especially being so patient for always a rather lengthy discussion. Hearing no one else, I think I will turn this call over to my co-chair. She's on the line.

(Chris): I'm sorry to interrupt. This is (Chris) from the Society for Academic Emergency Medicine. If you don't mind, I'd like to make a brief statement.

Edward Septimus: Oh, sorry. I thought we were finished with comments, I apologize. I didn't hear anyone else. Go ahead.

(Chris): Yes, I would like to, on behalf of the Society for Academic Emergency Medicine, echo the comments that were made by Jay Schuur regarding time of presentation. I don't want to get into the detail and rehash. I know that it's been addressed but I want to go on record and express concern on our behalf, number one.

Number two, I'd like to echo what Mike Phelan just mentioned that there are – it's clear that measuring and improving the care provided to this group of patient is critical, and it's important at this point. There are a lot places that aren't managing these cases. (On that stuff), I think we can agree upon that.

However, the individual measures or interventions and what exactly should be measured are clearly controversial. And the fact that the process, trials, and others are ongoing, it supports the fact that there is some concern that the bundle as is currently under discussion is not perhaps the one and only way to manage these patients.

I think that perhaps modifying NQF 500, looking the least controversial but probably the most important aspects care, i.e., you know, checking some degree of acuity as Mike mentioned, checking a lactate, initiating rapid and adequate fluid resuscitation, initiating blood cultures, and then prompt a broad-spectrum antibiotics and leaving out the more controversial aspects, CVP and ScvO₂ for example, I think it would be much more palatable for a broader spectrum of folks at this time until further data comes out in terms of process and some of the other trials that are ongoing, and I'll leave it at that. Thank you.

Edward Septimus: Thank you very much. Just to make sure, are there any other comments before we turn this over to the second measure?

Sean Townsend: You know, I apologize. I have one more comment to make, you know, someone said we touched this in 200 hospitals. Dr. Rivers, you know, did it in his large urban hospital. I think there's an un-realization of the burden that hospitals are finding themselves under to collect this data.

And I understand I think one of the comments in the comment letter that came back was while there's people that measured, 31 measures have skipped. Hospitals pay to be enrolled and skipped and a lot of money for that and they support it tremendously. But adding one more age component measure for abstractors to review, go over, to make sure before it gets submitted, it is not a – the word I'm thinking – it is a burden to the hospitals.

So, that's just the last comment I want to make about hospitals and the ability for them to just keep burdening them with very complex, difficult to collect measures versus something that maybe more palatable will identify three ICD-9 codes and move forward with it and it gets back to this side of let's not throw the baby out with a bath water. I think we need to measure sepsis somehow. I just don't think this is the right measure for it. Thank you.

Edward Septimus: OK, if there's no other ...

Reva Winkler: Ed, this is Reva. We will and perhaps you want to wait until later but we will have to have the committee make a decision on how they want to move forward on this measure in response to the comments.

Edward Septimus: I thought we'd wait until the second measure, Reva, if that's OK with you.

Reva Winkler: Fine.

Edward Septimus: There are some people who have tight time schedules as well, so.

Reva Winkler: Perhaps we can send them an e-mail with the vote.

Edward Septimus: Well, we can discuss that. Let's get through the second measures. Steve, are you on the line.

Steven Brotman: Yes, let's move to the second measure if you don't mind. OK, so the measure thus for evaluation for voting purposes is 0393 which is Hepatitis B, testing for chronic Hepatitis B, confirmation of Hepatitis C viremia. The original endorsement date was in July 31, 2008 and it failed originally when we reviewed it this year for evidence standards.

But the committee on November 9th during the call determined that the comments submitted requested reconsideration of the measure actually had merit and the developers agreed to update the submission form and the committee decided to reconsider the measure and that's where we are at this point at this point.

The lead discussant David Spach, and the backup discussant, (Ray Chung) I believe are both on the line. David, would you like to address the measure as we go through each category?

David Spach: Yes, I should mention this was originally endorsed in 2008 and this is the maintenance measure, and the two major stumbling blocks as you said really were related to data both related to data regarding the significance of actually measuring the viral load versus just getting an antibody test and how that might impact clinical outcome downstream.

And secondly, data regarding (inaudible) that was really a performance gap and there was significant new data that was submitted by the developers. So, just to reiterate the background related to this in terms of the impact, the opportunity, and evidence.

The high impact to this is based on the factor that approximately, three to four million people are living with Hepatitis C in this country which from a population prevalence standpoint is approximately about 1 in 50 people.

The article that was published in 2012 by Lee in *Annals of Internal Medicine* showed that in 2007, Hepatitis C surpassed HIV in terms of annual death and the gap has increased since 2007. Hepatitis C clearly has more annual deaths than HIV.

The estimates from articles such as (Rhyne) have estimated that if patients are not identified and not treated that an estimated 30,000 deaths per year will be occurring and peak time for this in terms of 2030 and 2040, and an estimate some people described this as a tsunami of Hepatitis C death awaiting if something is not done.

Now, in terms of looking at the benefit of using this measure in the data that was submitted, just as background, clearly the initial screening test for diagnosing Hepatitis C is an EIA antibody test and the only way to determine whether or not potentially needs long-term monitoring for Hepatitis C and potentially needs treatment for Hepatitis C is that Hepatitis C HCV RNA test.

The data that was submitted that was new was this meta-analysis of 31 studies. This was a data that showed that for essentially just really reiterated what I think clinicians have known for years which is basically that approximately one out of five people spontaneously clear their Hepatitis C after acute infection.

So, not everybody whose antibody positive will need ongoing care and treatment for their Hepatitis C, and the Hepatitis C viral load is the only test that adequately sorts this out. So, if Hepatitis C viral load is not done, those 15 percent to 20 percent of people may have completely resolved the Hepatitis C maybe mistakenly identified as having chronic Hepatitis C and receive unnecessary testing and followup.

And those are identified with chronic Hepatitis C in addition to potentially receiving treatment for that can receiving counseling on prevention, education

for alcohol use, and currently, the landscape for Hepatitis C treatment is dramatically different than it was years ago with the so-called SVR Sustained Virologic Response which in essence correlates with cure is now possible in approximately 70 percent of individuals with Hepatitis C even across all genotypes with new direct acting agents and the predictions are within probably two years, we'll be looking at estimates of 90 percent to 95 percent cure rates with very shortened and practical therapies for Hepatitis C. So, the landscape has changed. The need for identifying people has increased significantly.

Now, one of the issues is whether or not there is actually any data regarding mortality reduction and there are three trials that have now been published Backus, Morgan, and (Bud) that all showed significant decrease in mortality if individuals achieve a sustained virologic response and there are two trials that have shown a decrease in hepatocellular carcinoma that's – (Aguilar and Sengal).

So, I think in terms of the background for those that the importance of the measure and I don't know if you want me to go in terms of gap or if there's comment. So, Ray may want to make any comments now here as well.

Edward Septimus: Yes, sure. Let's go on to just some basic comments if anyone has at this point, then we're going to the gap. Ray, did you have any comments?

(Ray Chung): No, David said it beautifully.

Edward Septimus: OK. Anyone else? Any other members have any comment? All right, well then, David, why don't you just go on to the gap at this point?

David Spach: OK. In terms of the gap, this was a big stumbling block because one of the issues was, OK this maybe important but is there any need to actually have a measure for this because presumably everybody is already doing this?

Well, this was really I think the bulk of the new data that was submitted by the developers and the CDC comment was when they submitted their comments related to this was the CDC does not agree that such testing is performed so regularly that it can be regarded as standard of care.

We recognize the data and the NQF report demonstrate substantial adherence to the recommendation but they noted, “However, additional evidence provided by CDC both in the medical center and the Cleveland V.A. Medical Center shows that a substantial performance gap remains illustrating that in practice, confirmatory testing after initial Hep-C antibody testing is not being done often enough to constitute standard of care.”

They go on to site the specific data which includes the summary of more than 20,000 individuals regarding submissions to the CDC from state and local surveillance programs in 2006 and 2007, where approximately 48 percent of people did not have followup Hepatitis C RNA testing done after identifying them as antibody positive.

They then went on and showed this similar type of data from additional hospital center and I think most notably, there was a poster presentation that cite from the 2012 IDSA meeting that demonstrated a decline in the documentation from Hep-C viremia from 73 percent in 2005 to 2007 to 63 percent in a more modern era of 2008 to 2011.

And so, I think these measures were – or this new data was I think a significant difference on what individuals had to look at in August and we are looking at the measure. So, that’s the major new issue related to the performance gap.

Edward Septimus: OK, let’s just stop here. Any comment related to the performance gap issue? OK, hearing none, let’s go on to scientific acceptability and let’s break it down into reliability and then we’ll get to comments and go on to validity if you don’t mind.

David Spach: And I’ll make a couple of comments about the reliability and validity and Reva and I briefly discussed this as well. She may want to chime in as well too.

Just in terms of the reliability, the numerators in this were patients in whom Hepatitis C RNA was performed. The denominator with patients who are 18

or older seen with a diagnosis of Hepatitis C. The reliability and validity was done by automated EMR report.

The validity testing was – this is an evaluation by the EMR and by visual inspection of medical records. The specific – the literal testing involved 1,144 patient in counters and visual inspection was performed in 2010. There was a phase stability – validity that was assessed by a 22-member panel and the analytical method, there was the EMR was compared with a manual obstruction in the phase and they performed a rating scale based on a scale of one to five by this expert panel.

And the essence of this with this testing results were there was a phase validity based on this 4.92 out of 5 and the conclusion from the panel was this measure was highly reliable and the measure was a laboratory based measure.

And Reva or Ray, I don't know if you want to comment on this as well.

Reva Winkler: This is Reva. I just want to comment on the method of testing just to remind the committee that this an eMeasure, an EHR based measure and so the testing of the EHR based measures tend to wrap reliability and validity together. And looking at whether the automated eMeasure result provides a reliable and valid representation of performance by comparing it to a visual inspection of the record and the congruence of those two results.

So, I just want you to think about how we look at the other Hepatitis C and realize they were part of a group and that they were tested similarly.

Edward Septimus: Any other comments related to reliability and validity?

Aaron Milstone: This is Aaron. I have a different question. You know, as an I.D. doc, I know that if someone has Hep-C antibody that we should check PCR to make sure that they're not viremic. But I wonder with the new CDC recommendation, I think if we talked about this, please remind me.

If a primary care doctor gets a Hep-C antibody and doesn't know what to do and they refer that patient to a (hepatologist) or I.D. specialist, do we have

sense of how often that may happen and what's the kind of the catch (base) for a primary doctor that refers that doesn't do PCR.

And I think that they shouldn't do the PCR and first confirm if the patient is viremic. But if they don't know that and they refer them right away, how that's going to – is that an exclusion or is there some way to look at referral patterns as opposed to just PCRs, so that people don't get seen as not following up on that action?

Reva Winkler: This is Reva. Perhaps we can ask the measure developers. Anybody form PCPI on the line? That's a surprise.

(Ray Chung): I would say this, again, there is this performance gap. And that's notwithstanding I think the most PCPs, you know, at least in the sampling of our community PCPs, have referred patients on only after acquisition of the PCR panel, the HCV RNA test.

So, I mean, again, I think there may be pockets of, you know, a less penetrated message in other areas but at least for this academic medical center, I think we've got a pretty well percolated message about the reflects into an HCV RNA test for an antibody positive scenario.

David Spach: And this is David Spach again. And I think people are now viewing more sort of analogously to do an HIV antibody test and then confirming with the western blot where you would not just do an antibody test and then refer the person on to an HIV clinic before doing the reflexive western blot. And I think that's really where the standard of care is moving out (inaudible) that in our center of people would not be referring on to a specialist without getting a viral load test.

Edward Septimus: Any other discussion? David, why don't you go on usability?

David Spach: In terms of usability, I think this is pretty straight forward and that this is something that users can certainly understand the results of the – this is then in public reporting and the PQRS system has been in place since 2008. And the physician's can source in the PCPI, saying that the reporting is beneficial first step and the trajectory towards public reporting of performance results.

And you know, I didn't really have any major issues that I saw in terms of usability, but I don't know if Reva or (Ray) wants to – this didn't seem like – just seem like all the PCPI measures are suitable for Q.I. initiatives and they're made to be available. I did not see any major issues in the usability.

Edward Septimus: Anybody want to comment? OK. All right. How about David going on to feasibility then?

David Spach: Feasibility, I think is the easiest and that performing the test is done as part of a general examination and general evaluation that's not difficult process just part of a blood draw and the data sent as a laboratory data would be available in electronic health record. So, in terms of feasibility, it seems like the feasibility should not be an issue with this measure.

Edward Septimus: Any comments? And normally, if we were voting, we would be voting at each point, but we were not doing it at this point. We would be voting on suitability for endorsement next. Did you want to discuss comparison to related or competing measures by any chance?

David Spach: I didn't have any further comment on that (inaudible). Somebody's got their phone unmuted.

Reva Winkler: (Ashley), can we mute that line, please.

Operator: OK. One moment.

Reva Winkler: Thank you.

David Spach: Thank you. I think in terms of just a distinction is – to make is this is clearly a different measure than obtaining a viral load while you're monitoring someone on therapy. So, they do not overlap at all, and I think this is really a sentinel test that is done that is the fundamental dividing point that tells, somebody need chronic evaluation management referral for hepatitis C, or are they told they have an extremely high likelihood that they resolved their infection. And so, I think it's completely different than a measure that would be done prior to initiating therapy on someone and monitoring someone on therapy.

Edward Septimus: Very important comment. Thank you. Thank you for that thorough review. Are there any comments in general at this point? Should we go for public comments? At this time, let's see if there's any public comment.

Female: Reva, all the lines are open, so anyone could speak if they wish to.

Edward Septimus: Right. OK. So, that's great. So, hearing that there's none, Reva, did you want to mention the method of voting for the members at this point?

Reva Winkler: Sure. I think earlier today, we sent out the link to the SurveyMonkey tool that we'll ask you to vote on all of the sub-criteria and the main criteria as you've done before with all of the measures as well as your final recommendation. Does anybody have any question about that?

Given this information, this discussion has relatively freshen your mind and everybody's got a lot of other things to do this time of the year. I think it will probably be optimal if you're able to do it as soon as possible, and we really do need to get your responses by the end of the week. So, hopefully that will be straightforward with it being fresh in your mind after today's discussion.

Edward Septimus: Reva, I'm wondering if some sort of a tickler e-mail or something should be sent out in the next 24 hours just to – as a reminder to any members that this needs to be voted on.

Reva Winkler: OK. We will do that. Anything else on the hepatitis C reconsideration that folks need? If you're comfortable, you'll be able to make your evaluation. OK. I think we're finish with that one Ed, Steve.

Edward Septimus: Yes. So, how you want to proceed, Reva? I mean, should we (inaudible) the drop-off and we discuss sepsis before the two-hour limit's up ...

Reva Winkler: Well, the question is, whether there's any further discussion that needs to be entertained. And then, committee has to make a decision, whether based on review of the comment, they want to stick with their current evaluation and recommendation, whether they want to reconsider any of the evaluation criteria and submit and revote on some or all of the criteria or the entire

recommendation of the measure. You pretty much have to make a decision where you want to go from here.

Edward Septimus: I guess I could take a step, maybe, to stimulate some conversation. And I, like many of you, reviewed all of it. I've heard some very thoughtful discussion in the first hour or in 20 minutes. There are obviously some soft spots with (CDP), but I think when taken in composite with other interventions, it sort of make sense because you're going to put catheter to measure (SPO2) and there was very little controversy around that issue.

I think blood cultures are more of a quality issue. The triage issue, I mean, personally, because of the huge database that Sean Townsend and his group has put together, it seems to me that although not ideal, it seems like he's addressed that in the large database he has that's not a significant problem. All be it, there will be some people who might be penalized who developed the criteria for severe sepsis and septic shock later in the ED. But I think that's probably going to be the same for most of them.

So, I haven't heard anything compelling that would have me change my opinion at this moving forward. I think it is a – it's a leading cause of death in non-coronary ICUs. That's the most expensive diagnosis now. It's obviously going up and so our population ages, those facilities who have done this well have shown significant improvement.

I think that this will be a good measure for NQF to put out to try to stimulate us to do this on a more generalized basis. That's my opinion.

Steven Brotman: And this is Steve. I agree, there's been a lot of thoughtful discussion. And I do agree with you, Ed, that you know, I haven't heard anything compelling that would prevent moving this forward, so I'm in agreement with that. And over the NQF criteria is not – is not the same as an academic, you know, ad criteria, and so it's a little different. If you look at the criteria for NQF, I'm comfortable that the developers met the standard. Any other comments on this?

Aaron Milstone: This is Aaron. I guess I would – I think getting this as our first robust discussion of the entire measure, not just the first two components where we

stopped the discussion after our initial meeting. I would – I would push for a revote.

I think there are – there were some things that were clear from – there's a lot of discussion by the developers, but there was also some, I think, pointed important comments brought up by the public, one of which was that we, I think, all agree there are some sticking points to this.

And we can either say that just because it's the only sepsis measure that we should go ahead and push if we have something or we should reconsider if there's a better sepsis measure or, you know, one that's more feasible for everyone.

Edward Septimus: If the problem – I mean, I understand what you're saying here in the last comments, I think before we went over to hepatitis. The problem is, by looking (inaudible) the things that everybody can agree on, none of those have been tested. Most of them have been tested in the bundle situation.

Aaron Milstone: But that sounds like set one, though.

Edward Septimus: No, it's not. I mean, I think – I think if you look at (inaudible) understanding that each (inaudible) bundle may not have the same level of evidence, which I think is the sticking point. And again, the question from my mind, do you want to let (perfect) be the enemy of good here, or do you want perfect data. And I don't think – and Reva can kind of way in on this. I don't necessarily think that's what the NQF criteria is asking for, and I may be wrong, and I'll leave it weighing on that.

Female: Before Reva comes in, Ed, could I ask you a question? What are your thoughts now regarding the time zero component and the possibility of holding people accountable for treating something that didn't exist at that time zero, what are your thought on that and how that place on that?

Edward Septimus: I think it's the same for everybody. So, that no one's going to be 100 percent on that. And so, I think, as Sean and Manny's data indicate that that should not, by itself be a reason not to start crack at some point. And as you know, you may, you know, like in anything else, do you always know the exact

moment where somebody actually meets the criteria and the clock just start running in the ED which is, you know, is a busy time, three hours or something, and everybody can agree on.

Michael Farber: This is Michael Farber. I'd like to make a comment on the proceeding. We heard a tremendous amount of noise regarding the sepsis measure. We heard very little about the hepatitis, in other words, it was quickly resolved. When we met in person as it's been pointed out, there was a lot of controversy with the sepsis measure, and as I remember, we reconvened and then revoted on it again.

I'm not starting yet of where I would stand with it, but I – but I felt that the – that the breath of all the comments were quite compelling. One with triage, the question is that, yes in the flu season, there's no beds and people are going to stay in the ER so that it is, you know, the triage part is really dependent on time of day and time of year.

So, it's going to vary a great deal. You know, let's say also in the blood cultures, of course, you know, I believe that any time you have a sick patient, you should be doing blood cultures first for all the reasons that were given because in two days later, when they're not doing well, and you don't know why, you want to look at them.

But what I was pointing out is that people may show up with a condition that does not require blood cultures and then treatment is started, and then they get worse. And now they have – they're now in a situation of being treated for sepsis, but they meet the timeline anymore for getting blood cultures.

So, I guess, my comment is that I felt that there were a lot of controversy and I don't know that this meets the same degree of acceptance that we had with the 27 other measures. But I – but I do agree, you know, with the comments that, you know, you do treat things sometimes when you don't have complete data, but should NQF base it's decisions on that?

Edward Septimus: Reva, do you want to weigh in on any of these? Not to put you on the spot.

Reva Winkler: Again, I think, this is a committee decision. It looks like a goodly number of the steering committee members want to reevaluate the measure after listening to the comments in this further discussion, that's certainly, you know, one choice.

The other is, whether the entire committee feels comfortable just staying with their previous evaluation and recommendation.

Edward Septimus: I think, some of us are weighing, more comfortable one, would like to revote.

Reva Winkler: All right. Let's do this. How many on the members of the committee would like to revote it? Declare yourself.

Kathleen Brady: Kathleen Brady.

Reva Winkler: All right.

Edward Septimus: Before we declare ourselves, (inaudible) revote it meaning reopen it, or revote it meaning it's open, let's vote.

Reva Winkler: Well, I think that's really sort of the decision. What I'm asking is, now that you've had the chance to look at the comments, reflect here the decision, do you want to go back and redo your evaluation in voting on the entire set of criteria, because you may have changed your evaluation based on the further discussion.

Edward Septimus: So, if I say I want to revote it, meaning I think we need to reevaluate, if I say I don't want to revote it means, I'm content with not endorsing this measure, correct?

Reva Winkler: No. It means you're content with the current evaluation which did recommend the measure for endorsement.

Edward Septimus: If you're content to leave things exactly as is, if you're uncomfortable and you want the committee to revote, then we revote what we did the last time.

Male: And currently, we've endorsed this measure.

Male: That's right.

Male: OK. Thank you.

Male: Right.

Male: (Inaudible) I would like to revote.

Reva Winkler: OK. Anybody else?

(Tom): Yes, I would. This is (Tom).

Reva Winkler: OK.

Michael Farber: Michael. I would, but I wonder whether we should give some thought to it on our own and not vote right now. That would be my only comment on that.

Reva Winkler: What kind of a time frame are you talking about, Michael?

Michael Farber: Later in the week. But I'm willing to vote now if that's the issue. I guess, as I've said to you, that I feel, you know, since it's so controversial and difficult, it's hard for me to make a decision (inaudible) because I see so much controversy.

And, you know, should a measure have that much controversy starting in, and that's my major – my major issue and I think that the group needs to think about whether, you know, whether there isn't that much controversy and is it – is it settled, in other words, we should have a measure that has a lot of disagreement in the public about it.

And that would be my concern, and I'm not certain where, you know, what period of time we should use to decide that, you know. In other words, how much time.

Reva Winkler: Unfortunately, we really are – we really are a bit pushed to wrap this up. So, because this one is actually later than the rest of the measure set, so we really need to have any further evaluation completed by the end of this week.

Male: You know, I also support revoting this (inaudible).

Reva Winkler: OK.

Male: I think that's enough that we probably want to send it out for vote.

Reva Winkler: OK.

Male: (Inaudible) vote at this point then. Let's vote.

Reva Winkler: OK.

Male: (Inaudible) send that on the monkey survey, I guess.

Reva Winkler: Yes, we will. We'll send one out, again on a similar time frame, we should be able to send it out this afternoon, and we will also, probably in the next day or two, the recording and transcript from this call should be available and give it to you as quickly as possible if you happen to want to review any of the discussion prior to doing your voting.

Edward Septimus: The only thing I – well, I have to ask. There's a little bit of additional information that came out just before the call, but I'm not sure it's been shared with the committee. Reva, why don't we have a short conversation to see if we want to send out any additional stuff before the committee votes...

Reva Winkler: OK.

Male: ... and so we have everything?

Reva Winkler: All right.

Male: (Inaudible).

Reva Winkler: OK.

Edward Septimus: Well, we're going to reconsider this, I think, one of the things I want to ask all the committee to do is try not to vote on the motion, but try to vote on the best level of evidence that's been provided by both the commenters and by the developers.

And so, I think there were few comments, but occurred pretty late that I don't think we had a chance to share with the rest of the committee. So, I think, if it's OK with everybody, let Reva and I make sure we got the right stuff that hasn't been sent out and send it out to you for review, and then after that, if you'll – if you'll take the monkey survey. Does that sound OK?

Female: I just – I just have one question. We're talking about revoting and if we're talking about revoting, is there – if the developers wanted to make any modifications that were within the current framework that didn't change their reliability and validity that might be able to address some of their concerns, what are these thoughts regarding that?

Mohamad Fakih: You know, I support that. This is Mohamad.

Female: I'm just asking. I don't know how this process works.

(Muhammad): You need a black and white, do you think this is – I think they should be – I mean it doesn't have to be black and white, you know, either this way or that way. And you know, having a very divided – I mean there are many of the members that has some reservations here, and I think there's a metal ground that will benefit the patient at the end.

Female: Is Sean still on the phone?

Sean Townsend: Yes, I'm here.

Female: Sean, did you hear Tiffany's question?

Sean Townsend: Well, as I heard the question, and she was basically asking if there was any possibility that we can modify parts of the measure. And my understanding was the process that, given the strict standards on reliability and validity, then you would need new data in order to support that. and I tried to push this conversation obviously to the data because I believe the data is not critical.

I think the passions are critical, and I don't think that there is data to support any metal ground yet, and we would be pushing ourselves for five, ten years in the future. And I'm not – if I could – I could press upon people anything,

I'd say, you know, you don't always take compromise in life that's (inaudible), we just had a national election that was very divided, but made a decision, and this is in our – the interest of our patients in the most severe illness that our patients face in the hospital, and the number one cause of death.

And to turn our backs now on the grounds that we are wants a compromise, well that's what many people do.

Edward Septimus: You know, in fairness, Reva, I mean, I don't know how this is moderated, but I feel like we are getting – I mean this is a lot of editorialization, and I think it's unfair to those in the committee. We're trying – we tried to be impartial, we evaluated all these the same way. I'm getting this sense in developers like they think we don't care about patients, we're not trying to improve care, so I think that...

Sean Townsend: Well, I'm (inaudible) ...

Edward Septimus: But I agree (inaudible) and I think we got enough (inaudible).

Sean Townsend: ... then you won't have data, and I can't ...

Edward Septimus: You're not answering my question, you're ...

Sean Townsend: ... (inaudible) question.

Female: OK. All right – all right.

Edward Septimus: This is (inaudible). I agree completely. I think we'd had enough discussion.

Female: OK.

Edward Septimus: Reva, you're there?

Reva Winkler: Yes, I am.

Edward Septimus: Let me – let me clarify that. It's not that we – I agree completely with Aaron that we care about patients. It's a process we're trying to go through with

objective data. Everyone's had their chance to make the case, present their objective data, so that's it, OK? I don't think we need more editorialization.

Male: (Inaudible).

Male: (Inaudible), I mean it's ...

Male: I go down, you know.

Reva Winkler: All right. Ed, it sound like where we're at is that is that the committee wants to reevaluate the measure, the measure is as presented to you. We'll send you out another SurveyMonkey. Ed, you wanted to talk after the call and we can do that.

Edward Septimus: Yes. We'll simply talk just to talk about what things we've sent out, which things we haven't sent out ...

Reva Winkler: Correct.

Edward Septimus: ... so many things occurred late. Just so you can see it, for your own information and you can decide if that helps you with your evaluation.

Reva Winkler: So, is everybody clear? Any questions about the next step? Or I think we're probably finished for today. Any other questions from anybody? OK. Then you can expect to receive the SurveyMonkey tool and potentially, additional information from us, probably later today.

Male: Reva, you want to call me on that number?

Reva Winkler: Sure. Happy to.

Male: All right.

Reva Winkler: All right. Thanks everybody, really appreciate it.

Male: Bye everyone.

Male: Thank you.

END